



CAR-T Data Collection Initiative

Supporting Post-Authorization Studies (PAS) to monitor the long-term safety and/or effectiveness of CAR T-cell therapies

Clinical Study Unit (CSU), EBMT

BACKGROUND

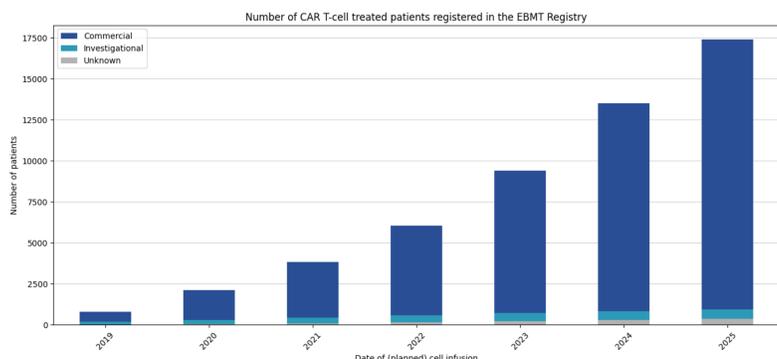
The European Medicines Agency (EMA) requires marketing authorization holders (MAHs) to conduct post-authorization studies (PAS) to monitor the **long-term safety and/or effectiveness of CAR T-cell therapies**.

EMA recommends a **15-year follow-up** using the data captured in the EBMT Registry, including:

- Infectious complications
- Non-infectious complications
- Effectiveness outcomes.

The EBMT Clinical Study Unit (CSU) supports EMA-mandated, non-interventional PAS and invites centers treating commercial CAR-T patients to participate in the CAR-T Data Collection Initiative (DCI).

Over 17,000 CAR-T treated patients (commercial and non-commercial) are currently registered in the EBMT Registry.



DATA COLLECTION

Where?

Data must be entered in the EBMT Registry

- Link to the EBMT Registry: <https://registry.ebmt.org/>
- The Data Collection Forms (DCF) and Completion Guidelines: <https://www.ebmt.org/registry/ebmt-data-collection>

When?

- **Day 0 (Treatment)**
 - Disease Status at Treatment form
 - Cellular Therapy Day 0 form
- **Follow-up**
 - Day 100
 - 6 months
 - Annually

Complete the Cellular Therapy Follow-up forms

⚠ Please also:

- Register the diagnosis using the diagnosis-specific form
- Complete pre- and post-HCT treatment data (if applicable)
- Enter data within **6 weeks** after patient visit/consent

STUDY PROGRESS

- First CAR-T PAS launched in 2020
- Enrollment closed for 5 CAR-T studies (see table below)
- Additional CAR-T products and indications expected soon

Manufacturer	Product	Contracted indications	Enrolment period	Enrolment target	Enrolment closure date
Kite	Yescarta	DLBCL+PMBCL	2020-2023*	1400	31-Dec-2023
Novartis	Kymriah	ALL+DLBCL	2020-2023*	700	24-Apr-2023
BMS	Abecma	MM	2021-2024	300	4-Jun-2024
BMS	Breyanzi	DLBCL+PMBCL+HGBCL+FL3B	2022-2025	200	21-Feb-2025
Kite	Tecartus	MCL	2023-2024	300	16-Oct-2024

ON-SITE MONITORING

To ensure data quality, on-site monitoring visits (OMVs) are conducted by EBMT monitors/Clinical Research Associates (CRAs).

Monitoring includes:

- 100% verification of Informed Consent Forms (ICFs)
- 10% Source Data Verification (SDV) per site, per PAS

Current status:

- 147 OMVs completed
- 72 unique sites visited
- >2,600 ICFs verified (>90%)
- 157 patients underwent (partial) SDV (~38%)
- SDV ongoing in 2026

DATA QUALITY & COMPLETENESS

High-quality, complete data is essential for robust safety and effectiveness analyses.

Please:

- Regularly review DCI patients
- Respond to outstanding data queries in the Registry
- Correct inconsistencies identified by EBMT

Your data directly supports regulatory evaluation and long-term patient safety.

PATIENT FOLLOW-UP & COMPENSATION

Follow-up requirements

- 15-year follow-up after CAR-T treatment (or until death)
- Timely entry of follow-up data is essential

Maintaining up-to-date data ensures continued evaluation of long-term outcomes and safety.

Financial compensation

Participating centers receive financial compensation for **complete and high-quality data entry**. Please contact your designated country lead for further details.

TAKE ACTION TODAY

- ◆ Review your CAR-T patients
- ◆ Complete missing forms
- ◆ Resolve open queries
- ◆ Keep follow-up data current

Together, we build the long-term evidence for CAR-T therapies.

CONTACT

If you have questions, please contact your **country lead** or send your question to the Registry Helpdesk at:

registryhelpdesk@ebmt.org

For more information, check our website:

<https://www.ebmt.org/registry/ebmt-car-t-data-collection-initiative>

www.ebmt.org