DARWIN EU® - Characterising microbiological pathogen and antibiotic resistance data in DARWIN EU® Data Sources a priori mapped to the OMOP CDM

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001118

Study ID

1000001118

DARWIN EU® study

Yes

Study countries

Croatia

Estonia

Finland

France

Spain

United Kingdom

United States

Study status

Ongoing

Research institutions and networks

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Italy

Lithuania

Netherlands

Norway

Poland

Portugal

Spain

Sweden

United Kingdom

United States

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Network

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/07/2026

Actual: 13/07/2026

Study start date
Planned: 10/09/2026

Actual: 10/09/2026

Date of final study report
Planned: 07/02/2027

Study protocol

DARWIN EU_Protocol_P5-C1-019_V4.0.pdf (1.87 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Antimicrobial resistance (AMR) surveillance and microbiological pathogen data characterisation within DARWIN EU® real-world data sources mapped to OMOP CDM

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Data collection methods:

Secondary use of data

Study design:

Retrospective descriptive observational study

Main study objective:

1. To estimate the annual rate of recorded pre-selected bacterial pathogen episodes over time, overall and by age and sex.
2. To characterise microbiological data associated with episodes of the pre-selected bacterial pathogens in terms of:
a. The proportion of pathogen episodes with recorded Gram staining, microbiological culture, rapid antigen testing, molecular testing, phenotypic characteristics (e.g. haemolysis patterns, catalase, coagulase, oxidase, indole, urease, and motility), and antimicrobial susceptibility and resistance information, overall and by age and sex;
b. The characteristics associated with pathogen episodes, including age, sex, type of infection, and prior and post antibiotic use in relation to the pathogen

episode index date.

Study design details

Outcomes

The pre-selected bacterial pathogens, based on those included in the European Antimicrobial Resistance Surveillance Network (EARS-Net)[4], are Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter species, Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis, and Enterococcus faecium. Pathogen identification will be based on relevant records across the OMOP CDM, including condition, observation, and microbiological records. Microbiological information associated with these pathogen episodes will be characterised separately.

For Objective 2a, the frequency of recording of the following microbiological data related to the pre selected bacterial pathogens will be assessed:

• Gram staining;

• Microbiological culture;

• Rapid antigen testing;

• Molecular testing;

• Phenotypic characteristics, including biochemical identification/profile, catalase, coagulase, oxidase, haemolysis, indole, urease, and motility, where available; and

• Antibiogram or antimicrobial susceptibility/resistance result for an identified microorganism.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No