EUROPEAN COMMISSION
Research Executive Agency

Director

GRANT AGREEMENT

NUMBER 952583 — MICAfrica

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **Research Executive Agency (REA)** ('the Agency'), under the powers delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by Head of Unit, Research Executive Agency , Industrial Leadership and Societal Challenges, Spreading Excellence, Widening Participation, Science with and for Society, Ales FIALA,

and

on the other part,

1. 'the coordinator':

SFAX UNIVERSITY (USFAX), established in ROUTE DE L'AEROPORT km 0,5, SFAX 3029, Tunisia, VAT number: TN580809M, represented for the purposes of signing the Agreement by LEAR, Abdalouahed Mokni

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT (INRAE)**, established in Rue De L'Universite 147, PARIS CEDEX 07 75338, France, VAT number: FR57180070039,

3. **MEDITERRANEE INFECTION (IHU MI)**, established in 27 BD JEAN MOULIN FACULTE DE MEDEINE AILE ROUGE 3E, Marseille 13005, France, VAT number: FR04501980882,

4. **UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI)**, established in Piazza San Marco 4, Florence 50121, Italy, VAT number: IT01279680480,

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to

implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

TERMS AND CONDITIONS

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled '**Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for Human Diseases at University of Sfax**' — '**MICAfrica**' **('action')**, as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **36 months** as of 1 January 2021 ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 896 885.00** (eight hundred and ninety six thousand eight hundred and eighty five EURO).

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100% of the action's eligible costs** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **896 885.00** (eight hundred and ninety six thousand eight hundred and eighty five EURO).

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs for subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies):** not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors,

irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

<u>Types of eligible personnel costs</u>

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[1] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

[1] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs, if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**') who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

the number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person in that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3): the hourly rate is calculated *per full financial year*, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the

reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with

Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[2] directly used for the action are eligible, if:

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[3]);

(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.

[2] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[3] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting and

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[4] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[4] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

Not applicable

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary), if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action;

(c) costs for infrastructures.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[5] (or 2014/24/EU[6]) or 'contracting entities' within the meaning of Directive 2004/17/EC[7] (or 2014/25/EU[8]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors

[5] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[6] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. (OJ L 94, 28.03.2014, p. 65).

[7] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[8] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

(ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

Not applicable

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

Not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

Not applicable

15.2 Financial support in the form of prizes

Not applicable

15.3 Consequences of non-compliance

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

Not applicable

16.2 Rules for providing virtual access to research infrastructure

Not applicable

16.3 Consequences of non-compliance

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

  (i) changes in its legal, financial, technical, organisational or ownership situation

(b) **circumstances** affecting:

  (i) the decision to award the grant or

  (ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of five years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these

conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the Agency (see Article 52) the technical and financial reports set out in this Article. These reports include requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 15
- RP2: from month 16 to month 36

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the Agency;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary, for the reporting period concerned;

(iii) not applicable;

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR **717 508.00** (seven hundred and seventeen thousand five hundred and eight EURO).

The Agency will — except if Article 48 applies — make the pre-financing payment to the coordinator

within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR **44 844.25** (forty four thousand eight hundred and forty four EURO and twenty five eurocents), corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the

balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Agency from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: BANQUE CENTRALE DE TUNISIE
Full name of the account holder: MICAFRICA
IBAN code: TN5900999000402476497818

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly.

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Agency or the Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[16] and No 2185/96[17] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[18], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

Not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or

[16] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[17] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[18] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors**, **irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Agency or the Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the EU programme.

Evaluations may be started during implementation of the action and up to five years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[19].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

[19] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) —

to affiliated entities[20] established in an EU Member State or '**associated country**'[21], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

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[20] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[21] For the definition, see Article 2.1(3) of the Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of

protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952583".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

If results are incorporated in a standard, the beneficiary concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952583".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Regarding the digital research data generated in the action (‘**data**’), the beneficiaries must:

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;

(ii) not applicable;

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the ‘data management plan’ (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> “This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 952583”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licenses

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) not applicable.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- identify the specific results concerned;
- describe in detail the new owner or licensee and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- pending the Agency decision, within the period set out above;
- if the Agency objects;
- until the conditions are complied with, if the Agency objection comes with conditions.

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).

31.6 Access rights for third parties

Not applicable

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[23], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

[23] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[24].

This implies compliance with the following fundamental principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;

- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

[24] European Code of Conduct for Research Integrity of ALLEA (All European Academies) http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

The documents must be kept on file and be submitted upon request by the coordinator to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[25], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[25] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

37.2 Classified information

Not applicable

37.3 Activities involving dual-use goods or dangerous materials and substances

Not applicable

37.4 Consequences of non-compliance

Not applicable

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952583".

For infrastructure, equipment and major results:

"This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding

from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952583".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency and the Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency and the Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the Agency's or the Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency or the Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[27], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the Agency or the Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the Research Executive Agency (REA) and the European Union (EU) under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[28] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Agency and the Commission websites.

[27] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[28] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibility towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

41.3 Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must have internal arrangements regarding their operation and co-ordination to

ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:

- internal organisation of the consortium;
- management of access to the electronic exchange system;
- distribution of EU funding;
- additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);
- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The consortium agreement must not contain any provision contrary to the Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will — after **termination of the participation of a beneficiary**, at the time of an **interim payment**, **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Agency will formally notify

the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **after termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if :

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the Agency reduces the grant **at the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the Agency will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) not applicable;

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[29] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

[29] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If the coordinator does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1**}**

multiplied by

the final grant amount (see Article 5.3)**}**.

If the coordinator has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Agency or the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend payments, in whole or in part and interim payments or the payment of the balance for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Agency will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Articles 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on

the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Agency will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Agency will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

  (i) resumption is impossible, or

  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Agency will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the Agency will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the Agency finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/myarea/projects

The Agency will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the official mailing address indicated on the Agency's website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

Not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[30], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

[30] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

As an exception, if such a dispute is between the Agency and SFAX UNIVERSITY, the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Abdalouahed Mokni with ECAS id n0023hnp signed in the Participant Portal on 27/06/2020 at 12:07:17 (transaction id SigId-31090-dpXeVMlnb5QtJ9m3xbUxBWtkFGCOmSvLRDVCqYFfOyMztHaJ4wTWErFQzK10U4gzkVzIMQdL2ZaW7hfzIQc6CrL-jpJZscgsw0KNihoCvhiTby-9CzxuhpGK4OQOoFsDby9iNa5RMzpXsg3cWmlZKuhXEUJPRzSVRTOOE68okY2EXAvhtAzWzl3Gq6sqMEZA3CNl5g). Timestamp by third party at Sat Jun 27 21:10:05 CEST 2020

For the Agency

Signed by Ales FIALA with ECAS id fialaal as an authorised representative on 28-06-2020 00:35:05 (transaction id SigId-31360-gcJjuJ5jDZxe7MlUSYGJL2SkrX3jHIzH1v6ziTcc5CJiGSWI2bImYcX3zyTacI2iHaox3eisqc8E7i50aR51Y8G-jpJZscgsw0KNihoCvhiTby-qOoyIEtRkJ7IA44INWpgt91PHna7AeDtxvstglnmkcTwHo37A3zHHFkkS7udnziqkAIKQYJcf7gatRl73dstOzG) Sun Jun 28 01:35:25 CEST 2020

EUROPEAN COMMISSION
Research Executive Agency

The Director

ANNEX 1 (part A)

Coordination and support action

NUMBER — 952583 — MICAfrica

Table of Contents

1.1. The project summary

Project Number [1]	952583	Project Acronym [2]	MICAfrica

One form per project

General information	
Project title [3]	Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for Human Diseases at University of Sfax
Starting date [4]	01/01/2021
Duration in months [5]	36
Call (part) identifier [6]	H2020-WIDESPREAD-2020-5
Topic	WIDESPREAD-05-2020 Twinning
Fixed EC Keywords	Nutrition related disorders, Bioinformatics, Oncology
Free keywords	Health sciences- Human Microbiome - Cancer - Diabetis - High throuput sequencing

Abstract [7]

TheThe analysis of the human microbiome (genome of memberThe analysis of the human microbiome (genome of members of microbiota that is composed of billions of micro-organisms) is an emerging research area of considerable interest in human health and diseases. Disruption of the microbial community is a major risk factor for many diseases such as metabolic syndrome, immune disorders, cancer development, and is linked to limited response to treatment. In the last decade, numerous initiatives and projects were launched to take advantage of new, high-throughput technologies to characterize the human microbiome and to explore its relationship with health/diseases. Also concrete actions were engaged to provide a tangible response to the need to standardize and harmonize study methods and protocols, as well as regulations.

Despite the increasing number of European and International initiatives on human microbiome, very few studies have been carried out in North Africa (NA). Therefore, there is an urgent need in NA for the development of skills in human microbiome analysis.

With the support of the EU partners (Institut National de Recherche Agronomique (INRA)-Jouy en Josas and Aix Marseille University () from France and Florence University (UNIFI) from Italy), USFAX, aims to be a leading force in the region by: (i) increasing its staff capacities using new technological approaches such as Shotgun metagenome sequencing for the analysis of the human microbiome (ii) adopting a standardized approaches for collecting samples and analyzing data (iii) setting up and coordinating a consortium on human microbiomeat NA level building to start with on existing collaborations with Morocco, Algeria and Egypt that we have named “the North African Human Microbiome Consortium” (NAHMC).

The MICAfrica objectives would be achieved through implementation of vertical coordination and support measures related to the definition of a scientific strategy for human and capital capacity building.

1.2. List of Beneficiaries

Project Number [1]	952583	Project Acronym [2]	MICAfrica

List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
1	SFAX UNIVERSITY	USFAX	Tunisia	1	36
2	INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT	INRAE	France	1	36
3	MEDITERRANEE INFECTION	IHU MI	France	1	36
4	UNIVERSITA DEGLI STUDI DI FIRENZE	UNIFI	Italy	1	36

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number[9]	WP Title	Lead beneficiary[10]	Person-months[11]	Start month[12]	End month[13]
WP1	Capacity building in metagenomics for human microbiome analysis	3 - IHU MI	24.00	3	15
WP2	Microbiota-Host interplay	2 - INRAE	26.00	3	36
WP3	Creation of North-African Human Microbiome Consortium (NAHMC)	1 - USFAX	18.00	18	36
WP4	Dissemination, Exploitation and Communication	4 - UNIFI	24.00	1	36
WP5	Project Coordination and Management	1 - USFAX	24.00	1	36
WP6	Ethics requirements	1 - USFAX	N/A	1	36
		Total	116.00		

1.3.2. WT2 list of deliverables

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Adoption of the state of the art standardization protocols	WP1	3 - IHU MI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	Qualified ER and ESR in Metagenomics studies	WP1	3 - IHU MI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	Qualified ER and ESR in studying the relationship microbiome/CRC in Tunisian patients	WP1	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.4	Validation of the protocols implemented for metagenomic studies	WP1	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D2.1	Qualified ER, and ESR in functional metagenomics studies	WP2	2 - INRAE	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D2.2	Knowledge gain in metabolomics	WP2	2 - INRAE	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D2.3	Implementation of a master module on human microbiome	WP2	1 - USFAX	Websites, patents filling, etc.	Public	18
D3.1	Signing the agreement of the NAHMC by NA members	WP3	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D3.2	Creation of NA microbiome database	WP3	1 - USFAX	Other	Confidential, only for members of the consortium	30

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
					(including the Commission Services)	
D3.3	Establishment of the strategy and the action plan of NAHMC	WP3	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.4	Applying to be a membership of the International Human Microbiome Consortium (IHMC)	WP3	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D4.1	Dissemination and exploitation plan	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D4.2	Creation of MICAfrica website	WP4	4 - UNIFI	Websites, patents filling, etc.	Public	2
D4.3	First report “NAHMC consortium and Database”	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D4.4	Second report “NAHMC consortium and NA Database”	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D4.5	First Report “Events for large public”	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D4.6	Second Report “Events for large public”	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	24

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.7	Third Report "Events for large public"	WP4	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.1	Work plan and schedule, delivered to project partners	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.2	Kick-off meeting (KoM) Minutes and establishment of the Steering Committe (SC)	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.3	Report on Project Management Work Plan	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	2
D5.4	Data Management Plan	WP5	1 - USFAX	ORDP: Open Research Data Pilot	Confidential, only for members of the consortium (including the Commission Services)	6
D5.5	First report "Risk and financial issues report"	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.6	Second report "Risk and financial issues report"	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	16
D5.7	Third report "Risk and financial issues report"	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.8	First Report on the evolution of the	WP5	1 - USFAX	Report	Confidential, only for members	2

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
	publications in high impact journals in the field of microbiome				of the consortium (including the Commission Services)	
D5.9	Second Report on the evolution of the publications in high impact journals in the field of microbiome	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.10	First Report on short term staff exchanges	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D5.11	Second Report on short term staff exchanges	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.12	Report on the involvement of ESRs from USFAX in MICAfrica action	WP5	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D6.1	H - Requirement No. 1	WP6	1 - USFAX	Ethics	Confidential, only for members of the consortium (including the Commission Services)	2
D6.2	POPD - Requirement No. 2	WP6	1 - USFAX	Ethics	Confidential, only for members of the consortium (including the Commission Services)	2

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	**Lead beneficiary** [10]	3 - IHU MI
Work package title	Capacity building in metagenomics for human microbiome analysis		
Start month	3	**End month**	15

Objectives

Objectives. The WP1 aims to improve the skills of ER, ERS and technicians in high-throughput sequencing technologies for human microbiome studies.

Description of work and role of partners

WP1 - Capacity building in metagenomics for human microbiome analysis [Months: 3-15]
IHU MI, USFAX, INRAE, UNIFI
High throughput sequencing technologies have added a new dimension to study the human microbiome and the challenge to analyse large data is increasingly addressed by the development of powerful bioinformatic tools. Through the WP1, ER and ESR will deepen their knowledge in metagenomics (Deep sequencing of 16S rRNA, rpoB gene and shot gun sequencing) and metabolomics to explore the complexity of the human microbiome.
Task 1.1. Setting up standardization protocols (Lead: IHUMI; Duration: M3- M12):
We aim to adopt standardized protocols for collecting stool samples from Tunisian healthy and CRC patients. It is important to optimize the fecal sampling pipeline in a prudent way to get high quality metagenomic DNA for an unbiased NGS and bioinformatic analysis. The fecal collection kit, transportation condition, storage status, and DNA extraction method have to be done according to standardized protocols. We will investigate the gut microbiome from a cohort of healthy Tunisian individuals and CRC patients (Subjects will be recruited after informed consent and according to the EU regulations: see Ethics section 5.1).
Task 1.2. Strengthening skills in metagenomics approaches ((Lead: IHUMI; Duration: M3- M12):
Usually, there are 2 main methods to study the human microbiome by metagenomics: deep 16S rRNA, rpoB gene sequencing and shot gun sequencing. High-throughput sequencing offers a powerful culture-independent approach to study the underlying diversity of microbial communities.
This task aims to provide a detailed understanding of cutting-edge techniques used in microbiome analysis with an emphasis on the analysis of biological samples. We will investigate the gut microbiome composition from a cohort of healthy Tunisian individuals. Microbial DNA extracted from stool samples using standardized protocol will be analysed by 16S rRNA and rpoB gene sequencing, then raw data will be processed using bioinformatics tools.
On the other hand, we plan to perform shotgun sequencing, a genome-wide approach, for the identification and characterization of all genes present within a given microbial community for few healthy individuals (5 samples) with the scientific support of the EU partners. It is important to note that, metagenomic sequencing is cost-effective and specific bioinformatics tools are needed to analyse raw data.
Task 1.3. Dysbiosis of gut microbiota and colorectal cancer (Lead: UNIFI; Duration: M3- M12):
Colorectal Cancer (CRC) is one of the most common malignancies worldwide, with over half a million deaths per year1. In Tunisia, the incidence of CRC is estimated to 4.5/100.000.
The pathogenesis of CRC is a complex and multifactorial process with accumulation of various genetic and epigenetic alterations. It was demonstrated that quantitative and qualitative changes in the intestinal microbiome, contribute to the development of CRC. The gut microbiome consists of at least one thousand species of bacteria that are responsible of several functions such as digesting food, controlling intestinal epithelium homeostasis… Thus, disturbing the balance of the gut microbiome leads to the development of inflammatory bowel diseases and CRC. Previous studiesbased on 16S rRNA sequencing reported high levels of specific bacterial species in stool samples of CRC patients (such as Fusobacterium nucleatum, Bacterioides fragilis, Enterococcus faecalis…) whereas some other species were lacking (such as Clostridiales, Faecalibacterium, Bifidobacterium…). Therefore, monitoring changes in the gut microbiome during CRC development could be an easy diagnostic tool, a useful biomarker for adapting the therapy in CRC patients. On the other hand, it is well established that the bacterial composition that colonize the human gut depends on several factors such as genetic background, environment, and diet.
A study on the gut microbiome including 10 Tunisian CRC patients will be performed by16S rRNA and rpoB gene sequencing. Data will be analysed by bioinformatics tools and bacterial communities between cancer patients and healthy individuals (see Task 1.2) will be compared to identify bacterial species present in the gut of cancer patients.

To reach these objectives, several events will be planned as follow:

- A conference for one day on “Metagenomic approaches in Human microbiome studies” for 50 participants will be organized at the USFAX with the involvement of lecturers from INRA and UHUMI.
- A lab course during 12 days dedicated to 10 ER, 10 ESR, and 3 technicians focusing on “High-throughput sequencing techniques and data analysis using bioinformatics tools”.
-A workshop for setting-up the standard procedures in microbiome analysis during 5 days at USFAX for 10 ER, 10 ESR, and 3 technicians.
- An internship for 7 ESR (30 days) and for 5 ER (15 days) at UHUMI to improve their skills in metagenomic and human microbiome analysis.
- An internship (15 days) for 7 ESR and for 5 ER at UNIFI will be planned in order to strength their knowledge in the study of gut microbiome and colorectal cancer (CRC).
- An entrepreneurial skills training (7 days) dedicated specially for ESR to provide them with the basics of starting and operating a small business and will include the ability to take initiative to identify business opportunities and forecast resource needs and to develop a business plan.

Task 1.4. Audit to validate the implemented procedures for microbiome analysis (Lead: USFAX; Duration: M12-M15): We will submit ourselves to a standard audit by one of the global initiatives on microbiome (expert from the advisor board) to check our alignment to international procedures according to The International Human Microbiome Standard (IHMS) and Microbiome Quality Control (MBQC). This will enable us to raise our profile as a credible partner able to integrate international consortium, to share data and to take part in common efforts on the human gut microbiome for the development of personalized treatment in the future.

Participation per Partner

Partner number and short name	WP1 effort
1 - USFAX	5.00
2 - INRAE	7.00
3 - IHU MI	8.00
4 - UNIFI	4.00
Total	24.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Adoption of the state of the art standardization protocols	3 - IHU MI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	Qualified ER and ESR in Metagenomics studies	3 - IHU MI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	Qualified ER and ESR in studying the relationship microbiome/CRC in Tunisian patients	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	12

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.4	Validation of the protocols implemented for metagenomic studies	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	15

Description of deliverables

The delivrables will be confidential reports that will be prepared by IHUMI, UNIFI and USFAX and delivered to EC at M12 and M15 by USFAX containing the data about the adoption of the standardization and validation of the protocols, the qualification of ER and ESRs in Metagenomics and relationship between microbiome and CRC

D1.1 : Adoption of the state of the art standardization protocols [12]

Confidentiel report about the doption of the state of the art standardization protocols

D1.2 : Qualified ER and ESR in Metagenomics studies [12]

Confidentiel report about the acquisition of new skills by ESRs in Metagenomics studies

D1.3 : Qualified ER and ESR in studying the relationship microbiome/CRC in Tunisian patients [12]

Confidentiel report about the qualification of ER and ESR in studying the relationship microbiome/CRC in Tunisian patients

D1.4 : Validation of the protocols implemented for metagenomic studies [15]

Confidentiel report about the validation of the protocols implemented for metagenomic studies

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Qualified scientific team in performing Metagonomic studies	3 - IHU MI	12	Mean of verification: Report of training (D1.2 Qualified ER and ESR in Metagenomics studies)
MS2	Setting up a standard protocol for metagenomic analysis of gut microbiome	3 - IHU MI	15	This Milestone corresponds to the date of the setting up of a standard protocol for metagenomic analysis of gut microbiome at USFAX, that will be used for research activities

Work package number [9]	WP2	**Lead beneficiary** [10]	2 - INRAE
Work package title	Microbiota-Host interplay		
Start month	3	**End month**	36

Objectives

The WP2 aims to initiate ER and ERS from USFAX to functional metagenomics in order to characterize the microbiota-host interplay.

Description of work and role of partners

WP2 - Microbiota-Host interplay [Months: 3-36]
INRAE, USFAX, IHU MI, UNIFI
Functional metagenomics allows the analysis of microbial communities functions and how they modulate the response of the host. It involves the study of the effect of commensal bacteria, metagenomics clones and microbial proteins using in vitro screening systems. Such function-based approach allows for discovery of novel enzymes whose functions would not be predicted based on DNA sequence alone.
Task 2.1. Capacity building in Functional Metagenomics (Lead: INRA; Duration: M3- M18):
To further characterize the microbiota-host interplay, the strategies that we will use to identify bacteria/bacterial effectors and to study their mode of action consist of i) construction of metagenomics libraries and their screening, ii) analysis of commensal bacteria effects and iii) study of the metagenomics catalogs aiming the identification of target genes.
To explore the effects of bacteria/genes, we will present the different developed high throughput in vitro systems including, cell reporter systems and protein activity measurements. Moreover, we will provide synthetic overview concerning the use of animal models to study the effect of bacteria/bacterial effectors candidate's in vivo (mice, rabbit and pigs).
Task 2.2 Improvement skills in Metabolomics (Lead: INRA; Duration: M3- M18):
Metabolomics is a powerful technique that detects hundreds of small molecules present in biological system such as fecal. Thus, examining the fecal metabolomes serve as a strategy for understanding the interactions between diet, human metabolism, and the gut microbiota composition in health and disease. In this regard, to analyse metabolites in biological samples, several mass spectrometry-based techniques (MS) and nuclear magnetic resonances spectroscopy (NMR) and GC-MS have been employed. Consequently, characterization of metabolic phenotypes can enable personalized medicine
To reach these goals, scientific events will be planed for ER and ESR as described below:
-A conference during one day dealing with the relationship between human microbiome and health/diseases, will be organized at USFAX for 50 participants with the involvement of lecturers from UNIFI and INRA. This conference will be open to scientists and clinicians from Tunisia and NA universities.
-An internship for 7 ESR (30 days) and for 5 ER (15 days) at INRA to improve their skills in functional metagenomics.
- An internship (15 days) for 7 ESR and for 5 ER at INRA will be planned in order to strengthen their knowledge in metabolomics.
Task 2.3. Development of a teaching module on human microbiome
(Lead: USFAX, with contribution of INRA, IHUMI, and UNIFI; Duration: M15- M36):
A teaching module on human microbiome and its relationship with health/diseases will be developed and dedicated to 20 students at Master level (USFAX and NA universities) from the 2nd year of the beginning of the project. This module aims to provide a detailed understanding of cutting-edge techniques used in microbiome analysis with an emphasis on functional metagenomics and clinical applications. This course will be available on the Moodle plateform of the Faculty of Medecine of Sfax.

Participation per Partner

Partner number and short name	WP2 effort
1 - USFAX	5.00
2 - INRAE	11.00
3 - IHU MI	5.00

Partner number and short name	WP2 effort
4 - UNIFI	5.00
Total	26.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.1	Qualified ER, and ESR in functional metagenomics studies	2 - INRAE	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D2.2	Knowledge gain in metabolomics	2 - INRAE	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D2.3	Implementation of a master module on human microbiome	1 - USFAX	Websites, patents filling, etc.	Public	18

Description of deliverables

The delivrables will be 2 confidential reports that will be prepared by INRAE and delivered to EC by USFAX at M18 reporting the data about the qualification of ER and ESR in functional metagenomics studies and metabolomics.
The third delivrable will be a module that will be prepared and implemented on human microbiome by USFAX with the participation of the other beneficiaries at M18. It will open to public

D2.1 : Qualified ER, and ESR in functional metagenomics studies [18]

Confidentiel report about the qualification of ER and ESR in functional metagenomics studies

D2.2 : Knowledge gain in metabolomics [18]

Confidentiel report about the nowledge gain in metabolomics

D2.3 : Implementation of a master module on human microbiome [18]

This delivrable corresponds to a Master module on human microbiome that will prepared, validate and implemented by USFAX in collaboration with EU partners; it will takes part of Masters programme in the field of biology implemented at USFAX and it will be accessible on line for EU and non EU students.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	Qualified scientific team in functional metagenomics	2 - INRAE	18	This Milestone corresponds to the date since wich the USFAX scientific team will be qualified in functional metagenomics that will be

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				verified by the Delivrable D2.1
MS4	Implementation of a master module on human microbiome	2 - INRAE	18	This milestone will corresponds to the date of the Implementation of a master module on human microbiome that will accessible in the Moodle plateforme at the Faculty of Medicine of Sfax.

Work package number [9]	WP3	Lead beneficiary [10]	1 - USFAX
Work package title	Creation of North-African Human Microbiome Consortium (NAHMC)		
Start month	18	End month	36

Objectives

Create and coordinate the North-African Human Microbiome Consortium (NAHMC)

Description of work and role of partners

WP3 - Creation of North-African Human Microbiome Consortium (NAHMC) [Months: 18-36]
USFAX, INRAE, IHU MI, UNIFI
This WP is dedicated to the creation and coordination of the North-African Human Microbiome Consortium (NAHMC). This consortium will bring together researchers from North African Universities (Mohammed V University in Rabat, (Morocco); Setif University, (Algeria) and Suez Canal University, in Ismailia, (Egypt), that will used common procedures to study the role of the human microbiome in health and diseases. The NAHMC's efforts will focus on generating a shared data that will enable us to characterize the diversity of human microbiome in NA population.
Task 3.1. Preparation of an agreement for the creation of the North-African Human Microbiome Consortium (NAHMC) (Lead: USFAX; Duration: M18-M24)
Firstly, an agreement summarizing criteria of the NAHMC (data release, quality assessment, standardization of procedures and protocols, consent of participants) will be drafted and approved by the NA universities members. Upon creation, a 5-year strategy will be discussed and an action plan outlining the objectives of the NAHMC will be prepared. The main objective of this consortium is to promote the generation of database that will be freely accessible for scientific community.
To reach this objective:
-A Meeting (2 days) involving Tunisian and NA ER and ESR with the support of IHUMI, INRA and UNIFI will be organized at USFAX. During this meeting, an agreement summarizing criteria of the NAHMC will be drafted and approved by the NA universities members.
Task 3.2. Coordination and planning the NAHMC strategy and action plan ((Lead: USFAX; Duration:M24-M36).
Thanks to the expertise in the field of microbiome, we will acquire with the support of our EU partners during the first 2 years of the MICAfrica, the leading position in NA and we will coordinate the activities of this consortium. Among its activities, the NAHMC will organize meetings, integrate the International Human Microbiome Consortium (IHMC), participateto international meetings as the next IHMC conference in, Spain, in 2020.
To reach these objectives, USFAX will coordinate the activities of the NAHMC consortium that will enhance networking between USFAX and (i) 3 EU partners; (ii) other Tunisian universities and (iii) NA partners.
With NA partners and Tunisian universities, networking activities (3 scientific workshops during 3 days) aim to spread good practices, to promote common protocols and interoperability, to encourage complementarity between the members of the consortium by widening participation of ER and ESR from Tunisian and NA universities. These workshops will be organized at at Algeria, Egypt and Morocco and will be opened to ER and ESR with consideration of gender balance.

Participation per Partner

Partner number and short name	WP3 effort
1 - USFAX	7.00
2 - INRAE	5.00
3 - IHU MI	3.00
4 - UNIFI	3.00
Total	18.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.1	Signing the agreement of the NAHMC by NA members	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D3.2	Creation of NA microbiome database	1 - USFAX	Other	Confidential, only for members of the consortium (including the Commission Services)	30
D3.3	Establishment of the strategy and the action plan of NAHMC	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.4	Applying to be a membership of the International Human Microbiome Consortium (IHMC)	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	20

Description of deliverables

All the delivrables of this WP will be related to the creation of the he NAHMC by NA members. Three of them will be confidential reports that will be prepared and delivred to EC by USFAX at M18, M20 and M24 about the signature of the agreement, the establishment of the strategy and the action plan and about the application to be a membership of the international Human Microbiome Consortium.
The forth delivrable will be the NA microbiome database that will be created at M30 by the members of NAHMC and will not be open to public (confidential).

D3.1 : Signing the agreement of the NAHMC by NA members [18]

This delivrable id a document signed by all North African (NA) members involved in the creation of the North African Human Microbiome Consortium.

D3.2 : Creation of NA microbiome database [30]

This delivrable is an electronic database that will created during the running of MICAfrica project in order to save and manage the data generated by the research activities and data from NA partners in the field of Human microbiome

D3.3 : Establishment of the strategy and the action plan of NAHMC [24]

This delivrable is a confidentiel report about the strategy and the action plan that will establish by the members of NAHMC

D3.4 : Applying to be a membership of the International Human Microbiome Consortium (IHMC) [20]

This delivrable will be the template of the membership request that will be prepared by the board of the NAHMC and that will be sent by the members of NAHMC for being members of the International Human Microbiome Consortium (IHMC)

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	NAHMC establishment	1 - USFAX	18	This milestone will corresponds to the date of the creation of NAHMC with the signature of the NAHMC agreement by NA partners. It will be verified by the delivrable D3.1 corresponding to the signed agreement
MS6	NA Microbiome database created	1 - USFAX	30	This milestone will correspond to the date of the creation of the NA Microbiome database that will be verified by the delivrable D3.2

Work package number [9]	WP4	Lead beneficiary [10]	4 - UNIFI
Work package title	Dissemination, Exploitation and Communication		
Start month	1	End month	36

Objectives

The main objectives:
- give visibility to all actions and activities carried out by the MICAfrica project and to establish an international cooperation network to promote innovation and address new societal and environmental challenges.
- raise awareness about the importance of developing research activities on human microbiome within the scientific and medical communities, as well as other stakeholders (governmental authorities, clinical private sectors, NGO and general public).
-share data with Tunisian, NA and European scientific community to reach the largest impact on target groups.

Description of work and role of partners

WP4 - Dissemination, Exploitation and Communication [Months: 1-36]
UNIFI, USFAX, INRAE, IHU MI
A plan for dissemination and exploitation will be achieved and uptaded in both the mid-term and final project reports (see draft in 2.2). It includes a record of activities related to dissemination and exploitation that had been undertaken, and those still planed.
Task 4.1 Dissemination:
To give visibility of the results obtained by MICAfrica project:
1- At national level:
Posters and oral presentations will be presented at the annual UNIV expo organized by the USFAX, the annual congress of the gastro-enterolgy society, the different congress on molecular biology and genetics.
2- At international level:
-The website for the project will be created and update all the events that will be organized during the MICAfrica project. The EU partners will also provide more visibility through their own websites.
-The networking site for professionals “LinkedIn” will be also used to establish networks on microbiome analysis. This will facilitate the creation of new groups to share content and connect with the microbiome researcher community.
-Peer-reviewed publications: 2 publications in international journal with high impact-factor (IF >5) and 3 publications after the end of the project.
-Publishing a periodic newsletter “MICAfrica” at the website describing all activities, the next seminars and conferences that will be led by MICAfrica.
-Two academic conferences will be organized on 2020 and 2021:
-The first one dealing with the “Metagenomic approaches in Human microbiome studies” will be organized at the end of 2021 at the USFAX with the participation of lecturers from INRA, IHUMI and UNIF. At least 50 participants from NA and EU partners will participate in this event with the involvement of ER, ESR.
-The second one will be organized at 2021 at the USFAX with the involvement of lecturers from INRA, IHUMI and UNIF on the “Relationship between human Microbiome and health/diseases”. At least 50 participants from NA and EU partners will participate in this event with the involvement of ER, ESR.
-Participation at European and International events to present the MICAfrica project, its objectives and its results.
-After the end of MICAfrica project and the achievement of the increased recognition of the scientists in USFAX, the number of international participants in the international events organized by the faculty of medicine and the faculty of science at USFAX will increased.
- Through the participation of clinicians from Sfax (2 public hospitals and more than 10 private clinics) and from the south of Tunisia (public hospitals and private clinics) to the different events organized during MICAfrica project, the awareness of the potential to use microbiome analysis in the management of diseases (colorectal cancer, diabetes …..) will be reached.
- The results of MICAfrica project will also be widely disseminated through different networks and media centers such as “Cordis Wire” to approach the large scientific public.
Task 4.2 Exploitation:
The output of the MICAfrica project:
-Lab course, workshops and internships dedicated to 10 ER, 10 ESR to enhance their capacities in microbiome analysis will be implemented.

