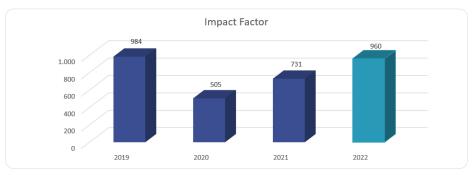


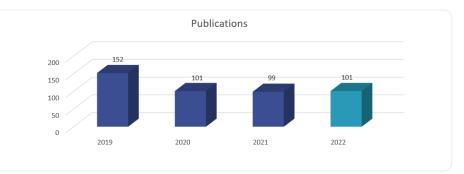
President Annual Activity Report for 2022

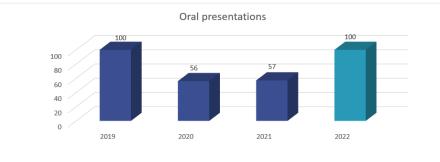
Anna Sureda, EBMT President

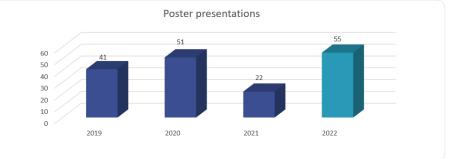


Scientific productivity









The Registry Upgrade Project

- Since 2022, the EBMT together with National Registries have worked to develop the new tool that will take ProMISe's place: the EBMT Registry, its first version will be with some limitation in its functionalities.
- The content within the data collection forms have been revised.
- A new data model has been adopted called OMOP-CDM, which will facilitate in the future fruitful collaboration with other Registries.
- EuroTraCTOR (European Transplant and Cellular Therapy Online Registry), an EU grant funded under the EU4Health programme: the project started at the end of 2022 and it aims at designing, launching and assuring the future sustainability of the new EBMT Registry. EBMT is the main beneficiary and a coordinating entity.

CAR-T Data Collection Initiative (1)

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

EBMT has focused on the performance of 5 PAS studies where EBMT is responsible for the data collection in these PAS studies performed by the Marketing Authorisation Holders:

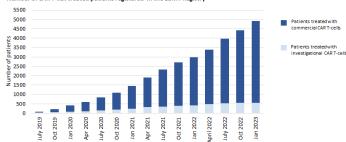
- 1. Kymriah (Tisagenlecleucel) by Novartis, approved for ALL and DLBCL
- 2. Yescarta (Axicabtagene ciloleucel) by Kite-Gilead, approved for DLBCL and PMBCL (FL will follow)
- 3. Tecartus (Brexucabtagene autoleucel) by Kite-Gilead, approved for MCL (ALL fill follow) (Research agreement expected to be signed Q4 2022)
- 4. Abecma (Idecabtagene vicleucel, ide-cel) by BMS-Celgene, approved for MM
- 5. Breyanzi (Lisocabtagene maraleucel, liso cel) BMS-Celgene, approved for DLBCL, PMBCL and FL.

CAR-T Data Collection Initiative (2)

Castor EDC, the database for cellular therapy, holds 4,600 CAR T-cell patients (see below).

The Data collection handbook for Castor EDC was created in 2022 together with the Cellular Therapy Forms Manual.

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

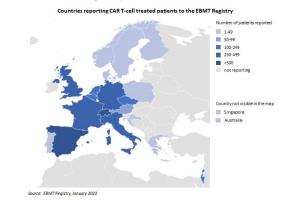


*Patients identified and marked with a CAR T-cell treatment, having at least minimal data on the diagnosis and treatment

Number of CAR T-cell treated patients registered^{*} in the EBMT Registry

Source: EBMT Registry, January 2023

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



Education

48th Annual Meeting of the EBMT

In March 2022, the Prague Congress Centre closed its doors to hosting the EBMT Congress in order to use it to support refugees from Ukraine. As a consequence, the 48th Annual Meeting of the EBMT was organised as a fully Virtual Meeting instead of the Hybrid format, as was initially planned.

The Annual Meeting was a success with 5,005 registered attendees from 90 countries.



