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)

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Study Cancelled

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000186

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

Study type list

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

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