An observational, prospective study to assess the use, effectiveness, and safety of voxelotor in patients with sickle cell disease (SCD) in a real-life setting (VoxEval)

First published: 05/06/2024

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Study Cancelled

Administrative details

EU PAS number

EUPAS1000000186

Study ID

1000000186

DARWIN EU® study

No

Study countries

☐ France

Study status

Cancelled

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jean-Benoit ARLET

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/07/2023

Study start date

Planned: 15/10/2024

Date of final study report

Planned: 31/12/2030

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:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study drug and medical condition

Name of medicine

OXBRYTA

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

VOXELOTOR

Anatomical Therapeutic Chemical (ATC) code

(B06AX03) voxelotor

voxelotor

Medical condition to be studied

Sickle cell disease

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable