

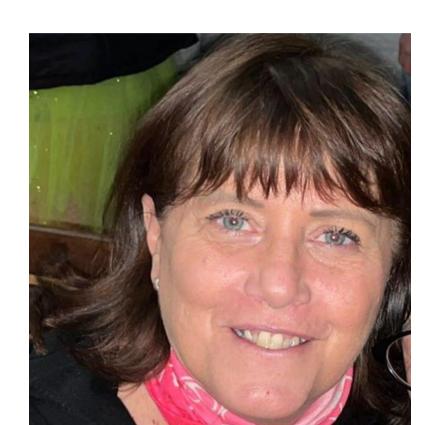
# JACIE Quality Management Committee (QMC) – Activity 2024-2025

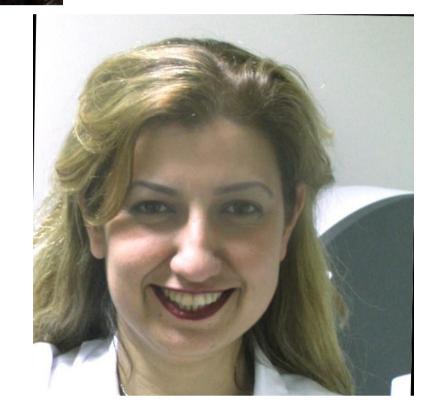
Anne Emmett<sup>1</sup>; Lea Brandt Kristensen<sup>2</sup>; Olivier Urbain<sup>3</sup>; Nick van Sinderen<sup>4</sup>; Laurel Anderson<sup>5</sup>; Julie Dolva<sup>6</sup>

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# QMC activity 2024-25







Above Left – Right: Rachel Luke, Nick van Sinderen, Anne Emmett (Chair), Olivier Urbain, Julie Dolva, Lea Brandt Kristensen. Side images: Top right: Laurel Anderson, Bottom: Ilknur Kozanoglu

A new Quality Management Committee convened at EBMT 50 in Glasgow, with three 'old hands' and five new members, and started on a program of activities to bring greater visibility to Quality activities.

A series of projects were agreed to be taken forward during the year, including developing the schedule for EBMT 51 in Firenze in 2025:

### Audit

One of the common areas for deficiencies from JACIE inspections are the Standards relating to Audit (e.g. B4.8, C4.8, D4.8). Setting up and carrying out relevant and applicable audits can be challenging for both Centres and the Quality Managers. The first resource QMC developed is a Quick Guide to Audit, which was published in August 2024 and is available through the EBMT website. There is a dedicated MTE session during the Annual Meeting 2025.

#### Survey to understand the problems related to CAR-T at an operational level

Introduction of commercial ATMP products has brought new challenges for Centres using these products and Centres now regularly liaise with the industry partners. The GoCART Coalition and the QMC have collaborated on a project to understand some of these challenges through a survey that was sent to EBMT Centres early in 2025. The results of the survey are being presented during the Quality Management Day.

#### Risk Assessment

The project proposes a model and a procedure as a basic tool for identifying common risks in stem cell collection processes. Centres are free to use, adapt or develop the template according to their specific needs and resources. It is a flexible and practical resource to help JACIE-accredited centres improve their risk management and process reliability. template and SOP are ready. Next, QMC and JACIE need to approve it and decide how to share it.

# Hub and Spoke Collection and Processing Facilities – advisory on how mobile facilities can work towards JACIE Certification

What will the accreditation process look like in a Mobile Facility, both from the implementation of JACIE and how the Inspectors will inspect a Mobile setup. A meeting was held with various stakeholders and a description of a Mobile setting was sent to the Quality Management Committee for discussion.

# We've also been working on

- > Preparing regular articles for the EBMT/JACIE Newsletter highlighting the activity of the QMC and covering Quality Management related topics
- > Coordinating the Quality Management Day for EBMT 2025 topics, schedule, speakers and Meet The Expert sessions
- > Reviewing the Quality Management Abstracts for EBMT 2025