

President Annual Activity Report for 2024

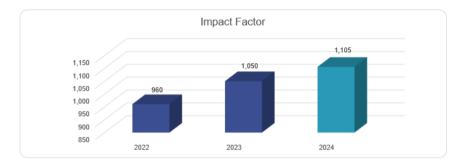
Anna Sureda, EBMT President

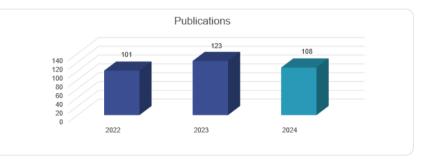


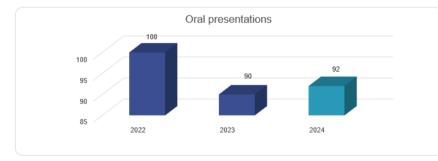
Key Achievements in EBMT Working Parties (WP)

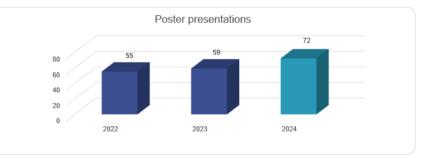
- A significant milestone achieved by the <u>ALWP</u> is the comprehensive data collection on next-generation sequencing and the use of novel therapeutics. This initiative aims to enhance the quality of the registry and strengthen the scientific impact of publications, ultimately improving patient care.
- The new <u>HWP</u> (Haemoglobinopathies WP) has celebrated its first year of activity and successfully presented real world data from the EBMT registry for sickle cell disease and Transfusion Dependent Thalassaemia.
- The <u>CTIWP</u> has conducted extensive research on transplant outcomes, including immunogenetics, conditioning regimens, and CAR T cell therapy. Key studies focus on post-CAR T fertility and its use in autoimmune diseases, in collaboration with the <u>ADWP</u>, expanding its application beyond malignancies. Another key area is CAR T outcomes in frail elderly patients, assessing toxicities and long-term results.
- The <u>CMWP</u> has led global guidelines on relapse management post-allograft for Myelofibrosis (MF), optimal pretransplant MF-related splenomegaly management, and multiple surveys on transplantation practices to identify unmet needs for consensus-based strategies.

Indicators









Advancements in the EBMT Registry

August 2024 marked the first anniversary of the **updated EBMT Registry**. Significant progress has been made, including the addition of new features and security enhancements to the MicroStrategy analysis tool, optimising user experience and system performance.

On 9 September 2024, the Registry reached a historic milestone by recording data for **10,000 CAR-T therapy patients**, underscoring the expanding role and impact of this innovative treatment.



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 enrolment closed
- 4. Abecma (Idecabtagene vicleuceI) by BMS-Celgene, including MM patients enrolment closed
- 5. Breyanzi (Lisocabtagene maraleucel) BMS-Celgene, including DLBCL, PMBCL, HGBCL and FL3B patients enrolment closed

Although enrolment is closed for these 5 studies, patient follow-up data will need to be collected for 15 years after CAR-T treatment (or until death).

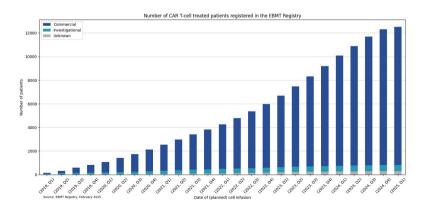
More (CAR-T) products and/or additional indications are expected to follow in the near future.

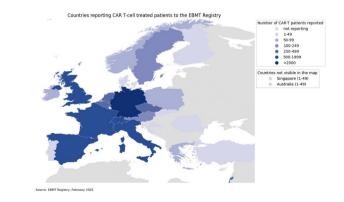
CAR-T Data Collection Initiative

THE EBMT REGISTRY HOLDS DATA OVER 12,000 CAR T-CELL PATIENTS

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

The map below highlights all reporting countries actively contributing data to the EBMT Registry, showcasing the global reach and continuous expansion of our dataset.





Practice Harmonisation and Guidelines Committee

The Practice Harmonisation and Guidelines Committee successfully conducted the 2nd annual workshop in September 2024, aimed at standardising HCT and CT clinical practices while harmonising procedures within EBMT.

Key achievements:

- 11 high-level publications
- 4 more publications forthcoming

Accessible in open access via the EBMT Educational Library.

Integration of basic & translational research into EBMT initiatives

EBMT is making significant progress in advancing the integration of basic/fundamental and translational cellular and gene therapy science across all our societies' initiatives.

Key Initiatives:

- Redefining the structure and content of current and future educational events
- Expanding grant opportunities to support research & innovation
- Establishing a robust bioinformatics support network, with a particular focus on incorporating machine learning approaches

Education

50th Annual Meeting Celebrating 50 Years of Community

The 2024 edition of the Annual Meeting was a special one celebrating **50 Years of EBMT**

- 4,718 in-person registered participants were complemented with 952 virtual registered participants, representing 107 countries.
- We counted with the presence of more than 511 chairs and speakers; high-level science, in the cutting edge of HCT and cellular therapy was delivered in 216 oral presentations and 1,494 posters (printed and e-poster).





