# Indications for systemic fluoroquinolone prescribing in Europe: a descriptive population based study

**First published:** 06/09/2017

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS20889

**Study ID**

25386

**DARWIN EU® study**

No

**Study countries**

France

Germany

United Kingdom

**Study description**

A descriptive analysis of indications for treatment with systemic fluoroquinolone antibiotics in Summary of Product Characteristics across the European Economic Area (EEA) will first be conducted. Secondly a descriptive analysis of clinical indications for treatment with systemic fluoroquinolone antibiotics in France, Germany and UK will be conducted using electronic health records. Time trends in fluoroquinolone antibiotic use will be evaluated. Indications for acute sinusitis, acute bronchitis and uncomplicated urinary tract infection will specifically be evaluated.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

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

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Daniel Morales

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 10/10/2016

Actual: 10/10/2016

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**Study start date**

Planned: 17/10/2016

Actual: 17/10/2016

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**Data analysis start date**

Planned: 14/11/2016

Actual: 14/11/2016

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**Date of final study report**

Planned: 13/11/2017

Actual: 06/08/2018

## Sources of funding

- EMA

# Study protocol

EUPAS20889.protocol.pdf (60 KB)

# Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To provide a descriptive analysis of broad indications for treatment with systemic fluoroquinolone antibiotics in Summary of Product Characteristics across the European Economic Area (EEA). To provide a descriptive analysis of clinical indications for treatment with systemic fluoroquinolone antibiotics in France, Germany and UK electronic health records

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Descriptive analysis

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J01MA) Fluoroquinolones

Fluoroquinolones

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**Medical condition to be studied**

Sinusitis

Bronchitis

Urinary tract infection

## Population studied

**Short description of the study population**

Patients were included from the IMS® Disease Analyzer France and Germany with a minimum period of 1 year follow-up defined according to their consultation and prescribing observability.

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Special population of interest**

Other

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**Special population of interest, other**

Sinusitis, Bronchitis, Urinary tract infection patients

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**Estimated number of subjects**

200000

## Study design details

**Outcomes**

1) Descriptive analysis of the proportion of Summary of Product Characteristics across Europe with an indication for treatment for different indication categories. 2) Broad clinical indications for incident fluoroquinolone antibiotic prescribing in primary care.

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**Data analysis plan**

The Summary of Product Characteristics for fluoroquinolone containing antibiotic products will be screened to identify what proportion have an indication listed for sinusitis, bronchitis and urinary tract infection. Incident fluoroquinolone prescriptions will be identified for adults in each electronic health record database. Read and ICD codes will be screened to identify the likely clinical indication for such recording. These will be broadly categorised according to different systems and specific information provided for sinusitis, bronchitis and urinary tract infection cross-sectionally. Time trends in the use of incident fluoroquinolone antibiotics will be provided for different broad system categories including for sinusitis, bronchitis and urinary tract infection for each database were data is available.

## Documents

**Study results**

Summary.results.pdf (120.24 KB)

**Study publications**

Morales DR, Slattery J,Pinheiro L, Kurz X, Hedenmalm K. Indications for Systemi…

# 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.

## Data sources

**Data source(s)**

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

**Data sources (types)**

Electronic healthcare records (EHR)

## 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

Unknown