
Delivering CAR-T Beyond Specialist Haematology: Early Sponsor Engagement and a Coordinated Operational Model

Authors – Mukul Verma¹, Laurie Baylor Curtis², John Isaacs¹

¹ Newcastle upon Tyne Hospitals NHS Foundation Trust

² Quell Therapeutics

Corresponding author:

Prof. John Isaacs

Email: john.isaacs1@nhs.net

The Challenge:

The UK is a global leader in advanced therapy investigational medicinal products (ATIMP) research, with internationally recognised expertise in cell and gene therapy and regenerative medicine, a research-active NHS, and a strong life sciences industry. Building on this scientific strength, the UK is now focused on accelerating the start-up and delivery of ATIMP trials through streamlined regulatory pathways, coordinated operational models, and specialist infrastructure. The ambition is clear, to make the UK the destination of choice for sponsors seeking fast, predictable, high-quality delivery of complex ATIMP clinical studies, while enabling patients to access cutting-edge therapies sooner.

ATIMP trials represent some of the most complex and resource-intensive studies in clinical research, placing significant strain on existing NHS trial set-up models. Compared to Clinical Trials of Investigational Medicinal Products (CTIMPs) and vaccine studies, ATIMP trials require additional layers of operational, regulatory, and logistical coordination. This case study highlights how early upstream work on an ATIMP clinical trial can expedite post clinical trial authorisation local level reviews, approvals, and set-up, to expedite study start-up timelines.

Key challenges associated with ATIMP studies include:

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Operational and manufacturing complexity

- Bespoke/centralised manufacturing, specialist logistics, and stringent chain-of-custody requirements across multiple sites
- Delivery across multi-site, multi-specialty hospital settings, involving multidisciplinary teams (MDTs) contributing to a single trial

Regulatory and governance burden

- Additional local regulatory and safety approvals, including Genetically Modified Safety Committee (GMSC) and clinical risk assessments
- Multiple layers of local governance processes that extend timelines and require cross-departmental coordination

System-level variability and lack of standardisation

- Variability in processes across NHS organisations, with a lack of standardisation across sites delivering ATIMP trials in the UK
- National Contract Value Review (NCVR) and ATIMP-specific costings, often led by a single site on behalf of multiple UK sites, which remain highly variable and complex

Workforce capability and experience gaps

- Variable workforce capability and ATIMP familiarity among coordinators, leading to inconsistent set-up, lower delivery confidence, and operational inefficiency
- Collectively, these factors lead to prolonged and often unpredictable set-up timelines, increased operational burden, and reduced historical confidence in delivery, limiting the NHS's ability to rapidly activate ATIMP trials at scale.

Following the publication of *Commercial clinical trials in the UK: the Lord O'Shaughnessy Review* in May 2023, the UK Government committed to reducing clinical trial set-up times and introduced new performance metrics for clinical trial activity. Since April 2025, there has been a national

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commitment to reduce clinical trial set-up timelines from over 250 days to 150 days by March 2026^{1*}.

Despite this, the inherent complexity of ATIMP trials means they remain particularly challenging to align with national expectations under traditional delivery models. This misalignment highlights the urgent need for innovative, coordinated, and operationally efficient approaches to trial set-up.

Operational Approach to Accelerated Study Start-Up:

The Newcastle upon Tyne Hospitals NHS Foundation Trust implemented a streamlined ATIMP set-up model with three core components:

- Initial and continuous sponsor engagement
- A site-level Operational Group for Advanced Therapies
- Parallel and coordinated review processes

Initial Sponsor Engagement (Pre-Site Selection Phase)

A key innovation of this model was initial sponsor engagement, as a distinct, structured phase, complementing traditional feasibility and site selection processes. This continuous engagement, with Quell Therapeutics, started prior to formal site selection, at the study design stage, and continued throughout the feasibility period and execution stage, ensuring that site selection decisions were based on a clear and shared understanding of:

- Site readiness and cross-departmental operational capability
- Study complexity and delivery requirements
- Sponsor expectations, timelines, and priorities

¹ [DHSC Policy Statement sets out details of the 150-day metric \(published 2 October 2025\)](#)

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This approach transformed feasibility into an active, collaborative readiness phase, so that by the time site selection was confirmed, most operational uncertainties had been resolved.

- Early bidirectional engagement between Quell Therapeutics and The Newcastle upon Tyne Hospitals NHS Foundation Trust was initiated at the point of study consideration by the industry team, PI and dedicated lead from the site-level Operational group of Advanced Therapies before site selection was planned and confirmed
- Structured discussions clarified study requirements, timelines, and operational expectations
- Key documentation, infrastructure needs, and local requirements were identified upfront by NIHR Clinical Research Facility delivery team
- Potential operational challenges and risks were explored early, with mitigation strategies agreed collaboratively
- Direct communication between sponsor and dedicated lead from the site-level Operational Group minimised delays and reduced iterative queries; this continuous engagement ensured alignment between sponsor expectations and site capabilities, enabling informed site selection decisions based on true operational readiness.

As a result, once the site was selected in the presence of the MDT team, the study entered the formal set-up phase with significantly fewer unknowns, reducing downstream delays and accelerating timelines.

Operational Group for Advanced Therapies

The Operational Group for Advanced Therapies is a Trust-wide coordination hub that brings together expertise from the NIHR Clinical Research Facility (Royal Victoria Infirmary), Freeman Hospital, Newcastle Advanced Therapies, Pharmacy Clinical Trials, the Newcastle Joint Research Office (NJRO) Industry Team, and the Northern Alliance Advanced Therapies Treatment Centre. It serves as a single point of contact for ATIMP clinical trial operations, enabling rapid resolution of cross-departmental operational challenges and ensuring consistent communication with both internal

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and external stakeholders. The group meets monthly to track and report progress across the ATIMP portfolio and supports local operational and governance processes in alignment with the Advanced Therapies Oversight Committee. This provides sponsors with one coordinated point of contact and enabled rapid resolution of cross-departmental issues.

Parallel and coordinated local review processes

- The sponsor, Quell Therapeutics, and the National Institute for Health and Care Research (NIHR) Industry Hub (who provided a single, coordinated point of contact) encouraged local site collaboration with the National Contract Value Review (NCVR) lead site, which resulted in an accelerated NCVR process leaving minimal chances of later cost escalations.
- Key approvals (Finance, Research & Development (R&D), GMSC, Pharmacy) were progressed in parallel wherever possible, reducing sequential delays.
- The NJRO internal tracking system provided real-time visibility of timelines, milestones, and accountability. The Florence e-site file system at The Newcastle upon Tyne Hospitals NHS Foundation Trust and paperless study management (e-site file) such as digital signatures made the process efficient and less time consuming.
- The advanced therapies governance process, led by The Newcastle upon Tyne Hospitals NHS Foundation Trust's ATMP Oversight Committee, supported an accelerated review of genetically modified activities associated with the investigational ATMP product.

Together, these elements created a coherent 'pre-activation' and activation pathway that reduced uncertainty and compressed start-up milestones.

The Advanced Therapy Treatment Centre network

The Newcastle upon Tyne Hospitals NHS Foundation Trust has been a lead organisation in the [Advanced Therapy Treatment Centre \(ATTC\) network](#) since [Northern Alliance ATTC's](#) (NA-ATTC) establishment in 2018; working with industry, NHS and academic partners the Trust has both contributed to, and realised benefit from, being a part of this unique collaborative ecosystem to