14 Educational Events in 2024 Working Parties & Nurses Group

June	IEWP Spring School	Montserrat, Barcelona, Spain
September	Cellular Therapies In Non-Malignant Haematology - HWP and SAAWP Joint Educational Meeting	Genova, Italy
September	16th Educational Meeting of the EBMT Nurses Group	Naples, Italy
September	IEWP Annual Conference	Helsinki, Finland
October	Immunology and Cellular Therapies in Autoimmune Diseases - ADWP and CTIWP Joint Educational Meeting	Milan, Italy
October	LWP Educational Course	Rotterdam, Netherlands
November	27th IDWP Educational Course	Geneva, Switzerland
November	CMWP Educational Meeting	Warsaw, Polan

14 Educational Events in 2024 Midsize Events

February	EBMT-EHA 6th European CAR T-cell Meeting	Valencia, Spain
Мау	3rd Joint ASTCT-EBMT Basic and Translational Scientific Meeting	Washington DC, United States
September	9th International Transplant and Cellular Therapy Course	Barcelona, Spain



14 Educational Events in 2024 JACIE Training Courses

March	JACIE Inspector Training Course	Barcelona, Spain
June	JACIE Inspector Training Course	Cambridge, UK
October	JACIE Inspector Training Course	Stockholm, Sweden



Educational Initiatives and Resources

Our commitment to education remains steadfast.

The EBMT **Educational Task Force** is thoroughly working towards providing a wider and updated portfolio on the latest trends and advancements in the rapidly evolving fields of HCT and CT, which will be accessible worldwide, through:

- the WP educational meetings and mid-size events
- the new online educational library and other e-learning resources
- the creation of the core curriculum and the EBMT exam

The <u>EBMT Educational Library</u>, introduced in April 2024, is a comprehensive resource hub offering open-access materials, including publications, guidelines, manuals, and recordings of key educational events.

The revised second edition of the **EBMT Handbook** was released in April 2024. It is downloadable in PDF for free.



Patient Care & Advocacy

JACIE

- Activity Update 2024

 Applications
 Inspections
 Accreditations

 JACIE Inspectors
 9th Edition Standards
- 4. JACIE Centres





JACIE Activity Update 2024

APPLICATIONS:

Strong Post-COVID performance

- 99 applications received in 2024
- 11% of applications for initial accreditation
- 9% for 4th re-accreditation

Growing global interest, with 5% of applications from the Middle East and beyond.

INSPECTIONS:

Record-high inspections

- 91 inspections conducted in 2024
- Highest number in JACIE's history (2023: 77 inspections)

Made possible by dedicated inspectors, some conducting 2-3 inspections per year.

ACCREDITATIONS:

Slight increase from previous years

 72 centres completed the accreditation process in 2024

Strong collaboration between Accreditation Committee and applicants

Inspectors - the backbone of JACIE and the accreditation process

• **Three Inspector Training Courses** held in 2024 in Barcelona, Cambridge, and Stockholm, with a total of 59 new inspectors trained.

A special thank to the BSBMTCT JACIE Committee and the Nordic Transplant Group for their support for these training events.

- **Grant Programme**: 72 grants were awarded to Inspectors to attend the 50th Annual Meeting of the EBMT in Glasgow, in-person or virtually.
- Inspector Incentives: the Per Diem for inspections was increased from €80/day to €120/day to ensure that inspectors do not incur expenses during visits.
- The **JACIE Inspector Committee** (new JIC Chair: Dania Arabi) continued to lead Inspector Webinars providing regular updates on the Standards and accreditation process.



- Strong commitment to inspector training and development
- Increased financial support and incentives
- Ongoing leadership and engagement within JIC

9th Edition Standards review process

- In 2024, JACIE continued the collaboration with FACT to develop the <u>9th edition of the HSC Standards and the</u> <u>3rd edition of the IEC Standards</u>.
- FACT-JACIE Steering Committee met in San Antonio, Texas, USA (February 2024) to review the drafts developed in the Sub-Committees for *Clinical*, *Collection*, *Processing* and *Quality Management* Standards.
- After further review by the sub-committees, the Standards were open for Public consultation in Q3 2024. The Sub-Committees will review the comments received and the prepare the final version for **publication in 2025**.

JACIE Centres

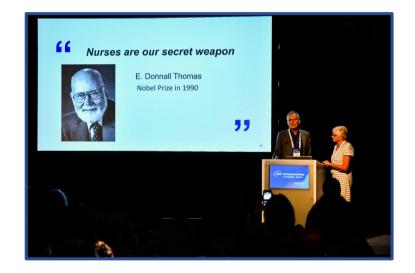
- **Supporting Centres in Accreditation**: JACIE is committed to supporting centres interested in any of the stages of the accreditation process. This work is led by the Quality Managers Committee that welcomed new members in 2024.
- E-Learning & Drop-in Sessions: Following the successful introduction of the Elearning programme for Centres in 2023, JACIE introduced quarterly Drop-in Sessions for Centres. These sessions are designed for new and ongoing accreditation participants.
- **Transition to Digital Certificates**: JACIE made a transition from paper to digital accreditation certificates in 2024.

