



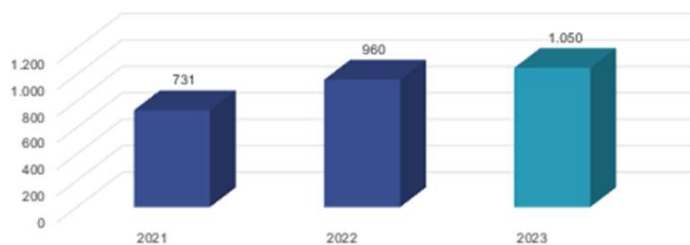
President Annual Activity Report for 2023

Anna Sureda, EBMT President

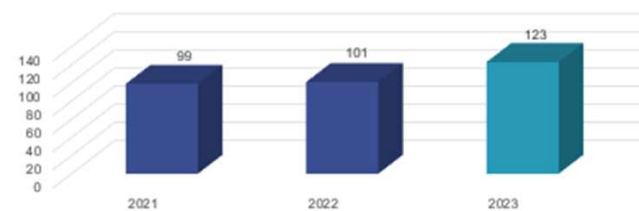
Science

Scientific productivity

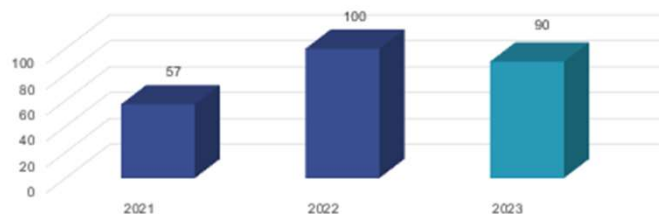
Impact Factor



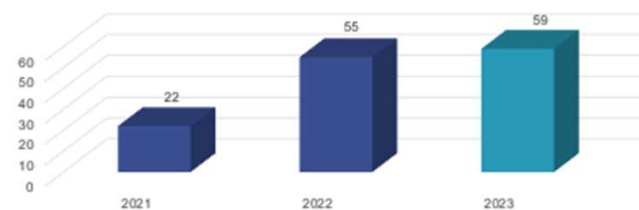
Publications



Oral presentations



Poster presentations



The Registry Upgrade Project

- ProMISe and Castor closed for data entry on the 28th of July 2023 and the drafts of the new Data Collection Forms and their corresponding completion guidelines were made available on the EBMT website.
- The **new and improved EBMT Registry database** was launched on the 24th of August 2023, streamlining data management practices for a more cohesive user experience (co-funded by the European Union under the EuroTraCTOR grant).
 - The clinical data of almost 700,000 patients were migrated from ProMISe and Castor to the new platform. This process will continue in 2024 until all core data has been migrated.
 - Over 500 users have been successfully activated in the new EBMT Registry.
- The EBMT Registry is in continuous development and new version have been released frequently, including adding new functionalities, improvements of existing functionalities, and bug fixes.



Co-funded by
the European Union

CAR-T Data Collection Initiative

EBMT has actively encouraged centres to report data on patients treated with CAR T-cell therapies to support Post Authorisation Safety (PAS) studies mandated by the EMA.

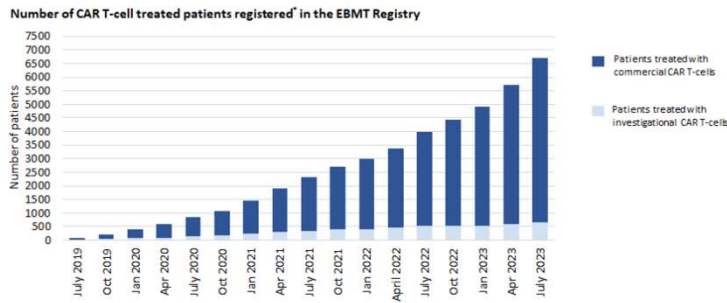
EBMT is involved in 5 PAS studies where EBMT is responsible for the data collection in these PAS studies performed by the Marketing Authorisation Holders:

1. Kymriah (Tisagenlecleucel) by Novartis, including ALL and DLBCL patients – enrolment closed
2. Yescarta (Axicabtagene ciloleucel) by Kite-Gilead, including DLBCL and PMBCL patients – enrolment closed
3. Tecartus (Brexucabtagene autoleucel) by Kite-Gilead, including MCL patients (ALL will follow)
4. Abecma (Idecabtagene vicleucel) by BMS-Celgene, including MM patients
5. Breyanzi (Lisocabtagene maraleucel) BMS-Celgene, including DLBCL, PMBCL and FL patients.

CAR-T Data Collection Initiative

THE EBMT REGISTRY HOLDS DATA ON 8,000+ CAR T-CELL PATIENTS

The graph below illustrates the steady growth of new reported cases into the EBMT Registry since 2019 and the reflected number of centres.

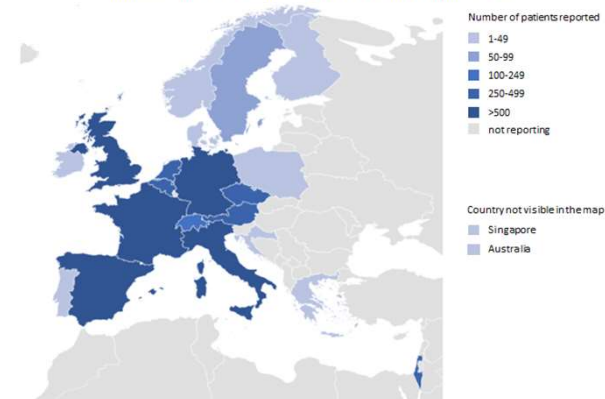


Source: EBMT Registry, July 2023

*Patients identified and marked with a CAR T-cell treatment, having at least minimal data on the diagnosis and treatment.

The map below represents a geographical approach in blue of all our reporting countries who are continually submitting data to the EBMT Registry.

Countries reporting CAR T-cell treated patients to the EBMT Registry



Source: EBMT Registry, July 2023

Education

49th Annual Meeting of the EBMT

The 2023 edition of the Annual Meeting was a special one after three years in a row of being virtual.

- More than 4,500 attendees on-site were complemented with more than 1,200 virtual attendees, representing more than 100 countries.
- We counted with the presence of more than 450 chairs and speakers; high-level science, in the cutting edge of HCT and cellular therapy was delivered in more than 200 oral presentations and 900 posters.



18 Educational Events in 2023

10 Working Parties & Nurses Group

January	CMWP Educational Meeting	Virtual
April	IEWP Spring School on Cellular Therapy for Inborn Errors of Immunity and Hematopoiesis	Frauenchiemsee, Germany
June	Midterm Meeting on New indications in Immune Dysregulatory, Autoinflammatory and Autoimmune Diseases (organised by the IEWP; ADWP; PDWP)	Brescia, Italy
September	TCWP Educational Meeting on How to survive stem cell transplantation and CAR T-cell therapy	Copenhagen, Denmark
September	2nd EBMT-China Nursing Forum and 3rd EBMT-China Scientific Forum	Beijing, China
September	IEWP Annual Conference	Graz, Austria
September	15th Educational Meeting of the EBMT Nurses Group	Madrid, Spain
November	LWP Educational Course	Warsaw, Poland
November	26th IDWP Educational Course	Athens, Greece
November	Educational Meeting on Immunology and Cellular Therapy in Plasma Cell Disorders (organised by the CTIWP; CMWP)	Hamburg, Germany

18 Educational Events in 2023

Midsized Events

February	EBMT-EHA 5th European CAR T-cell Meeting	Rotterdam, The Netherlands & Online
May	2nd Joint ASTCT-EBMT Basic and Translational Scientific Meeting	Sitges, Spain
September	8th International Transplant and Cellular Therapy Course	Barcelona, Spain
November	ASTCT-EBMT 6th International Conference on Relapse After Transplant and Cellular Therapy	Los Angeles, USA



