A Drug Utilization Study to Evaluate the Effectiveness of Risk Minimization Measures (RMMs) for Abrocitinib in the EU Using Electronic Healthcare Data (B7451085)

First published: 29/11/2024

Last updated: 07/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000345

Study ID

1000000345

DARWIN EU® study

No

Study countries

Denmark

France

Hungary

Spain

Sweden

Study description

The study objectives are to evaluate, to the extent measurable in the available routinely collected data, indicators of healthcare professional's adherence to the risk minimization measures in accordance with the abrocitinib Summary of Product Characteristics and prescriber's brochure.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | **Educational Institution** | **ENCePP partner**

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

The SIGMA Consortium (SIGMA)

Denmark
European Union
France
Germany
Italy
Netherlands
Norway

Spain

Sweden

United Kingdom

First published: 10/02/2013

Last updated: 19/01/2026

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/06/2022

Actual: 10/06/2022

Study start date

Planned: 31/12/2024

Actual: 31/12/2024

Data analysis start date
Planned: 16/05/2028

Date of interim report, if expected
Planned: 15/11/2025

Date of final study report
Planned: 15/11/2028

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

B7451085_ABROCITINIB PROTOCOL AMENDMENT 1_23MAY2024.pdf (590.14 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

B7451085

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Study design:

This will be a descriptive drug utilization study using secondary data from healthcare databases in Denmark, France, Sweden, Spain and Hungary.

Main study objective:

The study objectives are to evaluate, to the extent measurable in the available routinely collected data, indicators of healthcare professional’s adherence to the risk minimization measures in accordance with the abrocitinib.
Summary of Product Characteristics and prescriber’s brochure: indicators of adherence to performing laboratory tests of complete blood count (CBC), lipid panel, hepatitis B/C, and tuberculosis (TB) screening prior to initiation of abrocitinib treatment, indicators of adherence to performing laboratory tests of CBC and lipid panel at week 4 (± 2 weeks) after initiation of abrocitinib treatment, indicators of adherence to consideration of risk factors for venous thromboembolism (VTE), major adverse cardiovascular event (MACE), malignancy excluding non-melanoma skin cancer (NMSC), NMSC, and serious infection prior to treatment with abrocitinib, indicators of adherence to avoid live attenuated vaccines immediately prior to and during treatment with abrocitinib, indicators of adherence to contraindications for use during pregnancy, indicators of adherence to contraindications for use among patients with severe hepatic impairment, indicators of adherence to no use in patients aged < 12 years, and indicators of adherence to recommended posology (estimated average daily dose).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

CIBINQO

Study drug International non-proprietary name (INN) or common name

ABROCITINIB

Anatomical Therapeutic Chemical (ATC) code

(D11AH08) abrocitinib

abrocitinib

Additional medical condition(s)

Atopic dermatitis

Population studied

Short description of the study population

The study population will include patients with a dispensing of abrocitinib as recorded in routinely collected electronic healthcare data in Denmark, France, Sweden, Spain and Hungary during the study period (study start: country-specific aRMM distribution [01 March 2022, Sweden; 09 March 2022, Denmark; 31 July 2022, France; 30 Jan 2023, Spain; 05 April 2024, Hungary]; study end: December 2026). These countries have universal healthcare.

Age groups

Special population of interest

Hepatic impaired

Pregnant women

Study design details

Setting

The study population will include patients with a dispensing of abrocitinib as recorded in routinely collected electronic secondary population data in Denmark, France, Sweden, Spain and Hungary between the study start (country-specific additional Risk Minimization Measure (aRMM) distribution [01 Mar 2022, Sweden; 09 Mar 2022, Denmark; 31 Jul 2022, France; 30 Jan 2023, Spain; 05 April 2024, Hungary]) and study end (December 2026). Details on the data sources are in Section 9.4). All participating countries have universal health care.

Comparators

Not applicable

Outcomes

Outcomes include:

(1) the count and proportion of patients with evidence of having performed CBC, lipid panel, TB screening, and viral hepatitis B and C screening tests within 3 months prior to initiation of abrocitinib;

(2) the count and proportion of patients with evidence of having performed the CBC and lipid panel laboratory tests at week 4 (± 2 weeks) after initiation of abrocitinib;

(3) the proportion of patients with evidence of having risk factors and the number of risk factors for VTE, MACE, malignancy excluding NMSC, NMSC, and serious infection (including age 65 years or older, estimated dose of >100 mg/day for patients ages 65 or older, history of atherosclerotic disease, malignancy, pregnancy, history of VTE, use of combined hormonal contraceptives or hormone replacement therapy, major surgery, inherited coagulation disorder, diabetes, history of serious or opportunistic infection, TB) within 6 months prior to initiation of treatment with abrocitinib;

(4) the count and proportion of patients with evidence of having received live

attenuated vaccines (e.g., measles, mumps, rubella) 4 weeks prior to and during treatment with abrocitinib;
(5) the count and proportion (among all pregnant women identifiable in a given database) of women in whom pregnancy overlaps with abrocitinib use;
(6) the count and proportion patients identified with severe hepatic impairment up to 6 months prior to or during treatment with abrocitinib;
(7) the count and proportion of patients aged <12 years on the index date; and
(8) the count of proportion of patients with an estimated starting dose > 100mg/day, and a description of the duration of use (median and IQR).

Data analysis plan

For each country, patient baseline characteristics will be reported to the extent measured in each database, including demographics (age and sex), comorbidities (including asthma, food allergies, depression) and prior and current medication use (including treatments for atopic dermatitis and medications noted for interactions in the abrocitinib label as captured in outpatient dispensing data or other available secondary routinely collected data on medication use).
Other characteristics frequently diagnosed among patients with atopic dermatitis may be added given acceptable validity and completeness measured via diagnoses or treatment proxies and known in time for inclusion in planned data extractions; existing ethical and data protection permissions and the associated data applications may need to be amended to enable inclusion of additional variables. Counts and proportions for categorical variables and mean, median with range or interquartile ranges (IQRs) for continuous variables will be reported to address the study objectives.

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret
Système National des Données de Santé (French national health system main database)
The Information System for Research in Primary Care (SIDIAP)
Danish registries (access/analysis)
Swedish Cause of Death Register

Data source(s), other

Denmark: Danish National Patient Register, Danish Hospital Medicines Register, Danish Cancer Registry, Danish Register of Laboratory Results, Danish Medical Birth Registry;
France: the French nationwide administrative database (Système National des Données de Santé (SNDS); Sweden: Swedish National Health Registers (including the National Patient Register, Prescribed Drug Register, Total Population Register, Swedish Cause of Death Register, and Swedish Medical Birth Register);
Spain: the Information System for Research in Primary Care (SIDIAP); and Hungary: the National Insurance Fund Administration (NHIFA) database (including the following NHIFA registers: Demography, Drugs, Inpatient, and Outpatient).

Data sources (types)

Non-interventional study

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

Not applicable