# Clinical Systematic Literature Review (SLR) of Ph(-) B-ALL in High-risk First Relapse Paediatric Patients

**First published:** 02/07/2021

**Last updated:** 04/01/2022

Study    Finalised

## Administrative details

**EU PAS number**

EUPAS41675

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**Study ID**

44870

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**DARWIN EU® study**

No

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**Study countries**

☐   United States

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**Study description**

This study will conduct an SLR of evidence from clinical studies to assess the clinical effectiveness of treatments administered for paediatric populations (28 days - 18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-precursor Acute Lymphoblastic Leukemia (B-ALL). The review will include studies with participants in first relapse to first line treatment who were treated with any active anti-tumour treatment, including chemotherapy and Chimeric Antigen Receptor T-cell (CAR-T) therapy. The study designs eligible for inclusion in humans are: Controlled clinical trials, Observational real-world, and, single-arm studies. Electronic databases and congresses will be searched for evidence in line with NICE Health Technology Assessment (HTA) guidance. The process for study selection will be aligned with the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for the reporting of SLRs and meta-analyses.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

☐ United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

Institution

# Contact details

**Study institution contact**

Global Development Leader Amgen Inc.

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( **Study contact** )

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**Primary lead investigator**

Global Development Leader Amgen Inc.

( **Primary lead investigator** )

# Study timelines

**Date when funding contract was signed**

Planned: 09/10/2020

Actual: 09/10/2020

**Study start date**

Planned: 27/11/2020

Actual: 27/11/2020

**Data analysis start date**

Planned: 21/01/2021

Actual: 21/01/2021

**Date of interim report, if expected**

Planned: 26/02/2021

Actual: 26/02/2021

**Date of final study report**
Planned: 13/04/2021

Actual: 12/04/2021

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Amgen

# Study protocol

[Protocol-Published Original Blinatumomab 20200443.pdf](Protocol-Published Original Blinatumomab 20200443.pdf) (587.41 KB)

# 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 topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To conduct a SLR of evidence from clinical studies (controlled and observational) to assess the clinical effectiveness of treatments administered for paediatric populations (> 28 days and <18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-ALL

# Study Design

**Non-interventional study design**

Systematic review and meta-analysis

# Study drug and medical condition

**Medical condition to be studied**

Philadelphia chromosome negative

# Population studied

**Short description of the study population**

The review will include studies assessing paediatric populations (< 18 years of age) with high-risk Philadelphia chromosome-negative B-precursor ALL in first relapse to first line treatment. Some studies may have used MRD to identify/define relapse/response and will also be included when different definitions used. Studies will be excluded if patients do not have B-precursor ALL, in case of clinically relevant CNS requiring treatment or evidence of current CNS involvement by ALL or if studies report 2nd relapsed patient populations. If a study included patients with clinically relevant CNS involvement as well as those without, and this study separately reports the results for each category of patients, then this study will be included and information for the patients without clinically relevant CNS involvement will be extracted if the other inclusion criteria are met.

**Age groups**

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

**Estimated number of subjects**

0

# Study design details

**Data analysis plan**

Identified evidence will be extracted into an Excel workbook and a qualitative synthesis developed in Word. Tabulated summaries of the studies will be provided to allow the review of the evidence available for the clinical effectiveness and safety of treatments administered for paediatric populations

(>28 days and <18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-ALL, categorized by population, intervention, outcome type, and quality. The risk of bias in each included study will be assessed. Bias refers to a process at any stage of inference tending to produce results that depart from the true values. For quality assessment of clinical effectiveness studies (ie, randomised controlled trials RCTs, observational studies and single-arm studies), the Cochrane Collaboration's tool for assessing risk of bias will be used.

# Documents

**Study results**

Paediatric ALL clinical SLR report_AMSR008_Final report_Executive Summary__12 April 2021.pdf (117.23 KB)

# 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.

# Data sources

**Data sources (types)**

**Data sources (types), other**

Electronic databases and congresses

# 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