

# CLINICOM

**Committee for Evaluation of Protocols for Clinical Research**

"Bhooma", No.7, 17 A Cross, Malleswaram West, Bangalore 560 055

Tel: +91-80-41279794 E mail: [clinicom@gmail.com](mailto:clinicom@gmail.com)

Date: July 7, 2010

**Chairperson**

Mr. V V Raghavan  
M.Sc.  
Clinical Trials  
Expert &  
Pharmaceutical  
Technologist

**Vice Chairperson**

Dr. P H Prasad  
MBBS, FCCP  
Medical Scientist

**Member Secretary**

Ms. Vidya Sury  
B Sc, MBA, Dip.T&D  
Layperson & Home  
Maker

**Members:**

Dr. S Krishnamurthy  
LL.M, Ph.D,  
LL.D,D.Lit  
Legal Expert

Ms Vidhya Nuti  
BSc, LLB, PGDIPRL  
Legal Expert

Dr K Venkatesan  
M A, Ph D  
Scientist

Dr.Nandini Mundkur  
M D (Paed), MAMC  
Medical Scientist &  
Paediatric  
Consultant

Mr Arun Madhavan  
B Com, MBA  
Theologian

Ms.Renu Srinivasan  
M A, B.Ed  
Social  
Worker/Educationist

Ms. Chetana Sudhir  
M A, B.Ed  
Counselor & Social  
Worker

**AGENDA**

The following protocol will be discussed during our meeting on Thursday, July 8, 2010, at 4.30 pm at Clinicom, No.7, 17<sup>th</sup> 'A' Cross, Malleswaram West, Bangalore - 560055

Protocol Number: CLAF237AIN02

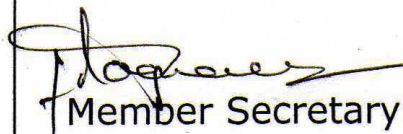
Observational Study "An Open label, Prospective, Observational study to evaluate diabetes control in Indian patients on Galvus or GalvusMet and compared with patients on Sulphonylureas or its combination with Metformin, in Type 2 diabetic mellitus who fast during Ramadan

**Received from:**

Dr. K. JAVEED NAYEEM

Consultant in Medicine, Cardiology & Critical Care  
Medical Consultancy Services  
4533, Radio Park, 2nd Cross, Shivaji Road  
N.R.Mohall, Mysore - 5700 07

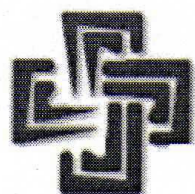
Cordially,  
**For CLINICOM,**

  
Member Secretary



Date: July 7, 2010





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Minutes of the meeting held on **Thursday July 8, 2010** at 4.30 pm at Clinicom, No.7, 17<sup>th</sup> 'A' Cross, Malleswaram West, Bangalore 560055

## **Chairperson**

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We discussed the Protocol Number: CLAF237AIN02 titled: An Observational Study "An Open label, Prospective, Observational study to evaluate diabetes control in Indian patients on Galvus or GalvusMet and compared with patients on Sulphonylureas or its combination with Metformin, in Type 2 diabetic mellitus who fast during Ramadan"

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Medical Consultancy Services  
4533, Radio Park, 2nd Cross, Shivaji Road  
N.R.Mohall, Mysore - 5700 07

The following members of CLINICOM were present

1. Mr.V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr.P.H.Prasad, (Medical Scientist), Vice Chairperson
3. Ms.Vidya Sury, (Homemaker & Layperson), Member Secretary
4. Dr.K Venkatesan, (Scientist), Member
5. Dr.S Krishnamurthy, (Legal Expert), Member
6. Ms.Chetana Sudhir, (Social Worker & Counselor), Member
7. Ms.Renu Srinivasan, (Social Worker / Educationist), Member
8. Mr.Arun Madhavan, (Theologian), Member
9. Dr.Nandini Mundkur, (Pediatric Consultant & Medical Scientist), Member

Ms Vidhya Nuti, Legal Expert and Member did not attend the meeting. However, she has reviewed the documents and has no objection to the conduct of the study.

