

Breadcrumb

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The GoCART Coalition has continued to work actively in 2024 bringing partners together to discuss issues on the complex field of cellular therapies. The GoCART Coalition, a joint collaboration by EBMT and EHA, aims to promote patient access to novel cellular therapies and to contribute to health and well-being by multi-stakeholder collaboration on clinical data, standards of care, education and training, and policy and advocacy. GoCART's vision is to create a collaborative platform driven by input of a diverse group of stakeholders who jointly develop projects that advance the field of cellular therapies in Europe. The GoCART Coalition's work is divided into five work packages.

Main achievements of 2024

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.

Revision of the EBMT cellular therapy form

- EBMT has implemented a process to regularly revise the data collection forms. GoCART is supporting the EBMT Cellular Therapy and Immunobiology Working Party to update the Cellular Therapy form and in 2024 we invited all major European stakeholders to review the form to ensure that it continues to capture the data we need. EBMT will adopt suggestions for changes based on feasibility for implementation and collection by the centres, and for alignment with CIBMTR. The revised data collection forms are planned to be released in 2026.

CART-CD - CART Data Harmonisation

- GoCART is collaborating with the T2Evolve consortium to develop a harmonised European parameter set and core data structure for the evaluation of CAR T-Cell therapies (CART-CD). We will do this by involving experts across major European institutions and study groups 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 for special clinical and/or biological purposes.
- To start the process, we held a joint workshop on “Data accessibility, comparability and shareability” at the CART24 meeting in Valencia to reach consensus and develop next steps. We identified the experts to develop the questions for the Delphi process. We reached out to experts in the field to provide invaluable input in shaping the future of CAR T-cell research to participate in this multi-round Delphi survey, where contributions will help ensure critical data are captured in a standardised and meaningful way. The first Delphi survey was sent out in October 2024, and GoCART and T2Evolve will hold a joint workshop at the 7th European CAR T-cell meeting, in Strasbourg on

February 6th, 2025, to discuss the results of the survey and next steps.

Work package: Standards of Care

Main aims:

Develop harmonised guidelines on patient and product management for health care professionals, and to 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.

Develop harmonised guidelines for pharmacists working on CART

- The GoCART Coalition Pharmacist Working Group had monthly meetings in 2024 and decided to develop a new manuscript on lymphodepletion for special cohorts of patients; weight extremes, renal impairment, hepatic impairment. It is anticipated that the manuscript will be completed in 2025.

Work package: Education and Training

Main aim:

Harmonised training requirements and educational materials for HCPs - Development of a CART passport

- We are developing a CART passport with industry partners and national country representatives of harmonised training requirements and educational materials for health care professionals (HCPs) in CAR T 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.
- As an integral step to develop a harmonised training curriculum for HCPs in CAR T-cell therapy, we will use the EBMT-EHA CAR T-Cell Handbook as the foundation for knowledge transfer to develop the CART passport training

curriculum. In 2024 we have been in the process of updating the Handbook. Editors have expanded the scope from the first from the second edition, and have invited representatives not only from academia, but also from the industry to contribute their view of CAR T-cells and IECs development and clinical use.
- The 2nd Edition will be named the European CAR T-Cell Handbook and will be online and open access. We are planning two launches of the Handbook, one at the Annual Meeting of the EBMT in March 2025 and one at the EHA Annual Meeting in June 2025.

Work Package: Policy and Advocacy

Main aim:

Represent and promote the interests of the GoCART Coalition and its stakeholders in EU policy making by engaging with EU institutions and other relevant stakeholders.

