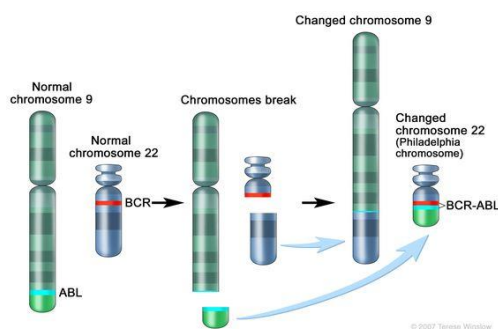


International Health Data Warehouse for Children and Adolescent with Chronic Myeloid Leukemia



GENERAL INFORMATION

Chronic myeloid leukemia (CML) is a malignant disease of the blood and bone marrow. It is characterized by excessive and persistent production of white blood cells (or leukocytes). The disease is linked to the appearance of a chromosomal abnormality characterized by the fusion of two chromosomes in hematopoietic bone marrow stem cells, resulting in the appearance of a small abnormal chromosome, the Philadelphia chromosome. The causes of its genesis are as yet unknown.



For more information on CML : <https://lmc-cml.org/>

CML is a rare disease in children and adolescents, accounting for between 2% and 3% of childhood leukemias. The characteristics of this disease have to be better described, and treatment modalities are evolving in this age group. Thanks to research advances, this disease has benefited from new treatments for several years now.

In 2011, we set up the International Childhood and Adolescent CML Registry (I-CML-Ped Study) at the Poitiers University Hospital, to improve the knowledge and the treatment of this disease. Given its importance in terms of public health and in order to comply with current regulations, this registry evolved in 2025 into a health data warehouse, known as health data warehouse I-CML-Ped. We record data on all CML patients under 18 years of age (regardless of disease stage, type of treatment, etc.). This data warehouse collects retrospective data (patients with a diagnosis from 2000 onwards) and prospective data reported in patients' clinical records and/or in existing databases.

MAIN OBJECTIVES

The main objectives of this data warehouse are the following:

- 1- To describe the characteristics of CML in a cohort of patients under the age of 18
- 2- To set up therapeutic strategies
- 3- To identify prognostic factors
- 4- To determine a prognostic score to optimize individual treatment choices
- 5- To determine the side effects and long-term effects of treatments

POPULATION

All patients under 18 years of age with newly diagnosed CML are eligible. Patients are eligible regardless of disease stage, type of treatment, and whether or not they are in a clinical trial.

METHODS

The health data warehouse I-CML-Ped was declared compliant with the CNIL (Commission for Information Technology and Civil Liberties) reference Framework relating to the processing of personal data implemented for the purpose of creating data warehouses in the field of health on December 11, 2024 under the number **2236819**. **An application for authorization from the CNIL is in progress in order to allow the reuse of data for research projects.**

It is registered on ClinicalTrials.gov under identifier number : NCT01281735.

The study is strictly observational. It **collects** retrospective and prospective data from patients' clinical records and/or existing databases.

REGISTRATION PROCESS OF REGISTRATION FORM

Registration procedure and data collection :

1. Information of patients and parents by providing :
 - Information letter for parents,
 - Information letter for minors,
 - Information letter for pediatric patients who have reached the age of majority
2. Filling out the registration form
3. Send the registration form to the Clinical Research Associate in charge of the data warehouse, Micheline KABORE, by email to ICMLPed@chu-poitiers.fr and barkwende-mecheline.kabore@chu-poitiers.fr)
4. Confirmation of Patient inclusion : the registration form with the inclusion number will then be returned to you.

5. Complete the Case Report Form and send it to us in secure form.
6. Update tracking data at least once a year

RIGHTS

Patients or parents whose children are involved in this study may object to the use of their data at any time.

If they have any questions or wish to exercise their rights (or those of their beneficiaries), they can contact the Data Protection Officer (DPO) at Poitiers University Hospital :

> by e-mail to the following address : dpo@chu-poitiers.fr or

> by post : CHU de Poitiers - Direction Générale, Délégué à la Protection des Données - 2 Rue de la Milétrie - 86021 POITIERS CEDEX (France)