**We approve this study from the ethics point of view, to be conducted in its presented form**

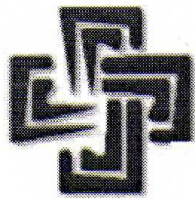
Cordially,  
**For CLINICOM,**

  
**V V Raghavan**  
**Chairman**



**Date: July 8, 2010**





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Tel: +91-80-41279794 E mail: [clinicom@gmail.com](mailto:clinicom@gmail.com)

**Our ref: 066/8.7.2010**

**Date: July 12, 2010**

**Chairperson**

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M.Sc.  
Clinical Trials  
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Technologist

**Vice Chairperson**

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4533, Radio Park, 2nd Cross, Shivaji Road  
N.R.Mohall, Mysore – 5700 07

Dear Dr K Javeed Nayeem,

Sub: Approval for referred study

Ref: Protocol Number: CLAF237AIN02 titled An Observational Study "An Open label, Prospective, Observational study to evaluate diabetes control in Indian patients on Galvus or GalvusMet and compared with patients on Sulphonylureas or its combination with Metformin, in Type 2 diabetic mellitus who fast during Ramadan"

CLINICOM met on **Thursday July 8, 2010 at 4.30 pm** to review and discuss your application dated July 2, 2010 to conduct the clinical trial study. The following documents were received and reviewed:

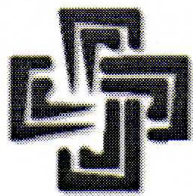
- The Protocol and Patient information and consent form.
- Case Report Form (CRF)
- Galvus / GalvusMet Pack insert
- Investigator CV

The following members of CLINICOM were present at the meeting held **Thursday July 8, 2010, at 4.30 pm.** at Clinicom, No. 7, 17th 'A' Cross, Malleswaram West, Bangalore – 560055

1. Mr.V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr.P.H.Prasad, (Medical Scientist), Vice Chairperson
3. Ms.Vidya Sury, (Homemaker & Layperson), Member Secretary
4. Dr.K Venkatesan, (Scientist), Member
5. Dr.S Krishnamurthy, (Legal Expert), Member
6. Ms.Chetana Sudhir, (Social Worker & Counselor), Member
7. Ms.Renu Srinivasan, (Social Worker / Educationist), Member
8. Mr.Arun Madhavan, (Theologian), Member
9. Dr.Nandini Mundkur, (Pediatric Consultant & Medical Scientist), Member

Ms Vidhya Nuti, Legal Expert and Member did not attend the meeting. However, she has reviewed the documents and has no objection to the conduct of the study.





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**We approve this study from the ethics point of view, to be conducted in its presented form. This approval is also valid for additional sites. Keep us informed about these sites, as and when added.**

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of this ethics committee.
- Deviations/ changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

1. Any changes to or deviations to the protocol approved by CLINICOM that you might implement to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

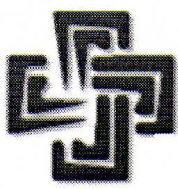
Cordially,  
**For CLINICOM,**

  
V V Raghavan  
Chairman



**Date: July 12, 2010**





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Counselor & Social  
Worker

## INVOICE

**Invoice no. 0079/Clinicom/2010-2011**

July 12, 2010

Dr. K. JAVEED NAYEEM  
Consultant in Medicine, Cardiology & Critical Care  
Medical Consultancy Services  
4533, Radio Park, 2nd Cross, Shivaji Road  
N.R.Mohall, Mysore - 5700 07

## Description:

**Being Charges towards Approval of the following study approved on Thursday July 8, 2010:**

Protocol Number: CLAF237AIN02  
Observational Study "An Open label, Prospective, Observational study to evaluate diabetes control in Indian patients on Galvus or GalvusMet and compared with patients on Sulphonylureas or its combination with Metformin, in Type 2 diabetic mellitus who fast during Ramadan

**Rs.10,000.00**

(Rupees Ten Thousand Only)

Note: **Cheque/DD may please be made** in favor of  
CLINICOM payable at Bangalore

Cordially,  
For CLINICOM,

**Dated July 12, 2010**

Authorized Signatory

