

DARWIN EU® - A RWD study to evaluate drug utilisation of Long-acting Insulin analogues and Neutral Protamine Hagedorn Insulin in clinical practice

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000001135

Study ID

1000001135

DARWIN EU® study

Yes

Study countries

 Croatia

 Denmark

 France

-  Germany
 -  Lithuania
 -  Spain
 -  Sweden
 -  United Kingdom
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Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Yuqing Hu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/07/2026

Actual: 30/07/2026

Study start date

Planned: 25/09/2026

Actual: 25/09/2026

Date of final study report

Planned: 18/01/2027

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Main study objective:

- To describe the overall rate of prescribing of NPH by calendar time (monthly, yearly) in patients with T1DM, overall and stratified by sex and age
- To describe the overall rate of prescribing of LAIA by calendar time (monthly, yearly) in patients with T1DM, overall and stratified by sex and age
- To describe switching patterns between NPH and LAIA at class level, as well as specific switching at ingredient level, in patients with T1DM per calendar year, overall and stratified by sex and age

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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