18 Educational Events in 2023

JACIE Training Courses

March	JACIE Inspector Training Course	Barcelona, Spain
September	JACIE Inspector Training Course (French)	Paris, France
November	JACIE Inspector Training Course	Istanbul, Turkey



The EBMT Educational Task Force

- The EBMT educational task force was created in 2023 and is led by the Scientific Council Chair and Co-Chair, the Scientific Council Educational Representative, and the EBMT Medical Officer.
- **Its mission:**
 - To ensure the involvement of representatives from all Working Parties, the Nurses Group, the EBMT trainees, and JACIE in order to create a wide spectrum of educational content in HCT and CT and provide resources for professional development.
 - To keep healthcare professionals updated on the latest trends and advancements in the rapidly evolving fields of HCT and CT while harmonising educational practices in Europe and beyond.
- **The resources include:** joint WP meeting recordings, featuring interactive Q&A sessions and live discussions, Annual Meeting and other educational event recordings, recommended publications and guidelines.

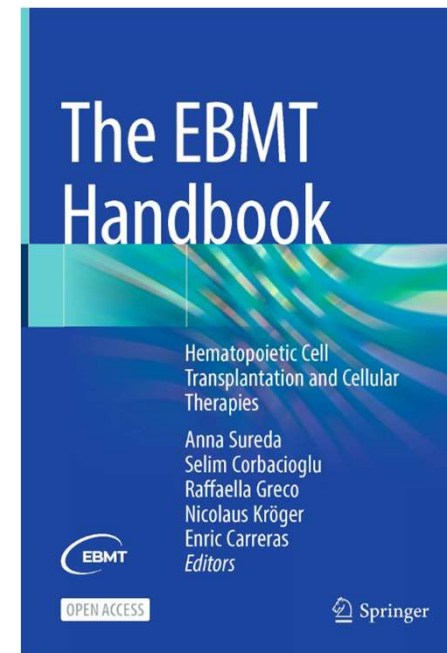
E-learning Courses and Webinars

- **E-courses**
 - **New EBMT Registry training e-courses:** for National Registries, data managers, and EBMT Staff. The modules were rolled out from May to August, and more than 850 participants have completed their training successfully so far.
 - **Chimera, an e-course from trainees for trainees,** has also continued to release modules.
 - **JACIE Accreditation e-course for Centres:** open access, e-learning course for centres who are starting, or already on, their JACIE Accreditation journey
- The **new podcast for nurses** hosted by Michelle Kenyon and Emma Chambers, *Blood Matters*, launched with great success in February 2023, having released 10 episodes throughout the year.
- The EBMT hosted **10 webinars** in 2023, including Physician webinars, Paediatric webinars, and JACIE webinars.

A New EBMT Handbook

This thoroughly revised second edition of the EBMT Handbook addresses the most recent developments and innovations in HCT and cellular therapy, presented by more than 200 authors, known as experts and well-recognised authorities in the field.

This updated version will be available in an open-access digital PDF after 14 April 2024.