- The trained ESR will also be able to create their spin-off or start-up in the field of microbiome analysis as new developed bioinformatic tools. Therefore it's expected that 50% of trained ESR will set up their business.
- By MICAfrica, USFAX with their partners and NA universities will develop a database on human microbiome analysis. This will permit to share the results with the scientific community. This database will be updated regularly, thus the visibility of USFAX will be enhanced.
- The NAHMC will enhance the collaboration and the networking between EU and NA universities increasing the international visibility.
- A module on the human microbiome will be integrated into the masters in life sciences at USFAX. Courses will be available on the Moodle platform of the Faculty of Medicine of Sfax.
-A master on "microbiome analysis" will be planned, after the consortium elaboration, for Tunisian and NAstudents. The topics of the courses in this master will deal with genetics, bioinformatics and the new technologies to study human microbiome from different body niches (skin, respiratory…..).
-After many exchanges and expert visits during the MICAfrica project, and through the participation to international conferences on human microbiome, new benefical relationship with international experts will be established facilitating the integration of the NAHMC in international networks such as Cost network and human microbiome consortiums.
Task 4.2 Communication:
A communication manager will be recruited to guaranty the implementation and the follow up of planned activities.
The benefit of the outcomes of MICAfrica project will be particularly for the general public and the political stakeholders. Therefore, a strategic communication plan will be implemented and different communication tools will try to target a large audience.
At general public level:
-To target a large audience, collaboration with patient associations such as the cancer associations, Diabetes association, etc....), social NGOs will be established and young students (primary and high schools) will also be implicated in the communication activities (briefings, meetings, especial events and awareness campaigns will be organized twice yearly by each association). This will allow to raise the awareness of the general public about the human microbiome and its relationship with diseases and the importance of a diet.
-To make the events more visible, the content on the website will be visible at least one month before the event.
-A Facebook page will promote the MICAfrica project allowing the post of a variety of content including pictures, videos, event invitations or reports, as well as links to presentations or available multimedia material. Facebook page will have fans who like the page and share the project information.
Audience will be involved by asking questions about the microbiome, diet….
-Several days before the events, a list of posts to tweet during the event will be created
During the event, there will be a live-tweet permitting to people who couldn't attend an event to catch up on the key moments and discussions (by looking at photos, videos and links and reading key discussion points).
A Facebook group will be created, including all partners and patients included in the database, their families. News will be published in this group as well as all information about microbiome role in our life.
Vulgarized scientific results and information coming back from conferences will be published regularly after each event.
A report on these electronic and printed communications will be performed biannually. We expect to have more than 10000 followers and more than 1000 like every report.
Printed communications include newsletters, brochures, posters, flyers that will be distributed in local language in every event particularly for
s and during the campaigns.
At political level:
MICAfrica project will engage interactions between researchers, policy makers (Health Ministry; Social Affairs Ministry) and other relevant stakeholders in the various research areas to raise their awareness of the topic. They will be aware of the importance of the MICAfrica project in the prevention and the early diagnosis of disease as cancer. These interactions will occur through dedicated meetings with the Higher Ministry delegates, arrangements for research collaboration) and specific outputs like expert reports, clinical guidelines, and scientific advices.

Participation per Partner

Partner number and short name	WP4 effort
1 - USFAX	7.00
2 - INRAE	5.00
3 - IHU MI	4.00

Partner number and short name	WP4 effort
4 - UNIFI	8.00
Total	24.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.1	Dissemination and exploitation plan	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D4.2	Creation of MICAfrica website	4 - UNIFI	Websites, patents filling, etc.	Public	2
D4.3	First report “NAHMC consortium and Database”	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D4.4	Second report “NAHMC consortium and NA Database”	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D4.5	First Report “Events for large public”	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D4.6	Second Report “Events for large public”	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D4.7	Third Report “Events for large public”	4 - UNIFI	Report	Confidential, only for members of the consortium (including the Commission Services)	36

Description of deliverables

These delivrables of WP4 will be principally confidential periodic reports prepared by UNIFI with the participation of USFX about the Dissemination and exploitation plan and activities (publications, conferences, public events, NAHMC activities, etc....).
The second delivrable will be the MICAfrica website that will be created and will be functional and open to public at M2

D4.1 : Dissemination and exploitation plan [3]

This delivrable is a document that will prepared by UNIFI with the contribution of USFAX entitrled "Dissemination and exploitation plan" that will describe concrete and well-timed measures for dissemination of all key results throughout project lifetime and after project end. It will describe also the roles and responsibilities of partners in exploiting results

D4.2 : Creation of MICAfrica website [2]

The delivrable will be a functional MICAfrica project website containing the key informations about the MICAfrica project, the members of the consortium. It will be accessible to the scientific and non-scientific public in EU and non EU coutries

D4.3 : First report “NAHMC consortium and Database” [24]

This delivrable will be a document reporting the activities of the NAHMC consortium in the first period after it's cration and the progress in the creation of the "NA database”

D4.4 : Second report “NAHMC consortium and NA Database” [30]

This delivrable will be the second report about the progression of the NAHMC activity and about the setting up of "NA Database”

D4.5 : First Report “Events for large public” [12]

This delivrable will be a document reporting all the data about the “Events for large public” that will be organised during the running of the project to target a large audience, with the aim to raise the awareness of the general public about the human microbiome and its relationship with diseases and the importance of a diet.

D4.6 : Second Report “Events for large public” [24]

This delivrable is a second report about the Events thoose will be organised for large public

D4.7 : Third Report “Events for large public” [36]

This delivrable is the third Report about the events those will be organized for large public

Schedule of relevant Milestones

Milestone number[18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS7	Creation and functional website	4 - UNIFI	2	This milestone corresponds to the date of the creation of the MICAfrica website that will be functional at M2. The delivrable D4.2 will be the mean of verification.

Work package number [9]	WP5	Lead beneficiary [10]	1 - USFAX
Work package title	Project Coordination and Management		
Start month	1	End month	36

Objectives

Objectives. 1. Administrative and financial management, budget controlling, communication to the EU Commission
2. Ensure coordination among partners
3. Ensure precise evaluation, risk management and reassessment, deliverables and milestones
4. Ensure an open and flexible decision making structure
5. Build up project management competences at USFAX through close interaction and support from INRA, IHUMI and UNIFI as experienced EU project managing organisation

Description of work and role of partners

WP5 - Project Coordination and Management [Months: 1-36]
USFAX, INRAE, IHU MI, UNIFI
This work package includes all management tasks necessary for a smooth execution of the project activities in order to schedule and complete them efficiently and successfully. The project management will ensure the organizational, financial and administrative management of the consortium and it will also ensure effective communication with the European Commission as well as between all involved partners.
Task 5.1 Project start-up (Lead: USFAX; Duration: from M1 to M2)
As required by the applicable H2020 rules, and before the MICAfrica project's Action starts, the four Consortium Beneficiaries will have concluded and signed the required Consortium Agreement (CA). No costs in relation to the drafting and preparing of the CA will be claimed by the MICAfrica project's EU-funding".
"The MICAfrica project's Kick-Off Meeting will be organised at the premises of the Coordinating Legal Entity (USFAX) by month 1 of the project. During this meeting also the Steering Committee (SC) will be established. The SC will be composed by the Contact Persons of each member of the consortium and administrative/technical staff (PC, Project manager and WPL) who will be actively involved in all activities. The SC will organize the first meeting (KoM) at USFAX to set up all principles of the project implementation and the work plans.
The SC will be composed by the Contact Persons of each member of the consortium and administrative/technical staff (PC, Project manager and WPL) who will be actively involved in all activities. The SC will organize the first meeting (KoM) at USFAX to set up all principles of the project implementation and the work plans.
Task 5.2 Project coordination and Pre-Training Planning (Lead: USFAX supported by INRA, IHUMI, and UNIFI; Duration: from M1 to M36)
Steering Committee Meetings will be held annually or more frequently when appropriate (some of these meetings might be via video-conferences while others would be held in a particular location) to review the project activities, to strengthen the best practices within the MICAfrica project members, to define the annual work plan and budget as well as to discuss other financial and administrative issues. It is foreseen to held 3 annual SC meetings: one in USFAX and one in each European partner countries to deepen the relationships among the partnerships. The last meeting will be organised at the end of the project at Sfax
As coordinator, the USFAX will be supported by EU partners and will be responsible to manage all strategies activities related to the coordination of the project at all levels (European Commission, Steering Committee, External Advisory Board, NAHCM) to achieve project objectives and project deliverables in time and with the required quality. The SC will be supported by EU partners in controlling the work progress and budget allocation. USFAX will guarantee the effective communication and commitment of all partners through periodically meetings and frequent on line exchanging (email, skype, …).
In addition, USFAX, with the support of all partners, will prepare the periodic and final reports to be submitted in time to the European Commission.
Task 5.3 Administrative and financial Management (Lead: USFAX, supported by INRA, IHUMI, and UNIFI; Duration: from M1 to M36)
This task includes daily activities of the project management such as administration, evaluation and monitoring, financial reporting, purchases and payments. An external financial audit will be required in order to ensure a proper financial management. All partners will be involved in this task under the supervision of USFAX.
Task 5.4 Logistic arrangements (Lead: USFAX supported by INRA, IHUMI, and UNIFI; Duration : from M1 to M36)

All partners, under the coordination of USFAX, will be cooperatively involved in supporting this task which includes all logistic arrangements and the implementation of procedures needed to support, define and carry out all project activities (preparation of travels, organization of meetings, workshop, accommodation....). The decision related to the logistic arrangements can be made even with the complete absence or the disagreement of one of the EU partners for appropriateness of the proposed management structure/decision making.
Some risks should be considered, in particular EU-TN contacts / conflict with EU and/or TN contacts and late financial transfer. To ovoid these risks, we will adopt as mitigation (see table 3.2b).
Task 5.5 KPI for Widening "Evolution of the publica tions in high impact journals in the relevant research fields" (Lead: USFAX, supported by INRA, IHUMI and UNIFI; Duration M2 to M36)
The coordinator (USFAX) will be responsible for this task that will measure the evolution in % of the peer-reviewed publications in of USFAX high impact journals in the field of microbiome. The peer-reviewed publications in the field of microbiome during the the three year preceding the start date of the project will be introduced on the funding and tenders portal before the end of month 2. After this date the project related current publications will be added to the list.

Participation per Partner

Partner number and short name	WP5 effort
1 - USFAX	11.00
2 - INRAE	5.00
3 - IHU MI	4.00
4 - UNIFI	4.00
Total	24.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.1	Work plan and schedule, delivered to project partners	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.2	Kick-off meeting (KoM) Minutes and establishment of the Steering Committe (SC)	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.3	Report on Project Management Work Plan	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	2
D5.4	Data Management Plan	1 - USFAX	ORDP: Open Research Data Pilot	Confidential, only for members of the consortium (including the Commission Services)	6

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.5	First report “Risk and financial issues report”	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D5.6	Second report “Risk and financial issues report”	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	16
D5.7	Third report “Risk and financial issues report”	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.8	First Report on the evolution of the publications in high impact journals in the field of microbiome	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	2
D5.9	Second Report on the evolution of the publications in high impact journals in the field of microbiome	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.10	First Report on short term staff exchanges	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D5.11	Second Report on short term staff exchanges	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D5.12	Report on the involvement of ESRs from USFAX in MICAfrica action	1 - USFAX	Report	Confidential, only for members of the consortium (including the Commission Services)	36

Description of deliverables

All the Delivrables of this WP5 will be confidential reports those will be prepared and delivered to EC by USFAX at several times. These documents will reports all data concerning the management of the project since the Kick-off meeting (KoM) (M1) until the end of the project (M36). They will include
the report on Project Management Work Plan (M2), the Data Management Plan (M6), ORDP, etc....

D5.1 : Work plan and schedule, delivered to project partners [1]

This delivrable is a document that will be prepared in the occasion of the Kick-Of meeting and it concerns the work plan and schedule that will be delivered to project partners

D5.2 : Kick-off meeting (KoM) Minutes and establishment of the Steering Committe (SC) [1]

This delivrable will be the Minutes of the Kick-off meeting (KoM) Minutes summarising the activities and the decisions those will be made by the consortium (establishment of the Steering Committe (SC), etc..)

D5.3 : Report on Project Management Work Plan [2]

Report on Project Management Work Plan

D5.4 : Data Management Plan [6]

This delivrable (DMP) is a written document that will describe the procedure of management,the data expected to be acquired or generate and stored during the course of the project and the mechanism that will be used at the end of the project to share and preserve the data.

D5.5 : First report “Risk and financial issues report” [1]

This delivrable is a document that will include any wrong information about financial reporting timelines; it helps identify and assess the risks which may lead to material mistakes in financial reporting.

D5.6 : Second report “Risk and financial issues report” [16]

This delivrable will be the second report “Risk and financial issues report” identifying and assessing the risks which may lead to material mistakes in financial reporting during the first period of the project.

D5.7 : Third report “Risk and financial issues report” [36]

This delivrable will be the final report “Risk and financial issues report” identifying and assessing the risks which may lead to material mistakes in financial reporting during the last period of the project.

D5.8 : First Report on the evolution of the publications in high impact journals in the field of microbiome [2]

This delivrable will be a document reporting the publications of USFAX in high impact journals in the field of human microbiome during the period preceding the start of the project

D5.9 : Second Report on the evolution of the publications in high impact journals in the field of microbiome [36]

This delivrable will be a document reporting the publications of USFAX in high impact journals in the field of human microbiome during the period preceding the start of the project

D5.10 : First Report on short term staff exchanges [15]

This delivrable is a document that will report updated data related to the short term staff exchanges completed

D5.11 : Second Report on short term staff exchanges [36]

This delivrable is a document that will report at the end of the project the updated data related to the short term staff exchanges completed during the project period

D5.12 : Report on the involvement of ESRs from USFAX in MICAfrica action [36]

This delivrable will be a document reporting all the data related to the involvement of ESRs from USFAX throughout the MICAfrica project

Schedule of relevant Milestones

Milestone number[18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS8	Project Start	1 - USFAX	1	This Milestone will correspond to the date of the start of the Project and it will be attested by the organisation of the Kick-off Meeting (D5.2) and by the establishment of the SC

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS9	Qualified support staff for management	1 - USFAX	5	This milestone will be the date since which the USFAX support staff for management will be completely operational in the management of the project with efficiency in project management and positive feedback from the EC
MS10	Publications produced as a result of MICAfrica action	1 - USFAX	36	This milestone corresponds to the date of the final report of Publications produced as a result of MICAfrica action and the delivrable D5.9 will be the mean of verification of the evolution of the publications in high impact journals in the field of microbiome

Work package number [9]	WP6	Lead beneficiary [10]	1 - USFAX
Work package title	Ethics requirements		
Start month	1	End month	36

Objectives

The objective is to ensure compliance with the 'ethics requirements' set out in this work package.

Description of work and role of partners

WP6 - Ethics requirements [Months: 1-36]
USFAX
This work package sets out the 'ethics requirements' that the project must comply with.

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.1	H - Requirement No. 1	1 - USFAX	Ethics	Confidential, only for members of the consortium (including the Commission Services)	2
D6.2	POPD - Requirement No. 2	1 - USFAX	Ethics	Confidential, only for members of the consortium (including the Commission Services)	2

Description of deliverables

The 'ethics requirements' that the project must comply with are included as deliverables in this work package.

D6.1 : H - Requirement No. 1 [2]

Regarding the collection of samples from humans: The procedures and criteria that will be used to identify/ recruit research participants must be provided; The informed consent procedures that will be implemented for the participation of humans must be provided; Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file; Details on incidental findings policy must be provided.

D6.2 : POPD - Requirement No. 2 [2]

The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s). The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR, it must be confirmed that a detailed data protection policy for the project is available and kept on file. The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the ‘data minimisation ‘principle). A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/ research participants must be provided. In case personal data are transferred from the EU to a non-EU country or international or-ganisation, confirmation that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679, must be provided. In case personal data are transferred from a non-EU country to

the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected must be provided. In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be provided.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

1.3.4. WT4 List of milestones

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS1	Qualified scientific team in performing Metagonomic studies	WP1	3 - IHU MI	12	Mean of verification: Report of training (D1.2 Qualified ER and ESR in Metagenomics studies)
MS2	Setting up a standard protocol for metagenomic analysis of gut microbiome	WP1	3 - IHU MI	15	This Milestone corresponds to the date of the setting up of a standard protocol for metagenomic analysis of gut microbiome at USFAX, that will be used for research activities
MS3	Qualified scientific team in functional metagenomics	WP2	2 - INRAE	18	This Milestone corresponds to the date since wich the USFAX scientific team will be qualified in functional metagenomics that will be verified by the Delivrable D2.1
MS4	Implementation of a master module on human microbiome	WP2	2 - INRAE	18	This milestone will corresponds to the date of the Implementation of a master module on human microbiome that will accessible in the Moodle plateforme at the Faculty of Medicine of Sfax.
MS5	NAHMC establishment	WP3	1 - USFAX	18	This milestone will corresponds to the date of the creation of NAHMC with the signature of the NAHMC agreement by NA partners. It will be verified by the delivrable D3.1 corresponding to the signed agreement
MS6	NA Microbiome database created	WP3	1 - USFAX	30	This milestone will correspond to the date of the creation of the NA Microbiome database that will be verified by the delivrable D3.2
MS7	Creation and functional website	WP4	4 - UNIFI	2	This milestone corresponds to the date of the creation of the MICAfrica website that will be functional at M2. The delivrable D4.2 will be the mean of verification.

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS8	Project Start	WP5	1 - USFAX	1	This Milestone will correspond to the date of the start of the Project and it will be attested by the organisation of the Kick-off Meeting (D5.2) and by the establishment of the SC
MS9	Qualified support staff for management	WP5	1 - USFAX	5	This milestone will be the date since which the USFAX support staff for management will be completely operational in the management of the project with efficiency in project management and positive feedback from the EC
MS10	Publications produced as a result of MICAfrica action	WP5	1 - USFAX	36	This milestone corresponds to the date of the final report of Publications produced as a result of MICAfrica action and the delivrable D5.9 will be the mean of verification of the evolution of the publications in high impact journals in the field of microbiome
MS11	Promotion of involvement of ESRs from USFX		1 - USFAX	36	This milestone will correspond to the date of the delivery of the final report about the promotion of the involvement of ESRs from USFAX in the project (D5.12)

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	LSmall financial deviations from initially planned budgets : may be requested by partners during the project (Low)	WP5	The cordinator will keep smooth and regular communication with partners to discuss any potential financial barrier and tackle it as soon as it is identified.
2	Unavailability of scientific experts at the date planned (Low)	WP2, WP3, WP4	Prepare a list of scientific experts in each aspect of the project. Invite another expert in case of the unavailability of the first expert
3	Partners do not respect deadlines of their corresponding deliverables and/or milestones (Low)	WP1, WP2, WP3, WP4, WP5, WP6	The cordinator will send reminders to partners through regular communication
4	Changes on planning execution (Low)	WP1, WP2, WP3, WP4, WP5, WP6	The management structure will allow changes and it is designed to permit smooth adaptations and modifications to the project execution
5	Lack of commitment from NA partners causing delays in deliverables (Low)	WP3	The coordinator makes efforts by continuous communications to convince NA partners to be engaged in the creation of NAHMC
6	Conflicts within the NAHMC or between partners may arise during the project execution (Low)	WP1, WP2, WP3, WP4, WP5, WP6	Partners and collaborators are aware that the coordinator is available at any time for any complaint or dissatisfaction with the working plan in order to find solutions. The SC can discuss by using video conference.
7	Failure to engage the significant stakeholders and interest groups (Low)	WP4	Identification and analysis of stakeholders and interest groups and planned targeted dissemination actions
8	Difficulty in publishing high – IF papers (delay in implementing activities)	WP2, WP4	Increase quantity and and improve quality of data
9	Limited opportunities to create a start up (Medium)	WP3	Creation of a spin-off with a participation of USFAX and the ministry of education and research

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	Total Person/Months per Participant
1 - USFAX	5	5	7	7	11	✓	35
2 - INRAE	7	11	5	5	5		33
3 - IHU MI	8	5	3	4	4		24
4 - UNIFI	4	5	3	8	4		24
Total Person/Months	24	26	18	24	24		116

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	18	Brussels/Onsite/Remote	
RV2	36	Brussels/Onsite/Remote	

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Agency). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

R	Document, report
DEM	Demonstrator, pilot, prototype
DEC	Websites, patent fillings, videos, etc.
OTHER	
ETHICS	Ethics requirement
ORDP	Open Research Data Pilot
DATA	data sets, microdata, etc.

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU	Public
CO	Confidential, only for members of the consortium (including the Commission Services)
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number:MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

VA	if virtual access,
TA-uc	if trans-national access with access costs declared on the basis of unit cost,
TA-ac	if trans-national access with access costs declared as actual costs, and
TA-cb	if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

CALL: H2020-WIDESPREAD-2020-5

TWINNING

ANNEX 1 TO THE GRANT AGREEMENT
(DESCRIPTION OF ACTION)

COORDINATION AND SUPPORT ACTION (CSA)

PROJECT ACRONYM:

MICAfrica

PROJECT No.:

952583

PROJECT TITLE:

Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for

Human Diseases at University of Sfax

HISTORY OF CHANGES

Page/Section	Nature of change and reason
	COO NOTE: All changes have been indicated with ***blue colour*** throughout the PART B for easier tracking of the additional information included, modifications and corrections made at GAP stage and based also on the document: "Guidance on Actions **(GAc)"**
PART A – Data in the Online Tabs/SYGMA	
Part A (online)	We made changes in the Deliverables of WP4: • For D.4.1 *Dissemination and Exploitation Plan* the Lead Ben. Is now only UNIFI. • The Del. for *the Creation of MICAfrica website* is now No. 2 and not No.3. There was a numbering mistake at proposal stage. • We added the Deliverables: 4.5, 4.6 and 4.7 for the *events* with dues dates 12, 24 and 36 respectively as per the GAP document GAc. • We split the initial Del. No. 4.4 into two different Dels. With due dates: M24 and M30.
	- We added in **the description** of WP5 the recommended sentence (in the beginning of Task 5.1 "Project start-up") (GAP document: GAc, point 8 – signature of the Consortium Agreement). - We also deleted the initial Deliverable "D5.2: Management work plan and **consortium agreement signed and approved**" as recommended in GAP document: GAc (points 8 and 15) and updated the list of Deliverables. - We also adjusted based on the GAc document and in agreement with the REA PO the relevant paragraph on the KoM as follows: *The MICAfrica project's Kick-Off Meeting will be organised at the premises of the Coordinating Legal Entity (USFAX) by month 1 of the project. During this meeting also the Steering Committee (SC) will be established. The SC will be composed by the Contact Persons of each member of the consortium and administrative/technical staff (PC, Project manager and WPL) who will be actively involved in all activities. The SC will organize the first meeting (KoM) at USFAX to set up all principles of the project implementation and the work plans.*
	- We added the task (Task 5.5) entitled "KPI for Widening "Evolution of the publication in high impact factor journals" in WP5 (GAP document: GAc, point 15). - One deliverable (D5.5) entitled "Report on the evolution of the publications in high impact journals in the field of microbiome", was also added in this WP5.
	As per the feedback in the GAP document GAc (points 8 and 15) the list of Dels. For WP5 was updated as follows: • We deleted the Deliverable D5.2 "Management work plan…" • For the Del. 5.1 now the due date is M1 to coincide with the start of the project. • The initial D. 5.3 is now 5.2. • We added the Del. 5.3 Report on Project Management Work Plan • Data Management Plan is now the Del., No. 5.4 M6.

	• For the initial Del. entitled: "Risk and financial issues report" there are now 3 separate Dels. Instead of 5 initially planned to better align with the project's reporting periods. • We added the Del. 5.9 on *Second Report on the evolution of the publications in high impact journals in the field of microbiome* to report at the end of the project's duration on the achievement in terms of publications for the project thanks to the TWINNING EU-funding. • We added the Dels. 5.10 + 5.11 to report in a precise manner on the short-term staff exchanges to take place for the project in the 1st and the 2nd Reporting Periods. • We added the Del. 5.12 *Report on the involvement of ESRs from USFAX in MICAfrica action* to report at the end of the project how the MICAfrica TWINNING Action helped the ESRs via the different activities performed and their overall involvement.
	- We checked the number of deliverables and the **level of their confidentiality** (public/confidential), and we made the appropriate changes (based on the GAP document: GAc, point 15).
	- We made the necessary changes concerning delivery date of Deliverables (WP4, WP5) in order to ensure that only one delivery date is assigned to each Deliverable (GAP document: GAc, point 15).
	- As recommended in GAP document GAc (point 15), we also modified the title and the confidentiality of Deliverable related to the Kick-of Meeting (KoM).
	- We added one Milestone (MS8) with due date M1 in WP5 "Project Start" (M1) as recommended in GAP document: GAc (point 15). - We also added the Milestone No. 11 with due date M36 with Title: *Promotion of involvement of ESRs from USFX* as per the discussion we had with the REA PO.
	We made the recommended – as per the GAP document: GAc (point 15) – changes in Milestones and added in the "Means of Verification" the numbers and names of the relevant Deliverables. For the initial Milestone No. 5 – NAHMC Establishment we changed the due date from M24 to M18 to better align with the overall work-plan. Means of verification is the Del. 3.1. Signing the agreement of the NAHMC by NA members.
	We added a Milestone (M10) – as per the GAP document: GAc (point 15) – with due date M36, related to the final report on publications produced as a result of MICAfrica action and added the names of the related WPs and described the means of verification.
Data Management Plan (DMP)	**DMP** Deliverable – **due date M6** and indicated as "**ORDP**: Open Research Data Pilot" concerning its report type.
SYGMA – Beneficiaries Tab	The Legal and short names of Ben N°3 were updated in Funding and Tenders portal:

	-Legal name: **MEDITERRANEE INFECTION** - Short name: **IHUMI** Overall: - Ben. No. 1 – Legal name: SFAX UNIVERSITY – Short name: **USFAX** - Ben. No. 2 – Legal Name: INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT– Short Name: **INRAE** - Ben. No. 3 – Legal Name: MEDITERRANEE INFECTION – Short - name: **IHUMI** - Ben. No. 4 – Legal Name: UNIVERSITA DEGLI STUDI DI FIRENZE – Short Name: UNIFI
Bank Account of the Coordinating Legal Entity – USFAX	A dedicated Bank Account was created for the purpose of the MICAfrica EU-funded Project. Process described in the GAP document GAc followed.
Question on Emails GAP Doc. GAc	The official University emails of the persons in charge of the submitted MICAfrica proposal are: - leila.ammar@fms.usf.tn - moez.rhimi@inrae.fr The personal emails are used, since they are more functional. REA PO informed as required.

PART B

Section 1: EXCELLENCE:

1.3.3 Methodology	We specified **GREEN and GOLD** open access in the Table under the sub-section 1.3.3 Methodology.
Excellence = ESR – Shortcoming	For the shortcoming under Criterion 1 – EXCELLENCE: *"However, there is little information on the interaction of MICAfrica with key stakeholders to support the long-term success of the project."* It was considered to be best addressed under sub-section 3.2 as follows: *** Interaction of MICAfrica with key stakeholders to support the long-term success of the project** Within MICAfrica, a Stakeholders' management plan that defines the processes, procedures, tools, and techniques in order to effectively engage stakeholders in the project's execution, based on the analysis of their interests and potential impact, will be prepared and implemented. At an early stage of MICAfrica significant efforts will be made in the recruitment and engagement of an appropriate set of stakeholders. A communication and involvement strategy with a structured approach will be implemented by the MICAfrica Team in order to:

	▪ identify relevant stakeholders per WP and task at an early stage; ▪ communicate objectives of the MICAfrica project, and what the project can do for the stakeholder; ▪ establish a process for ongoing engagement; ▪ continue to engage with all stakeholders throughout the assessment and implementation processes. During the activities included in the project and principally during the Kick off Meeting, conferences, networking activities, etc., the MICAfrica Team will make efforts to convince stakeholders to participate in the project's relevant activities. Networking activities offered by MICAfrica will also give opportunities for stakeholders to meet *face to face* with other stakeholders and establish collaborations with them. Through the communication activities, stakeholders will be well informed and would be interesting to be part of and to support the project and the long-term success of the project. In addition, with policy-makers contacts and intense exchange of relevant information, it can be interesting for stakeholders to be part of, as it may provide them with insights that they would otherwise not have heard of. Workshops dedicated to MICAfrica stakeholders will be occasions to collect information from stakeholders, but also to disseminate knowledge and results.
Section 2: IMPACT	
2nd ESR Shortcoming for IMPACT relevant also to the Call Topic specific element of: SFAX UNIVERSITY (USFAX) + the other already funded TWINNING EU-funded projects.	As requested in the GAP document GAc, we added detailed information describing the SEED project / GA No. 856592 – Title: STRENGTHENING THE SFAX UNIVERSITY EXPERTISE FOR DIAGNOSIS AND MANAGEMENT OF EPILEPTIC ENCEPHALOPATHIES, under the Call: H2020-WIDESPREAD-2018-03 and the SfaxForward project GA No. 857269 – Title: Cultural heritage in South Tunisia. A twinning project promoting interdisciplinary and participatory sciences for an inclusive society, under the Call: H2020-WIDESPREAD-2018-03 and in particular demonstrated both the: (i) the added value and (ii) the impact of the MICAfrica proposal in achieving the specific Twinning programme objectives (under the current CALL: H2020-WIDESPREAD-2020-5), in comparison to these two already funded Twinning Projects within the coordinating entity. This has as follows: *The coordinator of MICAfrica project (USFAX) has already been funded under other H2020 Twinning calls. Indeed, two Twinning projects called SEED (GA N°. 856592) and SfaxForwards (GA N°. 857269) are running now and are coordinated by USFAX.* *Based on these two projects coordinated by USFAX, one in the medical field and the other in the social sciences, MICAfrica project will reinforce the position of Sfax University as a leading university, not only in basic higher education in different disciplines, but also in the field of scientific research; especially in the management and coordination of collaborative projects with renowned European partners.* ***SEED project** aims to enable USFAX to achieve excellence in research in the field of epilepsy, particularly in the clinical and genetic diagnosis of epileptic encephalopathies (EE) that represent a group of severe epileptic diseases with early onset that lead to progressive cerebral dysfunction. This will be achieved through collaboration with two centers of excellence in the field, one from France (Aix-Marseille University) and the second from Belgium (Antwerp University).* *In line with EU orientations and Twinning requirements, the SEED project will strengthen the medical and technological capacity of USFAX in the field of EE and allow access to scientific*

	excellence at international level for members of the SU, which will lead ultimately to a better integration into international networks in MENA and EU regions. Through the completion of all activities included in the project (short exchange staff, trainings, conferences, workshops, etc. and with the support of AMU and UA, USFAX will be able to significantly reduce networking gaps, to increase its ability to compete for international research funds and to link further with stakeholders. In addition, thanks the SEED project, USFAX will become the reference center for the clinic and genetic diagnosis of EE in the MENA region. ***SfaxForwards** is a project in the field of Humanities and Social Sciences (MdMSH) that aims to strengthen the capacities of an innovative academic centre regarding Cultural Heritage: the Maghreb House of the Humanities and Social Sciences (MdMSH) at the University of Sfax. It aims also to renforce the position of Sfax partner as an international model for mutually beneficial relations between academia and civil society, with Heritage serving as a driving force of regional development and stability. SfaxForward postulates that Tangible and Intangible Heritage can play a central role in a territory's transformation and development. The characterization and subsequent participatory management of these common cultural assets should engender a more stable and inclusive society.* *So to achieve its goal, SfaxForward develops three types of initiatives: multidisciplinary conferences and workshops on the project's key themes, thematic schools dedicated to young researchers, and an Observatory of Southern Tunisian Heritage constructed in collaboration with civil society.* *The extensive interdisciplinary experience of the collaborating French and Belgian Houses of the Humanities and Social Sciences benefits MdMSH in constructing its own unique scientific identity, with an ambition for international excellence.* *The "**added value**" of the new MICAfrica project is the reinforcement of the position of USFX as a leader University at Sfax and Tunisia, and also at the North part of Africa. With the constitution of the North African (NA) Consortium within the MICAfrica project, the University of Sfax will play an important role in creating and strengthening synergy and networking with the NA countries and subsequently with other African countries. This steering position could be strengthened and developed in the future to cover other areas of research.* *The University of Sfax could become also a benchmark university in Northern Africa, and in Africa as a whole with respect to the management and coordination of European projects. Moreover, it will contribute to supporting the EU plan for development and cooperation that covers Africa as a whole; this EU plan supports projects with a trans-regional, continental or global added value in areas of shared interest, and offers new possibilities for the EU and Africa to work together.* *Furthermore, through the capacity building activities dedicated to young research from Tunisia and from NA countries, and to administrative/support staffs respecting the gender aspect, Sfax University could be a driver force in NA and in the rest of African countries by implementing collaborative program, in order to improve project management and leadership skills in a network with others as well ad to increase access to European funds for African universities; those are interested in develop International cooperation projects and learn a common base for all EU Programs.*
2.1 Expected impacts	- We **deleted** from the sub-section 2.1 Expected impacts ***the below reference to the two journals indicated at proposal stage in order to allow the possibility/flexibility*** of publishing also in other prestigious journals and to not be restricted to only two specific journals: ***Publication of scientific articles in high impact-factor journals** (2 publications by 2023 and 3 after the end of the project);*

	Microbiome Journal (ISSN 2049-2618); IF (2017-2018): 9.133 *Cancers (ISSN 2072-6694); (Impact Factor 2018: 6.162)* And we modified it as follows: **- *Publication of scientific articles in high impact-factor journals:*** *The consortium partners will reinforce the impact of dissemination activities by publishing reports and scientific articles in international peer reviewed journals with high impact factors.* The following sentence was also added concerning the use of the Open Access for peer-reviewed publications: *Through the MICAfrica activities, the scientists (ER and ESRs) will publish their research results in high-impact journals (IF>5) in open access to all scientific publications using combination of both **GREEN and GOLD open access ways.***
2.2 Measures to maximise impact	Based on the GAP document – GAc (point 16), and the discussion we had with the REA PO in charge of the MICAfrica GAP, for the contractual obligations of OPEN ACCESS in Horizon 2020, and the Article 29.2, we attested under Sub-section 2.2 – a) Dissemination and exploitation of results, that the project's peer-reviewed publications will be also available in repository with online open access (Green OA). We also specified that the 5 expected publications will be in open access (combination of GREEN and GOLD OA ways). The below paragraphs were added: *The MICAfrica Consortium beneficiaries will undertake any required measures/actions so as to ensure full compliance with the legal requirements set in the Article 29.2 of the Grant Agreement referring to: Open access to scientific publications. The Consortium acknowledges that under Horizon 2020, each beneficiary must ensure open access to all peer-reviewed scientific publications relating to its results. To meet this requirement, beneficiaries must, at the very least, ensure that any scientific peer-reviewed publication can be read online, downloaded and printed. Since any further rights – such as the right to copy, distribute, search, link, crawl and mine – make publications more useful, beneficiaries shall make every effort to provide as many of these options as possible. All peer-reviewed scientific publications that do not contain sensitive data and that will not be relevant for exploitation will be made available to the scientific community through open access (2 publications by 2023, and 3 after the end of the project) using in combination GREEN and GOLD ways. (…)* *The Consortium is well aware that the dominant type of scientific publication is the journal article. However, and based on the H2020 Mandate on open access to publications, the Consortium beneficiaries will make additional efforts so as to provide open access to other types of scientific publications, such as: monographs, books, conference proceedings, grey literature (informally published written material not controlled by scientific publishers, e.g. reports).* Concerning Data Management the below paragraphs were added: *A first version of DPM will be submitted within the first 6 months of the project's Action implementation. The DMP will be updated over the course of the project whenever significant changes arise, such as new data, changes in consortium policies (e.g. new innovation potential, decision to file for a patent), changes in consortium composition and external factors (e.g. new consortium members joining or old members leaving).*

