Assessing the Safety of Ixekizumab in European Psoriasis Registries (I1F-EW-B008)

First published: 06/06/2018

Last updated: 08/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS21980

Study ID

45112

DARWIN EU® study

No

Study countries

Germany

United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

University Medical Centre Hamburg-Eppendorf

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

British Association of Dermatologists Biologics Register Limited (BADBIR)

German Rheumatism Research Centre Berlin (Deutsches Rheuma-Forschungszentrum Berlin, DRFZ)

Germany

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

BRITISH ASSOCIATION OF DERMATOLOGISTS BIOLOGICS REGISTER LIMITED (BADBIR) UK,

University Medical Center Hamburg-Eppendorf (UKE) Germany, Deutsches Rheuma-Forschungszentrum (DRFZ) Germany

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Natacha Carragher

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/10/2016

Study start date

Actual: 25/05/2017

Date of final study report

Planned: 31/12/2029

Sources of funding

- Other

More details on funding

BADBIR, PsoBest, RABBIT

Study protocol

B008 PASS (0.1)_Redacted.pdf (658.03 KB)

B008 PASS (a)_Redacted.pdf (671.81 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:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Data from three independent European registries will be reviewed to provide information about the safety of ixekizumab. The registries included in this protocol are BADBIR, a UK-based psoriasis registry, and the German psoriasis and psoriatic arthritis registries of PsoBest and RABBIT-SpA.

Main study objective:

The objective of this study is to perform safety surveillance by monitoring the incidence of AEs occurring in temporal association with ixekizumab among patients with psoriasis enrolled in European biologic registries.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IXEKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC13) ixekizumab

ixekizumab

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

This study includes patients with psoriasis from the BADBIR and PsoBest registries and patients with psoriatic arthritis from the RABBIT-SpA registry; patients with axSpA will be also be included upon European Union approval of ixekizumab for the treatment of axSpA.

Age groups

- Adolescents (12 to < 18 years)
- 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)

Estimated number of subjects

2.500

Study design details

Comparators

BADBIR is a national registry of patients with psoriasis treated with conventional systemic therapy (Comparator cohort)

Data analysis plan

Analysis of BADBIR and PsoBest data is under the control of each registry.

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), other

BADBIR, PsoBest, RABBIT-SpA

Data sources (types)

Disease registry

Drug registry

Other

Data sources (types), other

Prospective patient-based data collection

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