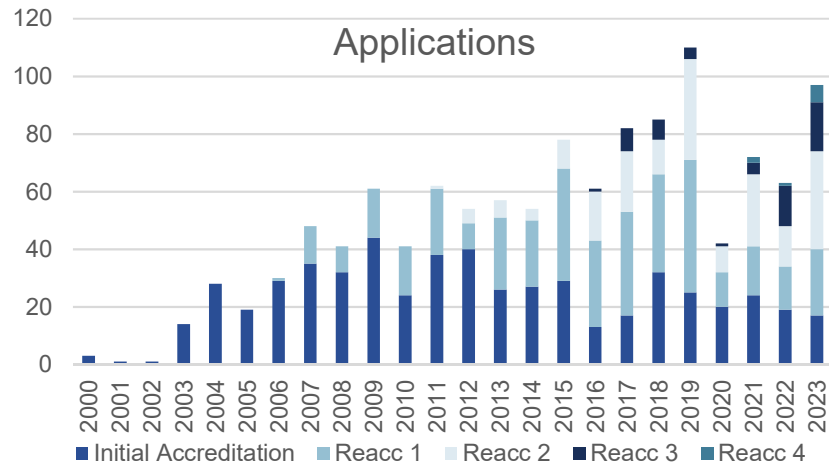


Patient Care & Advocacy

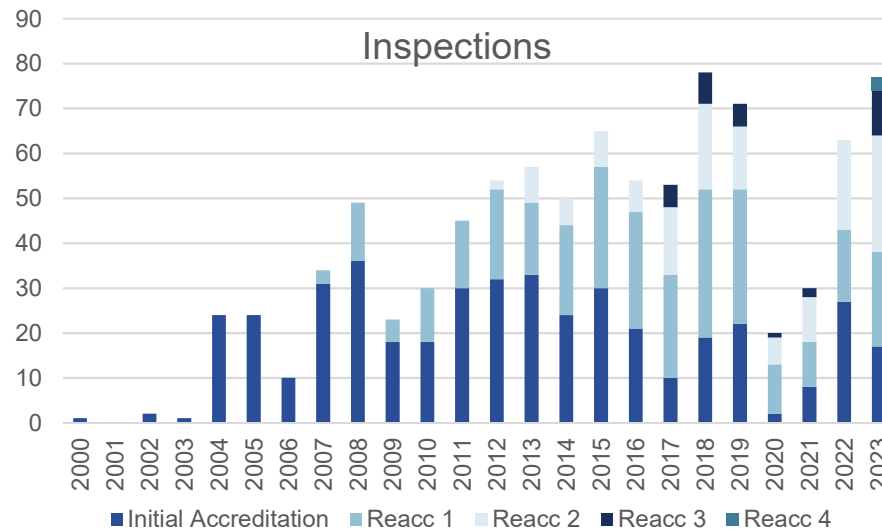
JACIE

JACIE received **97** applications in 2023 which is approximately 30% increase in comparison to 2022.

17% of the applications were for the initial accreditation with 6 centers (6%) applying for the 4th re-accreditation.

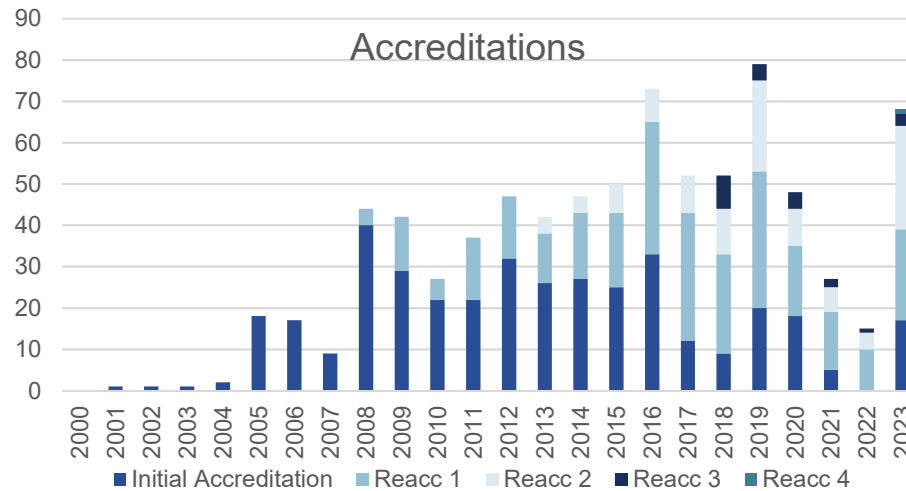


The number of inspections carried out by our inspectors increased to 77, which is the 2nd highest number of inspections in JACIE history (2019: 78 inspections). This shows that JACIE has firmly returned to pre-pandemic.



Accreditations

The number of centres accredited was 68 in comparison to 15 in 2022 and 27 in 2021.



