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 (MAHs) to conduct post-authorization safety (PAS) studies to monitor the long-term safety and efficacy 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 efficacy and safety data on infectious and non-infectious complications which are of special interest, as captured on the EBMT 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.

EBMT invites centres that treat patients with commercial CAR T-cell therapies to participate in the Data Collection Initiative (DCI) to support PAS studies mandated by EMA.
Centres that participate will be financially compensated.

DM DCI Training in Paris

DM2-1 CART Data Collection Initiative

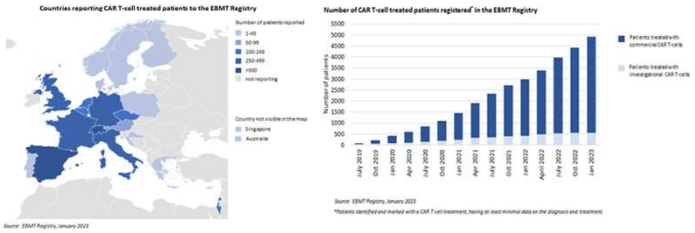
Day: **Monday, April 24**
Time: **16:30-17:45**
Room: **251**
Presenters: **Irene Groen and Jessica Lemaitre**

Inclusion criteria

- Patients treated with commercial CAR T-cell products
- Patients who have consented to share data with the EBMT Registry and their pseudonymised data with the MAH

CAR T-cell data in the EBMT Registry

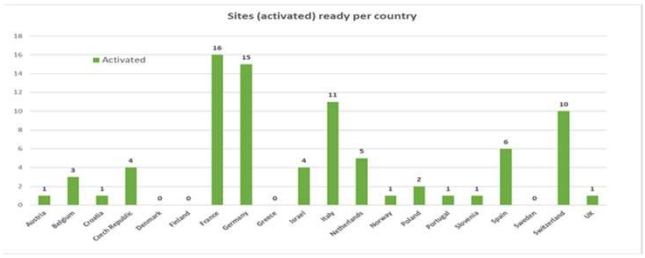
Currently >4,800 CAR T-cell therapies are registered in the EBMT Registry

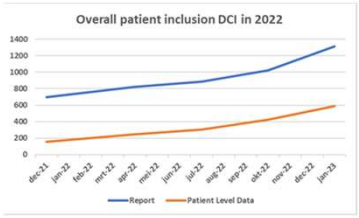


Please register all your consecutive CAR-T patients in the EBMT Registry

DCI status

As of March 2023, 82 sites are activated, which means the (local) ICF approval is in place and the site contracts are signed.





As of March 2023, data from 1314 patients are included in the DCI reports. Of these 1314 patients, 586 patients have signed the updated ICF that allows sharing pseudonymised data with the MAHs.

Important points for data registration

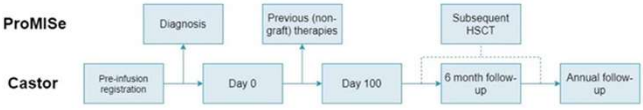
Registration in the EBMT Registry

EBMT Centre Identification Code (CIC) - The centre where the patient was originally registered in ProMISe. This is not always the centre where the patients received their CAR-T treatment.

EBMT Unique Identification Code (UIC) - The number with which the patient is registered in ProMISe.

Pre-treatments

Enter your pre-treatments in ProMISe.
In addition, please enter Diagnosis and (subsequent) HSCTs into ProMISe.
The Cell therapy, the infusion unit, infusion episode and follow-up including infectious and non-infectious complications will be entered into Castor.



Batch number

Please enter the Company's product specific batch number.

Secondary malignancy

Report all secondary malignancies.

Post-therapy treatments

Post-therapy treatments should be entered into Castor (except for HSCT after CAR-T), HSCT will be entered into ProMISe.
When entering post-therapy treatments, we distinguish between:

- Post-therapy treatment in relation to the cell therapy (maintenance/consolidation) and diagnosis (relapse/progression);
- Post-therapy treatment for complications and/or infections.

Contact

If you have questions, please contact your **country lead** or send your question to the Cellular Therapy Helpdesk at:
cellulartherapyhelpdesk@ebmt.org

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