

International health data warehouse for children and adolescents with chronic myeloid leukemia (I-CML-Ped Data Warehouse)

Information letter for the patient's parents

This notice is intended to provide, to the person with parental authority, a first level of information about the I-CML-Ped data warehouse set up for chronic myeloid leukemia (CML) in children and adolescents.

After reading this, you have the right to object to your child's data being stored in the I-CML-Ped data warehouse. Please, visit the Poitiers University Hospital website (<https://www.chu-poitiers.fr/specialites/centre-dinvestigation-clinique/axe-thor/#1595582696232-9e79c2cf-69e9>) for more information.

1/ What is the I-CML-Ped data warehouse ?

The aim of the I-CML-Ped data warehouse is to collect and store data from several sources in a single database over a long period of time, often from 10 to 20 years.

This data is intended for use in research by authorized professionals.

2/ I-CML-Ped data warehouse objectives

Health data can help doctors to provide better care for patients with CML, but it can also be used for research, to find solutions that improve health for patients with CML. All recorded data can be studied to improve our knowledge of the disease and treatments.

3/ I-CML-Ped data warehouse

Your child was diagnosed with CML and appropriate treatment is conducted. It is important for doctors to record all the data concerning your child's disease, his/her treatment and follow-up. Research based on these data will enable doctors to improve knowledge of CML and treatments. Your child's health data will be placed into the I-CML-Ped data warehouse. The Poitiers University Hospital supports the collection of data from children and adolescents with CML.

4/ Protection of collected data

The I-CML-Ped data warehouse does **not contain any administrative data enabling your child to be directly identified**, such as surnames, first names, addresses, etc.

Responsibility : The implementation of the I-CML-Ped data warehouse is part of the performance of a public interest mission entrusted to the data controller, Poitiers University Hospital. The use of the health data of your child could be used for reasons of public interest in the field of public health.

Accessibility: Data stored in the I-CML-Ped data warehouse is not accessible to the public.

Access to this data is restricted to authorized persons. These persons are :

- people responsible for setting up and implementing the I-CML-Ped data warehouse at Poitiers University Hospital, the technical and scientific teams who organize the warehouse and manage its security, as well as the French subcontractor (CASD, Secure Data Access Centre - health data host);
- researchers carrying out healthcare research projects, such as health establishments, public authorities and institutions, patient associations and European agencies. However, they can only use the data within the framework of well-defined projects and subject regulatory formalities.

5/ Use of data under authorization

In the context of research, data may be shared with researchers in Europe and, in exceptional cases, outside Europe. Within Europe, the protection of your data is guaranteed (EU Regulation 2016/679). Outside Europe, your data may be shared with researchers in countries that do not have the same level of data protection requirements. In such cases, Poitiers University Hospital will check the guarantees provided by the recipient (the countries concerned are subject to an adequacy decision by the European Commission).

Storage : Data from your child's healthcare facility are kept in the I-CML-Ped data warehouse for 20 years from the date of collection. At the end of this period, the data will be deleted from the I-CML-Ped data warehouse. It will continue to be stored by the original health care facility as part of your child's medical follow-up.

6/ Your rights and those of your child:

Your child has rights regarding his/her data stored in the I-CML-Ped data warehouse. Until he or she reaches the age of majority, the following rights may be exercised by the holders of parental authority:

- **Opposition** to the collection of his/her health data,
- **Access** and **correction** of his/her inaccurate or incomplete recorded data,
- **Deletion** of his/her data,
- **Restriction on the use** of his/her data.

To exercise these rights, please **contact the CHU of Poitiers Data Protection Officer** by e-mail : dpo@chu-poitiers.fr or by mail : CHU de Poitiers - Direction Générale, Délégué à la Protection des Données - 2 Rue de la Milétrie - 86021 POITIERS CEDEX France

Exercising your right to object will not affect your child's care or relationship with the medical team of the structure where he or she is being cared for.

When your child comes of age, he or she can revoke the rights you have granted on his or her behalf. The procedure is the same as that described above.

7/ Recourse

If, after contacting the Poitiers University Hospital, you feel that you have not received a response in line with your expectations about your child's rights concerning the use of his/her

data, you can contact the Commission Nationale de l'Informatique et des Libertés (CNIL) to make a complaint (<https://www.cnil.fr/plaintes> or CNIL - Service des Plaintes - 3 Place de Fontenoy - TSA 80715 - 75334 PARIS CEDEX 07 France). The CNIL is the supervisory authority responsible for overseeing the application of data protection rules, in order to protect the fundamental rights and freedoms of individuals with regard to data processing.

You will not be informed individually of the research carried out and the results obtained using data from the I-CML-Ped data warehouse on chronic myeloid leukemia in children and adolescents. If you would like to find out more about the studies using your child's data in the I-CML-Ped data warehouse, please consult the I-CML-Ped data warehouse transparency portal on the Poitiers University Hospital website (<https://www.chu-poitiers.fr/specialites/centre-dinvestigation-clinique/axe-thor/#1595582696232-9e79c2cf-69e9>). These studies will also be included in the Health Data Hub's [public directory](#).

8/ Contacts for further information or in an emergency

If you would like further information or if you encounter any problems during the participation of your child, please contact the physician-investigator or a member of his team:

Name :

Telephone :

Or Medical stamp

Made in duplicate

A copy given to the patient

A copy kept in the patient's medical file