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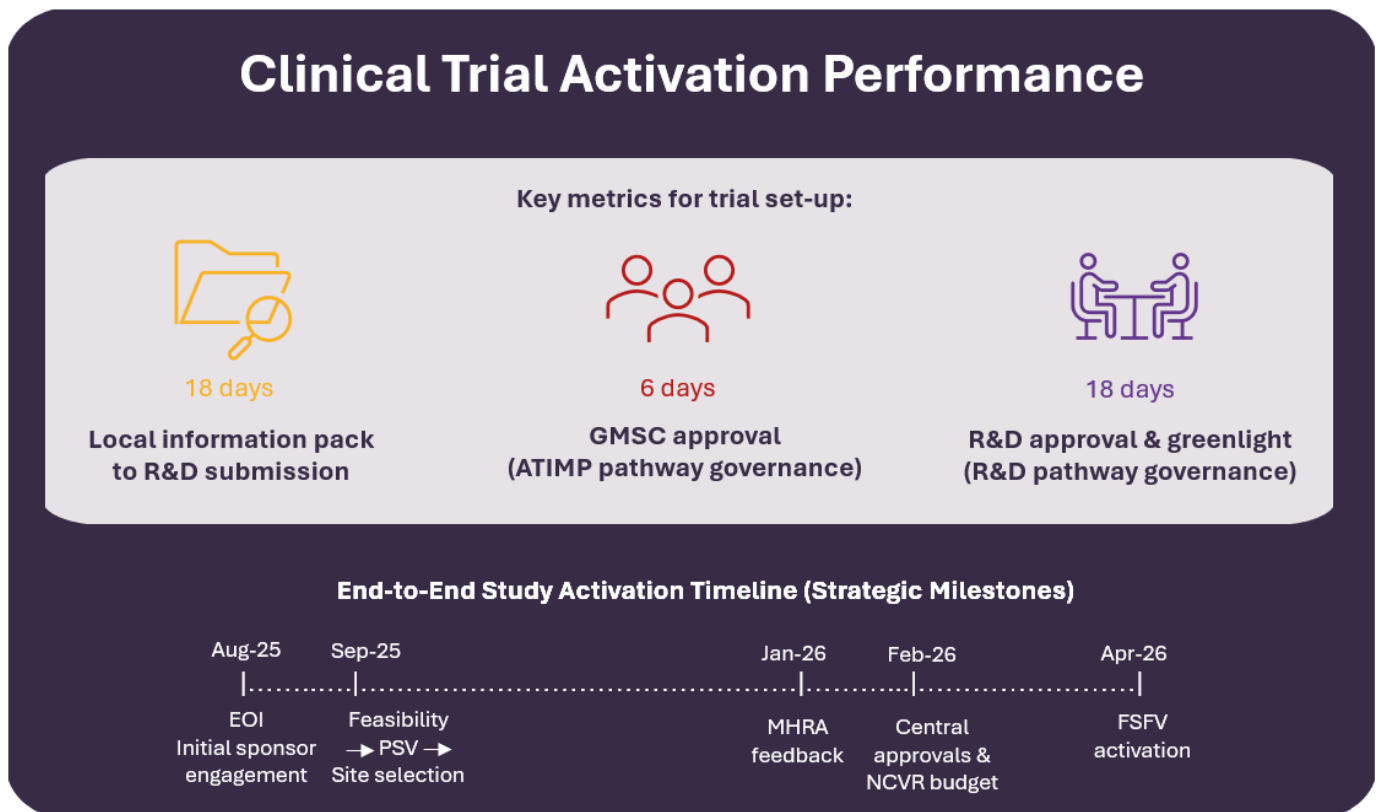
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support the delivery of adopted ATMPs at scale and the acceleration of ATMP clinical trials. The ATTC network’s current programme contributed to the Trust’s capacity to address challenges around ATIMP trials.

The results:

Implementation of this model has resulted in significant and measurable improvements in ATIMP trial set-up timeline Key Performance Indicators (KPIs) at a site and study level:



Local site set-up timelines

- Local Information Pack to R&D submission: 18 days
- GMSC approval: 6 days
- R&D valid submission to approval: 18 days

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Overall study start-up timeline

- Total study start-up time: **113 days**, positioning delivery well within the UK Government’s 150-day target

Regulatory and activation milestones

- Clinical Trial Agreement (CTA) filing to CTA approval: **71 days** (*42 days excluding a 29-day clock stop due to Request for Information*)
- CTA approval to site activation: **57 days** (*target: 60 days*)
- Site activation to first subject screened: **14 days** (*target: 30 days*)

These timelines demonstrate an unprecedented, highly efficient, coordinated, and responsive system for delivering complex ATIMP studies, positioning trial set-up well within the UK’s 150-day national target.