	Finally, to improve and maximise access to and re-use of research data generated by MICAfrica project, the microbiome data will be made ***as open as possible, as closed as necessary*** *in terms of sharing.* - We also made the appropriate changes for the Data Management Plan (DPM) (GAP document: GAc, point 16) - Moreover, based on the feedback provided in the GAP document GAc, and the discussion we had with the REA PO in charge of the MICAfrica GAP, we added **GOLD Open Access publication fees** for the: Beneficiaries N°2 (2000 Euros) and N°4 (2000 Euros). Please see the "Other Goods and services" item (in total 6000 Euros for publications using GOLD OA way). Relevant Tables under 3.4b.
IMPACT = ESR – Shortcoming	In order to address the below shortcoming for the **Criterion 2 – IMPACT:** "However, management of IPR is insufficiently described", we added a dedicated sub-section "Management of IPR" in the end of section 2: Impact as follows: ***- Management of IPR*** *Concerning the* ***management of intellectual property*** *(IP), the ownership, access rights, potential uses or related data, etc. will be also assessed. The Consortium Agreement will govern the rules and procedures for the management of IP.* *In detail, MICAfrica proposes a complete range of activities leading to the optimal visibility of the project and its results, ensuring a smooth handling of the individual intellectual property rights (IPR) of all partners involved; thus, paving the way for knowledge transfer.* *Internal knowledge management will be facilitated through a* ***secure professional collaborative space for project document sharing.*** *Project partners count on a solid individual IPR strategies and prior knowledge ownership (background) related to the project, which is already protected under diverse IPR mechanisms, as well as the intended foreground for the project.* *Additionally, a freedom-to-operate analysis has already been conducted to ensure the future exploitation of the MICAfrica solution.* *The overall IPR strategy will ensure that all partners are free to benefit from their complementarities and to fully exploit their market position.* *Beneficiaries will also define the background needed for the purposes of the project development in a written agreement and, where appropriate, may agree to exclude specific background.*
Section 3: IMPLEMENTATION:	

	- Additional information on the following two important elements of this specific Twinning Call Topic (involvement of early stage researchers (ESRs) and **promotion of gender equality among early stage researchers**) was added in the sub-section section "Implementation (**3.1 Work plan**) as per the feedback provided in the GAP document: GAc (point 15). *Throughout the project's Action implementation, particular attention will be paid on the involvement of the Early Stage Researchers (ESRs) in all the different training, networking and research activities **with respect to gender balance** (WP1, 2 and 3). ESRs from life science institutions and the medical school at the Coordinating Legal Entity (USFAX), will be informed and invited directly and via their institutions and supervisors by e-mail, facebook and via the website of MICAfrica project to register to the scientific activities, in order to ensure the development of their skills in High-throughput sequencing technologies in human microbiome, in bioinformatics and in the study of relationship between human microbiome and diseases. They will be also informed and invited to participate specifically in trainings on entrepreneurship that will provide them the basics of starting and operating a small business and will enhance their ability to take initiative, to identify business opportunities and forecast resource needs and to develop a business.* *ESRs from Morocco, Algeria and Egypt will be invited via their institutions and via the website to participate in the activities related to the creation of the North-Africa (NA) Consortium of Human Microbiome (NAHMC).* *On the other hand, the MICAfrica project will carefully take into account the involvement of ESRs in the organization of MICAfrica activities including dissemination, communication, and exploitation activities, allowing them to interact early with the larger research community and to raise their profile. Specific focus will be placed so as to respect the gender equality among ESRs who will be involved. Particular attention will be also placed on the distribution of funds by ensuring that ESRs will benefit from them with respect to gender balance.* In particular, concerning the special focus of this specific TWINNING Call Topic on the promotion of gender equality among early stage researchers, please see also the information already provided at proposal stage under Sub-Sect 1.3.3 – **Gender balance and involvement of ESR.**
	- We added one paragraph in response to the comment about the improvement of the skills of USFAX's staff on proposal preparation and project management/administrative during the Grant Agreement Preparation (GAP) (GAP document: GAc, point 15). *Thereafter, in order to ensure the improvement of the skills of USFAX's staff on proposal preparation and project management/administration skills, scientific and administrative staff will be invited to participate in the training organized by the European Project Management Unit H2020 (EPMU) in Tunisia (http://horizon2020tunisia.org/), in the perspective to set up a Project Management Office at USFAX. These trainings dedicated to both scientific and administrative staff of Tunisian Universities are implemented since 2019 by EPMU under the support of Education, Mobility, Research and Innovation (EMORI) program funded by the EC.*
IMPLEMENT	

ATION = ESR – Shortcoming concerning the Gantt Chart	As noted both in the GAP document: GAc and in the following ESR shortcoming: "*Planning of activities, as presented in the Gantt chart is unclear."* We improved and updated the **Gantt chart** concerning the Deliverables, due dates/Months and added the new WP on the Ethics Requirements and the corresponding Deliverables.
	We also revised the **PERT chart** according to the changes made in comparison to the proposal based on the GAP documents GAc.
Consortium Agreement (CA)	- As recommended in GAP document: GAc we added this sentence **(3.2Management structure and procedures):** *Before the signature of the grant agreement and at any case before the MICAfrica project's Action starts, the four Consortium Beneficiaries will have concluded and signed the required Consortium Agreement (CA). No costs in relation to the drafting and preparing of the CA will be claimed by the MICAfrica project's EU-funding.*
IMPLEMENTATION = ESR – Shortcomings	In order to address the following ESR Shortcoming: *"The participants have complementary expertise in microbiome research and a history of collaboration and successful research project management, which however, is not fully described regarding the added value of this Widening proposal."* We added one paragraph in the end of the section **"3.3 Consortium as a whole/Page"** about the *added-value* of MICAfrica regarding the **complementary expertise in microbiome research.** *Last, but not least, based on the previous collaboration between the MICAfrica Consortium Beneficiaries, and on their complementarity in the field of human microbiome analysis, the added value of MICAfrica project will be on the technological transfer from the European participants to the University of Sfax. In such a manner, USFAX will benefit and it will be substantially supported and enabled to become a Center of Excellence in the field of microbiome. Thereby, it will play the role of leader during the creation phase of the North African (NA) consortium of the human microbiome with the prospect of expanding the Consortium's network on both an African and international level.* In order to address the following ESR Shortcoming: *"However, risks associated with innovation management are insufficiently described"*. We also added a dedicated paragraph on risks associated with innovation management: In addition, some risks associated with innovation management will be considered. The potential for innovation of the MICAfrica project is related to the standardization and implementation at Sfax University of a new method of biological analysis (microbiome analysis) to improve the management of chronic diseases, such as CRC. Risks related to technical and administrative aspects could hamper the progress of the project and the achievement of its objectives. A risk management approach will be adopted, at all levels of the process, based on preventive measures and risk management: (i) Risk identification; (ii) Risk analysis and follow-up actions throughout the project (Each risk will be monitored by a specific person in order to facilitate monitoring and feedback); (iii) Assessment: at each progress meeting, or at least at each major milestone, risks will be evaluated and discussed: criticality of the risk, positioning in the progress of the works,

	mitigation plans (resolve the proven risk); (iv) risk treatment.
	We made the following changes in **3.4 Resources to be Committed** according to the comments, questions and feedback provided in the GAP document: GAc (point 13): - We added under the Sub-Section 3.4b "Other direct cost' items" the below confirmations: ▪ *The MICAfrica Project Coordinator confirms – on behalf of the whole MICAfrica Consortium – that it is acknowledged that this Twinning Action, as per the relevant Call Topic description (H2020-WIDESPREAD-2020-5) does not focus on equipment and research costs, and that such costs, and only in case of need, could be accepted if they constitute: (a) only a minor part (up to 10%) of the total Horizon 2020 funding requested and (b) are deemed necessary to fulfil the action's specific scope and objective. For grants awarded under this Twinning call topic and type of action the following cost categories will be ineligible costs: infrastructure costs.* ▪ *Moreover, we are aware and acknowledge that for the Equipment, at the reporting stage to the REA/EC, only the depreciation of the budgeted costs will be claimed.* ▪ *Moreover, we confirm that the tasks and different activities will be executed as per the MICAfrica Annex 1 of the Grant Agreement (DoA) and this applies to all four consortium beneficiaries.* ▪ We also confirm that the total estimated eligible costs that is the maximum EU contribution are the same as agreed in the proposal. To wit: **€896.885.** ▪ *The Project Coordinator, on behalf of the MICAfrica consortium, confirms that the indicated travel costs **are correctly identified, and are consistent with: (i) each of the Consortium Beneficiaries' usual policy for travel, and (ii) the activities planned (e.g. trips are directly linked to the specific Twinning Action).** The whole Consortium is aware that the travel costs may be verified through relevant supporting documents, such as: minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference. Therefore, such documentation **will be kept on file.*** - We revised the tables based on the analytical feedback provided per beneficiary under "General remarks – Corrections & Clarifications required per Consortium Beneficiary": ° The total of the "other direct costs" for the whole consortium is in line with the budget table in PART A, Section 3 "Budget" of the proposal. ° The amounts included in the Tables under the Sub-Section 3.4 "Resources to be committed" are consistent with the amounts included in the Annex II Estimated Budget for the Action. - In the Travel & Accommodation section, we removed "a lump sum" and changed 400 € for UNIFI to 350€.
	Beneficiary No. 1 – Coordinating Legal Entity – USFAX (Tunisia),

	Travels (3.4 Resources to be Committed): - We have made the necessary changes to clarify certain details and particularly to response to questions and comments: (a) The following amounts: €900, €1800, €1715, €636, €789, €810, €735, €690, €996, €798, €609 refer to accommodation and are transferred under the "other goods and services" in the corrected version of Table 3.4 b
	(b)The number of days has been updated for the entries from: 1) up to and including 9) in "travels" and in "Other goods and services" in the corrected version of Table 3.4 b
	(c)The amount of €300 (pages 44) corresponds to the travel costs for each participant (See point 9) in the corrected version of Table 3.4 b (Travel). The amount of €300 (page 45) corresponds to the cost of hiring the conference room and is transferred to "other goods and services"
	(d) As recommended, the total of 3101€ have been corrected into 3105€ in the corrected version of Table 3.4 b 'Other direct cost' items The amounts described in the DoA on page 44 is adjusted at €42.402 in the corrected version of Table 3.4 b 'Equipment' items (e) As requested, we changed in point 9 Algeria, Egypt and Morocco into IHIMI, INRAE and UNIFI (f) We added all "Accommodation costs" in travel costs and updated the total of "Travels"
	Equipment: We adjusted the amounts from €42.402 into 40.000
	Other Goods and Services (3.4 Resources to be Committed): We removed "Accommodation" costs and added them in travel coast and updated the total of "other goods and services" we have made the necessary changes to clarify certain details and particularly to response to questions and comments: - More clarifications have been added in the corrected version of Table 3.4 b 'Other direct cost' about the €300 that it corresponds in "travel" to the transport costs whereas in "other goods and services" it corresponds to the expenses for the hiring of a conference room and the means of sound system to carry out the events.
	- We specified in the in the corrected version of Table 3.4 b 'Other direct cost' that NA means North Africa and modified the sentence as following: "2 members from each EU partners, 2 members from Algeria, 2 members from Egypt and 2 members from Morocco …..
	- The number of persons has been modified into "7" and the total has been updated: 7 X (7X25€) = 1225€
	- The typo mistake has been corrected and "16" was corrected into 22 and detailed in table 3.4 b ('Other Goods and services', II Event fees). Other changes are made in the same section and the same page as requested We clarified that the same method was used for the calculation of the expenses for the hiring of conference (300 €) and the amount of 2x 300€ and 3x300€ correspond to the number of events (2 conferences for dissemination and 3 meetings for management). So, 2 x [2x (50x10€)] + 2 x 300€ correspond to 2 conferences x [2 days x (50x10€)] + 2 conferences x 300€ (for the hiring of the conference). Also, 3 x [2x (11x25€)] + 3 x 300€ correspond to 3 meetings x [2 days x (11x25€)] + 3 meetings x 300€ (for the hiring of the conference).
	- The costs related to the financial audit/CFS (€4.500) have been removed
	- **Expert fees' t has** been corrected in the corrected version of Table 3.4 b 'Other goods and services: Expert fees for audit of pilot study (WP1 Task 1.4 and WP5 Task5.3)= 4000€
	Beneficiary No. 2 – INRA (France) **Travels (3.4 Resources to be Committed):**

	We added "Accommodation costs" in travel costs and updated the total of "Travels" We corrected in point 5) and point 7) the cost for the flight ticket from 300€ into 350€ and updated the totals In point 5) we also corrected 3.500€ into 350€ we have made the necessary changes to clarify certain details and particularly to response to questions and comments: - The following amounts: "€423", "141", "282","€636", "€789", " €735", "€810", "€690" refer to accommodation and are transferred under the "other goods and services" in the corrected version of Table 3.4 b
	- The number of days has been updated in the calculations in "travels" and in in the corrected version of Table 3.4 b.
	- About 3 meetings at USFAX for 2 members of SC for 4 days, we give further details in the corrected version of Table 3.4 b "Travel" and 'Other goods and services' items :
	- Further details are given in the corrected version of Table 3.4 b "Travel" and 'Other direct cost' items about Travel for 2 meetings (3 days each) for management for 2 members of SC at IHUMI and UNIFI (WP5)
	Equipment: We adjusted the amount from €23.000 into €25.000
	Other Goods and services (3.4 Resources to be Committed): We removed "Accommodation" costs and added them in travel coast and updated the total of "other goods and services" In point 8) we updated the total (1380€) and revised the total of other goods and services Since we have chosen the option of "GOLD open access" for 3 scientific publications, we added publications fees: 2000 euros (cost for one publication) We finally adjusted the total of ODC from €69.227 into €68.627
	Beneficiary No. 3 – IHUMI (France) we have made the necessary changes to clarify certain details and particularly to response to questions and comments: **Travels** and "other goods and services" **(3.4 Resources to be Committed):** We added "Accommodation costs" in travel costs and updated the total of "Travels" We corrected in point 5) and point 7) the cost for the flight ticket from 300€ into 350€ and updated the totals We also changed in point 7) INRA by IHUMI Also we changed IHUMI by INRA in accommodations cost for meetings for management for 2 members of SC (WP5) We removed "Accommodation" costs and added them in travel coast and updated the total of "other goods and services" In point 8) we updated the total (1380€) and revised the total of other goods and services - We have specified that "€350" refer to transport and the following amounts:, "€423", "282", "141" refer to accommodation and are transferred under the "other goods and services" in the corrected version of Table 3.4 b
	- The amounts between brackets have been further defined in the corrected version of Table 3.4 b "travel " and 'Other goods and services '
	- The number of days has been updated in the calculations for points 1, 2, 4, 6 and 8 in the corrected version of Table 3.4 b 'Travel' and 'Other goods and services'
	- The number of persons has been added in the calculations for point 2 related to Lab course at USFAX with more clarity in the corrected version of Table 3.4 b "travel cost" and 'Other goods and services' in the corrected version of Table 3.4 b 'Other direct cost'.
	- Further details are given about point 5 in the corrected version of Table 3.4 b 'travel' and 'Other goods and services'
	- Further details are given about point 7 in the corrected version of Table 3.4 b 'travel' and 'Other goods and services' items

	- Fees are added in the corrected version of Table 3.4 b "travel" and "Other goods and services' items Finally, we adjusted the total of ODC from €40.202 into €39.602
	Beneficiary No. 4 – UNIFI (Italy) We have made the necessary changes to clarify certain details and particularly to response to questions and comments **(3.4 Resources to be Committed)**: **Travels and other goods and services:** We added "Accommodation costs" in travel costs and updated the total of "Travels" We confirm that the estimated cost for the flight ticket is 350€ and adjusted the amounts in point 7) We also replaced INRA by IHUMI in Travel coast for 2 meetings for management for 2 members of SC at IHUMI and UNIFI We removed "Accommodation" costs and added them in travel coast and updated the total of "other goods and services" - The number of days for the following entries: 1, 2, 4, 6, 8.has been updated in the calculation in the corrected version of Table 3.4 b 'Other direct cost'. We adjusted the total of other goods and services and the total of ODC from €32.938 into €32.438
	- The number of people and the total were also corrected.
	- Since we have chosen the option of **"GOLD open access"** for 3 scientific publications, we added publications fees: 2000 euros (cost for one publication)
Section 5. Ethics and Security	
Sub-Section 5.1 ETHICS	We made changes in the **Sub-Section 5.1 "Ethics"** according to the requirements in the EC Ethics Summary Report (EthSR). We addressed the PRE-GRANT Ethics Requirement and provided relevant information and confirmation for the other two applicable POST-GRANT Ethics Requirements.
Sub-Section 5.2 SECURITY	We deleted the below duplicated sentence: *All the activities of the MIC-GENCAP project will not raise security issues*

Table of contents:

1. Excellence

The analysis of the human microbiome is an emerging research area of considerable interest regarding its role in human health and diseases. The microbiome refers to the genome of members of microbiota that is composed of billions of microorganisms (bacteria, archaea, viruses…). The microbiota lives inside various body niches (gut, skin, vaginal mucosa…) and affects many physiological functions in both health and disease. It is dynamic and subject to important changes during the host life in response to various factors including diet, environment, medical interventions and disease states. Disruption of the microbial community, termed dysbiosis, constitutes a major risk factor for many diseases such as metabolic syndrome, immune disorders, cancer development and response to treatment.

Numerous initiatives and projects (e.g. the International Human Microbiome Consortium (IHMC) and the NIH Human Microbiome Project) were launched to take advantage of new, high-throughput technologies to characterize the human microbiome and to explore the relationship between changes in the microbiome and health/diseases. More recently, a broad effort through diverse initiatives such as the MicroBiome Quality Control project (MBQC; http://www.mbqc.org/) was started to comprehensively evaluate methods for profiling the human microbiome, to harmonize that research and identify gaps and needs worldwide in the microbiome field and health. Concrete actions were engaged to provide a tangible response to the need to standardize and harmonize study methods and protocols, as well as regulations.

Despite the increasing number of European and International initiatives on human microbiome, very few studies have been carried out in North Africa (NA). For the ones that have been done, they mainly used first generation sequencing of target 16S rRNA regions of isolated microorganisms (Tunisia[1,2], Morocco[3], Egypt[4]) which is a limited and out dated approach. This clearly leads to limits in volume and type of available data for exploitation in medical practice for disease prevention and therapeutic management of patients. Therefore, this means that today in NA the design of adapted diets, the development of functional foods or faecal transplantation and other personalised treatments are not possible.

Therefore, there is a need in NA for the development of skills in human microbiome analysis. With 4 years of experience in the field (through an intensive Tunisia-France programme of university cooperation with the team of Pr E. Maguin from INRA, involving 5 researchers) and the 3 years of the MICAfrica project, USFAX and its staff will have the strong potential to be a leading force in the region for future NA collaborative microbiome projects.

This will strengthen bilateral collaborations (Tunisia-Morocco, Tunisia-Algeria and Tunisia-Egypt), contributing to the creation of a microbiome database to help the development of personalized medical approaches in NA countries. USFAX will firstly drive effort to build on its existing capacities – such as studies of the microbiome in Tunisian patients with colorectal cancer and inflammatory bowel diseases and gain new skills in human microbiome data analysis. Secondly, it will manage and lead a capacity building effort regionally with NA partners (Morocco, Algeria, and Egypt). As we develop our strengths, USFAX will also be able to integrate international collaborative projects as a credible research peer; however, we must overcome some internal limitations (L):

L1. **Limited human capacities** of Experienced Researchers (ER) and Early Stage Researchers (ESRs) at USFAX and within our NA partners in using new technological approaches (metagenomics, metaproteomics, and metabolomics) for human microbiome studies. In addition, there are limited equipments to carry out such studies to create a microbiome database in Tunisia and NA partner countries. On the other hand, there are limited human capacities as far as research support staff qualified in project management (administrative and financial).

L2. **Non-alignment of human microbiome analysis methodology** used by USFAX and across Tunisia and NA research organisations with recent international efforts aiming at creating biological standards for microbial studies (sample collection, data analysis, functional metagenomic and metabolomics studies). This is due to the limited of material, human resources, and especially expertise in USFAX and NA partners.

[1] Kharrat et al. Data mining analysis of human gut microbiota links Fusobacterium spp. with colorectal cancer onset. Bioinformation (2019). 15(6):372-379.
[2] Fassatou et al. Gut microbiota imbalances in Tunisian participants with type 1 and type 2 diabetes mellitus (2019). Biosci Rep.(2019) 18;39(6).
[3] Allali et al. Gut microbiome of Moroccan colorectal cancer patients. Medical Microbiology and Immunology (2018) 207:211–225.
[4] Salah et al. New Insights on Obesity and Diabetes from Gut Microbiome Alterations in Egyptian Adults. OMICS (2019). 23 (10) : 477-485.

L3. **Limited capacities in NA to contribute to the global effort to decipher the cross-talk microbiome/host** in several diseases for personalized medicine. There is no organization today able to federate or coordinate a regional effort in the field.

1.1 Objectives

In order to overcome these limitations and to become a regional leader in the analysis of human microbiome and its relationship to diseases, USFAX – through the MICAfrica Twinning project – aims to: increase its staff capacities in: (i) using standardized metagenomic approaches for analyzing the human microbiome; (ii) identifying microbial effectors by functional metagenomics strategy and whether they affect the host response in microbiome-associated diseases; (iii) setting-up and then coordinating a regional effort that we have named "the North African Human Microbiome Consortium" (NAHMC).

Our project will therefore focus on **three specific objectives**:

⌗ **Objective 1**: Capacity building of USFAX and its research staff in metagenomic approaches (deep 16S rRNA, shotgun sequencing, and pyrosequencing) to investigate the association of microbiota dysbiosis and diseases.. Ten ER, 10 ESRs and 3 technicians will be trained in human microbiome studies; 3 support staff will also be part of the capacity building effort on transversal topics such as the project management activities. This will enable us to generate 5 publications in high impact-factor journals over the next 5 years (2 during the three years of the project); to send papers to 3 top ranked conferences in the next 3 years and to set-up our own cycle of 6 seminars on the topic over the next 3 years.

⌗ **Objective 2**: Strengthening the scientific staff skills of USFAX in functional studies (metaproteomic and metabolomics) Metagenomics studies of the human microbiome provide information on the large diversity of the bacterial community in one body niche such as the gut. However, to address the microbiome -host interaction, metabolomics and metaproteomic studies are needed to get a direct insight into the phenotypes of microorganisms at the molecular level. We will benefit from the large expertise of our EU partners in metaproteomic and metabolomics approaches, to develop our skills and acquire knowledge, which will allow us to better understand the association microbiome-disease in our population.

⌗ **Objective 3**: Create and coordinate the North African Human Microbiome Consortium (NAHMC) with Rabat University, Morocco; Setif University, Algeria, and Ismailia University, Egypt; this will be materialized through collaboration agreements to be signed with each of the 3 organizations (and possibly with several teams within each country); we will draft with our partners a 5-year strategy for the consortium including an action plan for opening the centralized database and a plan of joint research projects which will include wider collaborations with EU partners too and dissemination of our results; as a group, we will apply to join International Human Microbiome Consortium (IHMC) as NAHMC within 2 years at most after the end of the project.

1.2 Relation to the work programme

The MICAfrica project fits into the overall scope of the H2020 and particularly in spreading excellence and widening participation in the field of health, demographic change and human wellbeing through knowledge transfer, exchange of best practice between research institutions and leading partners. Furthermore, MICAfrica project is particularly in line with the priority of the European Commission (EC) to reduce the disparities between EU and developing countries in the field of human health[5]. As far as the specific challenge and scope of the Twinning WIDESPREAD-05-2020 call is concerned, MICAfrica pertinently addresses all of the EC's expectations, as follows:

[5] COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT Health and Poverty Reduction in Developing Countries Brussels, 22.03.2002 COM(2002) 129 final

Specific challenge and scope	**How MICAfrica addresses them**
The specific challenge is to enhance networking activities between the research institutions of the Widening countries and internationally-leading counterparts at EU level.	MICAfrica aims to enhance networking activities between USFAX and (i) 3 EU partners; (ii) other Tunisian universities and (iii) NA partners. - Networking activities with EU partners will focus on internships, short term staff exchanges outgoing and experts visits to catalyse the mutual coordination and the pooling of resources among the consortium of participants. - Networking with different Tunisians universities aims at spreading good practices, promoting common protocols, interoperability and encouraging complementarity. - With NA partners, networking activities aim to prepare the creation of NAHMC by widening participation of ER and ESR from NA universities. These activities will include 3 scientific workshops over the 3 years of the project and an exchange programme open to both ER, ESR and administrative staff (training, short term visits …).
Twinning will help raise the research profile of the institution from the Widening country as well as the research profile of its staff.	We are keen to boost the experience gained over the last 4 years (through an intensive Tunisia-France program) in this field, to become a leading force in NA for the study of the human microbiome. By doing so, MICAfrica will help raise the research profile of USFAX at three levels: - **Nationally:** The acquisition of new skills of USFAX researchers in human microbiome, thanks to the MICAfrica, will contribute to moreand higher quality publications and presentations at major conferences which will help to place USFAX as national reference and leader in the field of microbiome leading to establish new collaborations with other Tunisian universities. These collaborations will enhance the outreach of the entire scientific community of the country. - **Regionally (NA):** The capacity building of the USFAX (ER, ESR and support staff) as well as the exchange program with NA universities during the MICAfrica project will strengthen collaboration with NA partners to create NAHMC. - **Internationally:** MICAfrica will help raise the research profile of USFAX staff by creating a database (anonymous biological data) to ensure others can access and add to it (see section 2.2 for data management). The Consortium's efforts are focused on generating a shared comprehensive database that will enable investigators to characterize the relationship between the human microbiome dysbiosis and disease. This will lead to improve the visibility of USFAX and facilitate its integration in European and international consortiums as the International Human Microbiome Consortium (http://www.human-microbiome.org).
Successful Twinning proposals will have to clearly outline the scientific strategy for stepping up and stimulating scientific excellence and innovation capacity in a defined area of research	The scientific strategy of MICAfrica project will focus on stepping up and stimulating scientific excellence and innovation capacity in microbiome analysis and its relation to human diseases. The strategy will be built around our main objectives: Building staff capacity in metagenomics, metabolomics and metaproteomics with adopting standard procedures, Addressing functional genomic studies to investigate the interactions microbiome/host in disease Creating a NA consortium (NAHMC). To reach these objectives, the working group in MICAfrica project will focus on three areas of collaborative work: - Expanding the microbiome workforce in Tunisian and NA universities through educational opportunities (scientific meeting and training) and collaborative research in medicine, human health, to enable a predictive understanding of the function of human microbiome and its relationship with diseases. - Setting up in USFAX standard methodology for human microbiome studies including metagenomics, metaproteomics and metabolomics approaches. - Sharing knowledges and know-how on human microbiome between Tunisians and NA universities through exchange of ER and ESR and creation of an open access database that will help the creation and coordination of NAHMC and next the integration into international consortiums on human microbiome.

Such a strategy should include a comprehensive set of activities to be supported. These should include at least a number of the following: short term staff exchanges; expert visits and short-term on-site or virtual training; workshops; conference attendance; organisation of joint summer school type activities; dissemination and outreach activities	The scientific strategy will be based on a numerous activities: - Networking research activities (internships; expert visits and short-term on-site or virtual training, workshops) for competence development in the field of microbiome in NA and to promote the leader position of USFAX in the region in this field - Implementation of dissemination activities (scientific publications, national and international scientific conference attendance and other events, website, brochures, posters, flyer…) to spread information to the scientific community about the different activities of the project. Scientific publications will be in high impact-factor peer-reviewed journals to increase the dissemination and exploitation of knowledge. - Diffusion of the knowledge to other Tunisians and NA universities to share the new acquired skills in human microbiome studies including metagenomics analysis and bioinformatics competencies. - Dissemination & Outreach activities: workshops, lab visits, public talks (campaign) and awareness will be organized in order to present our research activities to a large public (school and high-school students, NGOs, patients associations and the wider public).
Scientific quality of the partners involved in the twinning exercise	The EU partners involved in MICAfrica are recognized as centers of excellent in the field of medical research and in management of European projects. - **Micalis Institute, INRA**: The INRA is a unique space environment offering a continuity of research on food, animals and microbes. The Micalis Institute That was created on 2010 by merging 8 food microbiology INRA laboratories located in the Ile-de-France region, is a mixed research unit associating INRA and AgroParisTech. Its mission is to develop innovative research in the field of microbiology of food for health. The Micalis Institute merges more than 340 people including 130 scientists, engineers and scientists-teachers, 70 scientific or administrative assistants as well as 140 PhD students, post-doctorant fellows and other students, organized in 20 research teams and 3 thematic axes. One of the three thematic axes corresponding to three-research priorities is "the microbial food and intestinal ecosystems and the functional interactions between food, microbiota and host". Micalis hosts a pre-industrial demonstrator platform "Metagenopolis" devoted for studying the impact of human intestinal microbiota on health and diseases. INRA actively participates to the production of different metagenomics catalogs including those from human and pig. - **Institut Hospitalo-Universitaire Méditerannée Infection (IHMU)** is created on 1 January 2012 and it is a multidisciplinary university. IHUMI is an intensive research university, which is among the top French universities in the Shanghai ranking. It has developed a site-wide strategy co-constructed in collaboration with the main research organizations (CNRS, Inserm, IRD, CEA...).The excellence of the site's research has been recognized in particular by the success of several national or European H2020 projects (IHUMI is thus the third French institution to collect funds under this programme). - **The University of Florence** is an important and influential centre for research and higher training in Italy (https://www.unifi.it/changelang-eng.html). It is well known for its research on the human microbiome. Prof. Amedeo Amedei (http/www.amedeoamedei.com) is a member of the Experimental and Clinical Medicine (DMSC) department and he is an expert in the fields of Immunology, inflammation and microbiota analysis. He has an international profile documented by scientific production (126 peer reviewed articles, 7 book chapters and one patent; H-index of 43) and has been a coordinator of several large co-operative research projects, as “Colorectal cancer: functional / metabolic characterization of the microbiota and the role of probiotics in the modulation of specific immune response”, “impact of intestinal microbiota and inflammation in weight gain and obesity”.
A dedicated focus towards promoting the involvement of early stage researchers in the first four years of their research	ESR are an essential public of the activities of MICAfrica; at least 10 ESR (7 Tunisians and 3 NA) will be included in the participation but also in the preparation, delivery and monitoring of workshops, conferences and training activities on microbiome related topics. A key activity will be internships for ERS at the labs and plateforms of EU partners to improve their knowledge in studying the relationship between human microbiome and health/diseases. Dedicated transversal training

careers.	activities will directly target ESR to promote their entrepreneurial skills and to encourage them for the creation of spin-off or start-up.
Proposals should also focus on strengthening the research management and administration skills of the coordinating institution from the Widening country.	To strengthen the research management and administration skills of USFAX, MICAfrica will include support activities dedicated to non-academic teams. EU Project Management Offices (PMO) will be actively involved in capacity building through knowledge transfer activities.
Equipment and research costs could be accepted if they constitute only a minor part (up to 10%) and are deemed necessary to fulfil the action's specific scope and objective.	In Tunisia and partner NA countries, available equipment's to carry out microbiome studies in NA population is very limited. To create microbiome databases in Tunisia and NA partner countries, we need reagents to perform the different steps of microbiome analysis (sample collection, DNA preparation, generation of the amplicon library pyrosequencing, , and bioinformatics tools). For this purpose, we propose that reagents, kits and software will be purchased. The overall budget for these research consumables will not exceed 10 % of the total project costs (see 3.3 resources for more details on costs).
If the coordinating entity has already been funded (as a coordinator) under other Horizon 2020 Twinning calls, these projects need to be described in the proposal. In particular, proposers need to clearly demonstrate the added value and impact of the proposal in achieving the Twinning programme objectives, in comparison to the already funded Twinning project within the coordinating entity	The European Commission selected one twining project named "SEED" in March 2019 coordinated by USFAX. It aims to enable USFAX to achieve excellence in research in the field of epilepsy, particularly in the clinical and genetic diagnosis of epileptic encephalopathies through the collaboration with teams from Aix-Marseille University from France and Antwerp University from Belgium. This collaboration with these EU universities, leaders in epileptic encephalopathies diagnosis, will contribute to strengthening Tunisia's participation in the European Research Area and support its sustainable development in the region. The added values and impact of the MICAfrica project, in comparison to the SEED Twinning project are: - Strengthening the capacities of USFAX staff in another field of medical research, which concerns the analysis of human microbiome and its relationship with human pathologies in order to promote the field of personalized medicine in Tunisia and North Africa. - The creation and coordination of the North-African Human Microbiome Consortium (NAHMC). Another Twinning project - "*SfaxForward" Cultural Heritage in South Tunisia* - promoting interdisciplinary and participatory sciences for an inclusive society (Grant agreement ID: 857269)" - was also selected last year. Although this project has no commonalities with MICAfrica, the capacity building of our central teams (PMO and Valorisation office) through all 3 projects will certainly greatly advance USFAX as a leading research and innovation university in NA. The top management is very aware of this fantastic opportunity and is aiming on capitalising greatly on it to make our university an engine in health research at regional level.

1.3 Concept and Approach (methodology – quality of the measures)

1.3.1 Concept

There are increasing evidences that the human microbiome is involved in several diseases such as inflammatory bowel diseases, cancer, and diabetes. Numerous initiatives have been launched so far to take advantage of metagenomics, metaproteomics, and culturomics to characterize the human microbiome and to explore the microbiota in particular to study their functions in development of many diseases using different functional strategies including cell lines and animal models. Several projects have been undertaken to better understand the complex relation between microbiome and host. Although, it is well

known that disruption of the microbial community diversity contribute to the development of several diseases, the pathways and genes involved in dysbiosis still poorly understood.