These certificates are now provided in a safe, digital format and can also be verified online for added convenience and security. This shift not only streamlines processes but also aligns with JACIE's commitment to reducing environmental impact.

The Nurses Group

Key achievements 2024:

- 1. 40 years
- 2. Grant opportunities
- 3. Next Generation community
- 4. Translated versions of the second edition EBMT Textbook for Nurses
- 5. "Blood Matters" podcast
- 6. 16th Educational Meeting
- 7. Collaboration with EBMT-China
- 8. Record abstract submissions for 2025 Annual Meeting



Nurses Group's Achievements

• **40 years of the EBMT Nurses Group**: The 2024 EBMT Annual Meeting provided an opportunity to celebrate the milestones of the EBMT Nurses Group since 1984. Former Presidents Carole Charley and Ton van Boxtel shared insights into the group's history and accomplishments during the 50th Annual Meeting of the EBMT.

• Commitment to inclusivity & education:

- Expanded <u>grant opportunities</u>, supporting early career transplant and cell therapy nurses.
- Growth of the EBMT NG <u>Next Generation community</u>, including an active LinkedIn group and the first Next Generation educational session in Glasgow.
- Launch of <u>translated versions of the second edition EBMT Textbook for Nurses</u>, in collaboration with France, Italy, Spain, and Germany. Free downloads available on the EBMT website.
- <u>"Blood Matters" podcast</u> rebranded with new co-host Hilda Mekelenkamp, continuing to engage and educate through expert discussions.

Nurses Group's Achievements

• Expanding global reach & engagement:

- Successful <u>16th Educational Meeting</u> in Naples with the GITMO nurses group, featuring bilingual sessions and interactive networking
- Strengthened collaboration with <u>EBMT-China</u>, leading to a second educational meeting
- Record <u>196 abstract submissions for the 2025 Annual Meeting</u>, showcasing growing international participation

Key achievements 2024, Work packages:

- 1. Data Harmonisation
- 2. Standards of Care
- 3. Education and Training
- 4. Policy and Advocacy
- 5. Scientific Excellence



The GoCART Coalition, a collaborative initiative by the EBMT and the EHA, made significant strides in 2024 to advance cellular therapies in Europe. The coalition's efforts are organised into five key work packages.

Work package: Data Harmonisation

• **Objective**: 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.

- 2024 Achievements:
 - Revision of the EBMT Cellular Therapy Form: Engaged major European stakeholders to update the data collection form, ensuring comprehensive data capture for collaborative studies and regulatory decisions.

Work package: Standards of Care

 Objective: 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.

• 2024 Achievements:

• Develop harmonised guidelines for pharmacists working on CART

Work package: Education & Training

• **Objective**: Enhance knowledge and skills of HCPs in cellular therapies.

- 2024 Achievements:
 - CAR T-Cell Therapy Passport: Collaborated with industry partners and national representatives to develop standardised training materials and requirements, culminating in a "passport" system tailored to various HCP roles.
 - Handbook Update: Initiated the second edition of the EU CAR-T Handbook, incorporating the latest practices and insights.

Work package: Policy & Advocacy

 Objective: 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.

- 2024 Achievements:
 - Stakeholder Engagement: Organised forums and discussions with regulators, healthcare providers, and patient representatives to address policy challenges and promote equitable access to treatments.

Work package: Scientific Excellence

- **Objective:** 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.
- 2024 Achievements:
 - **Fourth call for retrospective research proposals**: Launched in June 2024, resulting in the selection of three innovative projects:
 - Observatory Study in quest of the best third line therapeutic option after Diffuse Large B Cells Lymphoma (DLBCL) failure to second line CAR T cell therapy in the EBMT Registry. Lead PI: Hyacinthe Johnson-Ansah (France)
 - 2. Non-ICANS neurotoxicities (NINTs) following BCMA targeted CAR T cell therapy. Lead PI: Charlotte Graham (UK)
 - 3. Assessing the efficacy and tolerance of anti-CD19 CAR T cells in immunosuppressed patients with a history of solid organ transplantation or HIV and suffering from haematological B-cell malignancies. Lead PIs: Laure Ricard (France) and Margot Jak (the Netherlands).

2024 Elections



2024 Election Results



EBMT Secretary Raffaella Greco





Infectious Diseases Working Party Chair **Dina Averbuch**



Lymphoma Working Party Chair **Ali Bazarbachi**



EBMT Nurses Group President Hilda Mekelenkamp



EBMT Nurses Group Secretary **Elin Öfverberg**

EBMT PARTNERS

The EBMT would like to thank the 19 corporate partners for their generous support in 2024.







51st Annual Meeting

Florence, Italy 30 March - 2 April 2025

Shaping the Future of HCT and CT #EBMT25

Thank you.

