

Descriptive study on the treatment pathways of breast cancer patients in the United States using FLATIRON® data (MADISON)

Dear Sir/Madam

When you received medical care for breast cancer in the United States, your personal data was shared by your healthcare institution with the American company Flatiron Health.

In this context, Flatiron Health has been contractually authorized by your healthcare organization to allow the reuse of your previously pseudonymised personal data by research organizations around the world.

The Flatiron Health parent group F. Hoffmann-La Roche (Switzerland) and its various subsidiaries would like to be able to reuse your data - systematically in a confidential and secure way - for breast cancer research.

This information note is intended to inform you about the re-use of your data for a specific study conducted by Roche SAS, a French affiliate of Roche Group, as well as to inform you about your rights in relation to your data.

Presentation of the descriptive study on the treatment pathways of breast cancer patients in the United States using FLATIRON® data (MADISON)

The primary objective of this study is to describe the management of breast cancer patients in the United States.

It also aims to describe the evolution of this treatment over the years (since 2013) and the impact of the new treatments which appeared from 2019.

The results of the study will improve the scientific knowledge about breast cancer treatments.

This study will have no impact on your care or on the relationship you have with your healthcare staff. It simply aims to re-use your health and demographic data already collected during your medical treatment.

Protecting Your Data

Roche SAS ("Roche") is responsible for processing your data used in this study. Accordingly, Roche is committed to the confidential and secure collection and use of your data.

This study was authorized by the National Commission of Informatics and Freedoms (CNIL) on 09/08/2023 after favorable opinion of the Comité Ethique et Scientifique pour les Recherches, les études et les Evaluations en santé (CESREES) (Ethical and Scientific Committee for Research, Studies and Evaluations in Healthcare).

The processing of your data is based on Roche's legitimate interest as a pharmaceutical company to perform medical research in order to better understand the conditions for which it is developing drugs and the processing of your health data is necessary for scientific research purposes.

This research will analyze your demographic and medical data exclusively to answer the scientific questions in this study.

Your personal data will be kept strictly confidential throughout this study. They will be coded, i.e. you are identified by a code number for the purposes of the study, without mentioning your first and last names.

Only your doctor and the research team responsible for your follow-up under his/her authority will have access to your identity.

Your coded (i.e. non-identifying) medical data will be accessible to Roche research professionals. It may be accessible - always in a confidential and non-identifying way - to independent experts who may re-analyze the data to verify the study results under strict security conditions.

For the purpose of this study, Roche will only access but not store your remotely coded data.

Your data and rights

In accordance with the General Data Protection Regulation (GDPR), you have the following rights: right of access to your data, right of rectification, right of opposition, right to restriction of use and right to erasure.

To exercise your rights, as Roche does not have access to your identity, it is recommended that you first contact your doctor.

If you prefer, you can contact the Roche Data Protection Officer directly by post (Roche, Data Protection Officer, 4 Cours de l'Île Seguin 92650 Boulogne-Billancourt CEDEX, France) or by email (france.donneespersonnelles-pharma@roche.com). In this case, your identity (first name, last name) will be transmitted to him.

Point of attention: In order to keep your data strictly confidential and protect your right to privacy, Flatiron Health has preliminarily pseudonymized your personal data under the standards of the U.S. Health Insurance Portability and Accountability Act (HIPAA) of 1996. This pseudonymization process is designed to minimize the risk of re-identifying your data.

In practice, this process makes your re-identification even by Roche & Flatiron Health particularly complex. Therefore, in the event you wish to exercise your rights with regard to your data, Roche and Flatiron Health will need to request additional information from you in order to be able to identify the data about you and thus respond appropriately to your request.

In case you are not satisfied with it, you can also lodge a complaint with the Data Protection Commission (CNIL): <https://www.cnil.fr/fr/plaintes>.