

Chronic inflammatory immune-mediated diseases and immunosuppressive drugs: What evidence would you like to see generated from real-world data?

First published: 16/04/2026

Last updated: 16/04/2026

Study

Finalised

Administrative details

EU PAS number

EUPAS1000000982

Study ID

1000000982

DARWIN EU® study

No

Study countries

 Italy

Study description

This work aims to identify and characterise current clinical areas that should be prioritized using RWD from both patient and clinician perspectives in IMIDs, using a dedicated survey administered to both groups. As a secondary objective, differences in prioritization distributions between clinicians and patients will be analyzed.

Study status

Finalised

Research institutions and networks

Institutions

University of Verona

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Spini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/04/2026

Actual: 16/04/2026

Study start date

Planned: 01/01/2025

Actual: 01/01/2025

Date of final study report

Planned: 15/12/2026

Actual: 16/04/2026

Study protocol

[260120_Protocol survey + SAP.pdf](#) (592.78 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:

Other

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

This work aims to identify and characterise current clinical areas that should be prioritized using RWD from both patient and clinician perspectives in IMIDs, using a dedicated survey administered to both groups. As a secondary objective, differences in p

Data collection methods:

No individual level data collected for the purpose of the study

Study design:

This study will employ a cross-sectional observational survey design conducted entirely online using Google Forms, capturing priorities and unmet needs among patients with IMIDs and clinicians (gastroenterologists, rheumatologists, dermatologists).

Main study objective:

This work aims to identify and characterise current clinical areas that should be prioritized using RWD from both patient and clinician perspectives in IMIDs, using a dedicated survey administered to both groups. As a secondary objective, differences in prioritization distributions between clinicians and patients will be analyzed.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Additional medical condition(s)

Immune-mediated inflammatory diseases

Population studied

Short description of the study population

Patients with IMIDs and main specialists involved in the IMIDs treatment

Study design details

Setting

The target population for this survey consisted of patients with a diagnosis of an IMID and clinicians involved in the management of IMIDs. For patients, the survey link will be distributed through patient associations, using newsletters and the association's official website; for clinicians, the survey will be disseminated via scientific societies through their newsletters and institutional websites.

Interventions

The questionnaire structure will employ a conditional branching based on respondent type (31 total questions across 5 sections), with prioritisation scales (0-5 ranking), multiple-choice, Likert-type scoring, and open-ended items for additional endpoints.

The development of the items is based on literature search and expert opinions.

Firstly, the questions have been defined. Secondly, they have been validated by experts and patient organizations. To allow comparison between clinicians and patients regarding the unmet needs and the prioritization of real-world evidence, the same questions were provided but with some differences in terms of language:

- Clinician version: Technical language with precise medical terminology;
- Patient version: Simplified, accessible language tailored for non-technical comprehension.

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 sources (types)

[Other](#)

[Patient surveys](#)

Data sources (types), other

Survey regarding clinicals and patients

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown