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

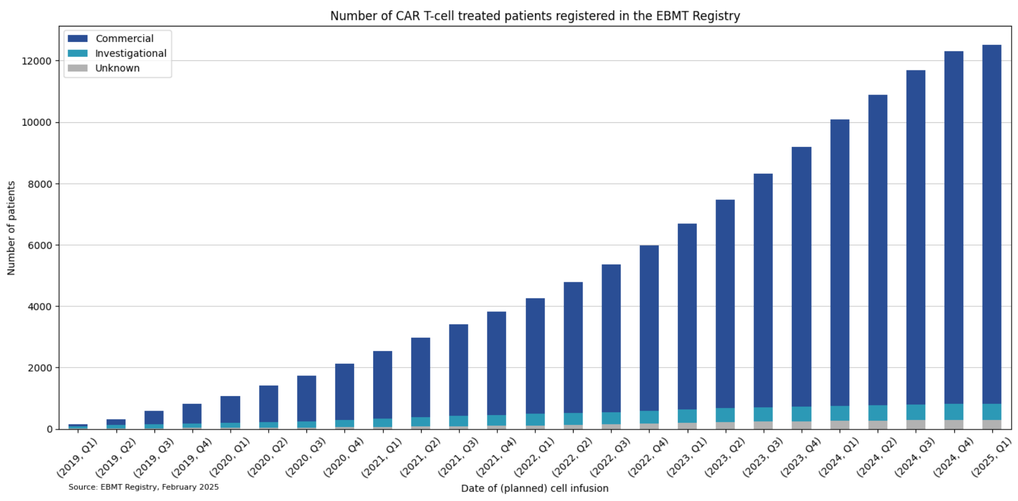
BACKGROUND

The European Medicines Agency (EMA) obliges 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 has recommended MAHs to conduct their PAS with a **15-year follow-up** using the data captured in the EBMT Registry. This data includes safety and effectiveness on infectious and non-infectious complications.

The Clinical Study Unit (CSU) of EBMT supports the conduct of these EMA mandated non-interventional PAS by the MAH. CSU has invited centers that treat patients with commercial CAR T-cell therapies to participate in the CAR-T Data Collection Initiative (DCI).

In September 2024, 10,000 CAR-T treated (commercial and non-commercial) patients were registered in the EBMT Registry.



REQUIREMENTS STUDY PARTICIPATION

To be able to participate in the CAR-T DCI, the following requirements should be fulfilled:

- Obtain **regulatory approval** (if needed) of EBMT ICF to allow sharing of pseudonymized patient data with MAH and monitoring of the data
- Signed **site contracts**:
  - Master Agreement -> to define responsibilities
  - Product-Specific Agreements (per product) -> for reimbursement
- **On-site monitoring visits** (OMV) need to be performed by a monitor/Clinical Research Associate (CRA) on behalf of EBMT:
  - Verification of 100% of the ICFs
  - Source data verification (SDV) of 10% of the patients (per site, per PAS)

DATA COLLECTION

Data entry in the EBMT Registry

- The Data Collection Forms (DCF) and Completion Guidelines can be found on the EBMT website: https://www.ebmt.org/registry/ebmt-data-collection
- Link to the EBMT Registry: https://registry.ebmt.org/

Data collection timepoints

- **Day 0** - Two forms need to be completed:
  - Disease Status at Treatment
  - Cellular Therapy Day 0
- **Day 100, 6 months and annually**:
  - Cellular Therapy FU forms should be completed
- **Note**: Please make sure you also register the diagnosis using the diagnosis-specific form and complete the information on pre- and post-HCT treatments, if available
- Please try to enter the data within 6 weeks after patient visit/consent

clinicalstudyunit@ebmt.org

STUDY STATUS

The first CAR-T PAS started enrolling patients in 2020. Currently, the enrollment period has closed for 5 CAR-T studies (see table below).

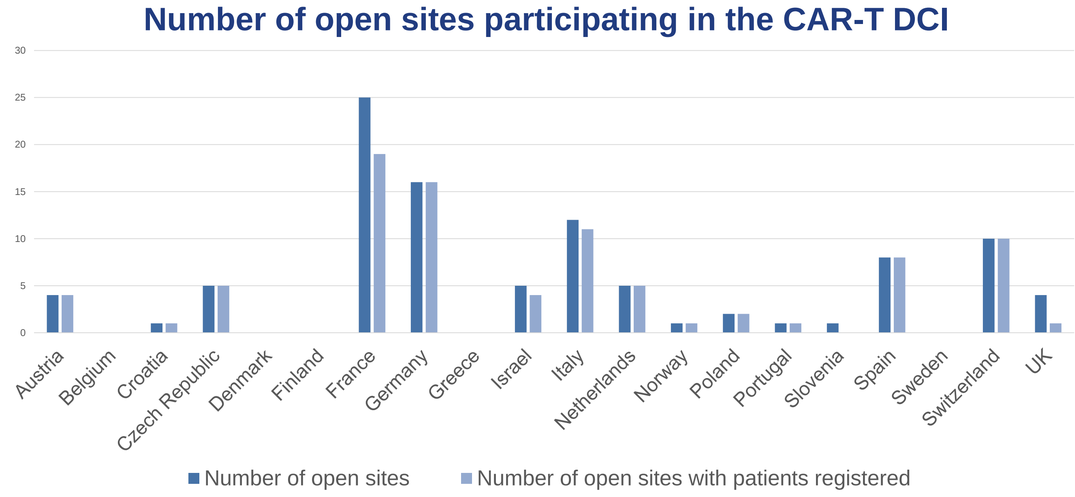
Status of the enrollment progress (per study):

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

More (CAR-T) products and/or additional indications are expected to follow in the near future.

Currently, 100 sites participate in the CAR-T DCI in 15 countries. Of these sites, 88 have reported CAR-T patients who fulfill the study inclusion criteria.

Number of open sites participating in the CAR-T DCI



PATIENT FOLLOW-UP AND NEXT STEPS

Patient follow-up

Patient follow-up data will need to be collected for **15 years after CAR-T treatment** (or until death).

Financial compensation

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

On-site monitoring

EBMT will conduct **on-site monitoring visits (OMV)** to ensure data quality. You will be contacted to schedule these visits.

Data Queries

Please check your DCI patients regularly for outstanding data queries in the EBMT Registry. EBMT checks for **inconsistencies or errors** that may have arisen during data entry.

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