

AI-powered stratification of autoimmune diseases

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Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/107903>

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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)

Estimated number of subjects

600000

Study design details

Data analysis plan

Scientia 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

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