# AI-powered stratification of autoimmune diseases

**First published:** 05/12/2023

**Last updated:** 05/12/2023

Study Planned

## Administrative details

**EU PAS number**

EUPAS107902

**Study ID**

107903

**DARWIN EU® study**

No

**Study countries**

France

**Study status**

Planned

## Contact details

**Primary lead investigator**

Bouget Vincent

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 05/12/2023

**Study start date**
Planned: 05/12/2023

**Date of final study report**
Planned: 05/12/2024

## Sources of funding

- Pharmaceutical company and other private sector
- Other

## More details on funding

Undisclosed, Scienta Lab

## Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Main study objective:**

The main objective of this study is to identify a cross-pathology stratification of immune-mediated inflammatory conditions.

## Study Design

**Non-interventional study design**

Cross-sectional

## Population studied

**Age groups**

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- 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)

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**Estimated number of subjects**

600.000

## Study design details

**Data analysis plan**

Scienta Lab will leverage its foundation model to stratify autoimmune patients using clinical and biological information. The results will be published in a peer-reviewed publications. Practice and patients' confidentiality will be maintained at any step of the study. Internal processes to ensure data safety and integrity are documented and have been shared with the data provider.

## 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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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)**

Optimum Patient Care Research Database

**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**

No