



PRESS RELEASE

The EBMT reaches major milestone: 10,000 CAR-T treated patients registered in its Registry

Barcelona, Spain - 9 September 2024 - The EBMT is proud to announce that its Registry has achieved a landmark milestone of 10,000 chimeric antigen receptor T-cell (CAR-T) therapy patients. This significant achievement underscores the growing impact and advancement of CAR-T therapy in the treatment of haematological malignancies.

CAR T-cell therapy and other cellular immunotherapies are advanced therapy medicinal products (ATMPs) manufactured from human primary living cells procured by hospitals or blood banks. CAR T-cell therapy is a highly personalised medicine administered to the patient in one treatment, as opposed to other forms of immunotherapies such as bispecific antibodies which are administered sequentially over prolonged periods of time. Long-term follow-up is needed to demonstrate the sustainability of safety and effectiveness of the treatment. Registries like EBMT play an essential role in this process, with a proven track record of long-term follow-up for large cohorts of patients undergoing complex therapeutic procedures such as hematopoietic cell transplantation (HCT). Leveraging this expertise, EBMT is expanding its focus to other forms of hematopoietic cellular therapies, including advanced therapy medicinal products (ATMPs) like CAR T-cells and other immune effector cells (IECs).

The EBMT Registry, established in 1974, provides a pool of data to healthcare professionals to perform studies, assess new developments, and ultimately improve the care of patients with haematological malignancies and other life-threatening disorders. As of 2024, the EBMT Registry contains data on over 700,000 patients who have received a HCT procedure and over 10,000 patients who have received CAR T-cell therapy.

Professor Anna Sureda, President of the EBMT, stated: "Reaching 10,000 registered CAR-T patients is a monumental achievement for the EBMT and the broader medical community. This milestone reflects the dedication of our member centres and the transformative impact of CAR T-cell therapies on patient lives. We remain committed to advancing the field of cellular therapy and look forward to continued progress and collaboration."

Professor Ibrahim Yakoub-Agha, Head of Cellular therapy Unit, Lille University Hospital, France, explains: "At Lille University Hospital, we launched our CAR-T therapy program in 2018, starting with just six patients. Since then, our activity has grown steadily, and we have now infused over 350 patients. Through this experience, we have developed a solid understanding of CAR-T efficacy across various diseases. However, our learning curve for managing toxicity is ongoing as we continue to learn about post-CAR-T complications, particularly those related to medium- and long-term toxicities.

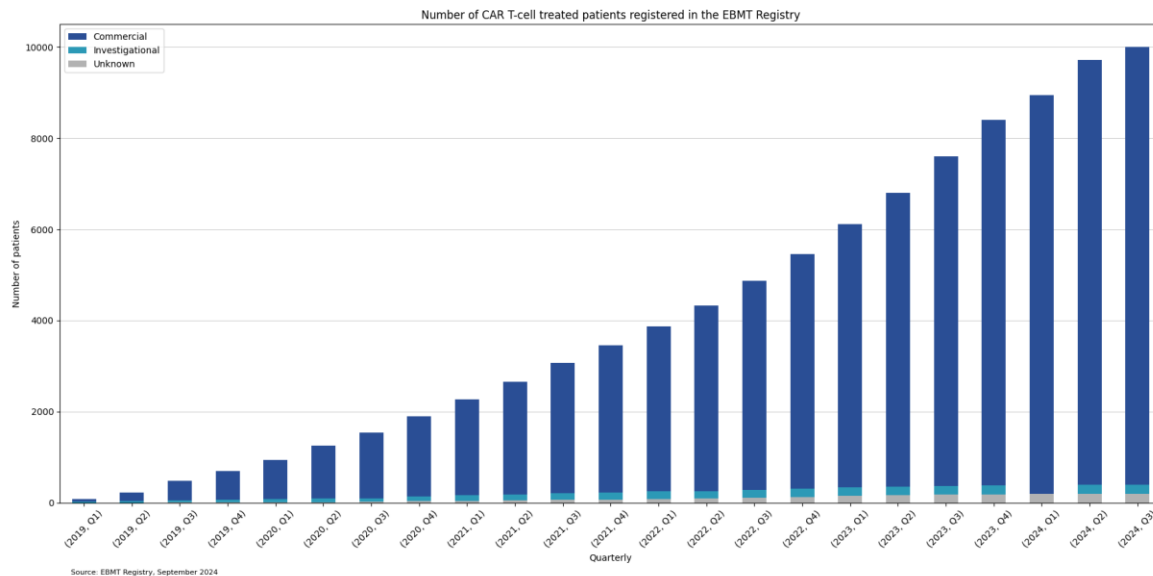
From the beginning, reporting to the EBMT Registry was a natural decision for us. We recognise the critical role of such a professional, multinational registry in helping us explore all aspects of these complex therapies. Our ultimate goal is to provide the best possible care for our patients, and the research and studies we can conduct using the EBMT Registry will play a significant role in achieving successful outcomes."

