English Version

PATIENT INFORMATION

Registre France PCI : Observatoire national de cardiologie interventionnelle

(France PCI registry : National observatory of interventional cardiology)

GENERAL INFORMATION

You are about to undergo a coronary angiogram and/or percutaneous coronary intervention (PCI). The present document aims at informing you that the medical center that will carry out this procedure takes part in a national observatory of interventional cardiology set up in France.

This study is promoted by France PCI. It is entitled « Registre France PCI : Observatoire national de cardiologie interventionnelle ».

The purpose is to identify and follow in an exhaustive and permanent survey, all the patients who have undergone coronary angiogram and/or PCI in all authorized French centers. We need your participation to better understand and describe patient coronary disease in order to improve the knowledge and management of the disease.

DATA COLLECTION

Medical data concerning your health at the time of hospitalization and during the procedure will be collected by your interventional cardiologist.

No additional medical act will be performed when participating in this observatory survey.

If you are treated for a heart attack (acute myocardial infarction with ST elevation) or if you undergo an angioplasty, a follow up will be done. In such case, the data of your hospitalization and the data up to one year after the procedure (possible cardiac events and treatments) will be filled in by a staff member from the participant center under responsibility of the principal investigator. You will be contacted one year after the intervention in order to check on your health.

PROCESSING AND USE OF YOUR DATA

The collected data will be pseudonymised i.e they will not identify you specifically. **Therefore your first and last name will never be mentioned.**

Data will be processed securely in order to ensure confidentiality in the national observatory which is computer processed and hosted in France. Data management is under the responsibility of the promoter.

In a scientific purpose, the coded data of the observatory may be transmitted to research organisms, providers, subcontractors as well as to health professionals. The results of the research are liable to be the subject of scientific publications in order to help improve the treatment of patient who, like you, have a heart condition. Under no circumstances will you be identified by your name in the publication of the results of the study. The data could also be subject to financial contracts with public or private partners. Should the observatory be lasting, the continuation of the study depends partly of yearly public and/or industrial fundings.

Your data will be saved for the duration of the observatory. If the study were to be ended, your data will then be stored for 15 years and then will be destroyed by the promoter.

REGULATORY AND LEGISLATIVE ASPECTS

The observatory is supported by the French state due to the absence of national data in interventional cardiology in the country. That is why the processing of your data within the frame of the study meets a health public interest and will help improve knowledge and management of coronary diseases.

The observatory is undergone according to European and French regulations (General Data Protection Regulation #2016/679 of 27 April 2016 called GDPR and law 78-17 “relative à à l'informatique, aux fichiers et aux libertés” of 6 January 1978 as amended). The right to access and rectify your data is available at any time. You are also entitled to

oppose the transfer of your data and to limit their management as well as to make a complaint to the Commission Nationale de l'Informatique et des Libertés (CNIL).
In order to exercise your rights, please contact the principal investigator of your center:

Dr Victor MIONE
Service de cardiologie
CENTRE HOSPITALIER MACON
Boulevard Louis Escande
71018 MACON cedex

In the case of such a demand, you should show proof your identity and name specifically the subject of your request.
If you exercise your right of opposition and as soon as it is known by the principal investigator of your center, your data will be deleted from the observatory. You are aware that the data which will have already been used in research will not be liable to be erased. However, they will no longer be used for future studies.

Because the observatory meets a public interest, the right to your data portability as well as their erasure is not applicable.

The France PCI registry was given regulatory approval by French authorities, i.e. the Commission Nationale de l'Informatique et des Libertés, a favorable opinion by the comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé and a favorable opinion by the comité d'évaluation éthique de l'Inserm. It was also given regulatory approval by the Comité de Protection des Personnes (CPP) Ile de France 3 on the 10 dec 2019.
In addition, the study ensures compliance with the reference methodology MR-003 which guarantees rightful processing of your data.

All staff involved in the France PCI registry is subject to the obligation of professional secrecy and must act accordingly and must comply with medical confidentiality and data protection regulations.

OBSERVATORY PARTICIPATION

Your participation is free and voluntary. If you were to decline it would entail no consequences on your treatment and on the relationship with the medical staff. You are allowed to end your participation at any time without justifications.
You are aware that if you do not oppose participation, you would be considered as having given your consent to take part in the study.

At the time of your hospitalization, the cardiologist informed you of this observatory. The present patient information letter is yours and you can discuss it with the doctor and/or your relatives. If in the course of the study, you asked yourself questions, you can contact at any time the principal investigator whose details are given on this document. On your request, you can also be informed of the general results of the study.

By participating to this observatory, you are helping us to better understand and treat coronary disease in France. Although there are no immediate expected benefits for you, your participation will contribute to improving the treatment of patients who will be in similar clinical conditions.

Thank you for your participation and for having read this patient information leaflet.