# Identification, Characterisation, and Data Quality Assessment of Data Sources for Real-World Safety and Effectiveness Studies of Chimeric antigen receptor T-cell (CAR-T cell) therapies

**First published:** 22/04/2026

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000954

**Study ID**

1000000954

**DARWIN EU® study**

No

**Study countries**

European Union

Iceland

Norway

Switzerland

United Kingdom

United States

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**Study description**

Chimeric antigen receptor T-cell (CAR-T) cell therapy has emerged as an important cellular immunotherapy for cancer treatment, with six treatments approved by the EMA since 2018. Non-interventional studies play a key role for supporting regulatory decision-making, especially when randomised controlled trials are unfeasible or unethical, which is often the case in the CAR-T cell area, where evidence on effectiveness and safety evidence often relies on single arm trials.

This study aimed to identify, describe and assess the data quality of a set of selected data sources relevant to the conduct of CAR-T cell non-interventional studies. It identifies 43 data sources from Europe and the US and compiled detailed metadata in a structured repository and assessed up to 22 pre-selected data sources across five dimensions of data quality, including reliability, extensiveness, coherence, relevance, and timeliness. The findings will inform future feasibility assessments, support data source selection, and enhance the interpretation of ongoing or planned real-world studies in CAR-T therapy.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

## Evidence and Access/Analytica Laser, Certara

France

United Kingdom (Northern Ireland)

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Institution | Non-Pharmaceutical company | ENCePP partner

# Contact details


**Study institution contact**

Nadia Quignot nadia.quignot@certara.com

Study contact

nadia.quignot@certara.com

**Primary lead investigator**

Artak Khachatryan 0000-0003-3888-2347

Primary lead investigator

**ORCID number:**

0000-0003-3888-2347


# Study timelines

**Date when funding contract was signed**

Actual: 08/12/2024

**Study start date**
Actual: 15/01/2025

**Date of final study report**
Planned: 15/07/2026

## Sources of funding

- EMA

## Study protocol

20250718_FWC_EMA_2020_46_TDA_L5.07_SC01 protocol objective 2 v1.0.pdf
(340.39 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

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**Study type:**

Not applicable

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**Scope of the study:**

Feasibility analysis

Scoping review (including literature review)

**Data collection methods:**

No individual level data collected for the purpose of the study

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**Study design:**

This study characterised 43 identified CAR-T cell therapy data sources and a data quality assessment was conducted for up to 22 pre-selected data sources.

**Main study objective:**

To identify, describe, and assess the quality of data sources relevant for conducting CAR T cell non interventional studies.

## Study drug and medical condition

**Medicinal product name**

ABECMA

BREYANZI

CARVYKTI

KYMRIAH

TECARTUS

YESCARTA

**Anatomical Therapeutic Chemical (ATC) code**

(L01XL07) idecabtagene vicleucel

idecabtagene vicleucel

(L01XL08) lisocabtagene maraleucel

lisocabtagene maraleucel

(L01XL05) ciltacabtagene autoleucel

ciltacabtagene autoleucel

(L01XL04) tisagenlecleucel

tisagenlecleucel

(L01XL06) brexucabtagene autoleucel

brexucabtagene autoleucel

(L01XL03) axicabtagene ciloleucel

axicabtagene ciloleucel

# Population studied

**Short description of the study population**

This study included European and US real-world data sources that capture data relating to CAR-T cell therapy recipients.

# Study design details

**Setting**

The study comprised data sources, such as registries, claims databases, and electronic health records from Europe and the US involving CAR-T cell recipients, identified using bibliographic databases (PubMed, Embase), online searches, and the HMA EMA Catalogue of real world data sources.

**Interventions**

This project did not involve any patient-level intervention and is neither a clinical trial nor a non-interventional study; rather, it was a non-interventional methodological assessment conducted solely to characterise and evaluate the data quality of selected real-world data sources for potential future regulatory studies on CAR-T cell therapies.

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**Outcomes**

A searchable Excel-based data repository was developed using data obtained from published sources, featuring a user-friendly interface and enabling filtering of data sources by key characteristics such as disease area or geography. It includes foundational data quality and descriptive metrics for 43 data sources and metrics. The data quality assessment was conducted for 22 data sources, with capture of metrics of data quality collected via published sources and direct contact with data owners.

# 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 source(s)**

Cancer Analysis System

Danish registries (access/analysis)

Norwegian Health Registers

Système National des Données de Santé (French national health system main database)

Therapy Monitor Multiple Myeloma Germany

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**Data source(s), other**

1. all4cure Multiple Myeloma Register
2. CART-SIE Registry
3. Center for International Blood and Marrow Transplant Research (CIBMTR) Registry
4. Cell Therapy Consortium Registry
5. Clinformatics Data Mart (OptumInsight)
6. ConcertAI EMR and Claims Datasets
7. COTA Real World Evidence Database
8. DESCAR-T (Dispositif d’Enregistrement et Suivi des patients traités par CAR-T cells)
9. Dutch CAR-T Tumorboard (“Follow that CAR!”)
10. EBMT CAR-T Cell Registry (European Society for Blood and Marrow Transplantation)
11. European Mantle Cell Registry
12. German Registry for Stem Cell Transplantation (DRST)
13. GELTAMO/GETH-TC Registry
14. IBM MarketScan Commercial and Medicare Databases
15. iKnowMed (US Oncology Network)
16. IQVIA PharMetrics Plus Database
17. Inovalon Closed Claims Database
18. Lymphoma Innovations ORIEN Network (LION)

19. Memorial Sloan Kettering Cancer Center Database
20. Medicare Fee-for-Service Database
21. National Cancer Database (NCDB)
22. National Inpatient Sample (NIS)
23. Nationwide Readmissions Database (NRD)
24. Norstella EMR/EHR (Panalgo)
25. OncoHealth
26. Pediatric Real World CAR Consortium (PRWCC) Database
27. PINC AI Healthcare Database (formerly Premier Healthcare Database)
28. RealySA Cohort (REal world dAta in LYmphoma and Survival in Adults)
29. Sarah Cannon Transplant and Cellular Therapy Network (SCTCTN) CAR-T Registry
30. SEER Program (Surveillance, Epidemiology, and End Results)
31. Sema4 (GeneDx) Electronic Health Records
32. Swedish National Population-Based Registries
33. Symphony Integrated Dataverse (IDV)
34. Touchstone (Definitive Healthcare)
35. TriNetX Research Network
36. University of California Health Data Warehouse
37. US Flatiron Health Research Database
38. Vizient Clinical Data Base (CDB)

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Cancer registry

Disease registry

Drug registry

Electronic healthcare records (EHR)

Population registry

## 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

**Data characterisation moment**

after data extraction

**Data characterisation details**

The foundational data quality and descriptive elements of 43 data sources were extracted based upon published information for each of the included data sources. This list of metrics was developed and adapted from the list of

metadata for the HMA-EMA Catalogues of RWD sources and studies.

## Data characterisation details

### 20250718_FWC_EMA_2020_46_TDA_L5.07_SC01 protocol objective 2 v1.0.pdf

English (340.39 KB - PDF)

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