



### **New JACIE IEC Certification pathway opens the door for centres beyond transplant**

**Barcelona, 08 May 2026 – JACIE has successfully completed its first-ever inspection under the 3rd Edition Immune Effector Cells (IEC) Standards at Guy's and St Thomas' NHS Foundation Trust — marking a major milestone for the certification of cellular therapy programmes beyond Stem Cell transplantation.**

This achievement comes at a time of rapid growth in Immune Effector Cell (IEC) therapies. While these advanced therapies, most notably CAR-T cell therapy, were pioneered and approved for haematological malignancies (such as leukaemia, lymphoma, and myeloma), they are currently being expanded to treat solid tumours and severe autoimmune diseases, with numerous clinical trials exploring these new frontiers. In this context, the need for a dedicated quality and certification framework has become increasingly urgent.

To address this, JACIE joined FACT in co-publishing the 3rd Edition IEC Standards — the first standalone standards specifically designed for IEC programmes. Developed over three years by an international expert committee and published in October 2025. The Standards officially came into effect on 2 February 2026.

This new edition introduces, for the first time for JACIE, a dedicated certification pathway for programmes delivering immune effector cell (IEC) therapies outside of a haematopoietic cell transplant setting, marking a significant expansion of JACIE's scope into broader clinical areas such as solid tumour oncology, autoimmune diseases, solid organ transplantation and advanced clinical trial environments.

The certification pathway comprehensively covers the full IEC therapy process, including patient selection, clinical care, cell collection, manufacturing (or coordination with external manufacturers), product receipt and handling, administration, post-infusion monitoring, and long-term follow-up. It also emphasizes critical aspects unique to IEC therapies, such as chain-of-identity, chain-of-custody, coordination with commercial partners, and the recognition and management of therapy-specific toxicities.

In a landmark achievement, JACIE has successfully completed its first-ever inspection under the IEC 3.1 Standards at Guy's and St Thomas' NHS Foundation Trust. As the pilot site, the Trust played a pivotal role in validating the new certification framework, demonstrating both feasibility and robustness of the process.

“The launch of this dedicated IEC certification pathway represents a natural and necessary evolution of JACIE's mission to improve patient outcomes through quality and certification,” said Charles Crawley, Chair of the JACIE Working Party. “With cellular therapies rapidly expanding



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beyond traditional transplant settings, it is essential that we provide a rigorous yet adaptable framework that supports innovation while ensuring patient safety and consistency of care.”

“This successful pilot inspection is a clear proof of concept,” added Debra Josephs, Consultant in Medical Oncology and Early Phase Clinical Trials at Guy's and St Thomas' and IEC Programme Director. “We now have a validated pathway that is ready to support a new generation of IEC therapy programmes.”

“We are grateful to JACIE for undertaking this robust external assessment of our cellular therapy programme which provides independent assurance of its quality and safety and is a key milestone in the aspiration of the Trust to expand patient access to IEC treatments across a wide range of future indications,” emphasised Nisha Shaunak, Head of Programmes, Advanced Therapies at Guy's and St Thomas'.

Charles Crawley concluded: “We strongly encourage centres delivering these therapies to engage with JACIE certification and become part of a growing, quality-driven network.”

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### 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](http://www.ebmt.org).

### About JACIE:

JACIE is Europe's only official certification body in the field of haematopoietic cell transplantation (HCT) and cellular therapy (CT). It promotes high-quality patient care and medical and laboratory practice through a profession-led, voluntary certification scheme.

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