Inspectors

- **Training Courses:** 3 training courses took place in Barcelona, Paris and Istanbul with a total of 55 new inspectors trained. The Paris and Istanbul courses were run in collaboration with the National Transplant.
- **JACIE Inspector Handbook:** JACIE launched an Inspector Handbook at the Annual Meeting in April 2023. The Handbook is provided to all inspectors to support them in their role with advice on the processes whether on how to book the travel or claim expenses to challenging Standards and how to assess them. The Handbook was developed in collaboration with the JACIE Inspector.
- **Inspector incentives:** Inspector Committee members developed a proposal for improved Inspector Incentives, which was submitted for approval by the EBMT Board. This proposal was based on the survey in July 2023 that was sent to all active inspectors. Further updates will be available in 2024. As one of the first steps, JACIE was able to offer 72 grants for JACIE Inspectors to attend the 50th Annual Meeting in Glasgow 2024.
- **Webinars:** The Inspector Committee continued with the Webinar series for the Inspectors sharing best practice and updates on process and Standards.



Accreditation e-course for Centres

- Together with the Quality Manager Committee, JACIE created a new, online, easy access, accreditation preparation course which aims to help all staff working in centres feel more confident in preparing for and undergoing the JACIE Inspection.
- The modules present information in a variety of formats, including presentations from experienced JACIE Quality Management Committee members as well as JACIE Accreditation Coordinators.
- **The learning goals are to:**
 - Understand how to apply for accreditation;
 - Be able to amend their errors by reviewing the Tricky Standards and reflecting on the content provided;
 - Reassure their staff of the accreditation processes and lessen the stress/anxiety around the inspection itself.

This new e-course is available to both members and non-members of the EBMT and is free to access at any time.

- The FACT-JACIE Standards are reviewed every three years and the latest process for the 9th Edition of Standards commenced in June 2023 with a Steering Committee 'kick-off' meeting in June.
- Five sub-committees (Clinical, Collection, Processing, Quality Management, and IEC) commenced their work in September 2023 with the work coordinated by the FACT office. The work will continue in 2024 with the Steering Committee meeting planned for February 2024, public consultation for summer 2024 and finally publication of the 9th edition in March 2025.

The EBMT Benchmarking

- The FACT-JACIE Standards require centres to review their clinical outcomes against wider datasets, referred to as benchmarking. EBMT as a registry holder is in a unique position to offer an international benchmarking scheme to centres that report data.
- The centres participating in the project received their report in September 2022 and a paper was published in *Bone Marrow Transplantation* in March 2023.
- The EBMT Benchmarking reports between 2017 and 2021 were released in November 2023.

Bone Marrow Transplantation

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Article | [Open Access](#) | Published: 09 March 2023

Benchmarking of survival outcomes following Haematopoietic Stem Cell Transplantation (HSCT): an update of the ongoing project of the European Society for Blood and Marrow Transplantation (EBMT) and Joint Accreditation Committee of ISCT and EBMT (JACIE)

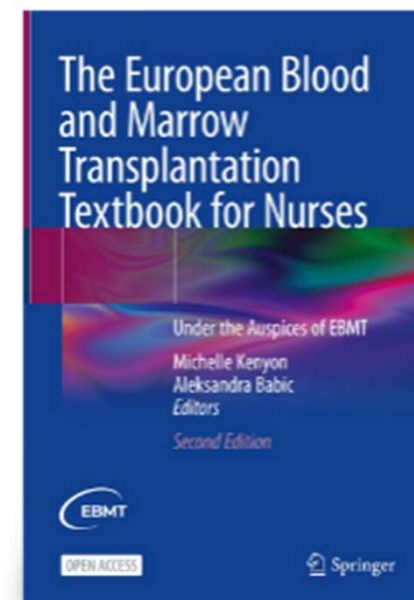
[Riccardo Saccardi](#) , [Hein Putter](#), [Dirk-Jan Eikema](#), [María Paula Busto](#), [Eoin McGrath](#), [Bas Middelkoop](#), [Gillian Adams](#), [Marina Atlija](#), [Francis Ayuketang Ayuk](#), [Helen Baldomero](#), [Yves Beguin](#), [Rafael de la Cámara](#), [Ángel Cedillo](#), [Anna María Sureda Balari](#), [Christian Chabannon](#), [Selim Corbacioglu](#), [Harry Dolstra](#), [Rafael F. Duarte](#), [Rémy Dulery](#), [Raffaella Greco](#), [Andreu Gusi](#), [Nada Hamad](#), [Michelle Kenyon](#), [Nicolaus Kröger](#), ...