In North Africa, the association between microbiome dysfunction and diseases is unexplored and only few descriptive data on bacterial 16S rRNA are available, that is mainly due to the limited availability of effective and appropriate tools and skilled human resources in the field of microbiome. Therefore, and through the MICAfrica, we plan to overcome this obstacle by leveraging the high expertise of our EU partners to strengthen our knowledge in the field of the human microbiome analysis based on new technological approaches. This enable USFAX to reach the scientific level of European research institutions and to be, by the end of this project, a leader in the NA region by the creation and coordination of a dedicated Network, the NAHMC.

Three key aspects that we want to focus our effort on, in the coming years, as part of our scientific strategy are to:

- Ensure that we adopt the state of the art standardization protocols during sampling to generate cohorts
- Determinate the gut microbiota composition using metagenomic approaches (16S rRNA, pyrosequencing and shotgun) aiming the analysis of the significant association between dysbiosis and diseases and reinforce the strength of targets using metabolomics.
- Identify the microbial effectors modulating the host response and access to the molecular basis of their mode of action using functional metagenomics strategy.

In fact, the translation of basic microbiome research to clinical application requires reproducible experimental and computational methods for analysing human-associated microbial communities. With the support of the EU partners, we will carry on studies on the role of the human microbiome in health and disease states with the degree of standardization including protocols for handling human samples and computational pipelines for microbial data processing.

Thanks to the expertise of our collaborators, we hope that during the first 2 years of the project, the staff of USFAX (ER, ESR) will fill the gaps and deepen their knowledge in the field of human microbiome studies and data analysis, using standardized protocols in conformity with international procedures. The acquired skills in metagenomics, metaproteomics, and metabolomics will allow us to be the leader in North Africa region and to create and coordinate the NAHMC. Establishing such a consortium is important because it will have several missions: (i) sharing data, (ii) setting-up a database on human microbiome in the NA region, (iii) organizing workshops for ER and ESR, (iv) implementation of a Master's degree module focusing on human microbiome and its relation with diseases dedicated for NA students. This module will be available on the Moodle platform of USFAX (Faculty of Medicine) by October 2020.

1.3.2 Linked activities

- National level

Since 2014, efficient collaboration was initiated between USFAX and INRA-Versailles-FRANCE (with the group of Pr Emmanuelle Maguin from INRA Jouy-en-Josas) through a CMCU project (Comité Mixte de Coopération Universitaire) on the role of the Serpines (serine–inhibitor proteases) of the human gut microbiome in inflammatory bowel diseases. During the 3 years of the project (2014-2017), 5 papers were published and 4 thesis were ensured and co-supervised. Regarding the interesting and promising results, the project was extended for an additional 3 years (2019-2021, code project 41786NC), which is exceptional for such projects. Sixty bacterial Serpins were isolated from the human gut microbiota and we demonstrated their capacity to inhibit some human proteases involved in digestive inflammation. The team of Micalis is well recognized at the international level as an expert in the human microbiota from handling samples to characterization of bacterial diversity by 16S rRNA deep sequencing, metagenomics, metabolomics and data processing by appropriate bioinformatics tools. In addition, the CMCU (code

project 41786NC) and the MICAfrica project, will overlap for two years, which will further stimulate our research on the human microbiome through various actions such as lab course, conferences, and workshops.

- International level

Through MICAfrica and secondly through the NAHMC, NA scientists will work together and with the consortiums and networks established in EU and outside to leverage their results in other linked activities to advance our project. On the other hand, the scientific activities of NAHMC have the potential to feed into and improve the synergy between selected projects performed in the field by EU and international consortiums such as:

- **International Human Microbiome Standards** (IHMS) that was conducted during the period between 2011 and 2015 in the frame of seventh framework program (**Grant agreement ID: 261376).** This project focused on three key aspects of data generation: (i) human sample collection, processing and identification via the associated metadata; (ii) DNA sequence quality obtained by the new generation methods from complex microbial mixtures; (iii) analysis of DNA sequence in conjunction with the metadata. Importantly, this project organized public access to the standard operating procedures and protocols to enable exchanges between the users and providers of the standards. It also gathered very strong international partnership including the leaders of other projects, which spanned three continents, Europe, Asia and America. This project was also an interface between the International Human Microbiome Consortium and additional projects from Africa and Australia. The outputs of this project will be useful during the implementation of MICAfrica project, particularly during the understanding and adoption phase of standardized methods.

- **Cancerbiome: Characterization of the cancer-associated microbiome (**CANCERBIOME) conducted between 2011 and 2016 (**Grant agreement ID: 268985 (FP7).** It aimed to identify microbial markers that correlate with cancer presence or progression. A reliable and robust pipeline has been developed and some microbial markers were characterized in populations from Paris, Heidelberg and from different countries. These markers showed a strong distinction between health and disease states and consequently a cheap and robust qPCR based method for non-invasive colorectal cancer (CRC) detection has been developed in order to progress towards clinical application. With regards of our expected activities (study of the relationship between microbiome and CRC), we plan to take benefit of courses (e-learning) and seminars organized regularly by the coordinator of the CancerBiome (EMBL-Heidelberg).

- **COST Action network: Statistical and machine learning techniques in human microbiome studies (CA18131)**. The COST action started in February 2019, aims to create productive symbiosis between discovery-oriented microbiome researchers and data-driven experts, through regular meetings, workshops and training courses. The consortium focuses on the optimization and standardization of used techniques, following the creation of publicly available benchmark datasets. Correct usage of these approaches will allow for better identification of predictive and discriminatory 'omics' features, increase study repeatability, and provide mechanistic insights into possible causal or contributing roles of the microbiome. This COST action will open novel and exciting avenues within the fields of microbiome research. We plan to join this COST action network as observer first (to attend their events) and later after achieving the first objective of the MICAfrica, we will apply to join this network as partner.

- **ONCOBIOME - Gut OncoMicrobiome Signatures associated with cancer incidence, prognosis and prediction of treatment response is an ongoing project (H2020 - 2019-2023) (Grant agreement ID: 825410).** It aims to identify and validate core or cancer-specific Gut OncoMicrobiome Signatures (GOMS) associated with cancer occurrence, prognosis, response to, or progression on, therapy and integrate these GOMS with other oncology hallmarks (clinics, genomics, immunomics, and metabolomics). The project expects to validate cancer or therapy-specific GOMS in breast,

colorectal, melanoma and lung cancers adjusting for covariates, to unravel the mode of action of these GOMS in innovative platforms, thus lending support to the design of cancer preventive campaigns using well characterized pre-and pro-biotics. The coordinator of the Oncobiome (Institut Gustave Roussy) has a huge expertise in Cancer and translational research, and several collaborative research activities (bilateral French Tunisian projects) were established with USFAX. Through MICAfrica, we project to reinforce these collaborations through participation at the events and development of new project in this field.

1.3.3 Methodology

The methodology adopted in MICAfrica project is based on the strengthening of the USFAX potential in both research in microbiome and in management of collaborative projects that give it the legitimacy to be a leading force in NA in human microbiome analysis and for future collaborative projects. The SWOT analysis presented below **(Table I)** shows that potential.

Table I: SWOT analysis

Strengths	Weaknesses
• Ongoing collaboration of 4 years with INRA (France) since 2014 • **USFAX** ranked first Tunisian university, in the ranking of the best global universities of 2019 published by Times Higher Education magazine (https://www.timeshighereducation.com/world-university-rankings). • Experience of more than 30 years in human genetics and genomics research, in bioinformatics, in identification and characterization of microorganisms by classical and molecular methods. • Strong expertise and participation of our 3 EU partners, INRA, IHUMI and UNIFI, in national and international networks on microbiome. • Availability of the NGS platform (Miseq Illumina) at USFAX. • Accessibility of patient's samples through strong collaborations between Faculty of Medicine of Sfax and the two Sfax academic Hospitals (Hedi Chaker and Habib Bourguiba). • Strong links with Tunisian NGOs (generic associations working on medical research and innovation such as ADREMED (Research association), and specifically those of supporting patients such as DAR El AMAL (Association for Fighting Cancer), STEDIAM (Association for Diabetes) that will help for communication purposes. • Bilateral agreements with leading research institutions in NA on life science, technology domains: Morocco, Algeria and Egypt. • Management of 17 European projects (FP7, Tempus, Erasmus +, H2020). • Accreditation of the Faculty of Medicine of Sfax by the International Association of Medical Colleges (IAOMC).	• Modest research capacity mainly due to limited budget. • Limited experience in human microbiome studies and data analysis (only 4 years). • Knowledge gap in the field of microbiome and diseases • Limited output of valorization and technology transfer (only national patents). • Limited publications in journals with high impact factor >5 (number of publications <10)

Opportunities	Threats
• European and International initiatives for networking such as COST Actions, ONCOBIOME, IHMC. • Support from national authorities (Ministry of Higher Education and Scientific Research and Ministry of Health) to facilitate the administrative procedures during the MICAfrica project. • Support by the national unit of European program management (Tunisian Ministry of High Education and Scientific Research/ EMORI program) to consolidate the Project Management Offices in research institutions. • Close scientific cooperation with EU research leaders in life sciences, health and genetics (Seed Twining project, Citrus and EXANDAS RISE projects, ERASMUS+ projects).	• Politic and economic instability. • Rigidity of some administrative and financial procedures of public research organizations such as USFAX. • Migration of scientifically qualified personnel (brain drain). • Highly international competitive topic.

From the SWOT analysis, it can be seen that USFAX is a very promising institution, well placed to conduct the activity plan of MICAfrica. Through close collaboration with experienced European researchers and technology transfer between the partner institutions, the three previously mentioned MICAfrica objectives could be achieved. They will be implemented through vertical coordination and support measures related to the definition of a scientific strategy for human and capital capacity building in metagenomics studies (WP1), in interactions microbiome-host and disease (WP2) and network development through principally the creation of the consortium and the opening of the scientific strategy to the North African partner countries (WP3). In addition, horizontal coordination and support activities of Dissemination, Exploitation and Communication (WP4) and project management (WP5) will also take place.

The dependencies of the key project activities and their related WPs are illustrated in Figure 1.

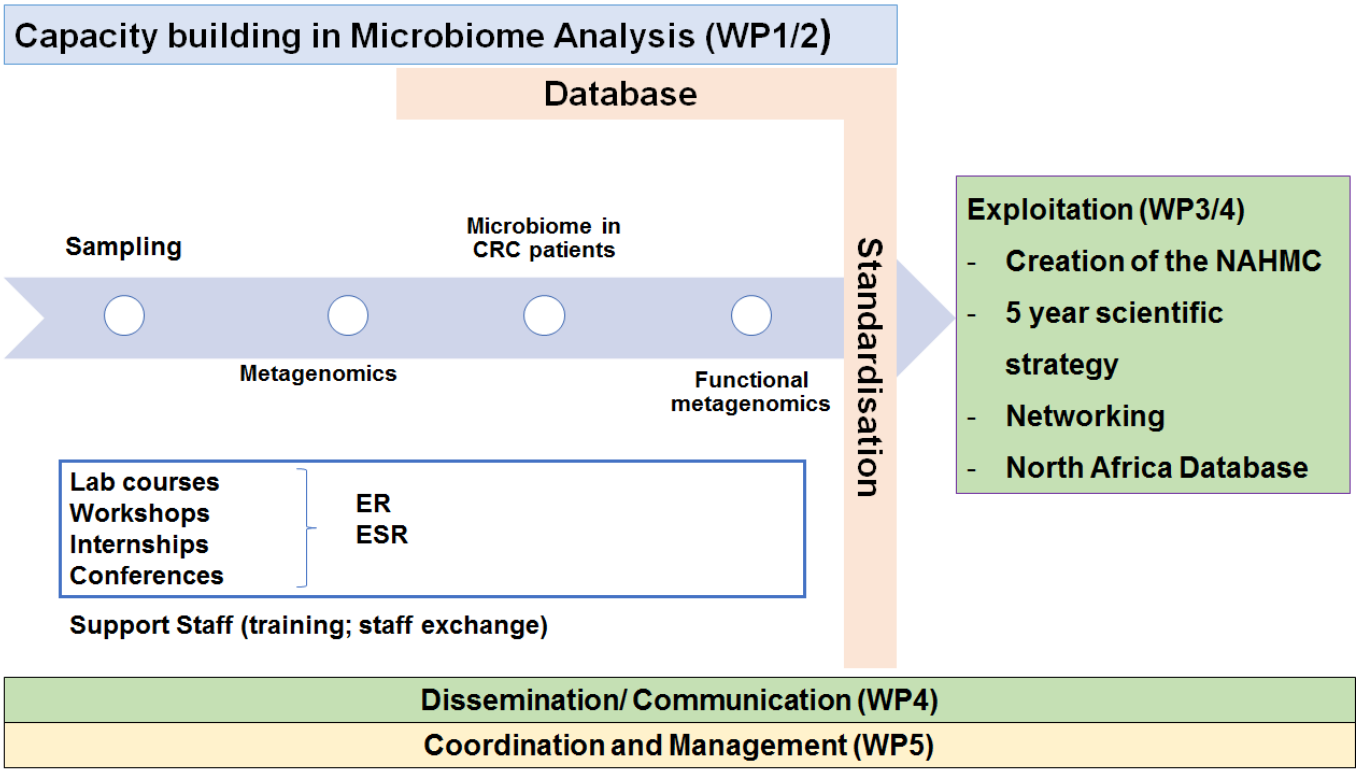

Figure 1: Schematic representation of the MICAfrica's Methodology revolving around the process of microbiome analysis

Scientific strategy (WP1/2/3)

To accelerate the consolidation of the position of USFAX as leader in microbiome analysis in North Africa, MICAfrica will develop and implement a sustainable scientific strategy opened to NA partner countries.

MICAfrica will connect the USFAX staff to actors in the field of metagenomics and metabolomics in human microbiome studies. The EU partners (INRA, IHUMI and UNIFI) have proved their excellence worldwide to enable USFAX to reach a similar level of expertise to that of EU scientists. USFAX will leverage this newly acquired expertise to take a leading position in NA where research on human microbiome is poorly developed, mostly using target sequencing of the microbiota 16S rRNA. It is important to mention that NA has fallen behind European countries in using new technological approaches to study the human microbiome to better understand its relationship with diseases.

Currently, in order to improve our understanding of complex human associated microbiome, researchs on human microbiome target the functional metagenomic aspects of the microbiota rather than determining the microbiome diversity to identify genes responsible to modulate the host response under specific condition. , USFAX with its European partners will put all these efforts to catch up and reach a competitive position in the few years after the end of the project lifetime.

The proposed MICAfrica project will allow Tunisian researchers to set-up and develop advanced technologies (High through put sequencing …) to better explore the human microbiome in health and diseases through close collaboration with IHUMI and UNIFI.

The methodology related to the WP1/2/3 will focuses on the following activities:

Horizontal activities strategy WP4/5

1) Building capacities in metagenomics studies (O1) dedicated to 10 ER (7 from USFAX and 3 from NA Universities), 10 ESR (7 from USFAX and 3 from NA Universities), and 3 technicians from USFAX (**WP1**) in microbiology, genetics and bioinformatics fields.
- Firstly, ***a conference for one day*** on **"Metagenomic approaches in Human microbiome studies"** will be organized at the USFAX with the involvement of lecturers from INRA and IHUMI. This conference will be open to scientists (ER and ESR) from USFAX and from other Tunisian universities and also from NA universities **(WP1).**
- This conference will be followed by ***one lab course*** during 12 days dedicated to 10 ER, 10 ESR, and 3 technicians and focusing on high-throughput sequencing techniques and data analysis using bioinformatics tools **(WP1)**.
- In addition***, 1 internship*** for 7 ESR (30 days) and for 5 ER (15 days) at IHUMI to improve their skills in metagenomic and human microbiome analysis as well as bioinformatic tools.
- On the other hand, ***1 internship*** (15 days) for 7 ESR and for 5 ER at UNIFI will be planned in order to strength their knowledge in the connection of microbiome and diseases (cancer, diabetes, obesity…) **(WP1).**
- An ***entrepreneurial skills training*** (7 days) dedicated specially to 7 ESR will be planned in the frame of WP1. It will provide the basics of starting and operating a small business and will include the ability to take initiative, to identify business opportunities and forecast resource needs and to develop a business plan. **(WP1)**
- ***An audit*** by one expert on microbiome (from the advisor board) to check our alignment to international and standard procedures. **(WP1)**

2) *Building capacities in Functional metagenomics studies* (O2):

- ***A workshop (5 days)*** dedicated to the 10 ER, 10 ESR, and 3 technicians previously trained in microbiome analysis (WP1) will take place in USFAX to study functional metagenomics **(WP2).**
- A ***conference*** during one day on" "**Functional metagenomics for human microbiome investigation"** will be organized at the USFAX with the involvement of lecturers from INRA. This conference will be opened to scientists and clinicians from Tunisia and NA universities **(WP2).**
-In addition**, *1 internship*** for 7 ESR (30 days) and for 5 ER (15 days) at INRA to improve their skills in functional metagenomic and metabolomics in human microbiome **(WP2).**

On the other hand, ***1 internship*** (15 days) for 7 ESR and for 5 ER at INRA will be planned to strengthen their knowledge in metabolomics. **(WP2).**

- Furthermore, a teaching module on human microbiome and its relationship with health/diseases will be developed and dedicated to 20 students at Master's level (USFAX and NA students). The programme of this module aims to provide a detailed understanding of cutting-edge techniques used in microbiome analysis. **(WP2).**

3) In line with the global scientific strategy of the MICAfrica project, and once the activities related to WPs1 and 2 successfully done, the progress of the project will be ensured through the creation and coordination of *the first North-African Human Microbiome Consortium (NAHMC) (O3; WP3).*

The main objective of this consortium is to promote the generation of database that will be freely accessible for scientific community. This consortium will be composed by researchers from Tunisian Universities (10 ER and ESR from USFAX, 10 ER and ESR from the North and the Center Tunisian Universities), and from at least 3 NA Universities (for a total of 6 ER and ESR from Morocco, Algeria and Egypt),

- Firstly, ***one meeting*** (2 days) involving Tunisian and NA ER and ESR with the support of EU partners support will be organized at USFAX. During this meeting, an agreement summarizing criteria of the NAHMC (data release, quality assessment, standardization of procedures and protocols, consent of participants) will be drafted and approved by the NA universities members; then a 5-year strategy will be prepared. **USFAX** will coordinate the activities of this consortium that will focus on networking between USFAX and (i) 3 EU partners; (ii) other Tunisian universities and (iii) NA partners.
- With NA partners and Tunisians universities ***networking activities (3 scientific workshops during 3 days)*** aim to spreading good practice, promoting common protocols and interoperability, encouraging complementarity between the members of the consortium by widening participation of ER and ESR from tunsian and NA universities. These workshops will be organized at NA partners and will be open to both ER, ESRs and administrative staff with consideration of gender balance (WP3).

Europe***a***n partners will help USFAX to reach and further to extend its leading position in an internationally competitive academic community through sharing best practices and implementing activities of Dissemination, Exploitation, Communication and Networking **(WP4 and 5).**

1) **The MICAfrica plan for dissemination and exploitation** (draft available at section 2.2) will be achieved and updated in both ***the mid-term and final project's reports***. It includes a record of activities related to dissemination and exploitation that had been undertaken, and those still planned **(WP4).**

- Each partner will be involved in the dissemination of project information via a dedicated ***website*** that will be created within two months with an appropriate protocol for updating information on activities and progresses of the project. The Coordinator will be in charge of this task and partners are encouraged to contribute with news related to the subject, local events or relevant information to be published. MICAfrica website will give visibility to all actions and activities carried out by the project and to spread the results achieved to other Tunisian, NA and worldwide universities **(WP4).**

European databases such "Cordis" constitute another way to disseminate the USFAX research potential.

Dissemination will be also guaranteed through the following activities:

- Creation of "Linkedin" account that will be used to facilitate the establishment of networks on microbiome analysis and to disseminate information and also to share content.
- ***Publications in highly impacted journal*** with an open access **(GREEN and GOLD),** participation to national and international conferences.

- ***Participation of ER and ESR to international conferences*** to disseminate the information around the MICAfrica and to prepare the creation of NAHMC,
- *Organisation of two conferences* at 2021 and 2022 to promote the dissemination of project information.

For exploitation, many activities will be conducted:

- ***Further research on human microbiome*** involving ESRs with respecting gender balance.
- ***Creation of spin-off by ESR*** (50% of trained ESR will start their business after the end of the project).
- Moreover, ***a Master on Human microbiome and Health/disease*** will be developed involving EU, NA partners to spread new knowledge on human microbiome, as well as to create opportunities to attract other funding resources **(WP4).**
- ***The update of the NA database (WP2) constitutes an exploitation activity which will allow*** to raise the research profile of USFAX staff at internationally level and ensures the sustainability of the NA consortium and its openness to other European and international networks
- ***Implementation of networking activities*** with EU partners to catalyse the mutual coordination and the pooling of resources among the consortium of participants. These networking activities will focus on in-going (EU partners participating in meetings) and o**u**tgoing visits (to EU partners during 3 days for 5 Tunisian ER) (WP4).
- ***Development of networking activities by the NA partners with the support of EU partners*** after the creation of NAHMC, in order to facilitate the integration to the International Human Microbiome Consortium (IHMC).

2) MICAfrica partners are fully aware of the importance of communication to promote the project outcomes. The main objective of communiction activities is to spread the relevance of the Human Microbiome analysis in the managment of chronic diseases such as diabetes, obesity and cancers, and to raise the awareness of the general public and politicians of the importance of the microbiome-based personalized medicine.
Communication activities will focus on:

- **A restricted area will be created on the website** for exchanges (information, deliverables, …) between the project consortium partners;
- **Development of a public open interface on the website** providing many vulgarized information about microbiome and health patients,
- **Additionally promotional material** (brochures, posters, flyer, and a quarterly newsletter) and media (TV, Twitter, Facebook …) will be used **(WP4).**

3) The project management by a dedicated team at USFAX will ensure the organizational, financial and administrative procedures of MICAfrica and will also ensure effective communication with the European Commission as well as between all involved partners.
All information will be given in time in order to avoid risks, and the communication between the partners will be strengthened and addressed by regular meetings and by also using several communication tools such as video conference **(WP5).**
Therefore, in addition to the kick off meeting (KoM), **3 other managment meetings (2 days) will be organized each year and a forth and last meeting (2 days) will** held at the end of the project During these events the Steering Committee will finalize the preparation of the reports and submit them to CE. The final report of MICAfrica project will be published on the website of MICA project immediately after validation by the EC.

Gender balance and involvment of ESR

MICAfrica project will carefully take into account the gender balance and the involvement of ESR in all activities. Specific attention will be focus on the recruitment of female scientists and ESR for the organization and participation in workshops, networking activities, training courses and internships (WP1, WP2), allowing them to interact early with larger research community, to raise their profile and to contribute productively. The distribution of funds will be monitored to ensure ESR benefit and no gender bias becomes evident in the distribution.
MICAfrica project will also support ESR through the following specific mechanisms:
-ESR will be part of the manager committees, and therefore will be involved in all decision-making processes (WP5).
- At least 25% of talks given by ESR (WP1, WP2)

1. Impact

The coordinator of MICAfrica project (USFAX) has already been funded under other H2020 Twinning calls. Indeed, two Twinning projects called SEED (GA N°. 856592) and SfaxForwards (GA N°. 857269) are running now and are coordinated by USFAX.

Based on these two projects coordinated by USFAX, one in the medical field and the other in the social sciences, MICAfrica project will reinforce the position of Sfax University as a leading university, not only in basic higher education in different disciplines, but also in the field of scientific research; especially in the management and coordination of collaborative projects with renowned European partners.

SEED project aims to enable USFAX to achieve excellence in research in the field of epilepsy, particularly in the clinical and genetic diagnosis of epileptic encephalopathies (EE) that represent a group of severe epileptic diseases with early onset that lead to progressive cerebral dysfunction. This will be achieved through collaboration with two centers of excellence in the field, one from France (Aix-Marseille University) and the second from Belgium (Antwerp University).

In line with EU orientations and Twinning requirements, the SEED project will strengthen the medical and technological capacity of USFAX in the field of EE and allow access to scientific excellence at international level for members of the SU; which will lead ultimately to a better integration into international networks in MENA and EU regions. Through the completion of all activities included in the project (short exchange staff, trainings, conferences, workshops, etc. and with the support of AMU and UA, USFAX will be able to significantly reduce networking gaps, to increase its ability to compete for international research funds and to link further with stakeholders. In addition, thanks the SEED project, USFAX will become the reference center for the clinic and genetic diagnosis of EE in the MENA region.

SfaxForwards is a project in the field of Humanities and Social Sciences (MdMSH) that aims to strengthen the capacities of an innovative academic centre regarding Cultural Heritage: the Maghreb House of the Humanities and Social Sciences (MdMSH) at the University of Sfax. It aims also to renforce the position of Sfax partner as an international model for mutually beneficial relations between academia and civil society, with Heritage serving as a driving force of regional development and stability. SfaxForward postulates that Tangible and Intangible Heritage can play a central role in a territory's transformation and development. The characterization and subsequent participatory management of these common cultural assets should engender a more stable and inclusive society.

So to achieve its goal, SfaxForward develops three types of initiatives: multidisciplinary conferences and workshops on the project's key themes, thematic schools dedicated to young researchers, and an Observatory of Southern Tunisian Heritage constructed in collaboration with civil society.

The extensive interdisciplinary experience of the collaborating French and Belgian Houses of the Humanities and Social Sciences benefits MdMSH in constructing its own unique scientific identity, with an ambition for international excellence.

The "**added value**" of the new MICAfrica project is the reinforcement of the position of USFX as a leader University at Sfax and Tunisia, and also at the North part of Africa. With the constitution of the North African (NA) Consortium within the MICAfrica project, the University of Sfax will play an important role in creating and strengthening synergy and networking with the NA countries and subsequently with other African countries. This steering position could be strengthened and developed in the future to cover other areas of research.

The University of Sfax could become also a benchmark university in Northern Africa, and in Africa as a whole with respect to the management and coordination of European projects. Moreover, it will contribute to supporting the EU plan for development and cooperation that covers Africa as a whole; this EU plan supports projects with a trans-regional, continental or global *added value* in areas of shared interest, and offers new possibilities for the EU and Africa to work together.

Furthermore, through the capacity building activities dedicated to young research from Tunisia and from NA countries, and to administrative/support staffs respecting the gender aspect, Sfax University could be a driver force in NA and in the rest of African countries by implementing collaborative program, in order to improve project management and leadership skills in a network with others as well as to increase access to European funds for African universities; those are interested in develop International cooperation projects and learn a common base for all EU Programs.

The implementation of the MICAfrica project's activities will have different forms of impacts on scientists, clinicians, political stakeholders, public and private sector. The overall objective of MICAfrica project is to strength the capacity of Sfax University and its' scientific and medical staff in the management of human diseases related to microbe variations. This will be achieved by the acquisition of new competencies in human microbiome analysis and in the studying the relationship between the variation of human microbiome and diseases such as obesity, diabetes, cancer, etc.

This project will have an impact on several stakeholders (Figure 2):

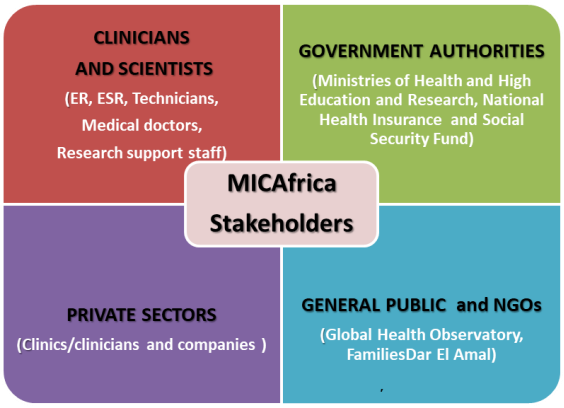

Figure 2: MICAfrica stakeholders

- **Clinicians and scientists:** those directly involved in MICAfrica will play an important role through the training and technology transfer **(WP1 and WP2).** They will improve the knowledge; enhance expertise and innovation in USFAX. The wider research community will be specifically targeted through our dissemination activities **(WP4).**

- **Government authorities** will be involved in dissemination activities **(WP4).** The MICAfrica project results will first and foremost advise the Tunisian government (mainly through the Ministry of Health) to implement recommendations and action plans to improve the healthcare services and management of diseases related to human microbiome and also to raise the awareness of scientific and medical community about the importance of developing research activities on human microbiome. The government authorities, through our guidance, will also encourage private companies to invest in research and to collaborate with Tunisian and African universities to develop research projects on human microbiome.

- **Private sector (mainly Tunisian clinics and medical and technical companies)** will play key roles in dissemination and outreach activities **(WP4)** to ensure excellence and awareness about the opportunity to collaborate in the field of human microbiome.

- **General public and NGOs** will actively participate in MICAfrica project through strengthening the relationship between academics and NGOs such as the Tunisian Association of Endocrinology, Dar El Amal (fighting cancer) or the Tunisian association for medical research (ADREMED) by raising the general public awareness of the role of human microbiome in health and diseases (WP4).

2.1 Expected impacts

a) Increasing USFAX's research excellence

The MICAfrica activities (conferences, trainings, workshops, internships...) will contribute to develop the USFAX staff skills (10 ER and 10 ESRs, 5 technicians and 3 administrators) and to **increase the USFAX's research excellence** in the field of human microbiome and its relationship to diseases. Through the MICAfrica activities, the scientists (ER and ESRs) will publish their research results in high-impact journals (IF>5) in open access to all scientific publications using combination of both **GREEN and GOLD open access ways.** The H-index of ER will increase (from 16 on average now in our group, to >25 on average – knowing that in our field after 15 years experience an excellent H-index would be of 30). Highly qualified experts in bioinformatics will implement and update a NA microbiome database and highly qualified clinicians will use microbiome data of Tunisian patients to improve the management of specific diseases (diabetes, colorectal cancer, neurodegenerative diseases…). On the other hand, the employability of ESRs will be improved (we expect that out of 10 ESR benefiting from the project, 50% will be recruited continue their research activities and teaching in the public sector and 50% will create their start up within 9 months of the end of their contribution). Furthermore, MICAfrica will enhance USFAX's staff capacity in research support activities (management, financial, technology transfer).

Through the standardisation activities, results of human microbiome analysis in NA countries will finally be comparable to those of partner countries leading to Tunisian and NA scientists to integrate European human microbiome networks (cost actions) and to become active members of the international microbiome consortium. The impacts of MICAfrica on scientific level are summarized in Table II:

Table II: Impact of MICAfrica project activities on scientific level

	Indicators of progress	Current situation	Targeted situation (at the project end)	Impact
Improvement of scientific skills of USFAX	Scientific staff trained in metagenomic analysis of human microbiome (O1, WP1)	2 ER	5 ER , 3 technicians and 5 ESRs	- Development of research skills in human microbiome analysis : - Increase the H index of ER (> 30) - Improving the employability of 10 ESRs (50% will be recruited in the public sector and 50% will create their start up)
	Scientific staff trained in metagenomic data analysis by bioinformatics tools (O1, WP2)	2 ER	2 ER , 2 technicians and 3 ESR	Development of bioinformatics competencies of metagenomics analysis : - Highly qualified experts in bioinformatics - Implementation and update of NA microbiome database
	Clinicians staff trained in personalized medicine (O1, WP1)	1	3 ER and 2 ESR	Highly qualified clinicians using microbiome data to improve patient care with specific diseases (diabetes, colorectal cancer…)
	Publication on human microbiome (O1, WP4)	2	5	- Publishing in highly impacted journal (IF>5)
	Standardized procedure used for human microbiome analysis (O2, WP2)	Inexistent	Procedure used	- Results of human microbiome analysis in NA countries will be comparable to those of partner countries
	North-Africa Consortium of Human Microbiome (NAHMC) (O3,WP3)	Inexistent	Created and coordinated by USFAX	- Ability to integrate international human microbiome networks and to be member of the international microbiome consortium
Capacity	Research support staff			

building of horizontal staff of USFAX in research support activities	trained in project management, financial and technology transfert (O1, WP5)	3	5	Enhancement of USFAX's staff capacity in research support activities (management, financial)

b) Enhancement of the reputation, attractiveness and networking USFAX channels

According to the expected impacts, the reputation and attractiveness of USFAX will be enhanced through several MICAfrica activities:

- The creation of a first of its kind, state-of-the-art module on microbiome for Life Sciences or Medicine Master's degrees that will offer the opportunity to twenty selected students (Tunisian and NA) each year to benefit from cutting-edge courses in microbiome delivered by EU partner experts. During the last year of the project, the module will be available and accessible to Tunisian students on the Moodle platform of the Faculty of Medicine (http:// moodle.devsfax.org/); post project, it will be open to NA students and ESRs (Average of 30 per year after 2023). This new course will put our institute on the map for the whole of North Africa for provision of state of the art teaching content on microbiome. We also envisage preparing with our EU partners the creation of a completely new degree (Master of Science) as a joint programme Erasmus (we would be an active partner of the project led by an EU partner). This will be discussed within the NAHMC.

- Creation of NAHMC, by going out of the local sphere and working towards international collaborations with a focus on North Africa will put our university at the centre of a dynamic to federate efforts on the microbiome and to enable us to play a role in the bigger initiatives such the COST Action network "Statistical and machine learning techniques in human microbiome studies" (CA18131) and the International Consortium of Microbiome (http://www.human-microbiome.org).

c) Improvement of the USFAX ability to compete successfully for national, EU and internationally competitive research funding opportunities.

Although USFAX has been involved in many collaborative projects (17) in the field of life sciences, there are no current projects on human microbiome. Through interactions and collaboration with EU partners (well experimented in the participation and coordination of EU and international projects: FP7, H2020, etc.), our ambition is to increase the number of EU and international projects coordinated par USFAX (from 17 to 25 by 2023). We also expect that USFAX will participate as partner or coordinator to least 3 international research projects on human microbiome by 2023.

d) Social, Economic and Political levels

- ***At the social level (public health):*** As a foreseen result of the MICAfrica project, USFAX will have the capacity to move from the use of conventional diagnostic tools to the practice of early diagnosis and better therapeutic strategy based on advanced research into disease mechanisms. Ultimately, this will enable USFAX and clinicians to deliver effective personalised medicine across several clinically relevant phenotypic traits and diseases. Through our targeted training activities (WP1), we expect hospitals (3public hospitals and 10+ private clinics) in the region to use these findings in both clinical and non-clinical research as soon as results are out. Through dissemination and communication activities and especially through our NAHMC we can expect to reach out to a larger community of clinicians across Africa and the EU.

