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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 has continued to work actively in 2025 bringing partners together to discuss issues on the complex field of cellular therapies.

The GoCART Coalition's work is divided into **five work packages**:

Main achievements of 2025

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 2025 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.
- We held a joint GoCART-T2Evolve workshop at the CART25 meeting in February 2025 in Strasbourg to review the results of the first round of the Delphi survey. Following the productive discussions, we worked with the experts to refine the questions for the second Delphi round, which was sent out in April 2025. Results from the second Delphi survey were reviewed at the joint GoCART-T2Evolve workshop at the EHA25 annual meeting in Milan in June 2025.

- We are now conducting the analysis to develop a white paper of recommendations. GoCART and T2Evolve will hold a joint session at the CART26 meeting in Palma de Mallorca to build upon the finalised results of the Delphi consensus survey and identify key areas where consensus remains elusive and explore pathways toward alignment.

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 met regularly in 2025 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 2026.

Survey to optimise the ATMP cell journey at hospitals

- GoCART and the JACIE Quality Management Committee conducted a survey to explore the challenges hospitals face when working with stakeholders on ATMPs and JACIE standards. The aim was to identify overlapping standards, best practices, and areas for improvement, with a focus on optimising bedside time to enhance the "Cell Journey" and improve efficiency. Results of the survey were presented at EBMT25 and published in Hemasphere in Oct 2025, clearly confirm what many already suspected: there is substantial overlap in standards between JACIE and industry requirements — and this urgently calls for change.

Work package: Education and Training

Main aims:

Develop a central portal for health care professionals to access training and educational materials on cellular therapies and to streamline the training supply to minimise duplication of efforts and develop a consensus-based curriculum that meets the needs of multiple stakeholders.

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 certification requirements.
- As an integral step to develop a harmonised training curriculum for HCPs in CAR T cell therapy, we have updated the 1st Edition of the EBMT-EHA CAR T Cell Handbook. The 2nd Edition, named the EU CAR T Handbook, marks a significant advancement in CAR T therapy. Building on the success of the first edition, this updated version reflects the rapid advancements in clinical practice, regulatory frameworks, and scientific innovation. With expanded indications, enhanced safety profiles, and evolving access strategies, the handbook underscores the EBMT and EHA’s commitment to advancing cellular therapies and improving outcomes for patients with haematological malignancies. The handbook was presented at the EBMT annual meeting in April 2025 and at the EHA annual meeting in June 2025. The handbook is available exclusively in digital format and is open access. It will serve as the foundation for knowledge transfer in the development of the CART passport training curriculum.

Observership Programme

In 2025 we launched a pilot of the GoCART Observership Programme to support physicians from emerging CAR-T centres to conduct 1-2 week placements at experienced CAR-T institutions. The goal is to facilitate knowledge transfer, promote best practices, and contribute to the development of high-quality CAR-T programmes across Europe. We are starting the Observership Programme off with a pilot, supporting an initial four trainees from the Czech Republic, Romania, Poland

and the Republic of Ireland to visit host centres in France, Germany and Italy in Q1 2026.

In the long term, this initiative aims to strengthen CAR-T infrastructure, enable multinational clinical trials and harmonised QA/QC processes, and build a pan-European network of CAR-T-trained physicians.

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.

In 2025 we published joint statements on several pertinent issues affecting CART:

- The EU's new regulation on SoHO which comes into effect mid-2027 - GoCART has contributed to the development of the new regulation through EBMT and EHA members and has provided support to the GoCART community with information on the GoCART website and newsletter in January 2025.
- The FDA’s Removal of the Risk Evaluation and Mitigation Strategy (REMS) for Autologous CAR T Cell Therapies: A Call for Proportionate Risk Management in Europe, published on the GoCART website and newsletter in July 2025.
- Hospital Exemption for ATMPs, published on the GoCART website and newsletter in October 2025.

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.

GoCART releases regular calls for research proposals to promote the conduct of collaborative studies. 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.

We are supporting 11 studies from four calls for research proposals.

PIs from two of the ongoing GoCART studies presented their studies at the EBMT25 annual meeting in Florence in April 2025 and at the ASH annual meeting in Orlando in December 2025.

PIs from a completed GoCART study published their results in 2025: Efficacy and safety of CAR T-cell therapy in patients with primary or secondary CNS lymphoma: A study on behalf of the EBMT and the GoCART coalition
https://pubmed.ncbi.nlm.nih.gov/40400509

Communication and Outreach

We continued to produce quarterly GoCART newsletter in 2025, which came out in January, April, July and October. You can join the mailing list for the newsletter on the GoCART website and catch up on our newsletters from 2025:
thegocartcoalition.com

GoCART was present at several international conferences in 2025 and held three sessions at the 51st Annual Meeting of EBMT in Florence.

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