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Collaboration is key to combat complex diseases and saving lives. The challenges in the field of cellular therapies require us to collaborate across stakeholders. EBMT is proud to be the founder of the GoCART Coalition, which aims to promote patient

access to novel cellular therapies and to contribute health and well-being by multi-stakeholder collaboration on clinical data, standards of care, education and policy.

Main achievements of 2021:

- **Work package 1: Data Harmonisation**. GoCART stakeholders reviewed the EBMT Cellular Therapy form to ensure the form is up-to-date with the latest developments in the field. The main challenge was to balance the expectations of regulatory authorities and pharmaceutical companies on the one hand, and the feasibility to collect RWD by centres on the other hand. Implementation of the new form in the EBMT Registry will follow in 2022.
- **Work package 2: Standards of Care**. The Work Group on harmonisation of site qualification standards works together with HCPs, JACIE and pharma representatives. The complexities of CAR T-cell therapies and their supply chain require pharmaceutical companies to qualify apheresis and treatment centres. However, with multiple CAR T-cell products on the market and many more in clinical trials, centres are confronted with an increasing audit workload. The aim of this group is to evaluate existing site qualification standards, work towards harmonisation by leveraging existing qualification schemes and ultimately reducing inspection workload on apheresis and treatment centres.
  As a result of the collaboration in this work group Bristol Myers Squibb, Janssen, Kite and Novartis will allow apheresis and cell therapy treatment centres to leverage their Joint Accreditation Committee (JACIE) accreditation. JACIE accredited centres will have the option of undergoing a reduced or remote audit focused on product-specific requirements for cell therapies. This result clearly shows the power of multistakeholder collaboration to deliver continuous improvements and harmonisation, ultimately to support delivery of the highest quality of care to patients.
- **Work package 3: HTA.** EUnetHTA, the European Network for Health Technology Assessment, has given input in the revision of the EBMT Cellular Therapy form within WP1 on Data Harmonisation
- **Work package 4: Education.** GoCART has launched two series of educational webinars that take place every month. In the Clinical Case Discussion series for physicians two cases are presented and discussed with experts in the field of CAR T-cell therapies. The aim is to discuss real-life clinical cases as instructive examples, foster lateral thinking to meeting participant’s own cases, contribute to a broader understanding of CAR T-cell treatments, toxicity management and

outcomes. This series is as valuable to trainees and establish physicians as it is to experts on our panel. The Nurses Best Practice Sharing Sessions focus on different aspects of the patient journey and/or the care nurses provide. In the meetings a nurse expert will present the theoretical background information and present a real-life case. The sessions promote peer-learning and sharing of best practices.

- **Work Package 5: Policy and Advocacy.** GoCART contributed to the public consultation from the European Commission on the Revision of the EU legislation on Blood, Tissues and Cells.
- **Work Package 6: Scientific Excellence.** In May 2021 the first call for retrospective study proposals was released. The focus of this call was on promoting use of existing Registry data and other sources of Real-World Data and on strengthening multi-stakeholder collaboration. Twelve study proposals were received and carefully evaluated by an expert panel consisting of: the former president of EHA, Prof. Dr. John Gribben, president of EBMT, Prof. Dr. Nicolaus Kröger and Prof. Dr. Marcelo Pasquini Senior Scientific Director at CIBMTR, the Center for International Blood and Marrow Transplant Research in the US. Three proposals were selected to receive a study grant. These proposals are currently carried out under the direction of EBMT Working Parties.

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