Educational events 2022

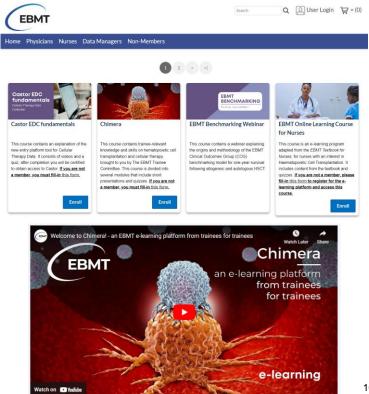
- January: 3 virtual Working Party meetings held by the CTIWP, CMWP, and SAAWP.
- February: EBMT-EHA 4th European CAR T-cell Meeting [virtual]
- March: 48th Annual Meeting of the EBMT [virtual]
- May: Joint ASTCT-EBMT Basic and Translational Scientific Retreat – Colorado, USA
- September: 7th International Transplant Course Barcelona, Spain



- September November: 7 in-person across Europe and 1 virtual educational meetings:
 - 1. ADWP Educational Meeting London, UK
 - 2. IEWP Annual Conference Paris, France
 - 3. TCWP Educational Meeting Berlin, Germany
 - 4. CMWP Educational Meeting Milan, Italy
 - 5. Nurses Group Study Days Brussels, Belgium
 - 6. IDWP Educational Course Florence, Italy
 - 7. PDW Educational Meeting Regensburg, Germany
 - 8. LWP Educational Course Virtual
- November:
 - 2nd EBMT-China Scientific Forum Hybrid, Tianjin, China
 - JACIE Training Course Castelldefels, Spain

E-learning

- Over the course of 2022, EBMT's e-learning project has also grown and matured. There are many resources available in the platform for continuous online education: E-courses, forums, and webinars.
- The E-Learning Unit organised **32 webinars** in 2022. There were **Physician** webinars, **Paediatric** webinars, JACIE Inspectors webinars, and GoCART webinars that included clinical discussions for Physicians and best practice discussions for Nurses. More details here
- The **Chimera e-course series**, a project lead by the EBMT's Trainee Committee that aims to cover all aspects surrounding HCT and cellular therapy with a focus on trainee-relevant knowledge and skills, was launched during the end of 2021, and many modules were added in 2022.



Advocacy & Quality of Care

JACIE – Accreditation in 2022

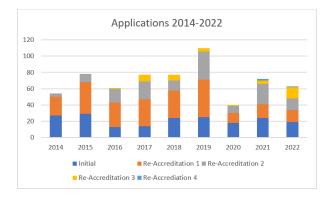
63 APPLICATIONS in 2022

The number of applications has remained relatively stable with the exception of 2020 with lower than average number of applications due to Covid -19 pandemic.

64 INSPECTIONS in 2022

2022 marked a return to nearly post-pandemic levels of inspection activity using all inspection modalities available ('short process', 'remote' and onsite inspections).

In total, 64 inspections were carried out in 2022 and 26 centres achieved JACIE accreditation.





JACIE – 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.

A further manuscript on Benchmarking Project was submitted at the end of 2022 and published in March 2023. Bone Marrow Transplantation Explore content Y About the journal Y Publish with us Y

nature > bone marrow transplantation > articles > article

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 I^{CI}, 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, ... Iohn A. Snowden + Show authors

Nurses Group Activities in 2022

- Content revision and chapter development for the 2nd edition of the EBMT Textbook for Nurses to be launched at the 49th Annual Meeting of the EBMT in Paris, April 2023. It will be the 1st of the NG publications to be fully translated and will be available in French among other languages.
- In October 2022 the EBMT Nurses Group Immune Effector Cell (IEC) Forum was launched. It is designed for nurses and AHPS looking after patients receiving Immune effector cells such as CAR-T therapy, anywhere in the patient pathway.
- The GoCART Coalition and the EBMT Nurses Group launched a webinar series on CAR-T therapies.
- 5 publications in peer reviewed journals.





Multi-stakeholder coalition collaborating to maximise the potential of cellular therapies manufactured from cells and tissues of hematopoietic origin.