- **At the economic level,** the new data generated by MICAfrica project will promote more effective and improved disease prevention and treatment programs compared to conventional methods and

consequently reduce the cost of health care services in Tunisia and NA countries. Indeed, the care of chronic diseases is very expensive and , and being able to assess an individual's microbiome and then making personalized recommendations based on these findings—is a great tool for practitioners. Clinicians could recommend eating patterns and behaviors to influence the gut microbiome and to prevent many diseases such as diabetes, obesity, inflammatory bowel disease, hypertension, colorectal cancer, autism spectrum disorder, etc..., since studies have found associations between reduced bacteria diversity and these diseases. In the future, it will be routine for practitioners to and microbiota-derived treatments are the future of precision medicine. On the other hand, the success of MICAfrica project will lead to the promotion of personalized medicine that will create new opportunities for industries and for the health sector. Indeed, the global personalized medicine market is expected to grow considerably by 2022, with an annual compound growth rate of 11.8%[6], more than double the expected growth rate for the entire health sector[7].

Wellness) And Segment Forecasts To 2022 », Grand View Research, juin 2015.
7 «World industry outlook: Healthcare and pharmaceuticals », Economist Intelligence Unit, mai 2014.

- *At political level,* MICAfrica project will engage interactions between researchers, policy makers (Health Ministry; Social Affairs Ministry) and other relevant stakeholders in the various research areas to raise their awareness of the topic so that they support further research and incentivise activities in that area, especially for what concerns the current strategy around cancer and diabetes. Ultimately, we hope to obtain of the Ministry of Social Affairs to reimburse the microbiome analysis as a routine test for patients and ultimately a prevention campaign around microbiome analysis (as it is done for colon cancer). These interactions will occur through direct personal contacts (dedicated meetings with the Ministry Higher representatives such as the Scientific Advisors of H2020 or the representatives in region, meetings, and arrangements for research collaboration) and specific outputs like expert reports, clinical guidelines, and scientific advice.

Main obstacles to reach expected impacts

Although the current conditions are quite favourable for MICAfrica to achieve the established objectives, some obstacles could minimize the expected impacts:

- The high costs of microbiome analysis could make it very difficult to use routine tests in prevention campaigns and early detection of chronic diseases such as diabetes and cancer;
- Due to these high costs, the Ministries of Public Health and Social Affairs may be reluctant to support new microbiome analysis tests as part of early detection;
- In addition, the unavailability in public health structures of heavy equipment for the implementation of NGS sequencing techniques, makes it difficult for clinicians to access these techniques, which would require the establishment of agreements and collaboration between hospitals and the few research centres that have NGS platforms;
- In addition, the lack of sufficient qualified human resources in the microbiome field (bioinformatician, clinician, technicians...) to develop and use the platform is another obstacle and requires a national strategy for capacity building at the national level.

All these obstacles could be overcome thanks to the newly elected politicians (Tunisian President and Parliament) who are placing the fight against corruption (which strongly affects the health sector) as the first priority on their political agenda in the next 5 years. This political will increase the funds needed to implement the national health strategy, which includes screening, awareness and prevention campaigns for diabetes, cancer and neurodegenerative diseases, which is in line with European priorities (horizon Europe).

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

Hereafter, we present the highlights of our Plan for disseminating and exploiting the results of MICAFRICA.

- Dissemination Strategy

The objective of our dissemination strategy is to give visibility to the results obtained by the MICAfrica project to the academic community and to create an international cooperation network capable of promoting innovation and meeting new societal and environmental challenges.

Wellness) And Segment Forecasts To 2022 », Grand View Research, juin 2015.
[7] « World industry outlook: Healthcare and pharmaceuticals », Economist Intelligence Unit, mai 2014.

The USFAX, IHUMI, INRA and UNIFI staff have experience in knowledge dissemination and will use their existing networks, within academia, and public administration to spread information about the different activities of MICAfrica. Towards this goal, there are several supportive mechanisms at disposal for USFAX. Therefore, USFAX has access to a network structure that gives insight into core competencies, challenges and framework conditions in different parts of the Mediterranean region. In this context, USFAX organize every year the UNIV expo and the forum of medical research and numerous other meetings in the field of medicine, life science and biotechnology. Through MICAfrica we want to take a proactive role in exchanging knowledge and information and create synergy effects with research projects of European excellence in the field of microbiome and genomics analysis (Table III).

Each project partner will be involved in disseminating information about the project at different levels: within the partnership itself, at the national level in Tunisia and at the international level (mainly to universities, research institutions and employer sectors).

Dissemination will be ensured via the following activities:

- Participation to the UNIV expo at Sfax University, the UNIV expo is an annual event that constitute an opportunity for all university institutions at sfax to highlight Sfax's academic skills and to present the training offered by various educational institutions.

- Publication of scientific articles in high impact-factor journals: The consortium partners will reinforce the impact of dissemination activities by publishing reports and scientific articles in international peer reviewed journals with high impact factors.

The MICAfrica Consortium beneficiaries will undertake any required measures/actions so as to ensure full compliance with the legal requirements set in the Article 29.2 of the Grant Agreement referring to: Open access to scientific publications. The Consortium acknowledges that under Horizon 2020, each beneficiary must ensure open access to all peer-reviewed scientific publications relating to its results. To meet this requirement, beneficiaries must, at the very least, ensure that any scientific peer-reviewed publication can be read online, downloaded and printed. Since any further rights – such as the right to copy, distribute, search, link, crawl and mine – make publications more useful, beneficiaries shall make every effort to provide as many of these options as possible. All peer-reviewed scientific publications that do not contain sensitive data and that will not be relevant for exploitation will be made available to the scientific community through open access (2 publications by 2023, and 3 after the end of the project) using in combination GREEN and GOLD ways. An embargo period is allowed, after which the full content of the publications shall be made freely available. Publication policy and authors lists will be decided by common consent and if necessary at the general assembly meetings. These publications will cover all aspects of the project (except where IPRs are involved, in which case patent applications will be prioritised and publications will be delayed accordingly.

The Consortium is well aware that the dominant type of scientific publication is the journal article. However, and based on the H2020 Mandate on open access to publications, the Consortium beneficiaries will make additional efforts so as to provide open access to other types of scientific publications, such as: monographs, books, conference proceedings, grey literature (informally published written material not controlled by scientific publishers, e.g. reports).

- **Creation of the MICAfrica website** within two months with an appropriate protocol for updating information on activities and progresses of the project. The Coordinator will be in charge of this task and partners are encouraged to contribute with news related to the subject, local events or relevant information to be published. MICAfrica website will give visibility to all actions and activities carried out by the project and to spread the results achieved to other Tunisian, NA and worldwide universities (WP4).

- **Use of social media to access young researchers** (Facebook, Twitter, Newsletter) and edition of quarterly scientific bulletins ("MICAfrica"). The newsletter and the quarterly scientific bulletins will contain information on achievements in the project, reports from meetings or conferences and announcements of upcoming events related to the project ongoing activities. Each newsletter and quarterly scientific bulletin will be published on the web Platform.

- **Participation in international conferences such as:**

  - International Conference on Bioinformatic Approaches for Human Microbiome (ICBAHM) – 16 July 2020 Copenhagen, Denmark (with one ESR and one ER at each at least and with respect gender balance);
  - Gut Week Summit 2020, 8-11 September 2020: Barcelona, Spain (with one ESR and one ER at each at least and with respect gender balance);
  - International Conference on Microbiome (ICM) – 03 december 2020 Amsterdam, Netherlands, (with one ESR and one ER at each at least and with respect gender balance);
  - International Conference on Microbiome Analysis (ICMA) - Tokyo, Japan 25 march 2021 (with one ESR and one ER at each at least and with respect gender balance);
  - Other European and international events in 2022 and 2023.

- **Organisation of two academic conferences on 2021 and 2022**

  - The first one focusing on the presentation and dissemination of information about the progress of MICAfrica activities will be organized at the beginning of 2021 at the USFAX with the involvement of lecturers from IHUMI, INRA and UNIF. At least 100 participants from NA and EU partners will participate in this event with the involvement of ER, ESR seeking gender balance.
  - The second one will be organized at 2022 at the USFAX with the involvement of lecturers from IHUMI, INRA and UNIF focusing on the dissemination of the preliminary results generated by the pilot study (WP1). At least 100 participants from Tunisian, NA and EU partners will participate in this event with the involvement of ER, ESR seeking gender balance.

- **Particular attention will be given to the wide dissemination of knowledge,** through the international events those will be organized by high-qualified scientists and physicians from Faculty of Science and Faculty of Medicine during and after the period of the project (after having achieved increased recognition). Through these events, USFAX will maximize the number of international participants and guaranty a wide dissemination of knowledge on human microbiome.

- **Through MICAFrica activities (WP1) targeting scientists and clinicians** at Sfax (2 public hospitals and 10 private clinics) and at the south of Tunisia (2 public hospitals and more than 10 private clinics, we expect that the awareness of the importance of human microbiome in health and diseases will considerably raise in this scientific community.

- **MICAfrica** will utilize the competencies of different networks and media centers, such as: "CordisWire" to publish news, events and articles related to MICAfrica project and to approach the broader scientific public.

- ***Exploitation strategy***

Our exploitation plan aims at enhancing the results of the MICAfrica project at the level of the scientific community concerned by the field of the human microbiome and to widen our network of collaboration on the African and European scale.

At the scientific level:

- The creation of a microbiome database will help to develop personalized medical approaches in NA countries.

- As a first step, USFAX will drive effort to build on its existing capacities – such as studies of the microbiome in Tunisian patients and gain new skills in human microbiome data analysis. The ***internships*** for 7 ESRs and 5 ERs performed in EU partners' laboratories and platforms (NGS and Bioinformatics) could improve their skills in microbiome analysis and data analysis. So, the trained ER and ESR will be able to develop further research and will generate new data on from human microbiome analysis n cohort of Tunisian patient that will enable investigators to characterize the relationship between the composition of the human microbiome (or of parts of the human microbiome) and health and disease. This will lead to improve the visibility of USFAX and facilitate its integration in European and international consortiums as the International Consortium of Microbiome (http://www.human-microbiome.org). The trained ESR will also be able to create their spin-off in the field of microbiome analysis. Therefore, it is expected that 50% of trained ESR will set up their business.
- As a second step, USFAX will develop the first database in NA dedicated to human microbiome analysis.

- In addition**,** the creation of this database could improve and share knowledge on human microbiome leading to the creation and coordination of NAHMC with EU and NA universities partners (building on existing collaboration agreements between universities Aix-Marseille/USFAX and INRA/USFAX – other collaborations with Africa on life sciences) and then the integration into international consortiums on human microbiome

- Furthermore, networking activities with EU partners (expert visits and outgoing visits during the different steps of the project) in addition to the participation to international conferences on human microbiome will facilitate the establishment of relationship with international experts on human microbiome and will facilitate the international networks such as Cost network and human microbiome consortiums.

- **At the educational level**

- As a first step, the module on the human microbiome which will be integrated into the masters in life sciences at USFAX will be available on the Moodle platform of the Faculty of Medicine of Sfax and will be progressively accessible to master students in other Tunisian and North African universities.

- At a second step, a master's degree on the human microbiome will be set up with our European and North African partners as part of the Erasmus + KA2 program in order to disseminate educational initiatives and foster internationalization. The launch of the master on moodle learning platform will promote the creation of relations between Tunisians, Africans and European ER and ESR who carriy out research work on the human microbiome.

Our project will generate several data and results that will be shared with the scientific community and will not be protected by a patent. So they are not concerned by intellectual property.

b) Communication activities

MICAfrica partners are fully aware of the importance of promoting the project outcomes and disseminating the benefits of knowledge transfer not only to scientific community, but also to the general public and the political stakeholders. Therefore, a strategic communication plan has been established including different events and tools. Communication will be carried out and monitored through a number of planned activities and tools proportionate to the scale of the project and tailored to the target audience:

- Communication specific objectives of MICAfrica:

Our key messages for the communication are the following:

- To spread the critical relevance of the Microbiome analysis and its tight association with health and disease especially the chronic pathologies such as diabetes, obesity and cancers.

- To raise the awareness of the general public and politicians of the personalized medicine and of the importance of the incorporation of microbiome based prevention diagnostics and therapeutics with other components of personalized medicine such as pharmacogenomics will be an integral part of the new era in patient care. This integration will further enhance the ability to find the right treatment for the right patient while, at the same time, reducing adverse events and health care cost. In fact, gut microbiome unlike host genes represents a modifiable factor that can be targeted by probiotics, and diet

- Target groups and communication tools

- ***At general public level***

To improve the social concern and collective knowledge about the role of microbiome in health, different communication tools will be used to reach the general public with a focus on the patient associations (Cancer associations, Diabetes association, etc....), social NGOs and the young generation (schools and high schools).

We will use verbal and electronic communications:

- Verbal (formal) communication approaches include public talks and person-to-person information exchanges in officially organized briefings, meetings, especial events and awareness campaigns (will be organized twice yearly by each association).
- A campaign around the launch of the NAHMC will be organized along with a creation of brand, and an identity.
- The MICAfrica website will include public open interface including a calendar of events, news related to the subject and relevant information about the project, media files will provide many vulgarized information about microbiome and health Patients will be subscribed to a mailing list and the SC will be responsible for the communication with them.
- A MICAfrica Newsletter: there will be 2 special newsletters every year.
- Internet tools (Facebook and Twitter).
- A facebook group will be created. News will be published in this group as well as all information about microbiome role in our life. Vulgarized scientific results and information coming back from conferences will be published regularly after each event.
- Printed communications include newsletters, brochures, posters and flyers that will be distributed in local language in every event particularly for patients and during the campaigns.

- A report on these electronic and printed communications will be performed biannually. We expect to have more than 10000 followers and more than 1000 like every report.

- ***At political level,***

- MICAfrica project will engage interactions between researchers, policy makers (Health Ministry; Social Affairs Ministry) and other relevant stakeholders in the various research areas to raise their awareness of the topic so that they support further research and incentivise activities in that area, especially for what concerns the current strategy around cancer and diabetes.

- Ultimately, we hope to obtain of the Ministry of Social Affairs to reimburse the microbiome analysis as a routine test for patients and ultimately a prevention campaign around microbiome analysis (as it is done for colon cancer). These interactions will occur through direct personal contacts (dedicated meetings with the Ministry Higher representatives such as the Scientific Advisors of H2020 or the representatives in region, meetings, and arrangements for research collaboration) and specific outputs like expert reports, clinical guidelines, and scientific advice.

Table III: Dissemination, exploitation and communication in MICAfrica project

	Type of activities	Indicators of progress	Current situation	Targeted situation
Dissemination	Website creation	- Functional website	- No website dedicated to the project	- Website created and updated
	- Publication on human microbiome in high impact-factor journals	-Number of articles published in high impact-factor journals (IF>5)	-	- 2 at the end of the project and 3 after
	- Participation in international conferences	- Number of ER and ESR and clinicians participating to international conferences	-	- 5ER and 5 ESRs
	- Organisation of academic conferences on human microbiome	- Conference organised on time	- No conference organised on human microbiome	- Two academic conferences organised on 2020 and 2021
Exploitation	- Creation of Microbiome database	- Microbiome database created in time	- No data base on microbiome analysis	- Database created and updated
	- Creation and coordination of NAHMC	- Meetings and Networking activities between NA partners	- No Consortium NA on human microbiome	- NAHMC created, agreement signed and 5year strategy prepared
	- Integration into EU and international consortiums on human microbiome	- Networking activities with EU and international experts on human microbiome	- No relationship with Eu and international consortium in Human microbiome	- Relationship and collaboration established between NAHMC and EU/ International consortiums
	- On line module on the human microbiome (MHM)	- MHM accepted by the national committee in High education Ministry	- No MHM created	- MHM created, accepted and accessible on line
	- Master's degree on HM as part of the Erasmus + KA2 program	- Master's degree on HM accepted by EC	- NO Master's degree on HM as part of the Erasmus + KA2 program	- Master's degree on HM as part of the Erasmus + KA2 program implemented and

Communication	- Use of social media (Facebook, Twitter, Newsletter) - Edition of quarterly scientific bulletins ("MICAfrica")	- Number of followers and like on MICafrica Facebook Group, Twitter account and Newsletter area	- No MICafrica Facebook Group, Twitter account created and no Newsletter area created in the website	Facebook Group, Twitter account and Newsletter area created and followed by
	- Biannual Report	- Report validated and published	- No report	- All reports accessible on line
	- Printed communications	- Flyers, brochures and booklets printed and number of posters prepared and presented in scientific events	- No flyers and other documents printed (brochures, booklets and posters)	- 10000 Flyers distributed, 1000 booklets distributed during MICAfrica events and 10 posters presented in scientific events.
	- Awareness campaign (Public talks , direct personal contacts)	- Number of Awareness campaign organised	- No awareness campaign organised	- Public talks, person-to-person information exchanges, meetings, awareness campaigns organized twice yearly

- Data Management

A first version of DPM will be submitted within the first 6 months of the project's Action implementation. The DMP will be updated over the course of the project whenever significant changes arise, such as new data, changes in consortium policies (e.g. new innovation potential, decision to file for a patent), changes in consortium composition and external factors (e.g. new consortium members joining or old members leaving).

The Data Management Plan for MICAfrica will focus on the security and robustness of local data storage and back up strategies, and on a plan for this repository-based sharing, where and when appropriate, where significant data sets will be generated.

MICAfrica activities will involve human participants for collection of fecal samples and patient personal data. All data require consent. All data will be anonymized and no personally identifiable data will be included in any data set.

Extracted DNA samples will be used for library construction and sequencing on the MiSeq Illumina platform with paired-end protocol. In particular, the V3-V4 region of bacterial 16S rRNA gene will be amplified via PCR using specific primers (806R and 515F) as we have previously described (doi: 10.3389/fmicb.2017.02699). Statistical analyses on the bacterial community distribution will be implemented in R (R Core Team, 2014) using the vegan package (version 2.3-2). Analysis of similarity (ANOSIM, "anosim" function) will be conducted to test the statistical significance of difference between distinctive bacterial communities (doi: 10.3389/fmicb.2017.02699). Consistency and quality of experimental data will be achieved by adhering to standard operating procedures (SOPs) for each experimental type. We will also compare our data to that produced by peers in the field to ensure consistency. Such data will be protected in accordance with the EU Data Protection Directive 95/46/EC "on the protection of individuals with regard to the processing.

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consistency. Such data will be protected in accordance with the EU Data Protection Directive 95/46/EC "on the protection of individuals with regard to the processing.

Experimental data will be stored on password and firewall protected computers, which are regularly backed up on a central server. All written records and electronic forms of data will be stored securely for at least 10 years after completion of the project, in agreement with Research Council guidelines. Experimental methods and standards will be documented within laboratory notebooks and within an on-line communal Laboratory Protocols folder, accessible to all laboratory staff.

Finally, to improve and maximise access to and re-use of research data generated by MICAfrica project, the microbiome data will be made ***as open as possible, as closed as necessary*** in terms of sharing. The microbiome data is suitable for sharing as it can be stored in a generic, open format and is compatible with other data generated in the same manner, our data may be released for sharing with other researchers in the field following dissemination in peer-reviewed journals or international conferences. In addition, the deposition of sequencing data in public repositories will ensure their long-term availability and utility. Careful detailing of methodology in the papers presenting this data will allow other researchers to maximise the data using.

The project coordinator will be responsible for deciding if research data may be shared with a new user. Except for the sequencing data, other raw data will not be deposited in any database other than that available on the laboratory computers or the departmental server.

The project coordinator will be responsible for ensuring that any external collaborators comply with a data-sharing agreement to protect our data from any unauthorised use. In addition, he will be responsible for ensuring the security and quality assurance of study-wide data management.

- Management of IPR

Concerning the **management of intellectual property** (IP), the ownership, access rights, potential uses or related data, etc. will be also assessed. The Consortium Agreement will govern the rules and procedures for the management of IP.

In detail, MICAfrica proposes a complete range of activities leading to the optimal visibility of the project and its results, ensuring a smooth handling of the individual intellectual property rights (IPR) of all partners involved; thus, paving the way for knowledge transfer.

Internal knowledge management will be facilitated through a **secure professional collaborative space for project document sharing.** Project partners count on a solid individual IPR strategies and prior knowledge ownership (background) related to the project, which is already protected under diverse IPR mechanisms, as well as the intended foreground for the project.

Additionally, a freedom-to-operate analysis has already been conducted to ensure the future exploitation of the MICAfrica solution.

The overall IPR strategy will ensure that all partners are free to benefit from their complementarities and to fully exploit their market position.

Beneficiaries will also define the background needed for the purposes of the project development in a written agreement and, where appropriate, may agree to exclude specific background.

3. Implementation

3.1 Work plan

The MICAfrica project is composed by **6 work packages (WPs)** dealing with different aspects: Capacity Building in human microbiome analysis (WP1); Standardisation of human microbiome analysis according to international procedures (WP2); Creation of North-Africa Consortium of Human Microbiome (NAHMC) (WP3); Dissemination, Communication and exploitation (WP4); Project coordination and management (WP5); Ethics Requirements (WP6).

- The **WP1 – Capacity building in metagenomics for human microbiome analysis** (Duration: M3 – M15) – aims to improve the skills of ERs, technicians and ESRs in High-throughput sequencing technologies in human microbiome and the development of bioinformatics competencies of data analysis. This WP will also help improve the skills of clinicians' staff in the study of relationship between human microbiome and diseases. All the activities of this WP will take place between **M1 and M15.**

- The overall objective of the **WP2 – Microbiota-Host interplay** (Duration: M3 – M36) – is to set up standard methodology for human microbiome analysis at USFAX according to international standard procedures (from sample collection to sequencing and data analysis). These procedures will be **applied to study human microbiome in North African populations** and will be validated by a technical audit.

- The main objective of **WP3 – Creation of North-African Human Microbiome Consortium (NAHMC)** (Duration: M18 – M36) – is to create the North-Africa Consortium of Human Microbiome (NAHMC) to improve the synergy between North Africa (NA) scientists and physicians and to develop collaboration with EU and international networks and consortiums. To achieve these objectives, we will draft with the Consortium Beneficiaries a 5-year strategy and an action plan for the MICAfrica consortium.

- The **WP4 – Dissemination, Exploitation and Communication** (Duration: M1- M36) – will cover the dissemination, communication, and exploitation activities for the project. This also includes: (i) the development of communication tools and a plan for internal and external project communication; (ii) the dissemination of the project results; (iii) the development of an exploitation plan in order to ensure long term running of the MICAfrica project's activities.

- The main objective of the **WP5 – Project Coordination and Management** (Duration: M1- M36) – is to enable the smooth management of the MICAfrica Project based on the applicable H2020 rules. All activities will be performed by the Project Coordinator Manager (PCM) and the Steering Committee (SC).

- The **WP6 – Ethics Requirements**: This work package was added during the Grant Agreement Preparation (GAP) stage and sets out the 'ethics requirements' that the project must comply with.They are included as deliverables in this work package (see PART A of the Annex 1 of the GA). Concerning the contractual obligations for the *Ethics Requirements* applicable is the ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY of the Grant Agreement.

Throughout the project's Action implementation, particular attention will be paid on the involvement of the Early Stage Researchers (ESRs) in all the different training, networking and research activities **with respect to gender balance** (WP1, 2 and 3). ESRs from life science institutions and the medical school at the Coordinating Legal Entity (USFAX), will be informed and invited directly and via their institutions

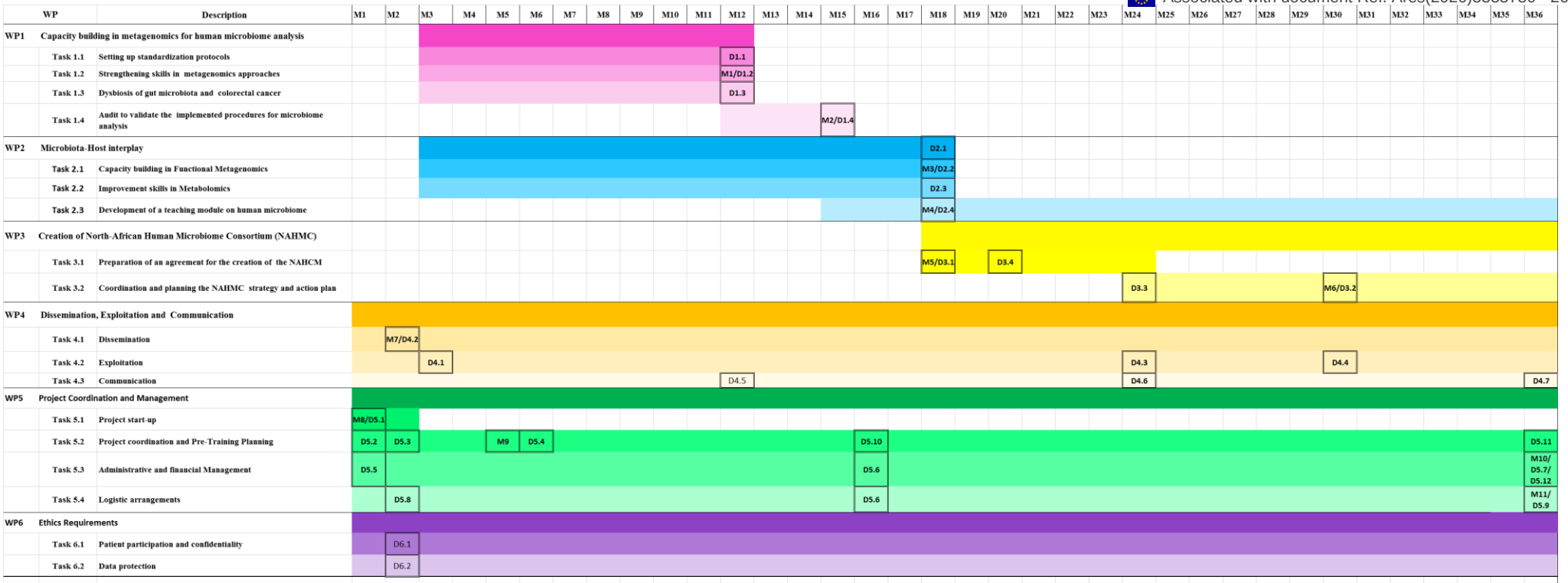
and supervisors by e-mail, facebook and via the website of MICAfrica project to register to the scientific activities, in order to ensure the development of their skills in High-throughput sequencing technologies in human microbiome, in bioinformatics and in the study of relationship between human microbiome and diseases. They will be also informed and invited to participate specifically in trainings on entrepreneurship that will provide them the basics of starting and operating a small business and will enhance their ability to take initiative, to identify business opportunities and forecast resource needs and to develop a business.

ESRs from Morocco, Algeria and Egypt will be invited via their institutions and via the website to participate in the activities related to the creation of the North-Africa (NA) Consortium of Human Microbiome (NAHMC).

On the other hand, the MICAfrica project will carefully take into account the involvement of ESRs in the organization of MICAfrica activities including dissemination, communication, and exploitation activities, allowing them to interact early with the larger research community and to raise their profile. Specific focus will be placed so as to respect the gender equality among ESRs who will be involved. Particular attention will be also placed on the distribution of funds by ensuring that ESRs will benefit from them with respect to gender balance.

Thereafter, in order to ensure the improvement of the skills of USFAX's staff on proposal preparation and project management/administration skills, scientific and administrative staff will be invited to participate in the training organized by the European Project Management Unit H2020 (EPMU) in Tunisia (http://horizon2020tunisia.org/), in the perspective to set up a Project Management Office at USFAX. These trainings dedicated to both scientific and administrative staff of Tunisian Universities are implemented since 2019 by EPMU under the support of Education, Mobility, Research and Innovation (EMORI) program funded by the EC.

The timeline of work plan, the five work packages, and their components are shown in Figures 3 and 4**.**



M1 : Qualified scientific team in performing metagonomic studies; **M2**: Setting up a standard protocol for metagenomic analysis of gut microbiome; **M3**: Qualified scientific team in functional metagenomics; **M4** : Implementation of a master module on human microbiome; **M5** : NAHMC established; **M6** : NA Microbiome database created; **M7**: Created and functional website; M8 : Project Start; **M9** : Qualified support staff for management; M10 : Publications produced as a result of MICAfrica action

D1.1 : Adoption of the state of the art standardization protocols; **D1.2**: Qualified ER and ESR in Metagenomics studies; **D1.3**: Qualified ER and ESR in studying the relationship microbiome/CRC in Tunisian patients; **D1.4** :Validation of the protocols implemented for metagenomic studies; **D2.1** : Qualified ER, and ESR in functional metagenomics studies; **D2.2** :Knowledge gain in metabolomics; **D2.3:** Implementation of a master module on human microbiome; **D3.1** :Signing the agreement of the NAHMC by NA members; **D3.2** : Creation of NA microbiome database; **D3.3:** Establishment of the strategy and the action plan of NAHMC; **D3.4** : Applying to be a membership of the International Human Microbiome Consortium (IHMC); **D4.1** : Dissemination and exploitation plan; **D4.2**: Creation of MICAfrica website; **D4.3:** First report "NAHMC consortium and Database"; **D4.4** :Second report "NAHMC consortium and NA Database"; **D4.5:** First Report "Events for large public"; **D4.6** :Second Report "Events for large public"; **D4.7** :Third Report "Events for large public"; **D5.1** : Work plan and schedule, delivered to project partners; **D5.2:** Kick-off meeting (KoM) Minutes and establishment of the Steering Committe (SC); **D5.3:** Report on Project Management Work Plan; **D5.4** :Data Management Plan; **D5.5:** First report "Risk and financial issues report"; **D5.6** :Second report "Risk and financial issues report"; **D5.7** :Third report "Risk and financial issues report"; **D5.8:** First Report on the evolution of the publications in high impact journals in the field of microbiome; **D5.9** :Second Report on the evolution of the publications in high impact journals in the field of microbiome; **D5.10** :First Report on short term staff exchanges; **D5.11** :Second Report on short term staff exchanges; **D5.12** :Report on the involvement of ESRs from USFAX in MICAfrica action; **D6.1** :Template of informed Consent; **D6.2** :Data protection procedure;

Figure 3: Gantt chart of MICAfrica project

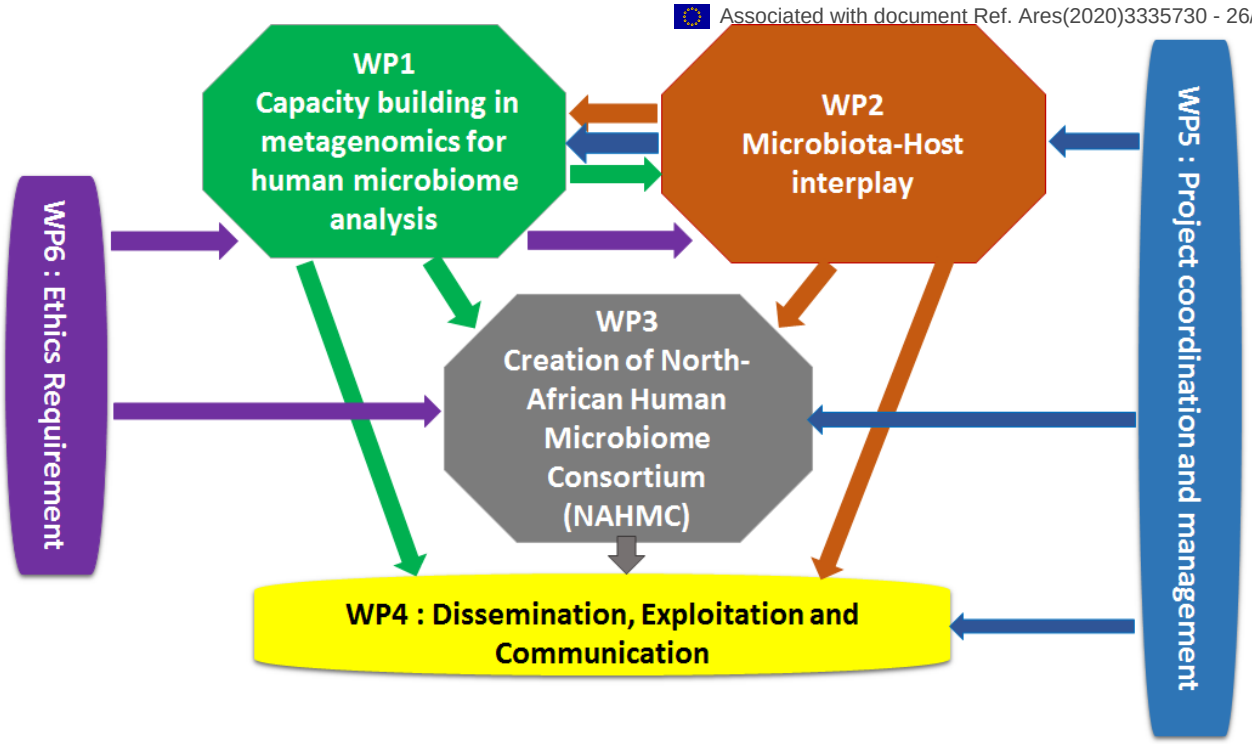


Figure 4: PERT diagram of MICAfrica project

3.2 Management structure and procedures

Before the signature of the grant agreement and at any case before the MICAfrica project's Action starts, the four Consortium Beneficiaries will have concluded and signed the required Consortium Agreement (CA). No costs in relation to the drafting and preparing of the CA will be claimed by the MICAfrica project's EU-funding.