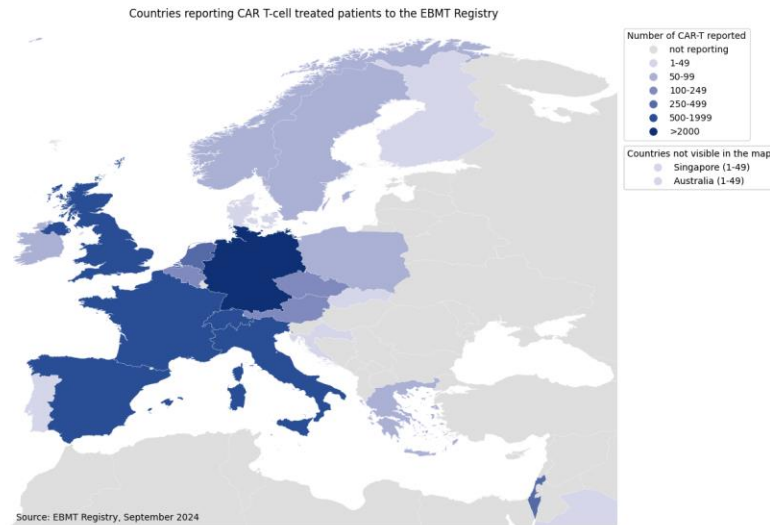


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Key Highlights:

- **Comprehensive Data Collection:** The Registry has data on HCT and cell-therapy-associated procedures including details on diagnosis and disease, first-line treatments, transplant type, donor type and stem cell source, complications and outcome. It contains data on patients who have undergone HCT and also patients who have received post-transplant cellular therapies, including but not limited to Donor Lymphocyte Infusions (DLI). The Registry also offers the possibility to enter donors' follow-up data, which is crucial to ensure maximum donor safety. The Registry underpins extensive European collaborative research which directly translates into changes in clinical practice and improvements in patient outcome and care.
- **European Medicine Agency (EMA)'s regulatory qualification:** EMA requires Marketing Authorisation Holders (MAHs) to conduct post authorisation safety studies to monitor the long-term safety and effectiveness of CAR T-cell therapies. The cellular therapy module of the EBMT Registry received a [positive qualification opinion from the EMA](#) in 2019, supporting the use of Real-World-Data captured in the EBMT Registry to inform regulatory decision making by health authorities.
- **FACT-JACIE accreditation** is a key requirement—and in some countries, even a prerequisite—for approval by health authorities to provide commercial CAR T-cell therapy. It is also highly valued by pharmaceutical companies, both those developing clinical trials and those manufacturing commercial products, who conduct their own inspections of the cell therapy programmes and facilities at each centre.
- **Global Collaboration:** The success of the EBMT Registry in reaching this milestone is a result of global collaboration and knowledge sharing among EBMT's network of over 600 member centres in more than 60 countries. In addition, the EBMT fosters collaborations with other scientific and medical associations, cooperative groups and continental registries to share data and knowledge, which is especially crucial in the CAR T-cell field.





About EBMT:

The EBMT is a non-profit medical and scientific organisation established in 1974 which hosts a unique patient registry providing a pool of data to perform studies and assess new trends. We aim to be the connection between patients, researchers and other stakeholders to anticipate the future of cellular and stem cell-based therapies. Our community of healthcare professionals is focused on innovation, research and the advancement of these fields to save and improve the lives of patients with blood-related disorders.

For more information, please visit www.ebmt.org.

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