- The GoCART Coalition continued to work actively in 2022 in the six Work Packages:
 - 1. Data Harmonisation
 - 2. Standards of Care
 - 3. HTA
 - 4. Education
 - 5. Policy and Advocacy
 - 6. Scientific Excellence



- EBMT and EHA released the 2nd call for retrospective research proposals within the WP6, in August 2022. Out of the 16 scientific projects that were presented, 3 of them were selected by the selection committee:
 - 1. "Impact of preceding therapy on the feasibility, safety and efficacy of anti-CD19 CAR-T cells in acute lymphoblastic leukemia" (co-PIs: Valentín Ortiz-Maldonado and Sebastian Giebel)
 - 2. "Efficacy and toxicity of CAR T cell therapy in patients with primary and secondary central nervous system lymphoma. A Retrospective Analysis of the Lymphoma WP of the EBMT" (PI: Anna Laube)
 - 3. "Infections following CAR-T therapy. A retrospective collaborative study between the IDWP, CTIWP, TCWP of the EBMT, the European Hematology Association (EHA), and the Medical College of Wisconsin" (PI: Dina Averbuch)
- The 16 proposals were evaluated against four criteria: *scientific impact, novelty, collaboration across stakeholders* and *feasibility of the proposal.*
- The selection committee was composed by Anna Sureda (President of the EBMT), Christian Chabannon (Past Chair EBMT CTIWP), John Gribben (Past President of the EHA), Martin Dreyling (Board Member of EHA) and Natacha Bolaños (Chair EBMT Patient Advocacy Committee).

Other key achievements in 2022

2022 Working Party elections



EBMT Acute Leukaemia Working Party Chair - Fabio Ciceri



EBMT Chronic Malignancies Working Party Chair - Donal McLornan



EBMT Cellular Therapy & Immunobiology Working Party Chair - Annalisa Ruggeri

New Haemoglobinophathies Working Party

- The establishment of the new Haemoglobinopathies Working Party was approved by the Board in October 2022.
- Two nominated candidates were Board of Association-approved at the EBMT Board Meeting 26-27 January 2023 in Paris:
 - Josu de la Fuente Professor of Practice (Cellular & Gene Therapy) and Consultant Haematologist, Imperial College London, UK
 - Emanuele Angelucci Transplant Program Director, San Martino Polyclinic Hospital, Genoa, Italy
- Voting for EBMT Elections opens on 11 April 2023 and the results will be announced at the General Assembly Meeting on 25 April 2023

New Practice Harmonisation Committee

- The new Practice Harmonisation Committee terms of reference were approved by the Board of Association and Scientific Council at the EBMT Board Meeting 26-27 January 2023 in Paris.
- This committee will be led by Ibrahim Yakhoub-Agha, ex-board member and CMWP Chair, and will take on the following tasks:
 - Draft a method of practice harmonisation (PH) and guidelines (G)
 - Liaise with WP chairs to select subjects of PH&G and to select potential experts
 - Track practice changes and update them as needed
 - Contribute to the strategic direction of the EBMT, including the definition of guidelines, policies and procedures as necessary
 - Liaise with Corporate Patrons and other sponsors to provide scientific input and encourage financial support activities beneficial to the EBMT

Publications by the EDI and the Trainee Committee

- The Equality, Diversity and Inclusion (EDI) Committee, published its first paper in *Bone Marrow Transplantation:* "The first steps towards a diverse and inclusive EBMT: a position paper" and a 4-year report on the achievements and challenges on EDI.
- The Trainee Committee published a paper in the Lancet Haematology: "Recognising inequalities in haematopoietic stem-cell transplantation and cellular therapy training".

Ukrainian Crisis Assistance Program

- In response to the Russian invasion of Ukraine and the devastating impact it had on civilians and patients in the affected regions, EBMT immediately set up an initiative called the EBMT Ukrainian Crisis Assistance Program (UCAP).
- This program has been continuously active throughout 2022 and has constructed a discussion forum of potential candidates for cellular therapy strategies.

Thanks!