*** Decision-making mechanisms**

The MICAfrica project will be democratically run with a focus on consensus among all the consortium beneficiaries. It has two different decision levels with different responsibilities, internal and external liabilities: Project Coordinator (PC) and Steering Committee (SC). Indeed, to ensure excellent results and intelligent project management, the Coordinator and the EU partners build a SC composed of PC and ten members from USFAX (4), IHUMI (2), INRAE (2) and UNIFI (2). An Advisor Board will be associated to the management structure. It will comprise high-level international experts that will provide advice and quality control of procedure standardization. It will include also North African (NA) members from Morocco, Algeria and Egypt universities who will actively participate to the creation of the NAHMC (preparation of the agreement and the strategy plan). This Advisor Board will interact tightly with SC and PC (Figure 5).

Transparency and accountability are core principles in the decision-making process and project management. Herein, every consortium beneficiary and the Coordinator represent one vote.

SC and PC make their best attempts to resolve conflicts and to take appropriate decisions at the right time. Conflicts could be observed when difference in opinion or some kind of disagreement between members

of the consortium occurs. Each conflict will be resolved effectively with a very open and collaborative mind. The SC will focus on resolving the conflict and finding the best alternative for the team and the creative solution acceptable to everyone. This collaborative decision-making strategy leads to a *win-win* outcom

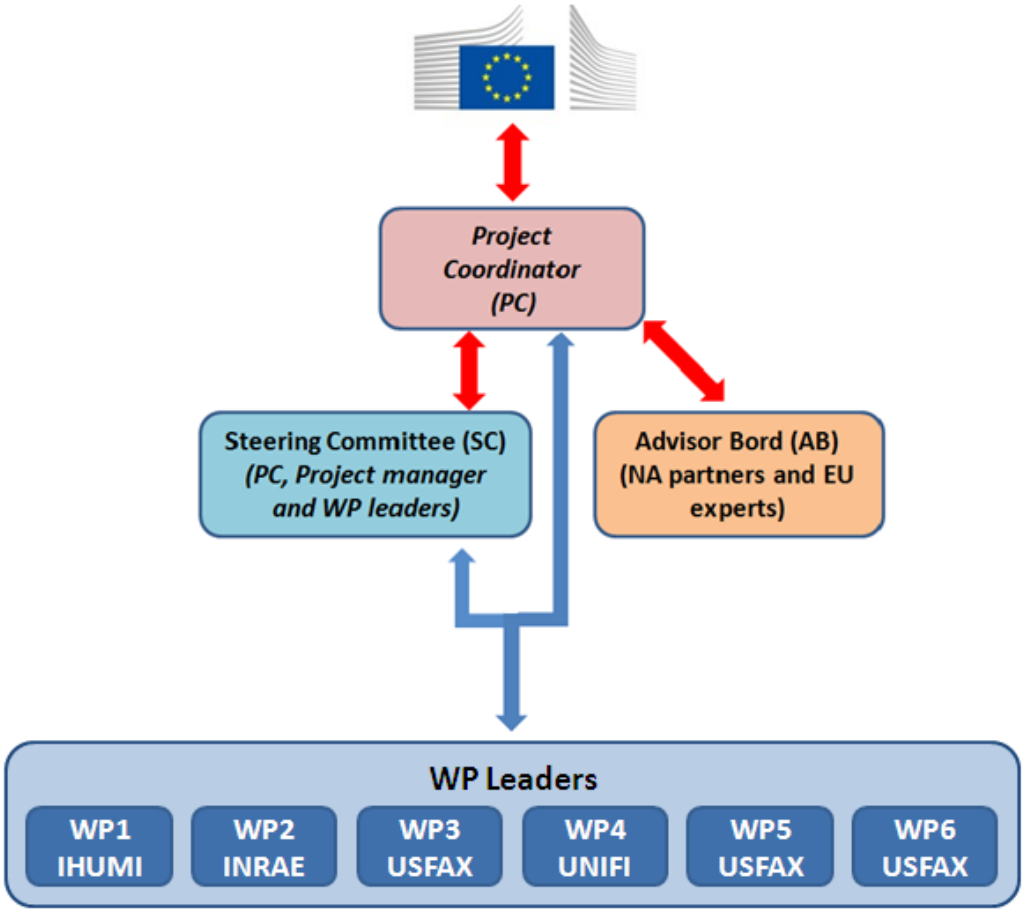


Figure 5: Project Management and Administration

*** Project Management and Administration**

- Overall management of coordination

The project management will ensure the organisational, financial and administrative management of the consortium and effective communication with the Research Executive Agency of the European Commission (REA/EC) (delivery of the different reporting packages based on the contractual obligations (1st and 2nd (final) Reporting Periods) and any additional reporting) and between the consortium beneficiaries so as to maximize the success of the MICAfrica project. Communication between the consortium beneficiaries will be strengthened and addressed through regular project meetings to take place via different means – apart from on-site meeting also via the use of other tools such as telephone, email, fax, Skype and video conferences. Feedback from the quality assessment and the evaluation of MICAfrica results will be taken into account in order to implement the necessary corrective measures.

The PC is responsible for the project direction and coordination as well as the overall management of the project. He will maintain close communication with the Research Executive Agency of the European Commission (REA/EC) and the European Commission (EC). The three EU partners, INRAE, IHUMI and UNIFI will support USFAX for the administrative management according to the set budget (Annex II of the Grant Agreement (GA)), deliverables and milestones and the overall Description of the Action (DoA) as per the Annex 1 of the Grant Agreement (GA).

During the creation of the SC, the role and responsibility of each consortium beneficiary and the overall structure is clearly defined, in order to ensure proper project management and minimize risks of conflict and failures.

This SC will:

- Continuously assess the project status and make strategic decisions.
- Strive to take unanimous decisions on general project aspects although for project decision-making a *two-thirds majority* is necessary.
- Discuss the project achievements on a monthly basis (remotely).
- Ensure the exchange between the project consortium beneficiaries.

SC meetings will be held annually, or more frequently as appropriate, to review project activities, reinforce good practices of consortium members, develop an annual work plan and budget, and discuss other financial and administrative issues. Some of these meetings can be held via videoconferences.

The first meeting (KoM) will take place at Sfax within the first month. It is planned to organise at least 3 other meetings in 3 different locations (Paris, Marseille and Florence). The SC will be supported by supporting organizations and national authorities.

The work package leaders (WPL) are in charge of:

- Ensuring the smooth running of the respective WPs.
- Ensuring timely execution and submission of the set deliverables and managing and ensuring the timely achievement of the set milestones.
- Reporting to the PC on WPs progress and potential change, if considered necessary and after informing in advance the REA/EC, of the work plan.
- Implementing decisions taken by the SC and PC in their WPs.

- Administrative and financial management:

This task includes *day-to-day* project management activities, such as administration, evaluation and monitoring, financial reporting, procurement and payments. Since the beginning of the project, the PC, will provide all its support to the local partners to explain and develop all the administrative and financial provisions for a correct, efficient and rational management of the project. An external financial audit will be necessary to ensure sound financial management. All partners are involved in this task under the supervision of USFAX.

- Logistic:

All consortium beneficiaries, under the coordination of USFAX, will jointly commit themselves to support this task, which includes all logistical arrangements and the implementation of the necessary procedures to support, define and carry out all project activities (travel planning, meeting organisation, workshop, accommodation, ...).

The decision related to the logistic arrangements can be made even with the complete absence, or the disagreement of one of the EU partners for appropriateness of the proposed management structure/decision making.

Some risks should be considered, in particular EU-TN contacts/conflict with EU and/or TN contacts and late financial transfer. To avoid these risks, we will adopt relevant mitigation strategies: (i) an appropriate choice of partners according to their skills with clarification of tasks, (ii) and adherence to deadlines for the various tasks and continuous work. In the **PART A of the Annex 1 of the GA** we have included, as required, the applicable for the project Table ***"1.3.5. WT5 Critical Implementation risks and mitigation actions".***

In addition, some risks associated with innovation management will be considered. The potential for innovation of the MICAfrica project is related to the standardization and implementation at Sfax University of a new method of biological analysis (microbiome analysis) to improve the management of chronic diseases, such as CRC. Risks related to technical and administrative aspects could hamper the progress of the project and the achievement of its objectives. A risk management approach will be adopted, at all levels of the process, based on preventive measures and risk management: (i) Risk identification; (ii) Risk analysis and follow-up actions throughout the project (Each risk will be monitored by a specific person in order to facilitate monitoring and feedback); (iii) Assessment: at each progress meeting, or at least at each major milestone, risks will be evaluated and discussed: criticality of the risk, positioning in the progress of the works, mitigation plans (resolve the proven risk); (iv) Risk treatment.

The indicators of progress of the structure management are represented in Table IV hereunder:

Table IV: Project coordination and management of MICAfrica project activities

	Theme	Indicators of progress	Current situation	Targeted situation
Project management	Constitution of management structures	Functional SC Efficient coordination between PC, SC and WP leaders	Reduced capacity in administrative and financial management	Strong capacity at USFAX to manage EU projects
	Training Management (ER, ESR, technicians and support staff)	Training provided in time	Limited training on human microbiome and project management	100% of USFAX staff involved in the project well trained in human microbiome and in project management
	Milestones and Deliverables	Milestones and deliverables in time	No Milestones and no deliverables	100% of milestones and deliverables achieved at time as planned
	Motivation and commitment of the partners	Partners are unites to achieve the objectives of the project	Engagement of all partners during the preparation of the proposal	Strong commitment from all partners until end of project (all project objectives achieved
	Project schedule and timeline	Activities accomplished on time	Project submission phase	100% of project activities carried out completely and on time
	The cost	Budget spent on time and according to the distribution presented in the proposal	budget not yet granted	Budget granted, paid and spent without delay and without deviation

*** Interaction of MICAfrica with key stakeholders to support the long-term success of the project**

Within MICAfrica, a Stakeholders' management plan that defines the processes, procedures, tools, and techniques in order to effectively engage stakeholders in the project's execution, based on the analysis of their interests and potential impact, will be prepared and implemented.

At an early stage of MICAfrica significant efforts will be made in the recruitment and engagement of an appropriate set of stakeholders. A communication and involvement strategy with a structured approach will be implemented by the MICAfrica Team in order to:

- identify relevant stakeholders per WP and task at an early stage;
- communicate objectives of the MICAfrica project, and what the project can do for the stakeholder;
- establish a process for ongoing engagement;
- continue to engage with all stakeholders throughout the assessment and implementation processes.

During the activities included in the project and principally during the Kick off Meeting, conferences, networking activities, etc., the MICAfrica Team will make efforts to convince stakeholders to participate in the project's relevant activities. Networking activities offered by MICAfrica will also give opportunities for stakeholders to meet *face to face* with other stakeholders and establish collaborations with them.

Through the communication activities, stakeholders will be well informed and would be interesting to be part of and to support the project and the long-term success of the project. In addition, with policy-makers contacts and intense exchange of relevant information, it can be interesting for stakeholders to be part of, as it may provide them with insights that they would otherwise not have heard of.
Workshops dedicated to MICAfrica stakeholders will be occasions to collect information from stakeholders, but also to disseminate knowledge and results.

3.3 Consortium as a whole

As the Coordinating Legal Entity, the Ben. No. 1 (USFAX) has established a partnership with 3 European centres of excellence; namely INRAE, IHUMI, and UNIFI that are selected for their complementary skills and expertise in scientific, technological, and management aspects in the field of human microbiome analysis and whether it's involved in health/disease states. Because the MICAfrica project aims to increase the capacities building of the USFAX (ERs, ESRs, Technicians, clinicians and support staff) in new developed tools to study the human microbiome, each one of our EU partners will contribute through various activities to reach these objectives. To overcome some limitations to investigate the human microbiome, USFAX needs to strengthen the capacity of its staff microbiome analysis according to the standardized procedures. Thanks to the high qualification of our EU partners, we aim to fill this gap in order to be a leader in the field of human microbiome in the North African (NA) region.

- Among the research topics developed at INRAE: "the microbial food and intestinal ecosystems and the functional interactions between food, microbiota and host", many facilities are available as the PAPPSO platform for metaproteomics and MetaGenoPoliS (MGPS: www.mgps.eu) those will be fully beneficial for ERs and ESRs to improve their knowledge through internships. Furthermore, INRAE has high competences in new bioinformatics pipelines for microbiome data analysis and thus, will be involved in the training of ER and ESR to acquire the *know how* in data processing.

- With regards to IHUMI partner, a large expertise in the field of innovative and routine laboratory diagnosis of infectious and tropical diseases has been reported. In addition, IHUMI has developed cutting-edge new technologies to use high-throughput deep sequencing of 16S rRNA for identification of most bacteria. Therefore, the IHUMI partner will significantly contribute to deepen the knowledge of ERs and ESRs from USFAX in high-throughput 16S rRNA sequencing via internships, workshop and conferences.

- The UNIFI has an expertise in studying the correlation between the microbiome and the immune response in the genesis of diseases such as Inflammatory Bowel Diseases, colorectal cancer. The UNIFI will train and support the USFAX staff (ERs and ESRs) in the characterisation of gut microbiome and in the analysis of data regarding the immune response microbiota-associated.

The scientifically and technological complementarities between the 3 EU partners is a major advantage that will guarantee the success of the MICAfrica project since each partners has large expertise in a specific area: INRA in metaproteomics and bioinformics, IHUMI in the high-throughput sequencing of the 16SrRNA of microbiota, and UNIFI in the association between microbiome and disease.

Furthermore, these EU partners have a great experience in the management of EU projects that will support the MICAfrica project to be well executed.

Last, but not least, based on the previous collaboration between the MICAfrica Consortium Beneficiaries, and on their complementarity in the field of human microbiome analysis, the added value of MICAfrica project will be on the technological transfer from the European participants to the University of Sfax. In such a manner, USFAX will benefit and it will be substantially supported and enabled to become a Center of Excellence in the field of microbiome. Thereby, it will play the role of leader during the creation phase of the North African (NA) consortium of the human microbiome with the prospect of expanding the Consortium's network on both an African and international level.

- The MICAfrica Project Coordinator confirms – on behalf of the whole MICAfrica Consortium – that it is acknowledged that this Twinning Action, as per the relevant Call Topic description (H2020-WIDESPREAD-2020-5) does not focus on equipment and research costs, and that such costs, and only in case of need, could be accepted if they constitute: (a) only a minor part (up to 10%) of the total Horizon 2020 funding requested and (b) are deemed necessary to fulfil the action's specific scope and objective. For grants awarded under this Twinning call topic and type of action the following cost categories will be ineligible costs: infrastructure costs.
  - Moreover, we are aware and acknowledge that for the Equipment, at the reporting stage to the REA/EC, only the depreciation of the budgeted costs will be claimed.
- Moreover, we confirm that the tasks and different activities will be executed as per the MICAfrica Annex 1 of the Grant Agreement (DoA) and this applies to all four consortium beneficiaries.
- We also confirm that the total estimated eligible costs that is the maximum EU contribution are the same as agreed in the proposal. To wit: **€896.885.**

In the Travel and Accommodation section, we have estimated the amounts costs to 300€ for USFAX, 350€ for INRAE, IHUMI and UNIFI.

In the personnel costs section, we referred to the EC Per diem table:

https://ec.europa.eu/europeaid/sites/devco/files/per_diem_rates_20190724.pdf

Table 3.4 b 'Other direct cost' items

1/ USFAX	Cost (€)	Justification
Travel	113919	**1)** Travel for 1 internship at IHUMI for 5 ER for 15 days and 7 ESRs for 30 days (Scientific staff trained in metagenomic and human microbiome analysis) (WP1) : Travel costs for 5 ER: 5 X 300€ = **1500€** Travel costs for 7 ESRs: 7 X 300€ = **2100€** **2)** Travel for 1 internship at INRA for 5 ER for 15 days and 7 ESRs for 30 days (Scientific staff trained in functional metagenomic) (WP2) : Travel costs for 5 ER: 5 X 300€ = **1500€** Travel costs for 7 ESRs: 7 X 300€ = **2100€** **3)** Travel for 1 internship at UNIFI for 5 ER and 7 ESRs for 15 days (Scientific staff trained in the study of gut human microbiome and colorectal cancer (WP1): Travel costs for 5 ER: 5 X 300€ = **1500€** Travel costs for 7 ESRs: 7 X 300€ = **2100€** **4)** Travel for 1 internship at INRA for 5 ER and 7 ESRs for 15 days (Scientific staff trained in metabolomic (WP2): Travel costs for 5 ER: 5 X 300€ = **1500€** Travel costs for 7 ESRs: 7 X 300€ = **2100€**

		5) Travel for 1 training at IHUMI for 3 support staff for 7 days (Research support staff trained in project management and financial) (WP5) : Travel costs for 3 support staff: 3 X 300€ = **900€** **6)** Travel for participation in 3 conferences (3 days each) for 2 ER and 1 ESR at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4): Travel costs for 2 ER and 1 ESR at Spain: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at Netherlands: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at Denmark: 3 X 300€ = **900€** **7)** Travel for 3 out-going visits at IHUMI, INRA and UNIFI for 2 ER and 1 ESR for 3 days each (networking with EU partners) (WP4) : Travel costs for 2 ER and 1 ESR at IHUMI: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at INRA: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at UNIFI: 3 X 300€ = **900€** **8)** Travel for 3 scientific workshops at Algeria, Egypt and Morocco for 2 ER and 1 ESR for 3 days each (NAHMC creation) (WP3): Travel costs for 2 ER and 1 ESR at Algeria: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at Egypt: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR at Morocco: 3 X 300€ = **900€** **9)** Travel for 3 meetings for management (3 days each) at IHUMI, INRA and UNIFI for 2 ER (SC) and 1 ESR for (WP5) : Travel costs for 2 ER and 1 ESR atIHUMI: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR atINRAE: 3 X 300€ = **900€** Travel costs for 2 ER and 1 ESR atUNIFI: 3 X 300€ = **900€** **10) Accommodation costs** -Accommodations for 1 internship at IHUMI for 5 ER for 15 days and 7 ESRs for 30 days (Scientific staff trained in metagenomic and human microbiome analysis) (WP1) Accommodations for 5 ER for 15 days : 5X 900€ = **4500€** (900€ for 15 days/ER) Accommodations for 7 ESRs for 30 days: 7X 1800€ = **12600€** (1800€ for 30 days/ESR) - Accommodations for 1 internship at INRA for 5 ER for 15 days and 7 ESRs for 30 days (Scientific staff trained in functional metagenomic) (WP2): Accommodations for 5 ER for 15 days: 5X 900€ = **4500€** (900€ for 15 days/ER) Accommodations for 7 ESRs for 30 days: 7X 1800€ = **12600€** (1800€ for 30 days/ESR) -Accommodations for 1 internship at UNIFI for 5 ER and 7 ESRs for 15 days (Scientific staff trained in the study of gut human microbiome and colorectal cancer (WP1): Accommodations for 5 ER for 15 days: 5X 900€ = **4500€** (900€ for 15 days/ER) Accommodations for 7 ESRs for 15 days: 7X 900€ = **6300€** (900€ for 15 days/ESR) -Accommodations for 1 internship at INRA for 5 ER and 7 ESRs for 15 days (Scientific staff trained in metabolomic (WP2): Accommodations for 5 ER for 15 days : 5X 900€ = **4500€** (900€ for 15 days/ER)

		Accommodations for 7 ESRs for 15 days : 7X 900€ = **6300€** (900€ for 15 days/ESR) -Accommodations for 1 training at IHUMI for 3 support staff for 7 days (Research support staff trained in project management and financial) (WP5) Accommodations for 3 support staff for 7 days: 3X 1715€ = **5145€** (1715€ for 7 days/ support staff) -Accommodations for participation in 3 conferences (3 days each) for 2 ER and 1 ESR at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4): Accommodations for 2 ER and 1 ESR at Spain for 3 days : 3X 636€ = **1908€** (636€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at Netherlands for 3 days: 3X 789€ = **2367€** (789€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at Denmark for 3 days: 3X 810€ = **2430€** (810€ for 3 days/ participant) -Accommodations for 3 out-going visits at IHUMI, INRA and UNIFI for 2 ER and 1 ESR for 3 days each (networking with EU partners) (WP4) : Accommodations for 2 ER and 1 ESR at IHUMI for 3 days: 3X 735€ = **2205€** (735€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at INRA for 3 days: 3X 735€ = **2205€** (735€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at UNIFI for 3 days: 3X 690€ = **2070€** (690€ for 3 days/ participant) -Accommodations for 3 scientific workshops at Algeria, Egypt and Morocco for 2 ER and 1 ESR for 3 days each (NAHMC creation) (WP3): Accommodations for 2 ER and 1 ESR at Algeria for 3 days : 3X996€ = **2988€** (996€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at Egypt for 3 days : 3X 798€ = **2394€** (798€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at Morocco for 3 days : 3X 609€ = **1827€** (609€ for 3 days/ participant) -Accommodations for 3 meetings for management (3 days each) at IHUMI, INRA and UNIFI for 2 ER (SC) and 1 ESR for (WP5) : Accommodations for 2 ER and 1 ESR at IHUMI for 3 days: 3X 735€ = **2205€** (735€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at INRA for 3 days: 3X 735€ = **2205€** (735€ for 3 days/ participant) Accommodations for 2 ER and 1 ESR at UNIFI for 3 days: 3X 690€ = **2070€** (690€ for 3 days/ participant)
Equipment	40000	**1)** Purchase of reagents and kits to perform the different steps of human microbiome analysis using High throughput methods for microbial 16S ribosomal RNA, *rpoB* genes and shotgun sequencing (for lab course (WP1) = 23040**€** **2)** Purchase of IT equipments for high throughput sequencing sequencing data storage and analysis required for lab course (WP1) and for pilot study (WP2): * Service stations = **4460€** * Software for bioinformatic analysis services on high-throughput sequencing data = **5000€**

		* Genomics Server for high throughput sequencing data storage = **7500€**
Other goods and services	35922	**II- Event fees:** - Organisation fees / participant = 45 euro/participant (2 Coffee breaks (10**€)** + Lunch (15€) + dinner (20€)) (Expenses for breaks, lunch and dinner of participants in conferences, workshop, lab course, training...**)** - Local fee/event = 300€/event (Expenses for the hiring of a conference room and the means of sound system to carry out the events) * Kick-off meeting fees for 2 days (WP5): • Expenses for the hiring of a conference room and the means of sound system to carry out the Kick-off meeting fees for 2 days = **300€** • Expenses for breaks, lunch and dinner for 11 participants (Members of the project) in the Kick-off meeting fees for 2 days: 2 days x (11 participants X 45€) = **990€** (45€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€) + dinner (20€)) • Expenses for coffee breaks for 80 participants (2 Coffee breaks/participant) in the Kick-off meeting for 1 day: 80 X 10€= **800€** (10€/participant/day = 2 Coffee breaks (10€)) * 1 conference on "Metagenomic approaches in Human microbiome studies" fees for 50 participants from EU , Algeria, Egypt, Morocco and Tunisian universities for one day (WP1): 50 X 25€= **1250€** (25€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€)) * 1 lab course focusing on "high-throughput sequencing techniques and bioinformatics tools" fees for 23 participants for 12 days (WP1): 12 x (23 X 25€)= **6900€** (25€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€)) ***** 1 conference dealing with the relationship between human microbiome and health/diseases for 50 participants from Algeria, Egypt, Morocco and Tunisian universities (WP2) for one day : (50 X 25€)= **1250€** (25€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€)) * 1 workshop for setting-up the standard procedures in microbiome analysis during 5 days at USFAX for 10 ER, 10 ESR, and 3 technicians (WP1): 5 x (23 X 25€)= **2875€** (25€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€)) ***** 1 training for 7 ESR for 7 days to promote their entrepreneurial skills (WP1): 7 X (7X25€)= **1225€** (25€/participant/day = 2 Coffee breaks (10**€)** + Lunch (15€)) *****1 meeting for the creation of NAHMC (22 members) (10 ER and ESR from Tunisian universities, 2 ER from INRA, 2 ER from UNIFI, 2 ER from IHUMI, 2 ER from Algeria, 2 ER from Egypt and 2 ER from Morocco) for 2 days (WP3): 2 x (22 X 45€)+300€= **2280€** (45€/participant/day (2 Coffee breaks (10€)

		+ Lunch (15€) + dinner (20€)) and 300€ (Expenses for the hiring of a conference room and the means of sound system to carry out the meeting for the 2 days) * 2 conferences for dissemination fees for 50 participants for 2 days (WP4) : 2 x [2 x (50 X 10€)]+2 x 300€= **2600€** (10€/participant/day (2 Coffee breaks (10**€**)) and 300€ (Expenses for the hiring of a conference room and the means of sound system to carry out the conferences for the 2 days) Explanation: 2x300€ is for 2 conferences *** 3** meetings for management for 11 participants (SC) for 2 days (WP5): 3 x 2 x (11 X 25€)+ 3 x 300€ = **2550€** (25€/participant/day (2 Coffee breaks (10**€**) + Lunch (15€)) and 300€ (Expenses for the hiring of a conference room and the means of sound system to carry out the conferences for the 2 days) Explanation: 3x300€ is for 3 Meetings **III-** Website and project app creation fees (WP4)= **3000€** **IV-** Printing of materials for dissemination activities fees (Brochures, Posters, Flyers, etc.) (WP4)= **3902€** **V-** Expert fees for audit of pilot study (WP1 Task 1.4 and WP5 Task5.3)= **4000€** **VI-** Publication in GOLD open access for one publication**: 2000€**
Total	**189 841**	

2/INRAE	**Cost (€)**	**Justification**
Travel	26008	**1)** Travel for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5): Travel costs for 2 researchers : 2 X 350€ **=700€** **2)** Travel for conference at USFAX on "metagenomics and Human microbiome analysis" for 2 researchers for 2 days (WP1): Travel costs for 2 researchers : 2 X 350€ **=700€** **3)** Travel for meeting at USFAX for the creation of NAHMC for 2 researchers for 3 days (WP3): Travel costs for 2 researchers : 2 X 350€ **=700€** **4)** Travel for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4): Travel costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 350€ = **=1400€** **5)** Travel for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4): Travel costs for participation for 2 researchers at Spain : 2 X 350€= **700€** Travel costs for participation for 2 researchers at Netherlands: 2 X 350€= **700€** Travel costs for participation for 2 researchers at Denmark : 2 X 350€= **700€** **6)** Travel for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5): Travel costs for 3 meetings at USFAX for management for 2 members of SC :

3 x 2 x 350€ = **2100€**

7) Travel for 2 meetings (3 days each) for management for 2 members of SC at IHUMI and UNIFI (WP5) :

Travel cost for meeting for management for 2 members of SC at IHUMI: 2 X 350 = **700€**

Travel cost for meeting for management for 2 members of SC at UNIFI: 2 X 350€= **700€**

8)Accommodation costs

-Accommodations for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5):

2 X 423€ **=846€** (423€ for 3 days/ participant)

-Accommodations for conference at USFAX on "metagenomics and Human microbiome analysis" for 2 researchers for 2 days (WP1):

Accommodations costs for 2 researchers 2 X 282€ **=564€** (282€ for 2 days/ participant)

- Accommodations for lab course at USFAX focusing on "High-throughput sequencing techniques and data analysis using bioinformatics tools" for 2 researchers for 6 days (WP1):

Accommodations costs for 2 researchers for 6 days : 2 x 846€ = **1692€** (846€ for 6 days/ participant)

- Accommodations for meeting at USFAX for the creation of NAHMC for 2 researchers for 3 days (WP3):

Accommodations costs for 2 researchers for 3 days : 2 X 423€ **=846€** (423€ for 3 days/ participant)

- Accommodations for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4):

Accommodations costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 564€ **=2256€** (564€ for 4 days/ participant)

- Accommodations for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4):

Accommodations costs for participation for 2 researchers for 3 days at Spain : 2 X 636€= **1272€** (636€ for 3 days/ participant)

Accommodations costs for participation for 2 researchers for 3 days at Netherlands : 2 X 789€**= 1578€** (789€ for 3 days/ participant)

Accommodations costs for participation for 2 researchers for 3 days at Denmark : 2 X810€= **1620€** (810€ for 3 days/ participant)

- Accommodations for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5):

Accommodations costs for 3 meetings at USFAX for management for 2 members of SC for 4 days: 3 x 2 x 564€ = **3384€** (564€ for 4 days/ participant)

- Accommodations for 2 meetings (3 days each) for management for 2 members of SC at IHUMI and UNIFI (WP5) :

Accommodations cost for meeting for management for 2 members of SC at IHUMI for 3 days: 2 X 735€ = **1470€** (735€ for 3 days/ participant)

Accommodations cost for meeting for management for 2 members of SC at UNIFI for 3 days: 2 X 690€= **1380€** (690€ for 3 days/ participant)

Equipment	25000	Purchase of reagents and kits to perform functional metagenomics (for lab course (WP2) = **25000€**
Other goods and services	17619	**II- Event fees:** - Organisation fees / participant = 50€ /participant (2 Coffee breaks (20€) + Lunch (30€)) (Expenses for breaks, lunch and dinner of participants in interships, meeting and outgoing visits) * 1 internship for 5 ER for 15 days (ER trained in functional metagenomics) (WP1): 15 x (5 X 20€)= **1500€** (20€/participant/day = 2 Coffee breaks (20€)) * 1 internship for 7 ESRs for 30 days (ESRs trained in functional metagenomics) (WP2): 30 x (7 X 20€) = **4200€** (20€/participant/day = 2 Coffee breaks (20€)) * 1 internship for 5 ER and 7 ESR for 15 days (Scientific staff trained in metabolomics) (WP2): 15 x (12 X 20€) = **3600€** (20€/participant/day = 2 Coffee breaks (20€)) * 1 outgoing visits for 2 ER for 3 days (networking) (WP4) : 2 X (3x20€) = **120€** (20€/participant/day = 2 Coffee breaks (20€)) * **1** meeting for management for 10 participants (SC) for 2 days (WP5): 2 x (10 X 50€) = **1000€** (20€/participant/day = 2 Coffee breaks (20€)+ Lunch (30€)) **III-** Printing of materials for dissemination activities fee (Brochures, Posters, Flyers, etc.) = **2199€** **IV-** Costs of printing documents for workshops, trainings and internships (WP1/WP2) = **3000€** **V-** Publication in GOLD open access for one publication**: 2000€**
Total	**68627**	

3/IHUMI	**Cost (€)**	**Justification**
Travel	26008	**1)** Travel for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5): Travel costs for 2 researchers : 2 X 350€ **=700€** **2)** Travel for conference at USFAX on "metagenomics and Human microbiome analysis" for 2 researchers for 2 days (WP1): Travel costs for 2 researchers : 2 X 350€ **=700€** **3)** Travel for meeting at USFAX for the creation of NAHMC for 2 researchers for 3 days (WP3): Travel costs for 2 researchers : 2 X 350€ **=700€** **4)** Travel for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4): Travel costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 350€ = **=1400€**

5) Travel for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4):
Travel costs for participation for 2 researchers at Spain : 2 X 350€= **700€**
Travel costs for participation for 2 researchers at Netherlands:
2 X 350€= **700€**
Travel costs for participation for 2 researchers at Denmark : 2 X 350€= **700€**
6) Travel for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5):
Travel costs for 3 meetings at USFAX for management for 2 members of SC :
3 x 2 x 350€ = **2100€**
7) Travel for 2 meetings (3 days each) for management for 2 members of SC at IHUMI and UNIFI (WP5) :
Travel cost for meeting for management for 2 members of SC at IHUMI:
2 X 350 = **700€**
Travel cost for meeting for management for 2 members of SC at UNIFI:
2 X 350€= **700€**
8)Accommodation costs
- Accommodations for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5):
2 X 423€ **=846€** (423€ for 3 days/ participant)
- Accommodations for conference at USFAX on "metagenomics and Human microbiome analysis" for 2 researchers for 2 days (WP1):
Accommodations costs for 2 researchers 2 X 282€ **=564€** (282€ for 2 days/ participant)
- Accommodations for lab course at USFAX focusing on "High-throughput sequencing techniques and data analysis using bioinformatics tools" for 2 researchers for 6 days (WP1):
Accommodations costs for 2 researchers for 6 days : 2 x 846€ = **1692€** (846€ for 6 days/ participant)
- Accommodations for meeting at USFAX for the creation of NAHMC for 2 researchers for 3 days (WP3):
Accommodations costs for 2 researchers for 3 days : 2 X 423€ **=846€** (423€ for 3 days/ participant)
- Accommodations for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4):
Accommodations costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 564€ **=2256€** (564€ for 4 days/ participant)- Accommodations for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4):
Accommodations costs for participation for 2 researchers for 3 days at Spain : 2 X 636€= **1272€** (636€ for 3 days/ participant)
Accommodations costs for participation for 2 researchers for 3 days at

		Netherlands : 2 X 789€= **1578€** (789€ for 3 days/ participant) Accommodations costs for participation for 2 researchers for 3 days at Denmark : 2 X810€= **1620€** (810€ for 3 days/ participant) - Accommodations for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5): Accommodations costs for 3 meetings at USFAX for management for 2 members of SC for 4 days: 3 x 2 x 564€ = **3384€** (564€ for 4 days/ participant) - Accommodations for 2 meetings (3 days each) for management for 2 members of SC at INRA and UNIFI (WP5) : Accommodations cost for meeting for management for 2 members of SC at INRA for 3 days: 2 X 735€ = **1470€** (735€ for 3 days/ participant) Accommodations cost for meeting for management for 2 members of SC at UNIFI for 3 days: 2 X 690€= **1380€** (690€ for 3 days/ participant)
Equipment	0	N/A
Other goods and services	13594	**II- Event fees:** - Organisation fees / participant = 50€ /participant (2 Coffee breaks (20€) + Lunch (30€)) (Expenses for breaks, lunch and dinner of participants in interships, meeting and outgoing visits) ***** 1 internship for 5 ER for 15 days (ER trained in metagenomic and human microbiome analysis) (WP1): 15 x (5 X 20€)= **1500€** (20€/participant/day = 2 Coffee breaks (20€)) ***** 1 internship for 7 ESRs for 30 days (ESRs trained in metagenomic and human microbiome analysis) (WP2): 30 x (7 X 20€) = **4200€** (20€/participant/day = 2 Coffee breaks (20€)) ***** 1 training for 3 supports staffs for 7 days (Research support staff trained in project management, financial) (WP4/WP5): 7 X (3x20€) =**420€** (20€/participant/day = 2 Coffee breaks (20€)) ***** 1 outgoing visits for 2 ER for 3 days (networking) (WP4) : 2 X (3x20€) = **120€** (20€/participant/day = 2 Coffee breaks (20€)) *** 1** meeting for management for 10 participants (SC) for 2 days (WP5): 2 x (10 X 50€) = **1000€** (20€/participant/day = 2 Coffee breaks (20€)+ Lunch (30€)) **III)** Printing of materials for dissemination activities fees (Brochures, Posters, Flyers, etc.) (WP4)= **2354€** **IV)** Costs of printing documents for workshops, trainings and internships (WP1/WP2) = **4000€**
Total	**39602**	

