



# GoCART COALITION

Founded by



## Mission

Be leading force in the field of cellular therapies and trusted partner to promote patient access to novel cellular therapies and to contribute health and well-being through multi-stakeholder collaboration on clinical data, standards of care, education and policy.



## Vision

Create a durable long-term platform driven by input of a diverse group of stakeholders who jointly develop projects that advance the field of cellular therapies in Europe.



## Values

Patient-centred

Build relationships and deliver results

Create value by sharing data

Transparency breeds trust

Grow and adapt

## Work Package: Data Harmonisation

### Main aim:

Create a central EU data registry for the harmonised collection of clinical data on patients treated with gene and cellular therapies from cells and tissues of haematopoietic origin to support collaborative studies and regulatory decision making.

### Activities:

- Convene stakeholders to review of the EBMT cellular therapy form to ensure that it is up-to-date with the latest developments in the field. The first key changes were implemented in 2022 and the revised cellular therapy form was implemented in the new EBMT Registry in 2023. Additional not yet implemented fields will be reviewed in the annual renewal process of updating the form, starting in 2024.
- Work with the T2Evolve consortium on the Development of a Harmonised European Parameter Set and Core Data Structure for Evaluation of CAR T-Cell Therapies (CART-CD) by involving experts across major European institutions and study groups in a Delphi process to establish systematically a minimal core/required parameter set ('must have') with additional expansion modules that capture extended clinical parameter sets and biological features for special clinical and/or biological purposes. Activities to be completed in 2024/25.

## Work Package: Scientific Excellence

### Main aim:

Promote the use of existing EBMT Registry data and other sources of Real World Data and to strengthen collaborations across stakeholders in the field of CAR T-cell therapies.

### Activities:

- Yearly calls for research proposals.
- Studies are conducted by the GoCART study team at EBMT, comprised of a study coordinator, data manager and statisticians.
- Studies from 2021 and 2022 calls will be presented on Wednesday.
- Two new studies selected in 2023 have begun activities:
  1. The Role of Bridging Therapy before CAR-T Cell Therapy in Diffuse Large B-cell Lymphoma: An Analysis of the Lymphoma Working Party of the EBMT and GoCART, P. Berning *et al.*
  2. Impact of Prior B-Cell-Directed Immunotherapy on the Outcome of CD19 CAR-T cell Therapy in Aggressive B-cell Malignancies, J. Schröder *et al.*

Watch out for the next call in June 2024!

## Join us at 3 GoCART sessions at EBMT24!

### Wednesday April 17:

- 08:30 AM – 09:45 AM – GoCART Scientific Excellence Research Studies
- 10:30 AM – 11:45 AM – National CART networks
- 12:30 PM – 01:45 PM – CART initiatives

## Work Package: Education & Training

### Main aim:

Develop harmonised educational programmes for health care professionals (HCPs).

### Activities:

- Develop a **CART passport** with industry partners and national country representatives of harmonised training requirements and educational materials for HCPs in CART therapy. We will consolidate a "core" training for HCPs, with industry partners providing additional product-specific training, with passports tailored to each HCP role which will act as a passport specific to the individual. The training will be harmonised with JACIE accreditation requirements. First passports, for doctors and nurses, will be completed in 2024/25.
- As an integral part of the CART passport educational materials, we will update the **EBMT-EHA CAR T Cell Handbook** with national stakeholders in 2024/25 to develop the 2<sup>nd</sup> Edition which will be online and open source.

## Work Package: Standards of Care

### Main aims:

Reduce inspection burden and redundancies by developing and implementing consensus-driven requirements and qualification standards for clinical teams delivering gene and cellular therapies from cells and tissues of haematopoietic origin, and develop harmonised guidelines on patient and product management for HCPs.

### Activities:

#### Harmonisation of Site Qualification WG

- Working with industry partners to allow apheresis and cell therapy treatment centres accredited by JACIE to leverage their accreditation as part of site qualification processes.

#### Pharmacist Working Group

- **Publication;** Implementation and Operational Management of Marketed CAR T Cell Therapy – a guidance by the GoCART Coalition Pharmacist WG, Nezvalova-Henriksen *et al.* BMT 2023
- Working on 2<sup>nd</sup> manuscript on lymphodepletion for special cohorts of patients; weight extremes, renal impairment, hepatic impairment.

#### Apheresis Working Group

- **Publication;** A guide to the collection of T-cells by apheresis for Advanced Therapy Medicinal Product (ATMP) manufacturing - recommendations of the GoCART Apheresis WG, Worel *et al.* BMT 2023
- Working on 2<sup>nd</sup> 'best practice' manuscript focusing on washout phases and manufacturing failures.

## Do you want to get involved?

Would you like to join the GoCART Coalition? Participate in our activities? Have new proposals or ideas?

Visit our website, sign up for our newsletter or contact us at: [info@theGoCARTcoalition.com](mailto:info@theGoCARTcoalition.com)

Sign up for our newsletter:

