CAR –T Data Collection Initiative

Supporting Post Authorisation Studies

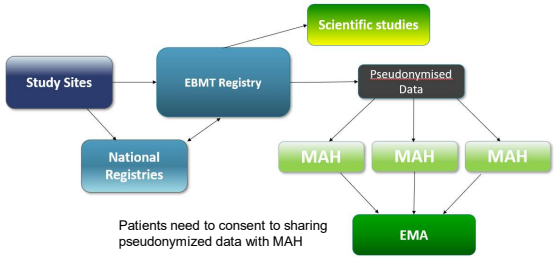
Background

CAR-T cell therapies are a very promising treatment option for many patients with haematological malignancies. However, the evidence on the long-term safety and efficacy of these treatments is limited. The European Medicines Agency (EMA) obliges marketing authorization holders (MAH) to conduct post authorization safety (PAS) studies to monitor the long-term safety and efficacy of CAR-T cell therapies.

With the qualification of the Cellular Therapy module Form of the EBMT Registry in 2019, the EMA has recommended MAHs to conduct their PAS with a 15-years follow-up using the data captured in the EBMT Registry. This data includes efficacy data and safety data on adverse events which are of special interest, as captured on the EBMT Advanced Cellular Therapy Form.

EBMT's collaboration with the MAH's lessens the burden of work through uniform processes of data collection for participating sites and ensures that the collected data is not siloed in private databases of MAHs but remains available to academic research through the EBMT registry.

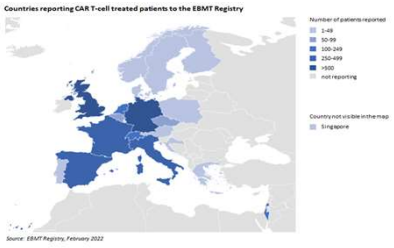
Data flow Data Collection Initiative



Inclusion criteria

- Patients treated with commercial CAR-T products
- Patients who have consented to share data with the EBMT Registry

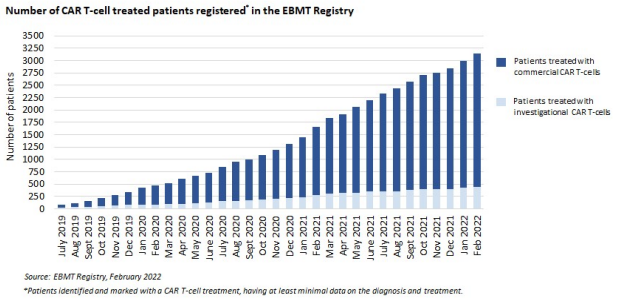
Participation



The number of centers and countries registering CAR-T Cell patients is growing

Please register your patients in the EBMT Registry

Data in the EBMT Registry



Important points for data registration

Registration in the EBMT Registry

- EBMT center members and national registries are requested to register CAR-T patients.

Batch number

- Please enter the Company's product specific batch number.

Complications (infectious/non-infectious)

- Report in the Registry as per available information in patient files.

Please indicate for each of the infectious and non-infectious complications, if they occurred or not.

Cytokine release syndrome (CRS) and neurotoxicity

- Please use ASTCT Consensus Grading scale.

Hypogammaglobulinemia

- Was hypogammaglobulinemia present before the cellular therapy?
- If yes, did it worsen after cellular therapy?

Secondary malignancy

Report all secondary malignancies.

Castor

New database for collecting cell therapy data
Go Live expected Q2 2022

More information:
https://www.ebmt.org/registry/cellular-therapy-data-collection-castor

Site start-up

The following documents should be in place:

- Informed Consent Form that allows data sharing with the MAHs
- Joint Controllership Agreement
- Site contract with Product Specific Addenda

Contact

If you have questions, please contact your country lead or send your question to EBMT_NK01@lumc.nl

For more information, check our website:
https://www.ebmt.org/registry/data-collection-car-t-cells