4/UNIFI	Cost (€)	Justification
Travel	25816	**1)** Travel for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5): Travel costs for 2 researchers : 2 X 350€ **=700€** **2)** Travel for conference at USFAX on "the relationship between human microbiome and health/diseases" for 2 researchers for 2 days (WP1): Travel costs for 2 researchers : 2 X 350€ **=700€** **3)** Travel for meeting at USFAX for the creation of NAHMC for 2 researchers for 3 days (WP3): Travel costs for 2 researchers : 2 X 350€ **=700€** **4)** Travel for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4): Travel costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 350€ = **=1400€** **5)** Travel for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4): Travel costs for participation for 2 researchers at Spain : 2 X 350€= **700€** Travel costs for participation for 2 researchers at Netherlands: 2 X 350€= **700€** Travel costs for participation for 2 researchers at Denmark : 2 X 350€= **700€** **6)** Travel for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5): Travel costs for 3 meetings at USFAX for management for 2 members of SC : 3 x 2 x 350€ = **2100€** **7)** Travel for 2 meetings (3 days each) for management for 2 members of SC at IHUMI and UNIFI (WP5) : Travel cost for meeting for management for 2 members of SC at IHUMI: 2 X 350 = **700€** Travel cost for meeting for management for 2 members of SC at UNIFI: 2 X 350€= **700€** **-Accommodation costs** **1)** Accommodations for kick-off meeting at USFAX for 2 researchers for 3 days at USFAX (WP5): 2 X 423€ **=846€** (423€ for 3 days/ participant) **2)** Accommodations for conference at USFAX on "the relationship between human microbiome and health/diseases" for 2 researchers for 2 days (WP1): Accommodations costs for 2 researchers for 2 days : 2 X 282€ **=564€** (282€ for 2 days/ participant) **3)** Accommodations for workshop at USFAX in microbiome analysis for 2 researchers for 5 days (WP1): Accommodations costs for 2 researchers for 5 days : 2 x 705€ = **1410€** (705€ for 5 days/ participant) **4)** Accommodations for meeting at USFAX for the creation of NAHMC

		for 2 researchers for 3 days (WP3): Accommodations costs for 2 researchers for 3 days : 2 X 423€ **=846€** (423€ for 3 days/ participant) **5)** Accommodations for 2 conferences at USFAX for project dissemination for 2 researchers for 4 days (WP4): Accommodations costs for 2 conferences at USFAX for project dissemination for 2 researchers : 2 x 2 x 564€ **=2256€** (564€ for 4 days/ participant) **6)** Accommodations for participation in 3 conferences (3 days each) for 2 researchers at Spain, at Netherlands and at Denmark (Dissemination of the results of the MICAfrica project activities) (WP4): Accommodations costs for participation for 2 researchers for 3 days at Spain : 2 X 636€= **1272€** (636€ for 3 days/ participant) Accommodations costs for participation for 2 researchers for 3 days at Netherlands : 2 X 789€**= 1578€** (789€ for 3 days/ participant) Accommodations costs for participation for 2 researchers for 3 days at Denmark : 2 X810€= **1620€** (810€ for 3 days/ participant) **7)** Accommodations for 3 meetings at USFAX for management for 2 members of SC for 4 days (WP5): Accommodations costs for 3 meetings at USFAX for management for 2 members of SC for 4 days: 3 x 2 x 564€ = **3384€** (564€ for 4 days/ participant) **8)** Accommodations for 2 meetings (3 days each) for management for 2 members of SC at INRA and IHUMI (WP5) : Accommodations cost for meeting for management for 2 members of SC at INRA for 3 days: 2 X 735€ = **1470€** (735€ for 3 days/ participant) Accommodations cost for meeting for management for 2 members of SC at IHUMI for 3 days: 2 X 735€ = **1470€** (735€ for 3 days/ participant)
Equipment	0	N/A
Other goods and services	6622	**II- Event fees:** - Organisation fees / participant = 50€ /participant (2 Coffee breaks (20€**)** + Lunch (30€)) (Expenses for breaks, lunch and dinner of participants in interships, meeting and outgoing visits**)** ***** 1 internship for 5 ER for 15 days (Scientific staffs trained to strength their knowledge in the study of gut microbiome and colorectal cancer (CRC)) (WP1): 15 x (5 X 20€)= **1500€** (20€/participant/day = 2 Coffee breaks (20€**)**) ***** 1 outgoing visits for 2 ER for 3 days (networking) (WP4) : 2 X (3x20€) = **120€** (20€/participant/day = 2 Coffee breaks (20€**)**) *** 1** meeting for management for 10 participants (SC) for 2 days (WP5): 2 x (10 X 50€) = **1000€** (20€/participant/day = 2 Coffee breaks (20€**)**+ Lunch (30€)) **III-** Printing of materials for dissemination activities fees (Brochures,

		Posters, Flyers, etc.) (WP4)= **752€** **IV-** Costs of printing documents for workshops, trainings and internships (WP1/WP2) = **1250€** **VI-** Publication in GOLD open access for one publication**: 2000€**
Total	**32 438**	

The Project Coordinator, on behalf of the MICAfrica consortium, confirms that the indicated travel costs **are correctly identified, and are consistent with: (i) each of the Consortium Beneficiaries' usual policy for travel, and (ii) the activities planned (e.g. trips are directly linked to the specific Twinning Action).** The whole Consortium is aware that the travel costs may be verified through relevant supporting documents, such as: minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference. Therefore, such documentation ***will be kept on file.***

4. Members of the consortium

4.1. Participants

The consortium is composed by four participants as follows:

- The Tunisian Beneficiary No. 1 is represented by the **University of Sfax (USFAX)** and acts as the Coordinator for this project;
- The two French participants – **INRAE** and **IHUMI;** they have a huge experience in biological research, and particularly in microbiome studies and in platform management;
- The third EU participant is Italian (**UNIFI**), having an expertise in the inflammatory role of the microbiome in human diseases.

P1	USFAX – SFAX UNIVERSITY

The USFAX is organized into 21 higher education institutions; among them, a Faculty of Medicine linked to two multidisciplinary university hospitals and a Faculty of Sciences with a focus on life science (human, animal and vegetal) and a research center in biotechnology. Researches on Human genetics are well developed in the USFAX.

The human molecular genetics laboratory is a research laboratory that has existed since 1999 at the Sfax Faculty of Medicine. The research team includes a large number of research teachers and young researchers who carry out numerous studies on genetic and multifactorial human pathologies, such as developmental and reproductive abnormalities, motor and sensory disabilities and cancers. Many theses and dissertations of masters were supported. Similarly, dozens of publications have been produced in international journals with impact factors. In addition, LGMH scientists have established numerous collaborations with Tunisian and European research teams that have resulted in high-level scientific results. Furthermore, at the Center of Biotechnology of Sfax (CBS), the Cancer Genetics team from the LBME focus on topics related to the analysis of molecular mechanisms involved in cancerogenesis and aims to identify biomarkers for diagnosis and prognosis.

Main tasks of the participant, with an explanation of how its profile matches the tasks in the proposal

The USFAX is in charge to coordinate the **MICAfrica** project through organization of events (KOM, steering committee meeting, training and symposium). USFAX has good experience in the management and coordination of EU projects such as Tempus, ERASMUS plus, FP6 and FP7.

The staff of USFAX will participate in EU events to increase the visibility of USFAX at the local ad European level. This will contribute to develop networking and collaboration opportunities that will strengthen research skills of scientists from USFAX.

Furthermore, USFAX will be in charge to deliver reports from each activity planned during the **MICAfrica** accordingly to the plan work and schedule.

Short bio-sketch of the persons, including their gender, who will be primarily responsible for carrying out the proposed research and/or innovation activities (approx. one paragraph per person)

Pr Leila Keskes (Female) is Head of The Laboratory of Molecular Human Genetics (LGMH) at University of Sfax. Leila Keskes began her career as a physician and as an assistant at the Faculty of Medicine in 1993. She joined the LGMH laboratory and led a research group on the genetics of reproductive disorders. She has supervised numerous master students and doctoral students whose work has led to the publication of numerous scientific articles. Since 2013 Leila Keskes is the head of the LGMH and she is leading research on the study of microRNA expression in ovarian, testicular and lung cancer. Since 2017 she is a member of a federated research project on the genetic and epigenetic aspects of cancers between the Faculty of Medicine of Sfax, the Biotechnology Center of Sfax and the hospitalist Habib Bourguiba of Sfax. She organized the first Tunisian-French Research Symposium in Human Molecular Genetics in 2014 and participated in the organization of the second French Tunisian symposium of human genetics in 2015. She is the author of over 130 scientific publications in the field of reproductive and genetics medicine. She has been the president of the Medical Research Development Association and is currently the director of research at the faculty of medicine at Sfax.

Pr Ali Gargouri (male) is has obtained Ph.D of Sciences at the Paris VI University, at the « Centre de Génétique Moléculaire » at the CNRS. Gif/Yvette Paris.

Currently he is the head of the Laboratory « Biotechnologie Moléculaire des Eucaryotes » since 2015.
Research interested fields: Fungal genetic, biochemistry, microbiology, fungal enzymes
He has published 170 articles in peer reviewed international Journals (IF 1 to 11), and participated in 26 Collaborative Research Project and 21 national Patents.
He is the Tunisian principal investigator in CMCU projects Role of serpins, serine protease
Inhibitor of the gut microbiota in inflammatory bowel disease

Pr Raja Gargouri (Female) Professor at the Centre of Biotechnology of Sfax, Head of the Group : Cancer Genetics and Production of human proteins of therapeutic interest The main research topics are related to Cancer Genetics, Expression analysis and Epigenetic modifications of cancer associated genes in solid tumours, Identification of mutation in major genes involved in hereditary cancers and identification of Biomarkers for cancer diagnosis and prognosis. She coordinates different national and international research projects. She is a member of the MEARC: Middle East Association for Cancer Research, and of the "Group of Nasopharyngeal Carcinoma".

Pr Ali Amouri,(Male) is a medical professor in Gastro-enterology at Hedi Chaker Hospital. His reseach studies focused on inflammatory diseases and colorectal cancer. He's a member of a CMCU project on the "role of serpins, serine protease inhibitor of the gut microbiota in inflammatory diseases.

Pr Radhouane Gdoura (Male) is a Head of the Research Laboratory of Environmental Microbiology-Toxicology and health at the Faculty of Sciences of Sfax. He is also responsible of the Professional Master in Food and Food Industry and Master in Biology course Microbial Biotechnology. He was a National coordinator of the Tempus project: Development of university-business partnerships in the field of life sciences and technologies in Tunisia: JPHES-530312-2012. His research activity focus on the development and application

of new technologies for the detection and identification of pathogens in food and in the diagnosis of diseases.

Pr Hayet Sellami (Female) is a professor in parasitology and mycology, MD and PhD.
The research field are yeasts, free amoeba. The studies were focused on genotyping and drug resistance of yeasts (*Trichosporon, Candida glabrata*). More than fifty scientific articles were published. She is the president of the Association of the Development of Medical research (ADREMED) at the Faculty of Medicine Sfax

Pr Basma Mnif (Female) is a medical microbiologist, MD and PhD, with more than 10 years of experience in studying the epidemiology and phylogeny of bacteria especially multi-drug resistant bacteria. She leads the group working on microbial epidemiology of the research laboratory "micro-organismes et pathologies humaines" of Habib Bourguiba university hospital, Sfax, Tunisia. She has previously worked in the field of bioinformatics, sequence analysis and analyzing various genomics data types with different tools and techniques, and has published more than 25 scientific articles.

Other **seniors** from Faculty of Medicine of Sfax shall be involved.

Three other ER and ten ESR (PhD students) shall be involved throughout the MICAfrica project.

5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content

1. Siropins, novel serine protease inhibitors from gut **microbiota** acting on human proteases involved in inflammatory bowel diseases.
Mkaouar H, Akermi N, Mariaule V, Boudebbouze S, Gaci N, Szukala F, Pons N, Marquez J, **Gargouri A**, Maguin E, Rhimi M.
Microb Cell Fact. 2016 Nov 29;15(1):201
2. Next generation sequencing in family with MNGIE syndrome associated to optic atrophy: Novel homozygous POLG mutation in the C-terminal sub-domain leading to mtDNA depletion. Felhi R, Sfaihi L, Charif M, Desquiret-Dumas V, Bris C, Goudenège D, **Ammar-Keskes L**, Hachicha M, Bonneau D, Procaccio V, Reynier P, Amati-Bonneau P, Lenaers G, Fakhfakh F. Clin Chim Acta. 2018 Nov 3;488:104-110.
3. RIP140 and LCoR expression in gastrointestinal cancers. Triki M, Ben Ayed-Guerfali D, Saguem I, Charfi S, Ayedi L, Sellami-Boudawara T, Cavailles V, **Mokdad-Gargouri R**. Oncotarget. 2017 N8(67):111161-111175.
4. Iatrogenic **colorectal** Kaposi's sarcoma complicating a refractory ulcerative colitis in a human immunodeficiency negative-virus patient. Chtourou L, Ayedi L, Rejab H, Boudabous M, Mnif L, Grati A, Boudaouara T, Mzali R, **Amouri A**, Tahri N.
Pathologica. 2017 Dec;109(4):371-374.
5. A broad-range PCR technique for the diagnosis of infective endocarditis. Boujelben I, **Gdoura R**, Hammami A. Braz J Microbiol. 2018 Jul - Sep;49(3):534-543.

5 Relevant previous projects or activities, connected to the subject of this proposal

1-Tempus project : Développement de partenariats universités-entreprisesdu domaine des sciences et technologie du vivant en Tunisie. Programme Tempus n°530312/tempus/2012/fr/jphes
2-French-Tunisian Collaborative Project (CMCU) 2015-2018 : Connexion RIP140 et voie Wnt/beta-caténine : Identification de marqueurs dans les cancers gastro-intestinaux
3-Project CMU 2013-2016 : Identification et synthèse de peptides ciblant l'oncoprotéine LMP1 du virus d'Epstein Barr : approche thérapeutique aux pathologies malignes associées à l'EBV. Coordinatrices: R. Mokdad-Gargouri (CBS-Tunisie) and M Baudy-Fl'och (Univ Rennes 2- France)
4-PRF (Projet de Recherche Fédéré) large national Project 2017-2020 funded by the ANPR (Agence Nationale de Promotion de la Recherche)

Infrastructure and/or any major items of technical equipment, relevant to the proposed work

The USFAX has an infrastructure developed in the various teaching and research institutions. Thus, the Faculty of Medecine and the University Hospital Center host about thirty research units and a dozen research laboratories in different medical laboratories. Among these laboratories, the LGMH, is a research laboratory in human molecular genetics; it is equipped with a genetic analyzer, a real time PCR device and many DNA amplification devices. LGMH have many others equipments (immunofluorescence microscope ; incubators ;….). Various genetic analyzes are also carried out in the affiliated genetics department at the Sfax University Hospital Center.

Similarly, two research laboratories in microbiology, parasitology and mycology exist in the faculty of Medicine and scientists carry out numerous studies to explore the genetic material of bacteria, viruses, parasites, yeasts and moulds in human infections. These laboratories have different research equipment enabling high level research work. The faculty of Sciences of Sfax also hosts a research laboratory in microbiology and food toxicology that carries out numerous collaborative research projects with many European and Tunisians teams in the framework of European and Tunisian projects. At CBS, equipments for genomic analysis still limited comporting one Miseq (Illumina) and capillary sequencing apparatus (Applied Biosystem), QPCR (CFX, Biorad), Pyrosequencing Q24 (Qiagen).

P2 INRAE – INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT

Main tasks of the participant, with an explanation of how its profile matches the tasks in the proposal

The mission of the INRAE is to produce scientific knowledge and contribute to innovation. By hosting more than 150 doctoral students, he is also actively involved in training young people by and for research. Research on animal biology, microbiology and food science is at the heart of its work; they mobilize mathematicians and computer scientists to understand the complexity of biological mechanisms studied and predict the functioning of living systems at different scales and for different purposes. The teams of our center are mobilized to combine fundamental and applied knowledge, exploring the diversity and variability, from the molecule to the individual in his environment. Among the research topics developed at INRA: "the microbial food and intestinal ecosystems and the functional interactions between food, microbiota and host", many facilities are available as the PAPPSO plateform for metaproteomics and MetaGenoPoliS (MGPS: www.mgps.eu) those will be fully beneficial for ER and ESR involved in the MICAfrica project to improve their knowledge through internships. Furthermore, INRAE has high competences in new bioinformatics pipelines for microbiome data analysis and thus, will be involved in the training of ER and ESR to acquire the know-how in data processing.

The Micalis Institute is a joint research unit (UMR) associating INRAE and AgroParisTech and part of the Paris-Saclay University (UPSaclay). Its mission is the development of innovative research in the field of "Microbiology of Food for Health".

The Micalis Institute brings together more than 340 people, including 130 researchers, engineers and research professors, 70 scientific or administrative support staff and more than 140 doctoral students, postdoctoral fellows and trainee students, forming 20 research teams organized into 3 thematic clusters. , and is home to 2 technology platforms, a Yeast Biological Resource Center and an Axenic Animal Facility. In addition, the Micalis Institute is closely associated with the pre-industrial demonstrator Metagenopolis.

Short bio-sketch of the persons, including their gender, who will be primarily responsible for carrying out the proposed research and/or innovation activities (approx. one paragraph per person)

Dr. Moez Rhimi is a Research Officer 1st class (CR1) at INRA, Micalis Institute, Jouy-en-Josas, France. He works within the "Microbiota Interaction with Human and Animal (MIHA)" group on the theme of functional Metagenomics. It has 42 publications, and several oral and poster communications, 4 patents, 40 oral communications, and 10 invited conferences.

He participated to 4 ANR projects, 1 ICGEB project, 3 evaluation projects (2 SATT Saclay and 1Rhône region), 1 INCa, 2 European projects (1 European Network Pilot project EU-New Indigo Program and 3 CMCU projects.

Dr. Emanuelle Maguin is the head of the Microbiology and Food Chain Department, which has 640 staff and 21 research units. She has participated in many research projects: 4 European projects (MetaHIT and EraSysApp (in progress) research. She coordinated the Tunisian-French bilateral collaboration (CBS) including the co-supervision of several thesis. In addition, she is a member of several INRAE commissions (evaluation of research units, scientific council of the microbiology department, specialized commission of INRAE, etc.). Her

H index is 30 et she has 60 publications and 4 patents.

Other young researchers will be involved in the project shall be involved.

5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content

1) **Human gut microbes impact host serum metabolome and insulin sensitivity.** Pedersen HK, Gudmundsdottir V, Nielsen HB, Hyotylainen T, Nielsen T, Jensen BA, Forslund K, Hildebrand F, Prifti E, Falony G, Le Chatelier E, Levenez F, Doré J, Mattila I, Plichta DR, Pöhö P, Hellgren LI, Arumugam M, Sunagawa S, Vieira-Silva S, Jørgensen T, Holm JB, Trošt K; MetaHIT Consortium, Kristiansen K, Brix S, Raes J, Wang J, Hansen T, Bork P, Brunak S, Oresic M, Ehrlich SD, Pedersen O. Nature. 2016 Jul 21;535(7612):376-81. Epub 2016 Jul 13.

2) **Beneficial metabolic effects of selected probiotics on diet-induced obesity and insulin resistance in mice are associated with improvement of dysbiotic gut microbiota.** Alard J, Lehrter V, Rhimi M, Mangin I, Peucelle V, Abraham AL, Mariadassou M, Maguin E, Waligora-Dupriet AJ, Pot B, Wolowczuk I, Grangette C. Environ Microbiol. 2016 May;18(5):1484-97. doi: 10.1111/1462-2920.13181. Epub 2016 Jan 26

3) **Disentangling type 2 diabetes and metformin treatment signatures in the human gut microbiota.** Forslund K, Hildebrand F, Nielsen T, Falony G, Le Chatelier E, Sunagawa S, Prifti E, Vieira-Silva S, Gudmundsdottir V, Pedersen HK, Arumugam M, Kristiansen K, Voigt AY, Vestergaard H, Hercog R, Costea PI, Kultima JR, Li J, Jørgensen T, Levenez F, Dore J; MetaHIT consortium, Nielsen HB, Brunak S, Raes J, Hansen T, Wang J, Ehrlich SD, Bork P, Pedersen O.
Nature. 2015 Dec 10;528(7581):262-26

4) **Identification and assembly of genomes and genetic elements in complex metagenomic samples without using reference genomes.** Nielsen HB, Almeida M, Juncker AS, Rasmussen S, Li J, Sunagawa S, Plichta DR, Gautier L, Pedersen AG, Le Chatelier E, Pelletier E, Bonde I, Nielsen T, Manichanh C, Arumugam M, Batto JM, Quintanilha Dos Santos MB, Blom N, Borruel N, Burgdorf KS, Boumezbeur F, Casellas F, Doré J, Dworzynski P, Guarner F, Hansen T, Hildebrand F, Kaas RS, Kennedy S, Kristiansen K, Kultima JR, Léonard P, Levenez F, Lund O, Moumen B, Le Paslier D, Pons N, Pedersen O, Prifti E, Qin J, Raes J, Sørensen S, Tap J, Tims S, Ussery DW, Yamada T; MetaHIT Consortium, Renault P, Sicheritz-Ponten T, Bork P, Wang J, Brunak S, Ehrlich SD; MetaHIT Consortium. Nat Biotechnol. 2014 Aug;32(8):822-8. doi: 10.1038/nbt.2939. Epub 2014 Jul 6.

5) **Dietary intervention impact on gut microbial gene richness**. Cotillard A, Kennedy SP, Kong LC, Prifti E, Pons N, Le Chatelier E, Almeida M, Quinquis B, Levenez F, Galleron N, Gougis S, Rizkalla S, Batto JM, Renault P; ANR MicroObes consortium, Doré J, Zucker JD, Clément K, Ehrlich SD.
Nature. 2013 Aug 29;500(7464):585-8. doi: 10.1038/nature12480. Erratum in: Nature. 2013 Oct 24;502(7472)580.

relevant previous projects or activities, connected to the subject of this proposal

- 4 European projects research (MetaHIT and EraSysApp (in progress): i) CMCU project: Tunisian-French bilateral collaboration (CBS); ii) 4 ANR projects; iii) 1 ICGEB project; iv) 2 European projects (1 European Network Pilot project EU-New Indigo Program and 3 CMCU projects.

Infrastructure and/or any major items of technical equipment, relevant to the proposed work

-INRA has a platform "PAPPSO" dedicated for metaproteomics and MetaGenoPoliS (MGPS: www.mgps.eu)
- The Micalis Institute is home to 5 platforms including 2 technological platforms (proteomics and microscopy) and Metagenopolis dedicated to impact studies of the human gut microbiota on health and disease. More specific information related to these platforms is available on their websites.

P3 IHUMI – MEDITERRANEE INFECTION

Main tasks of the participant, with an explanation of how its profile matches the tasks in the proposal

The IHU MI was created in 2012 with a support of the French “Grand Emprunt” program amounting to 72.3 million Euros following an international Grand Jury favorable evaluation. It is one of the six IHU created by the

French government after the *Future Investments* program launched in 2009. It gathers research laboratories with the aim of condensing French fundamental and clinical researches to fight infectious diseases. The IHU MI project puts a strong emphasis on translational research, in order to convert discoveries into innovations and to bring new products on the market. The creation of a large centre with an international dimension in the field of infectious diseases was judged essential in French national health and research strategy.

The IHU strategy can be divided in three key activity packages:

- Developing specialised and innovative clinical departments: researches in clinical activities are performed using the best innovative equipments available on the market. That includes 75 full hospitalisation beds, including 25 beds in high level isolating units (BSL3).
- Attracting international top-level scientists: the IHU gathers three excellent research units: URMITE, headed by Prof. Didier Raoult, EPV, headed by Prof. Xavier de Lamballerie and SESSTIM, headed by Prof. Roch Giorgi. Benefiting from high-level scientific equipments, they are placed in the best conditions to perform their activities.
- Converting knowledge into innovations: the IHU is bridging public and private sectors and welcomes, in its building, representatives from main French private medical actors. It is also incubating 8 start-ups (including POCRAMé) that were created to value innovations conducted within the research units.

The IHU researchers, especially from the MEPHI unit, have a large experience in the field of innovative and routine laboratory diagnosis of infectious and tropical diseases. They are running the largest clinical microbiology laboratory in France investigating about 2 million clinical specimens a year, covering all clinical microbiology fields (bacteriology, virology, mycology, parasitology and health-care environmental microbiology, biobanking) and techniques (culture, molecular diagnosis including real-time genome sequencing, serology and antigen detection). They are always looking for and developing cutting-edge new technologies and, as examples, were the first to use **DNA sequencing in routine**, **high-throughput deep sequencing in routine** and **MALDI-TOF mass spectrometry in routine** [Seng P, Drancourt M, Gouriet F, La Scola B, Fournier PE, Rolain JM, Raoult D. Ongoing revolution in bacteriology: routine identification of bacteria by matrix-assisted laser desorption ionization time-of-flight mass spectrometry. Clin Infect Dis. 2009;49:543-51]. They invented the **routine use of 16S rRNA gene sequencing for routine identification of most bacteria** [Drancourt M, Bollet C, Carlioz A, Martelin R, Gayral JP, Raoult D. 16S ribosomal DNA sequence analysis of a large collection of environmental and clinical unidentifiable bacterial isolates. J Clin Microbiol. 2000;38:3623-30] and **rpoB gene sequencing for the routine identification of mycobacteria** [Adékambi T et al. rpoB-based identification of nonpigmented and late-pigmenting rapidly growing mycobacteria. J Clin Microbiol. 2003;41:5699-708; Mollet C, Drancourt M, Raoult D. rpoB sequence analysis as a novel basis for bacterial identification. Mol Microbiol. 1997;26:1005-11]. More recently, they invented **culturomics** [Lagier JC et al. Culture of previously uncultured members of the human gut microbiota by culturomics. Nat Microbiol. 2016;1:16203], the **point-of-care laboratory for microbiology** [Drancourt M et al. The Point-of-Care Laboratory in Clinical Microbiology. Clin Microbiol Rev. 2016;29:429-47] and the **automated serology using immunofluorescence** [Gouriet F, Levy PY, Samson L, Drancourt M, Raoult D. Comparison of the new InoDiag automated fluorescence multiplexed antigen microarray to the reference technique in the serodiagnosis of atypical bacterial pneumonia. Clin Microbiol Infect. 2008;14:1119-27], which supported the development of the vaccinal status concept.

Short bio-sketch of the persons, including their gender, who will be primarily responsible for carrying out the proposed research and/or innovation activities (approx. one paragraph per person)

Prof. Michel Drancourt is assistant-director of the IHU Méditerranée Infection and assistant-Director of the MEPHI research unit; that has been created within the IHU in 2018.

He obtained his MD in 1989 and his PhD in Aix-Marseille-University in 1995 and completed the “Habilitation à Diriger les Recherches” which is the highest academic level in France. He has accomplished major achievements in the paleomicrobiology field, identifying the origin of previous epidemics by detecting pathogens, using real-time PCR, in the dental pulp of bodies founded in mass graves. In parallel, his team is currently studying the microbiology of the fastidious microorganisms and of complex flora, using notably the revolutionary microbiology technology MALDI-TOF. At last, he always run translational researches and valorization in the field of routine diagnosis in microbiology, promoting universal genes sequencing and MALDI-TOF mass

spectrometry as tools for identification of bacteria; and actively developing the point-of-care (POC) in microbiology with the installation of two POCs in Marseille University Hospitals, two additional POCs in remote rural villages in Senegal, POCs on-board cargo ships and nowadays developing the concept in the POCRAMé start-up.

Dr. Yanis Roussel: is a Ph.D in Biology-Health - Specialty Clinical Research and Public Health
Subject: Financing and administrative arrangements for medical research in France. He conducted research in MEPHI - Microbes Evolution Phylogeny and Infections Research Unit (MEPHI - E1 - Microbiota). He is qualified in management of research and innovation, management of innovative projects, management of innovative structures (support activities for research, innovation and valorization, development of innovative spin-offs and start-ups, expertise, studies and advice in organizations, firms or companies providing intellectual services, scientific expertise, prospective or strategic).

Other **seniors** from Faculty of Medicine of Sfax shall be involved.

5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content

1. Lagier JC, **Drancourt M**, Charrel R, Bittar F, La Scola B, Ranque S, Raoult D. Many More Microbes in Humans: Enlarging the Microbiome Repertoire. Clin Infect Dis. 2017 Aug 15;65(suppl_1):S20-S29. doi: 10.1093/cid/cix404. PubMed PMID: 28859350.
2. Appelt S, Armougom F, Le Bailly M, Robert C, Drancourt M. Polyphasic analysis of a middle ages coprolite microbiota, Belgium. PLoS One. 2014 Feb 28;9(2):e88376. doi: 10.1371/journal.pone.0088376. eCollection 2014. PubMed PMID:24586319; PubMed Central PMCID: PMC3938422.
3. Khelaifia S, Raoult D, Drancourt M. A versatile medium for cultivating methanogenic archaea. PLoS One. 2013 Apr 17;8(4):e61563. doi: 10.1371/journal.pone.0061563. Print 2013. PubMed PMID: 23613876; PubMed Central PMCID: PMC3629087.
4. Drancourt M. Archaea as emerging, fastidious members of the human microbiota. Clin Microbiol Infect. 2012 Sep;18(9):823-4. doi:10.1111/j.1469-0691.2012.03904.x. PubMed PMID: 22897826.
5. Drancourt M, Michel-Lepage A, Boyer S, Raoult D. The Point-of-Care Laboratory in Clinical Microbiology. Clin Microbiol Rev. 2016 Jul;29(3):429-47. doi: 10.1128/CMR.00090-15. Review. PubMed PMID: 27029593; PubMed Central PMCID: PMC4861988.

relevant previous projects or activities, connected to the subject of this proposal

CULTURE-TOP and POCRAMé are two start-ups co-created by M. Drancourt and D. Raoult over the last 3 years, devoted to the development and marketing of innovative solutions for the isolation and culture of pathogens and microbiota; and the point-of-care diagnosis. POCRAMé has been valorized up to 1.3 M€, three years after its creation, CULTURE-TOP has to scale-up after 2.5 years.
The IHU MI is leading an on-going FEDER-founded project of biological resources center hosting a fully automated biobank to secure the unique biological collection (FEDER 2016-2019).
The IHU MI is leading an on-going FEDER-founded project of upgrade of its diagnosis platforms, including the serology platform (FEDER 201—2019).

Infrastructure and/or any major items of technical equipment, relevant to the proposed work

IHU MI is hosting the largest collection of clinical specimens including a 500.000-serum collection, each serum being anonymized and flagged with major characteristics including sex, age, time of collection, geographical localization of collection and positive serology using the reference serological method.

P4 UNIFI – UNIVERSITA DEGLI STUDI DI FIRENZE

Description of the legal entity and the participating department / unit

The University of Florence (UNIFI) can trace its origins to the Studium Generale, which was established in 1321, and it is one of the largest organizations for research and higher education in Italy with over 50,000 students, 1,700 teaching and research staff, 1,600 technical and administrative staff and 1,600 PhD students and research fellows. Researchers at the University of Florence operate within 21 different departments and can benefit from approximately 40 research structures, including inter-departmental and inter-university centres, as well as specialized research, knowledge transfer and advanced training centres. The Department of Experimental and Clinical Medicine (DECM) has been awarded as one of the 180 Departments of Excellence of Italian Universities. The award consists of a five-year (2018-2022) Italian Ministry of Research and University (MIUR) special funding to strengthen and enhance the excellence in research and teaching. This very prestigious award acknowledges the outstanding research conducted by DECM members. Since this is a Department to which numerous centres, which also carry out health care activities, belong, the latter represents the other component that is essential and cannot be separated from the activities of Didactics and Research. The fact of operating within one of the largest hospital centres in Italy (Azienda Ospedaliera Universitaria Careggi-AOUC) offers the opportunity to draw on relevant clinical cases in centres of excellence recognized nationally and internationally.
The DECM as a professional aggregation of professors and researchers with different scientific disciplinary sectors that integrate the various disciplines in favour of the overall progress of the knowledge and the translation of the same in the best preventive, diagnostic, assistance, therapeutic and rehabilitative practices. The presence of scientific disciplinary sectors within the economic sciences also makes it possible to develop research objectives with a view to sustainability, in order to make the research results transferable to the maximum number of stakeholders. In the different laboratories, beyond the technologies, skills and knowledge of excellence are identified, which place the Department among the most advanced national and international companies in the various research fields. The DECM is the one of the biggest department of University of Florence and it's supported by a robust z core, which has more experience in European projects. In other words, the scientific and the administrative system can well face up the risks that might endanger reaching the action objectives of the

MICA-TUN proposal.
During the *project*, the DECM will train and support the USFAX in the characterisation of gut microbiome of different samples (tissue, saliva, stool) obtained by the different experimental conditions. In addition, the DECM will help the USFAX in the analysis of data regarding the immune response microbiota-associated. The laboratory of Prof. Amedei is fully equipped to conduct studies in microbiota and correlated immune response, starting by different organic material (cancer tissue, intestinal mucosa, skin, faeces, and saliva). The Animal Facility of the UNIFI is fully equipped for breeding and management of laboratory animals (wild-type, transgenic rodent colony and immunodeficient mice) with all the infrastructures and technologies for transplant, including 2 sterile rooms.

Main tasks of the participant, with an explanation of how its profile matches the tasks in the proposal

The UNIFI developed experimental and clinical research activities in epidemiological studies with the focus on investigation and risk factors. Therefore, the main contribution of the UNIFI in **MIC-GENCAP** project will be the the organisation of courses and research training focused on microbiome DNA processing and Analysis through "Next-Generation-Sequencing" (NGS) and on the role of the gut microbiome in the development of gastro intestinal inflammatory and cancer diseases. Furthermore, the UNIFI will support and coach the USFAX scientists and researchers to prepare EU research proposals or integration in other consortia and to increase the USFAX visibility at both EU and International levels.

