Background

Chimeric antigen receptor T-cells (also known as CAR T-cells) are T-cells that have been genetically engineered to recognize cancer cells in order to more effectively target and destroy them. Clinical results of CAR T-cell therapies have been impressive, however many questions regarding these personalized medicines remain, particularly concerning long-term effectiveness and safety of the products.

The EBMT developed a specific Cellular and Gene Therapy Form to standardize registration of patients treated with cellular therapies such as CAR T-cells. This module of the EBMT registry has been qualified by the European Medicines Agency (EMA) as a suitable platform for the collection of long-term follow-up data for post-authorization safety and efficacy studies of CAR T-cell products.

Objectives

- Evaluate the long-term safety of patients treated with CAR T-Cells in a real world setting as measured by type and frequency of adverse events.
- Determine the overall survival rate and causes of death after administration of CAR T-Cells.
- Evaluate the efficacy and the time to next treatment after administration of CAR T-cells.
- Assess the safety and effectiveness profile by gender, age and in special populations.

Inclusion criteria

- Patients treated with CAR T-cell products
- Patients who have given informed consent

Participation

The number of centers and countries registering CAR T-cells is growing! Thank you for registering the CAR-T cell data!!

- Please prioritize data registration of commercial over investigational CAR T-cell products.
  - EBMT is also interested in registration of patients treated with investigational CAR T-cells. The data of investigational CAR T-cell products will be used only if the investigator/sponsor provides permission for use.
- ‘GoCART’-initiative is underway!
  The initiative aims to create a multi-stakeholder network of all interested parties to maximize the potential of CAR T, focusing on:
  - Pre- and post-marketing registry
  - CAR T-center accreditation
  - CAR T-cell educational program
  - CAR T-cell policies and legislation

Data

![Graph showing number of CAR T-cell treated patients registered in the EBMT Registry](image)

Data Forms

EBMT center members and national registries are requested to complete:

- **Cellular Therapy form**
  The form was designed to capture essential information describing the administered product and patient follow-up. The form can be found on our site [https://www.ebmt.org/registry/data-collection](https://www.ebmt.org/registry/data-collection)

Data request

There are additional items that are not captured in ProMISE and that are collected in a separate data request using excel.

Please send in your CAR-T cell data by completing the forms!

Important points for data registration

**Complications (infectious/non-infectious)**

- Provide each complication on the follow-up forms

**Commercial products**

<table>
<thead>
<tr>
<th>Cell infusion unit</th>
<th>Manipulation of the cell infusion unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of marketing authorization holder</td>
<td>Name of the (CIU) package/product</td>
</tr>
<tr>
<td>Novartis</td>
<td>Tecartus (Kymriah)</td>
</tr>
<tr>
<td>Kite Gilead</td>
<td>Yescarta</td>
</tr>
</tbody>
</table>

- Dose: use the specifications on the label of the commercial product

**Previous therapy**

- Please register any line of therapy given before the Cellular therapy

**Unavailable data**

- Complete “unavailable” or “unknown” if data is really not available

**Batch number**

- Enter Company’s specific batch number which is reported on the label of the product (this may be kept in the pharmacy)

**Molecular markers**

- Provide molecular markers

Contact

Please send your data to CTIWP@lumc.nl

Questions? Contact EBATCTO@lumc.nl

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