European Clinical Research Alliance On Infectious Diseases (ECRAID)-Base

First published: 01/02/2024

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Data source | Human | Biobank | Hospital inpatient records | Other

Administrative details

Administrative details

Data source ID

1111205

Data source acronym

ECRAID-Base

Data holder

European Clinical Research Alliance on Infectious Diseases (ECRAID)

Data source type

Biobank

Hospital inpatient records

Other

Data source type, other

Electronic health records

Main financial support

European public funding

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – GP, community pharmacist level

Primary care – specialist level (e.g. paediatricians)

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.ecraid.eu/

Contact details

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Main

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Data source regions and languages

Data source countries

Albania

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czechia

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Israel

Italy

Latvia

Lithuania

Netherlands

Norway

Poland

Portugal

Romania

Serbia

Slovakia

Slovenia

Spain

Sweden

Switzerland

Türkiye

United Kingdom

Data source languages

English

Data source establishment

Data source established

01/03/2021

Data source time span

First collection: 04/08/2022

The date when data started to be collected or extracted.

Publications

Data source publications

Perpetual observational studies: new strategies to support efficient implementation of observational studies and randomized trials in infectious diseases

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

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.

No

Pregnancy and/or neonates

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

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

MedDRA

SNOMED CT

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

CDISC CT, SNOMED CT

Dispensing of medicines

Captured

Dispensing vocabulary

other

Dispensing vocabulary, other

CDISC CT, SNOMED CT

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

MedDRA

SNOMED CT

Medical devices

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

Yes

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

Other

SNOMED CT

Procedures vocabulary, other

CDISC CT

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.

No

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

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

Biomarker vocabulary, other

CDISC CT

Patient-reported outcomes

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

Yes

Patient-generated data

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

Yes

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

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

MedDRA

Other

SNOMED CT

Diagnosis / medical event vocabulary, other

CDISC CT

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

ATC

RxNorm

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Ethnicity

Gender

Socioeconomic status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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

0.005% (This rough estimate is based on the number of patients enrolled at one site i.e. Centre hospitalier universitaire à Limoges of the POS-VAP study as the numerator and the population of the area covered by this hospital i.e. Nouvelle Aquitaine region as the denominator)

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)

None

Family linkage

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

Ad hoc

Population

Population size

2462

Active population size

386

Population by age group

Age group	Population size	Active population size
Adults (18 to < 46 years)	399	62
Adults (46 to < 65 years)	740	112
Elderly (≥ 65 years)	1323	212
Adults (65 to < 75 years)	700	105
Adults (75 to < 85 years)	460	86
Adults (85 years and over)	163	21

Median observation time

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

0.08

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

0.04

Data flows and management

Access and validation

Biospecimen access

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

Yes

Biospecimen access conditions

Biospecimen reuse will be mediated by the ECRAID-Base DAC

Access to subject details

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

No

Description of data collection

The POSs in ECRAID-Base collect study-specific, participant-level data using dedicated electronic Case Report Forms (eCRF) implemented using the CASTOR electronic data capture (EDC) system.

Event triggering registration

Event triggering registration of a person in the data source

Other

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

Eligibility criteria met and Informed consent obtained

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

Death

Other

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

Discharge, End of study period, Withdrawal

Event triggering creation of a record in the data source

Eligibility criteria met and Informed consent obtained

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?

Yes

Linkage description, pre-linked

In POS-Disease X, the routine diagnostics assay data from the study site's local laboratory information management system (LIMS) will be exported and directly uploaded to the UMCU digital research environment (DRE) by the local study site team

Linkage description, possible linkage

Patient samples collected in the POSs will be transferred to the Laboratory of Medical Microbiology of the University of Antwerp (UA) for long-term storage and further analysis in the "Biobank Antwerp" (BB190007).

Patient samples will be registered with a unique sample ID in the laboratory information management system (ClinSLIMS) used at the Laboratory of Medical Microbiology of the University of Antwerp
Additional sample analyses will be performed at the central Lab (i.e. University of Antwerp) and the analysis results will be uploaded to the UMCU DRE. This data can be linked with the participant-level clinical data from the eCRFs

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Biobank Antwerp

Linkage variable

Unique Subject ID and sample ID

Pre linked

Is the data source described created by the linkage of other data sources?

Yes

Data source, other

Laboratory information management system (LIMS)

Linkage variable

Unique Subject ID

Data management specifications that apply for the data source

Data source refresh

Monthly

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

Participants provide broad consent for future use. Intervention studies require specific consents.

Common Data Model (CDM) mapping

CDM mapping

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

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data source ETL CDM version

5.4

Data source ETL frequency

6,00 months

Data source ETL status

In progress

Data source ETL specifications (link)

https://github.com/edencehealth/ecraid_etl