

# Les STIMS - Patients who did not relapse after stopping tyrosine kinase inhibitor treatment for chronic myeloid leukaemia

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## General

### Identification

Detailed name Patients who did not relapse after stopping tyrosine kinase inhibitor treatment for chronic myeloid leukaemia

Sign or acronym Les STIMS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL n°1245229

### General Aspects

Medical area Immunology

Keywords Tyrosine kinase inhibitors, stopping treatment, complete molecular remission, relapse.

### Scientific investigator(s) (Contact)

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Organization Université Bordeaux

Name of the director Bouvier

Surname	Séverine
Collaborations	
Funding	
Funding status	Mixed
Details	PHRC 2006
<b>Governance of the database</b>	
Sponsor(s) or organisation(s) responsible	Université Bordeaux Ségalen
Organisation status	Public
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Subjects meeting inclusion and exclusion criteria must sign a consent
<b>Database objective</b>	
Main objective	To monitor patients who discontinued tyrosine kinase inhibitors for at least two years in order to determine their molecular status and collate potential late molecular relapses.
Inclusion criteria	Men or women aged 18 years and older Chronic myeloid leukaemia in chronic or accelerated phase under treatment with Imatinib for at least 3 years Complete molecular remission under treatment with Imatinib for at least 2 years For the women old

enough to procreate, a method of effective contraception Subjects covered by or affiliated with a social security scheme Negative HIV serology and absence of chronic hepatitis B or C Free and informed consent in writing Molecular monitoring as recommended by European "LeukemiaNet"

## Population type

Age  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)

Population covered Sick population

Gender  
Male  
Woman

Geography area National

Detail of the geography area France

## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY) 2010

### Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 100

### Data

Database activity Current data collection

Type of data collected  
Clinical data  
Biological data

Clinical data (detail) Medical registration

Biological data (detail) BCR-ABL transcript level

Presence of a biobank No

Health parameters studied Health event/morbidity

Health event/mortality  
Health care consumption and services

Care consumption (detail)

Medicines consumption

## Procedures

Data collection method

After the accuracy of the data is verified, they are collected by mail or directly on site by the person in charge of verification every 3-6 months. The same person enters the data in an Access database, which is then transferred to a biostatistician. This is done centrally.

Participant monitoring

Yes

Details on monitoring of participants

The BCR-ABL transcript level is measured by quantitative RT-PCR in molecular biology laboratories every 3 months following a blood sample from the patient.

Links to administrative sources

No

## Promotion and access

### Promotion

Link to the document

<http://tinyurl.com/Pubmed-STIMS>

Description

List of publications in Pubmed

### Access

Terms of data access (charter for data provision, format of data, availability delay)

Publications Data are accessible by other researchers by request if required (via secure Excel files graphics, etc.)

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only