

# BELpREG: the Belgian pregnancy registry

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

**Last updated:** 17/10/2024

Data source

Human

Other

## Administrative details

### Administrative details

**Data source ID**

1111212

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**Data source acronym**

BELpREG

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**Data holder**

[KU Leuven](#)

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**Data source type**

Other

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**Data source type, other**

Prospective pregnancy registry, not medicine or disease specific

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**Main financial support**

Funding by own institution

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### Care setting

Hospital outpatient care

Primary care – GP, community pharmacist level

Secondary care – specialist level (ambulatory)

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### 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

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### Data source website

<https://www.belpreg.be>

## Contact details

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## Data source regions and languages

### Data source countries

Belgium

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### Data source languages

Dutch

English

French

# Data source establishment

## Data source established

01/11/2022

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## Data source time span

**First collection:** 06/11/2022

The date when data started to be collected or extracted.

# Publications

## Data source publications

[Development and design of the BELpREG registration system for the collection of real-world data on medication use in pregnancy and mother-infant outcomes](#)

# Studies

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

[Safety of IL-17 and IL-23 inhibitors as treatment for immune mediated inflammatory diseases at conception and during pregnancy: an ENTIS study. \(SAFE-PPREG\)](#)

## 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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## **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

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## **Pregnancy and/or neonates**

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

Yes

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## **Hospital admission and/or discharge**

Yes

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## **ICU admission**

Is information on intensive care unit admission available?

Yes

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## **Cause of death**

Captured

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## **Cause of death vocabulary**

Not coded (Free text)

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## **Prescriptions of medicines**

Captured

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## **Prescriptions vocabulary**

ATC

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## **Dispensing of medicines**

Captured

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## **Dispensing vocabulary**

ATC

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## **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

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## **Contraception**

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

Yes

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## **Indication for use**

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

Captured

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## **Indication vocabulary**

ICD

MedDRA

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## **Medical devices**

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

No

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## **Administration of vaccines**

Yes

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## **Procedures**

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

Captured

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## **Procedures vocabulary**

Not coded (Free text)

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## **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

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## **Clinical measurements**

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

No

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## **Genetic data**

Are data related to genotyping, genome sequencing available?

Not Captured

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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.

Not Captured

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## **Patient-reported outcomes**

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

Yes

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## **Patient-generated data**

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

Yes

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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.

No

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## **Unique identifier for persons**

Are patients uniquely identified in the data source?

Yes

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## **Diagnostic codes**

Captured

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## **Diagnosis / medical event vocabulary**

ICD

MedDRA

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## **Medicinal product information**

Captured

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## **Medicinal product information collected**

Active ingredient(s)

Brand name

Dosage regime

Dose

Route of administration

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### **Medicinal product vocabulary**

ATC

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### **Quality of life measurements**

Captured

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### **Quality of life measurements vocabulary**

Not coded (Free text)

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### **Lifestyle factors**

Captured

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### **Lifestyle factors**

Alcohol use

Other

Tobacco use

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### **Sociodemographic information**

Captured

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### **Sociodemographic information collected**

Age

Education level

Ethnicity

Marital status

Other

Socioeconomic status

Quantitative descriptors

## **Population age groups**

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

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

the registry was established in november 2022. Currently, we have enrolled about 400 pregnant women, but the registry is growing every day as more healthcare professionals in Belgium are becoming aware of BELpREG and motivate their pregnant patients to participate. Overall, 60 000 pregnant women per year in Flanders, Belgium (i.e., Dutch speaking part of Belgium).

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## **Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)**

enrolment in BELpREG by pregnant women is voluntary.

## Family linkage

### **Family linkage available in the data source permanently or can be created on an ad hoc basis**

Permanently

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### **Family linkage available between the following persons**

Mother-child

## Population

## Population size

400

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## Active population size

400

## Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	100	100
Adults (18 to < 46 years)	400	400

## Median observation time

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

31.00

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

31.00

## 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).

<https://doi.org/10.3389/fdsfr.2023.1166963>

## **Biospecimen access**

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

No

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## **Access to subject details**

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

Yes

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## **Description of data collection**

digital questionnaires as part of a REDCap project

# Event triggering registration

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

Other

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## **Event triggering registration of a person in the data source, other**

Being currently pregnant

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

Other

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

Miscarriage, elective abortion, ectopic pregnancy or stillbirth

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

pregnant women enroll themselves by completing the digital informed consent through the BELpREG website (see [www.belpreg.be](http://www.belpreg.be))

# 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

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## **Linkage description, possible linkage**

Not yet, but opportunities with linkage to other databases in Belgium are being explored (e.g., with respect to infant development, health administrative data, ..). In the future, data pooling with BELpREG data may also occur with other institutes belonging to the European Network of Teratology Information Services (ENTIS) who also collect medication exposure in pregnancy data and outcomes.

# Data management specifications that apply for the data source

## **Data source refresh**

Monthly

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

Required for all studies

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### **Possibility of data validation**

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

Yes

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### **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?

No

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### **Data source last refresh**

06/10/2023

## Common Data Model (CDM) mapping

### **CDM mapping**

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

No