Short bio-sketch of the persons, including their gender, who will be primarily responsible for carrying out the proposed research and/or innovation activities (approx. one paragraph per person)

Prof. Amedeo AMEDEI (Male) of the Department of Experimental and Clinical Medicine (University of Florence) - will be responsible for project management of UNIFI team and monitoring all the research activities that will be carried out by UNIFI. He graduated with full marks and honours in Biology at Florence University.

He has started his scientific career with a scholarship (1997-1999) studying the role of Th1/Th2 lymphocytes in several diseases (graft versus host disease, atopic dermatitis, kidney rejection crisis). On January 2003 began his doctor's degree in "Clinical and Sperimental Medicine". From February to December 2003 he has collaborated on the " Stem cells and immune-therapy of cancer" financed project by Tuscany Region. In March 2005 he became a scientific researcher at Department of Experimental and Clinical Medicine (University of Florence), where in November 2015 he was appointed Associate Professor.

In the last years, the Prof. Amedei has focused his scientific interests on the cancer, studying, the anti-cancer immune response and the role of cancer microenvironment. In detail, the quality of immune response, exploring the role of the different T cells' subset: effector (e.g Th1, Th17, Th9) and regulatory (Tregs).

For the important scientific impact of obtained data, recently, he was a member of the team of researchers involved in the world project "Halifax Project" (http://www.gettingtoknowcancer.org/). The project involves about 300 international researchers focused on the investigation of advanced cancer treatments and carcinogenic potential of exposure to low doses of mixtures of chemicals in the environment.

The current scientific topic of Prof. Amedei is the evaluation of the correlation between the microbiome and the immune response in the genesis of diseases, inflammatory-correlated; in detail colorectal cancer, celiac disease, Inflammatory Bowel Diseases, Becet Diseases and Amyotrophic Lateral Sclerosis (ALS).

The great quality of his international profile is documented by scientific production that, to date, is composed of 136 peer reviewed articles (https://www.ncbi.nlm.nih.gov/pubmed/?term=amedei+a), H-index: 42,69 and 6.064 Citations (https://www.researchgate.net/profile/Amedeo_Amedei/scores), 8 book chapters and one patent (WO/2007/039451), in addition to active participation in various (57) national/international congress. In simple terms, considering the 13 years of current University career, it means 10 publications and 4 congress for year.

In addition, the Prof. Amedei is Co-Editor in Chief or member of the Editorial Board of 51 International scientific journals and finally, he regularly carries out activities as scientific reviewer for international research projects of private and public entities: 2012 - Latvian Science Council (Latvia); 2013 - Latvian Science Council (Latvia); 2015 - Government agency of National Science Centre (Narodowe Centrum Nauki – NCN- Poland); 2015 - MS Research Australia (MSRA) (Australia); 2015- Université de Toulouse (France).; 2016 - FWF Austrian Science Fund (Austria); 2017 - Università degli Studi di Roma "Tor Vergata" (Italy), FWF Austrian Science Fund (Austria); 2019 French National Cancer Institute (France), European Science Foundation (Belgium), King Abdullah International Medical Research Center (KAIMRC) (Saudi Arabia), Singapore Minister of Health (Singapore), University of Insubria (Italy), MRC (United Kingdom). From 2016, he is in the Scientific Council of "Toscana Life Sciences" (TLS).

Dr. Elena NICCOLAI Female), Ph.D. – will be responsible for immunological data analysis. She is a PostDoc fellowship holder in the Department of Experimental and Clinical Medicine of the University of Florence. Her research fields are inflammation, adaptive immune response and T cells, with particular interest in the specific T cell response to cancer. In her recent studies, she has investigated the nature and function of microparticles in different inflammatory diseases, and currently she is studying the relation between gut microbiota and intestinal inflammatory response in colorectal cancer. Her expertise in laboratory techniques as: long and short-term cell culture of human cells, T cell high efficiency cloning, proliferation and cytotoxicity tests, ELISA, multiplex immunoassay protein quantitation using Luminex & biological test for determination of cytokines, Elispot, PCR, RT-PCR, RNAse protection assay, mass spectrometry, immunohistochemistry analysis, flow cytometry.

Dr. Edda RUSSO (Female), Ph.D. – will be responsible for processing of microbiome analyses. She is a PostDoc fellowship holder in the Department of Experimental and Clinical Medicine of the University of Florence. Her research fields are microbiota, immune response and T cells, with particular interest in the specific T cell response to microbiota. In her recent studies, she has investigated IBD and Colorectal cancer and currently she is studying the relation between gut microbiota and intestinal inflammatory response in several diseases. ." She is a team member of the project "Fas Salute 2016 – Colon rectal cancer: characterization of the microbiota's functional/metabolic and the probiotics role on the specific immune response modulation". Funded by Tuscany Region

Prof. Antonio TADDEI (Male) – will be responsible for oncological clinical studies. He is a Professor in the Department of Surgery and Translational Medicine of the University of Florence. He is part of the "Italian Group for Gastric Cancer-Onlus". He is a member of the Italian Society of Surgery and in the three-year period 2008-2011 he was part of the "Publishing Commission" of the Company. He is a member of the Tosco-Umbra Society of Surgery. He has performed more than 2,000 surgeries as the first operator, including numerous advanced laparoscopy and, since January 2014, advanced robotics in the field of oncology. He is teacher in: School of Specialization in Digestive Surgery and Surgical Digestive Endoscopy of the course of "Operating Techniques of General Surgery", School of Specialization in General Surgery, School of Specialization in Emergency Medicine, in which he is a member of the Ordering Committee.

Dr. Maria Novella RINGRESSI (Female), MD – will be responsible for oncological clinical studies. She is a University Research Scientist and Medical Doctor at Careggi University Hospital, Florence (Italy). Her research experiences are: evaluation of the prognostic impact of the expression of circulating tumour cells and immunological profile in patients with colon cancer; comparison of laparoscopic surgery versus robotic surgery for the treatment of low rectal cancer; Colorectal Cancer: functional and metabolic characterization of the microbiota and evaluation of the role of probiotics for the modulation of the specific immunological response.

5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content

1: Pagliai G, Russo E, Niccolai E, Dinu M, Di Pilato V, Magrini A, Bartolucci G, Baldi S, Menicatti M, Giusti B, Marcucci R, Rossolini GM, Casini A, Sofi F, **Amedei A**. Influence of a 3-month low-calorie Mediterranean diet compared to the vegetarian diet on human gut microbiota and SCFA: the CARDIVEG Study. Eur J Nutr. 2019 Jul 10. doi: 10.1007/s00394-019-02050-0. [Epub ahead of print] PubMed PMID:

31292752.

2: De Almeida CV, Lulli M, di Pilato V, Schiavone N, Russo E, Nannini G, Baldi S, Borrelli R, Bartolucci G, Menicatti M, Taddei A, Ringressi MN, Niccolai E, Prisco D, Rossolini GM, **Amedei A**. Differential Responses of Colorectal Cancer Cell Lines to Enterococcus faecalis' Strains Isolated from Healthy Donors and Colorectal Cancer Patients. J Clin Med. 2019 Mar 20;8(3). pii: E388. doi: 10.3390/jcm8030388. PubMed PMID: 30897751; PubMed Central PMCID: PMC6463247.

3: Russo E, Bacci G, Chiellini C, Fagorzi C, Niccolai E, Taddei A, Ricci F, Ringressi MN, Borrelli R, Melli F, Miloeva M, Bechi P, Mengoni A, Fani R, **Amedei A**. Preliminary Comparison of Oral and Intestinal Human Microbiota in Patients with Colorectal Cancer: A Pilot Study. Front Microbiol. 2018 Jan 12;8:2699. doi:

10.3389/fmicb.2017.02699. eCollection 2017. PubMed PMID: 29375539; PubMed Central PMCID: PMC5770402.

4: **Amedei A**, Cappon A, Codolo G, Cabrelle A, Polenghi A, Benagiano M, Tasca E, Azzurri A, D'Elios MM, Del Prete G, de Bernard M. The neutrophil-activating protein of Helicobacter pylori promotes Th1 immune responses. J Clin Invest. 2006 Apr;116(4):1092-101. Epub 2006 Mar 16. PubMed PMID: 16543949; PubMed Central PMCID: PMC1401483.

5: **Amedei A**, Bergman MP, Appelmelk BJ, Azzurri A, Benagiano M, Tamburini C, van der Zee R, Telford JL, Vandenbroucke-Grauls CM, D'Elios MM, Del Prete G. Molecular mimicry between Helicobacter pylori antigens and H+, K+ --adenosine triphosphatase in human gastric autoimmunity. J Exp Med. 2003 Oct

20;198(8):1147-56. PubMed PMID: 14568977; PubMed Central PMCID: PMC2194239.

5 relevant previous projects or activities, connected to the subject of this proposal

- Grant From Tuscany Region – Project - *Colorectal cancer: functional / metabolic characterization of the microbiota and the role of probiotics in the modulation of immune specific response*. 2015
- Announcement Celiac Disease Foundation - *Functional characterization of the intestinal microbiota and the immune response associated, in patients with "Celiac Disease Potential* 2016
- Italian Ministry of Health (Finalized Research) - *Interplay between gut microbiota and adaptive immunity in Amyotrophic Lateral Sclerosis: a clinical trial* 2016
- Por ERDF Marche- Project Probiosenior- promote innovative solutions to meet the challenges of local communities in health and well-being through collaborative projects of research and experimentation between

undertakings and public / private organizations that provide services to citizens - *Development of new foods probiotic and nutraceutical preparations to improve the quality of senior life* 2017 - University of Florence, Department of Clinical and Experimental Medicine: Grant for the institution of a PhD position in Clinical Sciences. Title Paleopathology: *characterization of human paleomicrobioma and immune response through the development of in silico interaction models* 2018
Infrastructure and/or any major items of technical equipment, relevant to the proposed work
The laboratory of Prof. Amedei has the facilities needed for the study of cellular and molecular immunology and microbiota. The laboratory of 200 square meters is fully equipped for molecular biology: 2 Eppendorf microcentrifuge, 2 thermocycler of Biometra, 1 UV transillumination integrated with photographic system (Canon PowerShot) and computer with programs (BioDocAnalyze - Biometrics) of gel analysis; thermal cyclers for PCR and real-time PCR; luminometers; image analyzer infrared scanner ODYSSEY (Li-Cor); time-lapse video-microscope; microplate readers; all apparatus required for agarose and PAGE electrophoresis and Northern/Western blotting; time-lapse confocal microscope; two-photon confocal microscope; FACS-Aria; FACS-Sorter; IVIS Spectrum Pre-clinical In Vivo Imaging System; Seahorse XF Analyzer; Agilent HES gas chromatography (GC) MS system. About the cell biology: 4 hoods sterile laminar flow (2 single and 2 double work), 1 chemical hood, 2 incubators, 1 beta-counter equipped with computer, tools (Packard Instruments) for assessment of radioactive material incorporation into the cell (for cell proliferation or cytotoxicity test), 4 optical microscope Leica (2 inverted light), 1 a fluorescence microscope with incorporated photography system (Leica DMRBE), 3 centrifuges, 1 container storage of cells in nitrogen (160 litres), 2 cytofluorometry instrument of BD Biosciences (FACSCanto), 1 Elisa reader (Bouty), and 1 ELISPOT reader (AID), 1 Luminex® MAGPIX® suitable for medium-throughput multiplex immunoassays, 1 autoMACS® Pro Separator instrument for high-speed magnetic cell sorting of multiple samples, 1 gentleMACS™ Octo Dissociator with Heaters instrument for the fully automated and standardized tissue dissociation or homogenization of up to eight samples. In addition, the laboratory is equipped with cold room 4 °C (5 square meters), several freezers (3 of - 80 °C and 4 of -20 °C), 4 refrigerators, 2 microwave and 5 personal computer for data processing. The laboratory of the mass spectrometry facilities provides 2 GC-MS (Agilent 5971, Agilent 5973) and 1 GC-MSn (Saturn 2000). Moreover, in order to evaluate other biomarker, the lab share with the project 3 LC-MS/MS (triple quad VARIAN 1200, VARIAN MS 500, SCIEX QTRAP 6500) all of them are equipped with autosampler for the automatic injection, and moreover the VARIAN triple quad 1200 and the SCIEX QTRAP6500 are equipped with a binary pump and an auxiliary pump for SPE on-line. The lab has all the facilities for sample preparation (off-line SPE device, heating block for derivatization, a device to evaporate samples under N2, an automated system for solid sample homogenization: Bertin Precellys 24 equipped with a cryolis module for low temperature homogenization, 1 centrifuge and 1 microcentrifuge). For Nuclear Magnetic Resonance (NMR)-based metabolomic studies we have Bruker 600 MHz spectrometer equipped with HR-MAS TXI 1H/13C/15N probe for solid state samples.

4.2. THIRD PARTIES INVOLVED IN THE PROJECT (INCLUDING USE OF THIRD PARTY RESOURCES)

P1 USFAX	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**NO**
Does the participant envisage that part of its work is performed by linked third parties	**NO**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**NO**

P2 INRA	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**NO**
Does the participant envisage that part of its work is performed by linked third parties	**NO**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**NO**

P3 IM	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**NO**
Does the participant envisage that part of its work is performed by linked third parties	**NO**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**NO**

P4 UNIFI	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**NO**
Does the participant envisage that part of its work is performed by linked third parties	**NO**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**NO**

5. Ethics and Security

5.1 Ethics

The objectives, concept and methodology of MICAfrica project were submitted to the local research ethics committee at SFAX University for evaluation and approval before the project start (see approval of this Committee as Annex). This Committee takes into consideration the laws and regulations in Tunisia as well as EU and international norms and standards:

- The ***Tunisian Medical Code of Ethics requirements***, adopted in 1973 (http://www.legislation.tn/en/affich-code/Code-d%C3%A9ontologie-m%C3%A9dicale__102);

- WMA declaration of Helsinki – ***Ethical principles for medical research involving human subjects*** (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/);

- Regulation (EU) No 1291/2013 of the European Parliament and of the council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing (Decision No 1982/2006/ECArticle 19 Ethical principles);

- Regulation (EU) No 511/2014 of the European Parliament and of the council of 16 April 2014 on ***compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union;***

- Article 16 of the ***Universal Declaration on the Human Genome and Human Rights, with the Convention on Human Rights and Biomedicine*** (Oviedo, 4 April 1997: https://www.coe.int/fr/web/conventions/full-list/-/conventions/rms/090000168007cf98).

According to national and international regulations, the MICAFrica activities will be conducted with basic principles such as the respect of life and dignity, respect of the patient's autonomy and privacy, cooperation among physicians and fair distribution of the benefits and burden of research.

According to The **Tunisian Code of Medical Ethics**, which also regulates the research involving human subjects, all the patients involved in MICAfrica project will be informed of the nature and objectives of the research and its effects on their life and health (Article N° 106).

An **informed consent** will also be obtained in advance from each patient (Article N° 107). Participants will give their consent in writing (e.g. by signing the informed consent form and information sheets). If consent cannot be given in writing – for example because of illiteracy – non-written consent must be formally documented and independently witnessed. We will ensure that participants have fully understood the information and that they do not feel pressured or coerced into giving consent.

- Participants will be clearly informed about the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue. Participants will be also informed about the procedures that will be implemented in the event of unexpected, or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings.

- According to the **International Declaration on Human Genetic Data** and to the **Universal Declaration on the Human Genome and Human Rights** and the **international law of human rights**, the human dignity will be respected; the values, rights and interests of the research participants will be protected. The human rights and fundamental freedom will be protected during the collection, processing, use and storage of human genetic and proteomic data. The biological samples of patients and donors used for screening, predictive testing, epidemiological and population-based genetic studies will be kept with the requirements of equality, justice and solidarity.

- We will also ensure that our research methodologies do not result in discriminatory practices or unfair treatment. In fact, participants will be included regardless their ethnic origin, skin color and social level. They will be explicitly informed that their participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time without any consequences.

- For the processing of human genetic data, human proteomic data and biological samples we will take the necessary measures to ensure the accuracy, reliability, quality and security of these data and the processing of biological samples. Honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples will be basic principles during the whole implementation of the MICAfrica proposed project.

Coordinator's NOTE, on behalf of the whole Consortium, included at GAP stage

RESULTS OF THE ETHICS SCREENING PERFORMED BY THE EC AND ETHICS ISSUES TO BE ADDRESSED BEFORE AND AFTER THE SIGNATURE OF THE GRANT AGREEMENT (GA).

We would like to note that the MICAfrica proposal, as it was required, was subject to an **Ethics Screening** by the EC services. The **Ethics Screening Report (EthSR)** (with Ref. **Ares(2020)1717021 - 23/03/2020**) is available in the Funding and Tenders portal. Based on the outcome of the Ethics Screening, MICAfrica has been granted the following ethics opinion: **CONDITIONAL Ethics CLEARANCE.**

The Coordinator, on behalf of the Consortium acknowledges that the Screening Ethics Requirements identified in the **EthSR** were examined during the Grant Agreement Preparation (GAP) stage as **they become contractual obligations.**

Ethics obligations in the EthSR for **MICAfrica** were flagged both as (**a)** ***"BEFORE GRANT AGREEMENT SIGNATURE"*** *(compliance date month 0)* => Ethics obligations must *be* addressed during the GAP preparation; (**b)** ***"AFTER GRANT AGREEMENT SIGNATURE"***.

PRE-GRANT ETHICS REQUIREMENT – Category THIRD COUNTRIES:

In case activities undertaken in non-EU countries raise ethics issues, the applicants must ensure that the research conducted outside the EU is legal in at least one EU Member State. This must be specified in the grant agreement.

ANSWER BY THE COORDINATOR ON BEHALF OF THE CONSORTIUM:

The MICAfrica Coordinator, on behalf of the Consortium, informs and confirms in writing as follows:

The activities planned in the MICAfrica project's Action cover numerous biologic procedures and tests that will be undertaken in EU and non-EU countries (Tunisia), and all these research activities will raise ethics issues.

We confirm in writing that all the research activities that will be undertaken in the non-EU country concerned – Tunisia – will be legal according to Tunisian and EU regulations (legal in at least one EU Member State). Based on this principle, the objectives, concept and methodology of the MICAfrica project's Action were submitted to the **Local Research Ethics Committee** at Ben. No. 1 (USFAX) for evaluation and approval at proposal stage and before the start of this proposed project (please see the official approval of this Committee in ANNEX). This Committee takes into consideration the laws and regulations in Tunisia as well as EU and international norms and standards.

For the collecting of personal data in non-EU countries (Tunisia) it will be ensured that processing, notification, consent and accountability provisions meet the applicable **EU law** and the **General Data Protection Regulation (GDPR)** standards. The consortium will also comply with the Tunisian laws including national data-protection laws. The consortium will be under the obligation to notify or seek permission for research from national authorities, or data protection regulators. Thereby, it will request authorisations to transfer personal data including health and patient outside the non-EU country (Tunisia). The onward transfer of personal data by members of the MICAfrica consortium and any other recipients outside the framework of such agreements will be prohibited. The Consortium will also implement appropriate organisational and technical measures to ensure that personal data, in case of transfer, will be transferred securely.

The Consortium will ensure that research participants understand and consent to the export of the personal data they provide to an EU Member State, or an non-EU country. All the Consortium Beneficiaries will ensure that ***the personal data to be collected will be anonymized before they are processed/analyzed by using relevant anonymisation/pseudonymisation techniques so as to minimize any risks to data subjects***. In addition, appropriate organisational and technical measures will be implemented to ensure that personal data are transferred securely.

POST-GRANT AGREEMENT ETHICS REQUIREMENT No. 1 – Category: HUMANS (Applicable due date: **Month 2):**

POST-GRANT AGREEMENT ETHICS REQUIREMENT No. 2 – Category: PROTECTION OF PERSONAL DATA (POPD) (Applicable due date: **Month 2):**

ANSWER BY THE COORDINATOR ON BEHALF OF THE CONSORTIUM:

We acknowledge that during the Grant Agreement Preparation (GAP) stage a dedicated Work Package (WP) on **'Ethics Requirements' (WP6)** was *automatically inserted by the system*. No PMs were added to this WP.

The overall duration of the WP is M1 to M36 (end of the project's duration). The Lead Beneficiary for this WP is the Coordinating Legal Entity –Ben. No. 1: **USFAX.**

Full compliance will be ensured with respect to the applicable **Post-Grant Ethics Requirement**s described in detail in the PART A of the Annex 1 for the MICAfrica project's Action. The compliance will be ensured throughout the whole duration of the project's Action. Moreover, it is confirmed that the REA, via the responsible Project Officer, will be always informed in advance in case of any new ethics issues/ethics concerns that may arise during the action's implementation, and/or any further research activities involving ethics issues, and this will be done be before the start of the relevant activities.

The below sources will be always rigorously consulted, including the recommendations provided in the European Commission Ethics Self-Assessment Guidelines, in terms of addressing the applicable ethics requirements and any other ethics issues that may occur after the signature of the Grant Agreement (GA) and during the implementation of the MICAfrica EU-funded project's action.

We also confirm that we will ensure compliance with the Article 34 of the GA referring to: ETHICS AND RESEARCH INTEGRITY.

- **Guidance How to complete your ethics self-assessment**

https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

- **Guidance Note on Ethics and Data Protection**

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

- **The following links of the H2020 ONLINE MANUAL on Ethics will be equally consulted:**

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/from-evaluation-to-grant-signature/grant-preparation/ethics_review_en.htm#ethics_impl

PROPOSAL_952583-MICAfrica-H2020-WIDESPREAD-2020-5-Ethical_Issues

ANNEX

Ethics Approval from the local research Ethics Committee at SFAX UNIVERSITY
(Ben. No. 1 - USFAX)

République Tunisienne
Ministère de la Santé

MINISTERE DE LA SANTE
COMITE DE PROTECTION DES PERSONNES SUD
« C.P.P.SUD »

Le Comité de Protection des Personnes Sud « C.P.P.SUD ».a été saisi, Samedi le 02/11/2019 pour un avis d'éthique, concernant une étude intitulée :

Towards a North-African Consortium of the Human Microbiome (NACHM) through Strengthening the capacities in Microbiome Analysis for Human diseases at University of Sfax « MICAfrica – Microbiome CApacity Africa (MICAfrica) »

Référence : « CPP SUD N° 0203/2019 »

Cette étude élaboré par : **Leila Ammar Keskes** [1], **Hayet Sellami** [1], **Basma Mnif** [1], **Raja Gargouri** [2], **Radhouen Gdoura** [3],

- [1] Faculté de Médecine de Sfax
- [2] Centre de Biotechnologie de Sfax
- [3] Faculté des Sciences de Sfax

Cette étude à été présenté par : **Leila Keskes**

Après discussion, les membres du Comité ont émis un : **avis favorable**

à la réalisation de ce travail qui obéit aux règles d'éthique de notre pays.

Date
2..11..2019...

signature du Président
Comité de Protection des Personnes
Le Président
Professeur Zouhir Bahloul

5.2 Security

Please indicate if your project will involve:

- Activities or results raising security issues: **NO**
- 'EU-classified information' as background or results: **NO**

ESTIMATED BUDGET FOR THE ACTION

Associated with document Ref. Ares(2020)3335730 - 26/06/2020

	Estimated eligible[1] costs (per budget category)										EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%							
	a	Total b	No hours	Total c	d	*[e]*	f	Total g	h = 0,25 x (a +b+c+f+g *+[i1]*[13]*+[i2]*[13]-n)	j = a+b+c+d *+[e]*+f+g+h *+[i1]+[i2]*	k	l	m	n	Yes/No	
1. USFAX	63 000.00	0.00	0.00	0.00	0.00	0.00	189 841.00	0.00	63 210.25	316 051.25	100.00	316 051.25	316 051.25	0.00	No	n/a
2. INRAE	132 000.00	0.00	0.00	0.00	0.00	0.00	68 627.00	0.00	50 156.75	250 783.75	100.00	250 783.75	250 783.75	0.00	No	n/a
3. IHU MI	96 000.00	0.00	0.00	0.00	0.00	0.00	39 602.00	0.00	33 900.50	169 502.50	100.00	169 502.50	169 502.50	0.00	No	n/a
4. UNIFI	96 000.00	0.00	0.00	0.00	0.00	0.00	32 438.00	0.00	32 109.50	160 547.50	100.00	160 547.50	160 547.50	0.00	No	n/a
Total consortium	387 000.00	0.00			0.00	0.00	330 508.00	0.00	179 377.00	896 885.00		896 885.00	896 885.00			0.00

[1] See Article 6 for the eligibility conditions.
[2] Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).
[3] This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Agency decided to grant for the action) (see Article 5.1).
[4] The 'maximum grant amount' is the maximum grant amount decided by the Agency. It normally corresponds to the requested grant, but may be lower.
[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
[6] See Article 5 for the forms of costs.
[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice.
[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).
[9] Unit and costs per unit : calculated according to the beneficiary's usual accounting practices.
[10] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E).
[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).
[12] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc).
[13] Only specific unit costs that do not include indirect costs.
[14] See Article 9 for beneficiaries not receiving funding.
[15] Only for linked third parties that receive funding.

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

⚠ **Transitory period: Until SyGMa fully supports Annex 2a, you must prepare it manually (using this template by choosing and deleting the options/entering the appropriate data).**
For the 'unit cost tables': either fill them out manually or use currently existing tables from Annex 1 or the proposal.
The document can then be uploaded in SyGMa and attached to the grant agreement.

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*][*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{the monthly living allowance for researchers in MSCA-IF actions / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 650**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 880**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page)

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- beneficiary/linked third party [short name]: EUR [insert amount]
- beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] *]*

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

2. Costs for energy efficiency measures in buildings

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m^2 per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[1]

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

[1] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

Research infrastructure unit cost

3. Access costs for providing trans-national access to research infrastructure

Units[2]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years}^{3}\text{)}}{\text{average annual total quantity of access to the installation (over past two years}^{4}\text{)}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[5]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

Clinical studies unit cost

4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each sequence (if any), clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for the cost components of each task, as follows:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1

{1720 * number of full-time-equivalent for doctors for year N-1}

multiplied by

estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1

{1720 * number of full-time-equivalent for other medical personnel for year N-1}

2 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

3 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

4 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

5 Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: **'**average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1

{1720 * number of full-time-equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1

total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1

total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Unit cost table: clinical studies unit cost[6]

Task, Direct cost categories	**Resource per patient**	**Costs year N-1 Beneficiary 1 [short name]**	**Costs year N-1 Linked third party 1a [short name]**	**Costs year N-1 Beneficiary 2 [short name]**	**Costs year N-1 Linked third party 2a [short name]**	**Costs year N-1 Third party giving in-kind contributions 1 [short name]**
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1						

[6] Same table as in proposal and Annex 1.

XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

1

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT (INRAE), established in Rue De L'Universite 147, PARIS CEDEX 07 75338, France, VAT number: FR57180070039, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('2')

in Grant Agreement No 952583 ('the Agreement')

between SFAX UNIVERSITY **and** the Research Executive Agency (REA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled 'Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for Human Diseases at University of Sfax (MICAfrica)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Thierry PINEAU with ECAS id npinethi signed in the Participant Portal on 06/07/2020 at 21:46:41 (transaction id SigId-25293-OhTlbp0jzzbLzmj1BjlA4b88KZr3KXDkzaA4d2YkKzzsYaJ8JJTtrDjnGmzdvnORsmJug1ZkMp9qGh5mypNCeHui-jpJZscgsw0KmE9q55QdRE4-UDIJBclwAzYxUzUBct7WFo9xW5B58ew88373RWzVzzTaSA8zfTsGJ3PosLYejjxsQjoZLrF8oJlpKphzXidMKYSi). Timestamp by third party at Mon Jul 06 22:46:48 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MEDITERRANEE INFECTION (IHU MI), established in 27 BD JEAN MOULIN FACULTE DE MEDEINE AILE ROUGE 3E, Marseille 13005, France, VAT number: FR04501980882, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('3')

in Grant Agreement No 952583 ('the Agreement')

between SFAX UNIVERSITY **and** the Research Executive Agency (REA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled 'Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for Human Diseases at University of Sfax (MICAfrica)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Didier RAOULT with ECAS id nraouldi signed in the Participant Portal on 29/06/2020 at 09:50:13 (transaction id SigId-33987-zhgT9sDwsCSKjMDbRjztnGwdZT7tYTX7aQVzzvSaPg1ehTSQrzc14JGFjsqwVAAZNyEwbevzOXaNniD4rHVzGnwC-jpJZscgsw0KNihoCvhiTby-xo7YYCy3JqNraWVNMAVC7hWBO0hI7zmik4okpJcsMWxyWxuPfgINIzXQtHjQCQek9nKcWOSrISqWeJsKl2drJv). Timestamp by third party at Mon Jun 29 10:50:18 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI), established in Piazza San Marco 4, Florence 50121, Italy, VAT number: IT01279680480, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('4')

in Grant Agreement No 952583 ('the Agreement')

between SFAX UNIVERSITY **and** the Research Executive Agency (REA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled 'Towards a North-African Consortium of the Human Microbiome (NACHM) through strengthening the Capacities in Microbiome Analysis for Human Diseases at University of Sfax (MICAfrica)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Corrado POGGESI with ECAS id npogesco signed in the Participant Portal on 01/07/2020 at 08:13:30 (transaction id SigId-1642-1pHbnujKbxLX4umREowGwOR4ezoQ8zT9Jbvlv4Rf68i4BjFpBCP3lUpbgEJA89qOfwgEzzHr25m5ocEeLSkhzGG-rS0vSrmBGYCr5Skwj6lcNm-djzTnBZfuDby57fFiCMlXUzNNmG2h6QKAqaohG46mf2ldE8ccG6nSfV7vjnRHuGiehm4Ja8g2SlsBvHNxJOmln). Timestamp by third party at Wed Jul 01 09:13:35 CEST 2020

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)												Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs			E. Indirect costs[2]	*[F. Costs of …]*		Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of …]*	*[F.2 Costs of …]*		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Unit	Flat-rate[5] 25%	Unit		*[Unit][Lump sum]*					
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	Total h	i=0,25 x (a+b+ c+f+*[g]* + h+ *[j 1]*[6] +*[j2]*[6] -p)	No units	Total *[j1]*	Total *[j2]*	k = a+b+c+d+*[e]* +*f* + *[g]* +h+ i + *[j1]* +*[j2]*	l	m	n	o	p
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less,

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

TABLE OF CONTENTS

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission *[Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission*[, the Agency],* the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission *[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the *[Commission] [Agency]* in evaluating whether the *[Beneficiary's] [Linked Third Party's]* costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the *[Commission] [Agency]* for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, the Beneficiary's usual remuneration practice for projects funded under national funding schemes…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-17 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed.	
		15) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 18-21 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll;	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself..	
		If personnel is seconded against payment: 20) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 22-27 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		23) Productive hours were calculated annually.	
		24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A**. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B**. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C**. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month). *If the Beneficiary applied method C.* 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs): If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. II) For individual hourly rates: The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates;	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied] *For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 29) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; ○ (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	32) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 37-41 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	○ they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 51) The amount charged corresponded to the actual usage for the action. 52) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: ○ the contracts did not cover tasks described in Annex 1; ○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with	53) Contracts for works or services did not cover tasks described in Annex 1. 54) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 55) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 56) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.	58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	In the cases that a positive ex-ante assessment has been issued *(see the standard factual findings 58-59 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 60 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 60 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 61-65 listed in the next column, the Auditor: ○ obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; ○ verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of	61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. 62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding. 63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other	

	internally invoiced goods and services (see Article 6 GA); ○ verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, and correspond to objective and verifiable information. ○ verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. ○ verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	budget categories. 64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service. 65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm),*	66) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	67) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[1] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

[1] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[2] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[2] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *…]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].* X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 employees are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s) complemented by other employees irrespective of their assignments until he has reached 10 employees.].* For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
(including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- …]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional

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	remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

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Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
If method C is applied XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. If method C is applied 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:**

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	19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 employees referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

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present certificate[1]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

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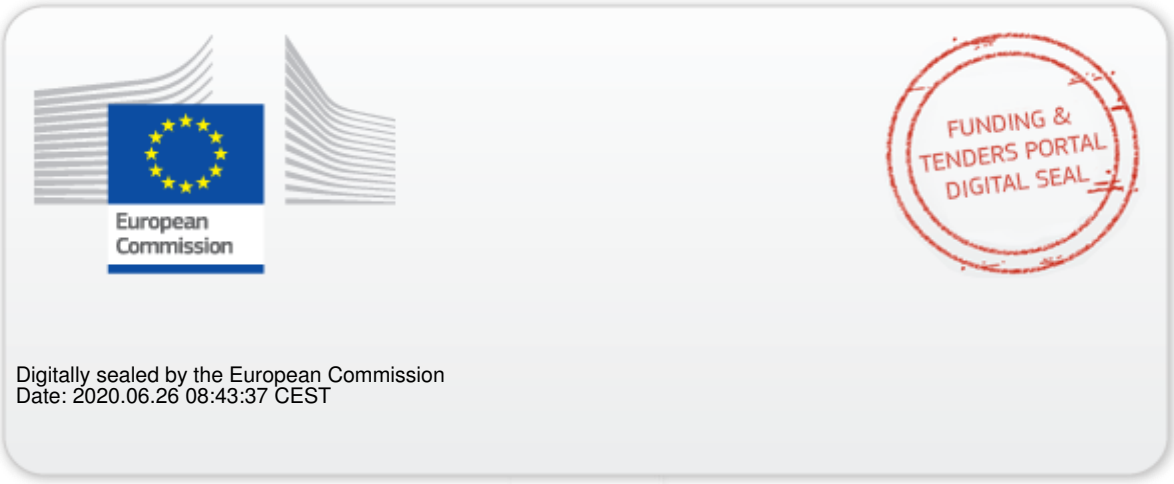
[official name of the *[Beneficiary] [Linked Third Party]**]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature of the*** *[Beneficiary] [Linked Third Party]>*	***[official name of the Auditor]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature*** *of the Auditor>*



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