While individual milestone performance demonstrates strong operational execution and adherence to established KPIs, the overall end-to-end timeline from Expression of Interest (EOI) to First Subject First Visit (FSFV) is not directly comparable to standard UK benchmarks, as the initiation of site engagement preceded formal regulatory submission timelines.

In this context, the timeline should not be interpreted as a measure of system-level efficiency alone, but rather as reflecting a modified pathway in which early sponsor engagement occurred upstream of traditional activation processes.

A key strength of this approach was the integration of ‘early’ and ‘continuous’ sponsor engagement, supported by a dedicated ATIMP operational team. This enabled critical feasibility, budgetary, and operational discussions to be addressed proactively effectively functioning as “pre-activation groundwork” prior to formal study set-up.

As a result, downstream activation processes were streamlined, with reduced uncertainty, fewer iterative delays, and improved cross-functional coordination. This translated into compressed

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timelines for local regulatory approvals, reflecting a high level of site-level procedural maturity and execution efficiency.

Quell Therapeutics's proactive early engagement, flexibility, and understanding of local operational and regulatory requirements enabled efficient set up of the trial. The collaborative discussions with the operational leadership at the lead site, the NCVR R&D costing team, and the Clinical Research Facility (CRF) Business Manager at Newcastle Hospitals, supported by the sponsor, finalised site-specific ATIMP costs. This approach not only prevented the usual formal cost escalations at local sites but also fostered shared best practices, allowing complex budget costings to be completed rapidly and ensuring that local site costs were ready in time for NCVR budget release. Such collaborative, knowledge-sharing work between ATTC sites represents a significant and scalable approach to reducing trial set-up timelines and improving operational efficiency across the UK.

Beyond set-up efficiencies, this model also enabled successful clinical delivery model through a collaborative, cross-specialty approach. The Principal Investigator (PI), sub-investigators, and NIHR Clinical Research Facility delivery team collaborated with Newcastle Advanced Therapies, Haematology specialists and CAR-T specialist nurses at Apheresis centre to design and implement a robust operational model at the Newcastle upon Tyne Hospitals NHS Foundation Trust.

The NIHR Clinical Research Facility at The Newcastle upon Tyne Hospitals NHS Foundation Trust has established a portfolio of early-phase, complex ATIMP trials, providing the infrastructure and an experienced workforce required to safely deliver advanced therapies. The PI's decision to deliver this study within the CRF was centred on the specific characteristics of the ATIMP product which was biological behaviour of regulatory T cells (Tregs), rather than cytotoxic (killer) T cells which was further supported by the sponsor's preclinical data and favourable safety profile observed in comparable studies.

This combination of clinical expertise, multidisciplinary collaboration, and strategic alignment between product characteristics and site capability enabled the safe and successful delivery of the first CAR-T study outside a traditional specialist haematology setting at The Newcastle upon Tyne

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Hospitals NHS Foundation Trust, and further the first of its kind CAR-Treg study in autoimmunity in the UK.

Wider impact

This model demonstrated how initial sponsor engagements, structured operational leadership, and cross-specialty clinical collaboration can transform the delivery of complex ATIMP trials within the NHS. The successful accelerated set up of this UK CAR-T study outside a traditional specialist haematology setting, and further a first of its kind CAR-Treg study in autoimmunity in the UK, represents a significant step-change in advanced therapy delivery, showcasing the capability of Newcastle Hospitals' multidisciplinary teams and research infrastructure to safely expand beyond conventional models of care, while also achieving the 'global first recruitment' milestone for this trial.

For Sponsors:

- Predictable timelines and reduced set-up uncertainty
- A single, site-level, coordinated point of contact in the Operational Group for Advanced Therapies
- Increased confidence in site capability and delivery

For Patients:

- Earlier access to innovative and potentially life-saving therapies
- Access to advanced treatments closer to existing care pathways

For NHS Research and the UK Life Sciences Ecosystem:

- A scalable and transferable model aligned with the 150-day national target
- Increased capacity to deliver complex advanced therapy trials
- Strengthened positioning of the UK as a global leader in clinical research delivery

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