

From first patient dosed to future capacity and capability: building a scalable NHS model for complex Advanced Therapy Medicinal Product (ATMP) trial delivery and workforce capability

The Challenge:

Within the NHS there is experience delivering advanced therapy investigational medicinal product (ATIMP) trials for oncology but there is limited experience in other settings such as autoimmunity. ATIMP trials particularly involving autologous cell-based gene therapies require coordination across multi-disciplinary functions such as research delivery teams, pharmacy, cell therapy services, external manufacturing pathways and senior operational leadership. This requires additional trial set-up processes, particularly where the recruiting specialty has limited previous experience of delivering advanced therapy studies.

Leeds Teaching Hospitals NHS Trust (LTHT), a member of the Advanced Therapy Treatment Centre (ATTC) network through Northern Alliance-ATTC, experienced this during set-up of the Quell Therapeutics' CHILL study; a Phase 1/2 multinational clinical trial evaluating QEL-005, a CD19 B-cell activated engineered Treg (regulatory T cell) therapy for refractory rheumatoid arthritis and systemic sclerosis. The study required close collaboration from LTHT specialists in rheumatology, haematology, the NIHR Leeds Clinical Research Facility (CRF): Leeds, pharmacy, NHS Blood and Transplant (NHSBT), the Trust's Research and Innovation (R&I) leadership, and colleagues at the University of Leeds. The key challenge was to create a safe, coordinated and efficient delivery model while also building workforce capability and service capacity for future ATIMP studies.

The Solution:

LTHT established a structured multidisciplinary operating model early in the set-up process. This included two complementary weekly forums: an operational set-up meeting to work through the patient pathway and allocate responsibilities, and a senior R&I meeting to maintain visibility of risks and unblock barriers quickly. These meetings are led by the NIHR CRF: Leeds's Senior Research Nurse at St James's University Hospital (SJUH) and designated Advanced Clinical Practitioner.

The operational forum brought together LTHT's rheumatology, haematology, NIHR CRF: Leeds, pharmacy, and NHSBT. The group reviewed the protocol in detail, broke down the patient pathway, and assigned clear responsibility for each stage of delivery. Rheumatology led pre-screening, screening, recruitment and long-term follow-up, while haematology led the cell therapy work up, product delivery and the initial 28-day post-infusion monitoring period,

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including oversight of toxicity management. Activities were co-ordinated through the NIHR CRF: Leeds.

This approach created a clear handover point after early post-treatment monitoring, helping to protect haematology capacity while ensuring patients continued to receive appropriate specialist monitoring and follow-up. The separate senior R&I forum provided a route for rapid escalation and resolution of operational issues before they affected delivery timelines. The internal weekly forums were kept distinct from sponsor-facing communications. This allowed LTHT teams to focus on coordination, role clarity and service readiness, while maintaining structured communication with Quell Therapeutics through established sponsor channels.

The Results:

The new approach supported LTHT to complete set-up of the CHILL study within the 150-day target and achieve the milestone of first global patient dosed on 20 July 2026. This represented an important operational achievement for an early-phase, ATMP clinical trial requiring coordination across multiple clinical and research services.

Beyond the immediate dosing milestone, the model delivered several important operational benefits. It created clearer accountability across the pathway, improved communication between rheumatology and haematology, and enabled teams to share expertise in setting up and supporting complex ATMP trials. The NIHR CRF: Leeds's set-up team at SJUH shared practical set-up knowledge with rheumatology colleagues, supporting transfer of skills into the recruiting specialty. Rheumatology colleagues are now leading set-up activity for a later-phase ATMP clinical trial, demonstrating how capability can be embedded beyond the original study team. The model is also now informing next-stage workforce capability building at LTHT, including work to expand NIHR CRF: Leeds's SJUH site involvement in future cell therapy delivery and develop advanced therapy skills among NIHR CRF: Leeds SJUH site research nurses.

Professor Chris Twelves, Director of the NIHR Clinical Research Facility: Leeds said, *"At Leeds Teaching Hospitals, we have extensive experience delivering early-phase advanced therapy trials safely and effectively for people with blood cancers. The CHILL study is the first time we have brought together specialist teams across the Trust to deliver this type of advanced therapy for autoimmune disease. We're delighted to be the first site to safely recruit and commence treatment to the first patient within two weeks of the trial opening. This has been possible thanks to close collaboration and commitment of our specialist clinical and research teams working together. By exploring whether these innovative treatments are safe and effective in conditions that are difficult to treat, we hope to pave the way for new treatments for patients in the future."*

Wider Impact

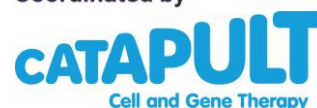
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The LTHT's model demonstrates how NHS organisations can move from delivering a single ATMP clinical trial to building sustainable local capacity and workforce capability. The case study is therefore not only about achieving first UK patient dosed, but about creating a practical, repeatable model for multidisciplinary trial delivery.

This has wider relevance for the ATTC network and for other NHS sites preparing to deliver advanced therapy trials outside traditional oncology and haematology settings. As more ATMP clinical trials move into non-oncology specialties, sites will need operating models that support safe delivery while developing capability in recruiting specialties that maybe newer to cell therapy pathways.

Case studies such as this support one of the ATTC network's aims which is to identify and share best practice from delivery sites that can be adapted, scaled and embedded across the network. By capturing LTHT's experience, this case study provides other sites with an example of how multidisciplinary coordination can strengthen trial delivery while building sustainable workforce capability and service capacity.

The approach taken at LTHT offers a scalable model: establish early multidisciplinary coordination, map the protocol against the patient pathway, assign clear ownership, create a mechanism for senior escalation, and use the set-up process as an opportunity to build future workforce capability and service capacity across specialties.

Find out more about the NIHR Clinical Research Facility: Leeds and its role in supporting early-phase and complex clinical research. [Home - NIHR Clinical Research Facility: Leeds](#)