# Secured Access to innovative medicines for CHildren, adolescents and young adults with cAncer

**First published:** 01/02/2024

**Last updated:** 04/11/2026

Data source | Human | Drug registry

Spontaneous reports of suspected adverse drug reactions

## Administrative details

### Administrative details

**Data source ID**

1111161

**Data source acronym**

SACHA INTERNATIONAL

**Data holder**

Gustave Roussy

**Data source type**

Drug registry

Spontaneous reports of suspected adverse drug reactions

**Main financial support**

Funds from patients organisations, charity and foundations

Other

**Care setting**

Hospital inpatient care

Hospital outpatient care

Secondary care – specialist level (ambulatory)

**Data source qualification**

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

No

**Data source website**

SACHA

# Contact details


## Pablo Berlanga pablo.berlanga@gustaveroussy.fr

**Main**

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# Data source regions and languages

**Data source countries**

Australia

Austria

Belgium

Denmark

France

Ireland

Italy

New Zealand

Slovenia

Spain

Sweden

United Kingdom

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**Data source languages**

English

## Data source establishment

**Data source established**

01/01/2020

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**Data source time span**

**First collection:** 01/01/2020

The date when data started to be collected or extracted.

# Publications

## Data source publications

Measuring Safety and Outcomes for the Use of Compassionate and Off-Label Therapies for Children, Adolescents, and Young Adults With Cancer in the SACHA-France Study

Chemo-immunotherapy with dinutuximab beta in patients with relapsed/progressive high-risk neuroblastoma: does chemotherapy backbone matter?

Centralized Investigator Review of Radiological and Functional Imaging Reports in Real-World Oncology Studies: The SACHA-France Experience

Chemo-Immunotherapy Rescue for High-Risk Neuroblastoma Patients With Progressive Disease Before High-Dose Chemotherapy: Real-World Data From the SACHA-France Study

## Studies

### List of studies that have been conducted using the data source

An ambispective real-life study on the effectiveness and safety of crizotinib for pediatric patients with ALCL or IMT, treated within the SACHA Cohort.

## Data elements collected

### The data source contains the following information

**Disease information**

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

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**Disease details (other)**

Collection of real-world safety and efficacy data of compassionate and off label used innovative anti-cancer therapies, with adequate pharmacovigilance declaration. For off-label therapies, they are only collected if first approved in adults in Europe after the implementation in 2017 of the EU Pediatric Regulation (1901/2006/EC)

### Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

Yes

### Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

No

### Hospital admission and/or discharge

No

### ICU admission

Is information on intensive care unit admission available?

No

### Cause of death

Captured

### Cause of death vocabulary

Other

### Cause of death vocabulary, other

Cancer, AE related to drug of interest, other reason (and then free text)

### Prescriptions of medicines

Captured

### Prescriptions vocabulary

DrugBank

### Dispensing of medicines

Captured

### Dispensing vocabulary

DrugBank

### Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

### Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

### Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

### Indication vocabulary

Other

### Indication vocabulary, other

ICCC-3

## Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

## Administration of vaccines

No

## Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

## Procedures vocabulary

Not coded (Free text)

## Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

Yes

## Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

## Genetic data

Are data related to genotyping, genome sequencing available?

Captured

### Genetic data vocabulary

Other

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### Genetic data vocabulary, other

Drop-down box values

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### Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs ( objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Captured

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### Biomarker data vocabulary

Other

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### Biomarker vocabulary, other

Drop-down box values

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### Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

No

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### Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

No

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### Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

Yes

### Unique identifier for persons

Are patients uniquely identified in the data source?

No

### Diagnostic codes

Captured

### Diagnosis / medical event vocabulary

Other

### Diagnosis / medical event vocabulary, other

ICCC-3

### Medicinal product information

Captured

### Medicinal product information collected

Brand name

Dose

Formulation

Route of administration

### Medicinal product vocabulary

Other

### If 'other,' what vocabulary is used?

Drop-down box values

**Quality of life measurements**

Captured

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**Quality of life measurements vocabulary**

Not coded (Free text)

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**Lifestyle factors**

Not Captured

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**Sociodemographic information**

Captured

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**Sociodemographic information collected**

Age

Country of origin

Gender

# Quantitative descriptors

## Population Qualitative Data

**Population age groups**

Paediatric Population (< 18 years)

Adults (18 to < 46 years)

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**Estimated percentage of the population covered by the data source in the catchment area**

In France, early drug access before marketing authorization is granted by the French National Agency for the Safety of Medicines and Health Products (ANSM)

in case on unmet need, positive benefit/risk balance of preliminary data and no access within clinical trials. More than 90% anticancer prescriptions approved by the ANSM from 01/01/2024 to 31/12/2024 for patients < 18 years-old are included in the SACHA-France study.

## Population

**Population size**

1.600

**Active population size**

600

## Population by age group

| Age group | Population size | Active population size |
|---|---|---|
| Paediatric Population (< 18 years) | 1.450 | 550 |
| Adults (18 to < 46 years) | 150 | 50 |

## Median observation time

**Median time (years) between first and last available records for unique individuals captured in the data source**

1,00

**Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt**

2,00

# Data flows and management

## Access and validation

**Governance details**

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

### SACHA Methodology and Governance

English (416.73 KB - PDF)

View document

**Biospecimen access**

Are biospecimens available in the data source (e.g., tissue samples)?

No

**Access to subject details**

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

**Description of data collection**

Electronic eCRF for individual patients

## Event triggering registration

**Event triggering registration of a person in the data source**

Start of treatment

**Event triggering de-registration of a person in the data source**

End of treatment

**Event triggering creation of a record in the data source**

Voluntary enrollmet of patient by physician after prescription of an anticancer off label or compassionate use medicine

# Data source linkage

**Linkage**

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

No

# Data management specifications that apply for the data source

**Data source refresh**

Quarterly

**Informed consent for use of data for research**

Other

**Possibility of data validation**

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

Yes

### Data source preservation

Are records preserved in the data source indefinitely?

Yes

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### Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

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### Informed consent, other

According to the French Law (Loi Jardé), only collection of non-opossition is needed

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### Data source last refresh

17/04/2023

## Common Data Model (CDM) mapping

### CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No