[John A. Snowden](#) [+ Show authors](#)

The Nurses Group

EBMT Nurses Group's activities

- Release of the [2nd edition of the EBMT Textbook for Nurses](#) (Open Access). It is free to download and includes a new chapter on cell therapy.
- [15th Educational Meeting](#) of the EBMT Nurses Group - 28-29 September 2023 / Madrid, Spain. A total of 47 faculty members, including patients, nurses, physicians, physiotherapists and engineers from academic and clinical settings, came from 13 different countries.
- Launch of the [Nurses Next Generation Group](#) building a community for early career Transplant and Cell Therapy nurses.
- Introduction of [Blood Matters](#) – an EBMT podcast for Nurses.



The GoCART Coalition

Activities in 2023

- The GoCART Coalition continued to work actively in 2023 bringing partners together to discuss issues in the complex field of cellular therapies.
- The GoCART Coalition's work is divided into five work packages:
 1. Data Harmonisation;
 2. Standards of Care;
 3. Education and Training;
 4. Policy and Advocacy;
 5. Scientific Excellence



The key achievements of each of the five work packages are explained on the following slides.

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.

- 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.
- GoCART consolidated its **collaboration with the T2Evolve consortium** to develop a harmonised European parameter set and data structure for the evaluation of CART therapies. In 2023, the project plan and funding process were developed to begin activities in 2024.

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 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.

Bone Marrow Transplantation

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nature > bone.marrow.transplantation > perspectives > article

Perspective | Published: 01 August 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

[Katerina Nezvalova-Henriksen](#)  [Claudia Langebrake](#), [Tiene Bauters](#), [Maria-Estela Moreno-Martinez](#), [Emelie Ahnfelt](#), [Heidi Ekelund](#), [Vera Domingos](#), [Vera Pires](#), [Agnes Bonnin](#), [Ines Bojanić](#), [Yolanda Cabrerizo](#), [Sofie Terwel](#) & [Alice Tam](#)

Bone Marrow Transplantation **58**, 1069–1074 (2023) | [Cite this article](#)

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Perspective | Published: 06 April 2023

A guide to the collection of T-cells by apheresis for ATMP manufacturing—recommendations of the GoCART coalition apheresis working group

[Nina Worel](#)  [Andreas Holbro](#), [Hans Vrieling](#), [Claudia Ootjers](#), [Kaatje Le Poole](#), [Ingrid Beer-Wekking](#), [Tuula Rintala](#), [Miquel Lozano](#) & [Halvard Bonig](#)

Bone Marrow Transplantation **58**, 742–748 (2023) | [Cite this article](#)

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**.

The aim is to consolidate a "core" training for HCPs, with industry partners providing additional product specific training. This would be tailored to each HCP role and would act as a passport specific to the individual. Therefore, the trained / qualified individual can move between centres and only require additional product specific training.

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 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.

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.

- The third call for retrospective research proposals was released in June 2023. Out of the ten scientific projects that were presented, the GoCART Selection Committee selected **two winning proposals**:
 1. 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
 2. Impact of Prior B-Cell-Directed Immunotherapy on the Outcome of CD19 CAR-T cell Therapy in Aggressive B-cell Malignancies

2023 Elections

Elections



EBMT Severe Aplastic Anaemia Working Party Chair -
Antonio Risitano



EBMT Treasurer - Mette Hazenberg



EBMT Paediatric Diseases Working Party Chair -
Krzysztof Kalwak



EBMT Haemoglobinopathies Working Party Chair -
Emanuele Angelucci

EBMT Partners

**The EBMT would like to thank the 19
corporate partners for their generous support
in 2023**

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Thanks!

