

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

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Data source

Drug registry

Spontaneous reporting of adverse drug reactions

Administrative details

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1111161>

Data source ID

1111161

Data source acronym

SACHA France

Data holder

[Gustave Roussy](#)

Data source type

Drug registry

Spontaneous reporting of 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

<https://www.gustaveroussy.fr/fr/sacha>

Contact details

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Data source regions and languages

Data source countries

France

Data source languages

English

Data source establishment

Data source established

01/01/2020

Data source time span

First collection: 01/01/2020

The date when data started to be collected or extracted.

Publications

Data source publications

[Securing access to innovative anticancer therapies for children, adolescents, and young adults outside clinical trials: The SACHA study of the French Society of Pediatric Oncology](#)

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

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

Prescriptions of medicines

Captured

Prescriptions vocabulary

DrugBank

Dispensing of medicines

Captured

Dispensing vocabulary

DrugBank

Advance 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

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

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

Biomarker data vocabulary

Other

Patient-reported outcomes

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

No

Patient-generated data

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

No

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

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dose

Formulation

Route of administration

Medicinal product vocabulary

Other

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Adults (18 to < 46 years)

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. All anticancer prescriptions approved by the ANSM from 01/01/2020 to 31/12/2021 for patients < 18 years-old have been analyzed. In the 2020-2021 period, 28 different therapies were prescribed to 188 patients in a French Society of Pediatric Oncology (SFCE) center. Of them, 14 patients never received the prescribed drug, mainly due to early death. 107 of 174 (61%) eligible patients from 21 SFCE centers were included in the SACHA study (56% in 2020 and 67% in 2021)

Population

Population size

500

Active population

Active population size

300

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

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

Approval for publication

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

Yes

Informed consent, other

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

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