Evaluation of the Effectiveness of the Additional Risk Minimisation Measures for Hemgenix®: PASS Survey Among Physicians in European Countries

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001088

Study ID

1000001088

DARWIN EU® study

No

Study countries

Austria

France

Germany

Ireland

Italy

Norway

Spain

United Kingdom

Study description

This observational, post-authorization study aims to evaluate the effectiveness of additional Risk Minimisation Measures (aRMMs) tools described in the Risk Management Plan (RMP) for Hemgenix® through a survey of physicians involved or potentially involved in Hemgenix prescription, administration and/or post-treatment monitoring.

Study status

Ongoing

Research institutions and networks

Institutions

CSL Behring

Contact details

Study institution contact

Study Registration Coordinator clinicaltrials@cslbehring.com

Study contact

clinicaltrials@cslbehring.com

Primary lead investigator

Study Registration Coordinator

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/01/2025

Study start date

Planned: 01/09/2026

Actual: 01/09/2026

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CSL Behring

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study drug and medical condition

Medicinal product name

HEMGENIX

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

ETRANACOGENE DEZAPARVOVEC

Anatomical Therapeutic Chemical (ATC) code

(B02BD16) etranacogene dezaparvovec

etranacogene dezaparvovec

Population studied

Short description of the study population

physicians involved or potentially involved in Hemgenix prescription, administration and/or post-treatment monitoring

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Yes