



**PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM**

**INTERNATIONAL DIABETES MANAGEMENT PRACTICES STUDY**

**Study Number OBS13847**

Dear Madam or Sir,

Your physician proposes that you participate in an observational study. Before you decide to participate, it is important that you know why the study is being done and what it will involve.

This document is intended to provide you with all the information you may need to know. You can ask as many questions as you want to get a full understanding of this study.

**WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to collect information about patients with type 1 and type 2 diabetes mellitus at the time the patients visits his/her physician (one visit).

Your physician will record specific information about you and how your diabetic disease is managed. The study will be performed in approximately 21 countries around the world. A team of diabetes experts will look at the information to better understand how the diabetic disease is managed around the world. The goal of this study is to improve quality of care of diabetic patients.

**DO I HAVE TO TAKE PART?**

Participation in this study is entirely voluntary. Your treatment and the attitude of your physician towards you will not be affected should you decide not to take part in this study.

If you decide to take part, you will need to sign to confirm that you have been explained the purpose, duration and foreseeable effects of the study and that you have given your consent to participate. You may still withdraw from the study at any time, without affecting any benefits to which you would otherwise be entitled.

**WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you agree to take part in this study and you are suffering from type 1 diabetes mellitus or type 2 diabetes mellitus, your physician will fill out one survey about you and your diabetic disease at a time point when you will visit him.

The survey asks questions about you such as your age, gender, socio economic profile and relevant medical history including signs and symptoms usually associated to diabetes. It also collects information about the type of diabetes you have, the treatment your physician gives you, your glycaemic control and if the screening of diabetic complications is done.

**Your participation in this study will have no impact on the treatment decisions made by your physician. He will treat your diabetes in order to achieve the best clinical benefit for you.**



**WHAT ARE THE RISKS OF THE STUDY?**

This program is only observational and does not involve the taking of any medication outside of the treatment that you are getting in the routine medical practice by your doctor. As such, there will be no direct risk to you from your participation.

**WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?**

The benefit of this study is to collect data that will help to continuously improve the knowledge of the management of diabetic patients in your country.

**WHAT ABOUT CONFIDENTIALITY?**

The data collected in this study will be reported to Sanofi, the sponsor of the study. The sponsor will store and process all study data with electronic data processing systems.

Qualified representatives of the sponsor, the Institutional Review Board (IRB)/ethics committee (EC), and/or domestic or foreign regulatory authorities according to local regulations may review your medical records in order to determine the accuracy of the reported data and/or to protect your safety and welfare. Records that reveal your identity will be kept confidential by the people who review them. Your personal identity (your name, address, and other identifiers) will not be collected and will remain confidential. In the sponsor's database, you will only be referred to by a code number. Only your physician will be able to link the code number to your name.

Any information derived from this study that personally identifies you will not be voluntarily released or disclosed by these entities without your consent, except as specifically required by law. You will not be identified in any research publications including journal articles, papers, and/or research presentations.

Data obtained in this study may, even after the study is over, be used for additional research and data re-analysis.

**WHAT ABOUT THE COSTS?**

You will not receive any compensation for your participation to the study. Treatment is determined solely by the physician, which falls within the scope of the physician general liability insurance coverage.

**CONTACT FOR FURTHER INFORMATION**

You will be given a copy of this signed informed consent document and you may ask for additional information, at any time during the study from Dr \_\_\_\_\_ (*physician*) at \_\_\_\_\_ (*phone no.*).



I \_ I \_ I \_ I \_ I \_ I \_ I      I \_ I \_ I \_ I  
Center N°                      Patient N°

**INFORMED CONSENT FORM**

1. I have read the informed consent for this observational study. I have received an explanation of the purpose, duration and possible benefit of the study and what I will be expected to do. My questions have been answered satisfactorily.
2. I agree to take part in this study.
3. I understand that my participation in the study is voluntary and that I may refuse to participate or may withdraw at any time, without penalty or loss of benefits to which I am otherwise entitled.
4. Representatives of the sponsor, Independent Ethics Committee/Institutional Review Board, or local or foreign regulatory authorities according to local regulations, may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.
5. I understand the description in this document of the extent that my protected health information will be used or disclosed for research and for treatment in connection with research. I also understand the description in this document of the extent to which my protected health information will not be used or disclosed.

**Last name:** \_\_\_\_\_ **First name:** \_\_\_\_\_  
(block letters) (block letters)

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
(To be completed by subject  
at time of consent)

**Physician or person who conducted the Informed Consent discussion**

I confirm that I have personally explained the nature, purpose, duration, and foreseeable effects and risks of the trial to the subject named above.

**Last name:** \_\_\_\_\_ **First name:** \_\_\_\_\_  
(block letters) (block letters)

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Witness (If required)**

**Last name:** \_\_\_\_\_ **First name:** \_\_\_\_\_  
(block letters) (block letters)

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_