- GoCART has contributed through our founding organisations EBMT and EHA to the development of the new European Commission on the Revision of the EU legislation on Blood, Tissues and Cells. The EU's new regulation on Substances of Human Origin (SoHO), which comes into effect mid-2027, will have a major impact on the governance of human-derived substances used for medical purposes. The European Commission presented a proposal for a regulation on standards of quality and safety for SoHO intended for human application on 19 July 2022. The European Council adopted new rules aimed at improving the safety and quality of blood, tissues and cells on 27 May 2024. The European Commission and DG Sante (the operational arm of the European Commission) hosted an event in Brussels on 24 June 2024 to mark the conclusion of the political process to agree on the new SoHO regulation.
- Although the new regulation has now been agreed, there is a lot of work for everyone involved in the SoHO field to ensure that the community is ready for the implementation of the new regulation. DG Sante will now work to establish the infrastructure outlined in the new regulation and there are opportunities for professional societies such as the EBMT and EHA to ensure that the needs of the professionals and the patients are heard and taken into consideration.

- The new SoHO regulation represents a proactive step towards safeguarding public health while encouraging innovation in the medical field. As members of the SoHO community, it is crucial that GoCART Coalition members stay informed and compliant with these changes to leverage the benefits and uphold the standards expected of us. GoCART will aim to keep the community informed on changes and requirements as they are developed to help them prepare.

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.

Scientific research on gene and cellular therapies increased substantially over the last years. With Real-World Data becoming increasingly available, many scientific questions, from different perspectives, can be explored. Only by working together can we leverage enough data to conduct meaningful research. GoCART wants to maximise the use of data collected in the central EBMT registry as well as data available to other stakeholders, and to facilitate further collaboration between stakeholders. While strongly protecting confidentiality, the guiding principle should be ‘collect once, use often’ to advance our knowledge in the field of gene and cellular therapies, support better decision making and drive efficiencies for all stakeholders.

The fourth call for retrospective research proposals was released in June 2024 and seven proposals were submitted. The proposals were evaluated against four criteria: 1) scientific impact, 2) novelty, 3) collaboration across stakeholders, and 4) feasibility. Equity, diversity and inclusion was also taken into consideration. Three winning proposals were selected:

1. Observatory Study in quest of the best third line therapeutic option after Diffuse Large B Cells Lymphoma (DLBCL) failure to second line CAR T cell therapy in the EBMT Registry
   Lead PI: Hyacinthe Johnson-Ansah (France)

2. Non-ICANS neurotoxicities (NINTs) following BCMA targeted CAR T cell therapy
   Lead PI: Charlotte Graham (UK)

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
   Lead PIs: Laure Ricard (France) and Margot Jak (the Netherlands)

The GoCART Scientific Selection Committee is composed of Prof Anna Sureda (President of EBMT), Prof Christian Chabannon (Past Chair EBMT Cellular Therapies and Immunobiology Working Party), Prof Chiara Bonini (Board Member of EHA), Prof Martin Dreyling (Board Member of EHA), Natacha Bolaños (Chair EBMT Patient Advocacy Committee), and Prof John Snowden (Past EBMT Executive Committee member).

The studies are conducted by the GoCART study team based at EBMT. The team is comprised of a study coordinator, a data manager, a clinical data specialist and two statisticians. EBMT economically supports the GoCART studies by providing dedicated personnel resources - the GoCART study team - to conduct the studies. The GoCART study team also conducts the feasibility assessment during the selection process.

In addition to the new studies, the GoCART study team are conducting eight studies from the previous three calls. PIs from ongoing GoCART studies presented results from their studies at the EBMT annual meeting in Glasgow in April 2024 and at the ASH annual meeting in San Diego in December 2024.

Communication and Outreach

We continued to produce quarterly GoCART newsletter in 2024, which came out in January, April, July and October, as well as revamping the GoCART website in 2024. You can join the mailing list for the newsletter on the GoCART website and catch up on our newsletters from 2024: thegocartcoalition.com

GoCART was present at a number of international conferences in 2024 and held three sessions at the 50th Annual Meeting in Glasgow.

If you want to get involved in the GoCART activities and work with different stakeholders to maximise the potential of cellular therapies, please visit thegocartcoalition.com website or send an e-mail to GoCART@ebmt.org

Visit the GoCART coalition website