GoCART COALITION

Founded by EBMT EHA

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:

- Supporting the CTIWP to revise EBMT cellular therapy form.
- Working with the T2Evolve consortium on the Development of a Harmonised European Parameter Set and **C**ore **D**ata Structure for Evaluation of **CAR T**-Cell Therapies (**CART-CD**).
  - Invited experts across major European institutions and study groups to take part in a Delphi process to systematically establish a minimal core/required parameter set (‘must have’) with additional expansion modules that capture extended clinical parameter sets and biological features.
  - 1st Delphi survey sent out in Oct 2024 - results reviewed at the GoCART-T2Evolve workshop at CART25 in Feb 2025.
  - Next steps; develop and launch 2nd Delphi survey and develop a white paper of recommendations.

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.
- Supporting 8 studies, many will be presented at EBMT25.
- Three new studies were selected in 2024:

1. Observatory Study in quest of the best third line therapeutic option after Diffuse Large B Cells Lymphoma failure to second line CAR T cell therapy - Hyacinthe Johnson-Ansah and Gandhi Damaj
2. Non-ICANS neurotoxicities (NINTs) following BCMA targeted CAR T cell therapy - Charlotte Graham *et al*
3. Assessing the efficacy and tolerance of anti-CD19 CAR T cells in immunosuppressed patients with a history of solid organ transplantation or HIV and suffering from haematological B-cell malignancies - Laure Ricard and Margot Jak *et al*

Watch out for the next call in 2025!

Join us at 3 GoCART sessions at EBMT25!

Tuesday April 1:

- 11 AM – 12:15 PM – Turning the power of cells & genes into actual treatments
- 2:30 PM – 3:45 PM – GoCART Scientific Excellence Research Studies
- 4:30 PM – 5:45 PM – Collect once, use often: how RWD can inform decisions

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 passport, for doctors, will be completed in 2025/26.
- We have updated and expanded the 1st edition **EBMT-EHA CAR T-Cell Handbook** to be an integral source of educational materials for the CART passport. This 2nd edition, now named the **European CAR T-Cell Handbook,** is online and open source, with the editorial board made up of GoCART Secretariat members.

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

- Working on a manuscript on lymphodepletion for special cohorts of patients; weight extremes, renal impairment, hepatic impairment.

Apheresis Working Group

- Working on ‘best practice’ manuscript focusing on washout phases and manufacturing failures.

Do you want to get involved?

Would you like to participate in our activities? Have new proposals or ideas?

Visit our website, sign up for our newsletter or contact us at: info@theGoCARTcoalition.com

Sign up for our newsletter:

“If you want to go fast, go alone. If you want to go far, go together.” // **www.theGoCARTcoalition.com**