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The GoCART Coalition has continued to work actively in 2023 bringing partners together to discuss issues in 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 from 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 2023

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.

- A number of multi-stakeholder meetings were held in 2020-2022 to review the EBMT cellular therapy form to ensure that it is up-to-date with the latest developments in the field and these first key changes were implemented in 2022. The revised cellular therapy form has been used for the new EBMT registry in 2023. Additional yet not implemented fields will become part of the annual renewal process of updating the cellular therapy form.
- In 2023 GoCART consolidated its collaboration with the T2Evolve consortium to develop a harmonised European parameter set and data structure for the evaluation of CART therapies. We will do this 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. In 2023 we developed the project plan and funding process to begin activities in 2024.

Work package: Standards of Care

Main aims:

Develop harmonised guidelines on patient and product management for healthcare 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.

- The GoCART Coalition Pharmacist Working Group published in 2023 a practical guidance on implementation and safe operational use of marketed CAR T

products within hospital pharmacies primarily throughout Europe. The guideline outlines the key areas where pharmaceutical expertise should focus on as well as key considerations for the hospital pharmacies. Discussions began in 2023 to develop a second manuscript on lymphodepletion for special cohorts of patients; weight extremes, renal impairment, hepatic impairment.
- The GoCART Coalition Apheresis Working Group has worked on guidelines on ‘best practice’ in apheresis for optimal starting materials. These guidelines will be published in two manuscripts. The first manuscript, published in 2023, focuses on pragmatic aspects of apheresis in order to optimise the collection including venous access and apheresis platforms and technical aspects of the procedure. Discussions began in 2023 to work on the second manuscript, which will describe washout phases and manufacturing failures, sampling of the apheresis product, labelling and cryopreservation, as well as provide an outlook.

Work package: Education and Training

Main aim:

Develop harmonised educational programmes for different groups of healthcare professionals (HCPs) and patients.

- GoCART held discussions with industry partners in a number of meetings in 2023 to explore harmonisation of training requirements and educational materials. We aim to consolidate a "core" training for HCPs, with industry partners providing additional product specific training. This would be tailored to each HCP role, i.e. doctors, nurses, etc, and would act as a passport specific to the individual – in the same way a driver’s license is specific to an individual. Therefore, the trained / qualified individual can move between centres and only require additional product specific training.

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 contributed through our founding organisations EBMT and EHA to the draft proposal by the European Commission on the Revision of the EU legislation on Blood, Tissues and Cells. Key areas identified were the introduction of the joint regulation approach promoting harmonisation across the Member States as well as the principles of voluntary unpaid donations and donor protection measures. The European Parliament adopted the EU Commission's proposal for Substances of Human Origin (SoHO) Regulation in September 2023. This now needs to be approved by the EU Council (i.e. EU Member States). If not all of the amendments are adopted, or countries wish to add their own amendments, the proposal will go back to Parliament for a second reading.
- Further plans include developing a shared policy and advocacy strategy to advocate key Coalition positions with policy makers in order to contribute to European policy making on gene and cellular therapy topics including SoHO regulation and Hospital Exemption.

Work Package: Scientific Excellence

Main aim:

Promote the use of existing 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. 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.

The third call for retrospective research proposals was released in June 2023 and ten proposals were submitted. The ten proposals were evaluated against four criteria: scientific impact, novelty, collaboration across stakeholders and feasibility of the proposal. Three proposals were selected by the GoCART Selection Committee to undergo a feasibility assessment.

The selection committee was composed by 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) and Natacha Bolaños (Chair EBMT Patient Advocacy Committee).

Following the feasibility assessment by the GoCART study team, composed of a study coordinator, data manager and statisticians, the GoCART Selection Committee selected two winning proposals, listed below. EBMT will economically support the selected studies by providing dedicated personnel resources - the GoCART study team - to conduct the studies.

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

Philipp Berning[1], Michael Oertel[2], Imke E. Karsten[1], Maud Ngoya[3], Anna Ossami Saidy[4], Anna Sureda[5], Hans Theodor Eich[2], Georg Lenz[1], Bertram Glass[4], Norbert Schmitz[1]

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[2] Department of Radiation Oncology, University Hospital Muenster, Muenster, Germany.
[3] European Society for Blood and Marrow Transplantation, Hôpital St. Antoine, Paris, France.
[4] Department of Hematology and Stem Cell Transplantation, Helios Clinic, Berlin-Buch, Germany.
[5] Hematology Department, Institut Català d'Oncologia Hospitalet, IDIBELL, Universitat de Barcelona, Barcelona, Spain.

Impact of Prior B-Cell-Directed Immunotherapy on the Outcome of CD19 CAR-T cell Therapy in Aggressive B-cell Malignancies

Jan C. Schröder, Lucas Mix, Claudia Lengerke and Wolfgang A. Bethge

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Publication

2023
Implementation and operational management of marketed chimeric antigen receptor T cell (CAR-T Cell) therapy-a guidance by the GoCART Coalition Pharmacist Working Group
Group
GoCART Coalition
1st listed author
Katerina Nezvalova-Henriksen
Journal
Bone Marrow Transplant.
2023
A guide to the collection of T-cells by apheresis for ATMP manufacturing-recommendations of the GoCART coalition apheresis working group
Group
GoCART Coalition
1st listed author
Nina Worel
Journal
Bone Marrow Transplant.

We started the regular production of a quarterly GoCART newsletter, which comes out in January, April, July and October. You can join the mailing list for the newsletter on GoCART website and catch up on our newsletters from 2023: thegocartcoalition.com

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