
Building a Scalable Shared Care Model to Deliver Complex Advanced Therapy Clinical Trials

The Challenge:

Complex ATMP clinical trials increasingly require expertise that is distributed across specialties, services and NHS organisations. For a Chimeric Antigen Receptor T-cell (CAR T) autoimmune trial, two iMATCH partners - Northern Care Alliance NHS Foundation Trust (NCA) and Manchester University NHS Foundation Trust (MFT) - needed to deliver one participant pathway across two clinical specialties and two NHS organisations (distinct legal entities) because the required disease-specific and CAR T expertise was not located within a single Trust.

The protocol required NCA to identify, consent and recruit participants; MFT to deliver specialist CAR T-cell treatment and acute monitoring; and participants to return to NCA for ongoing follow-up. This created a shared care model with practical challenges around handover, communication, safety monitoring, data capture, escalation and continuity of participant care.

A key challenge was to give the sponsor confidence that trial delivery could be managed safely, consistently and with accountability across organisational boundaries. NCA and MFT needed to align local processes, study documentation, and biosafety governance and contracting, while clearly defining responsibility for study activities, participant care, safety reporting, Principal Investigator oversight and escalation. Both organisations also had to ensure participants had access to both disease-specific clinical expertise and CAR T specialist support throughout recruitment, treatment and follow-up.

The Solution:

iMATCH partners developed a shared care approach that set out how trial activities would be coordinated across NCA and MFT. The model defined the participant pathway from recruitment and consent at NCA, through specialist CAR T-cell treatment and acute monitoring at MFT, and back to NCA for follow-up and ongoing care. It also clarified handover points, information sharing, escalation routes and responsibility transfer between the two organisations.

A participant pathway and detailed Scheme of Delegation were developed to provide sponsor assurance and allocate responsibilities on a visit-by-visit basis, including trial delivery, data

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management, safety reporting and participant care. Supporting templates and process materials were created to provide a practical framework for coordinating set-up activity, documenting responsibilities, managing operational oversight and to maintain consistent communication across the shared care pathway.

The approach also highlighted the importance of contractual arrangements and Principal Investigator oversight when delivering interventional advanced therapy research across more than one trial location. By aligning the model with Health Research Authority (HRA) and IRAS guidance, the partners clarified governance requirements with the sponsor and strengthened confidence in the delivery model.

The ATTC network identified the establishment of shared care arrangements as a key challenge in ATMP trial set-up, highlighting it as a broader barrier across ATMP clinical trials. Learnings from NCA and MFT were captured through a local working group, which produced practical guidance, a process flowchart and supporting templates covering key steps from pre-set-up through to close-out.

The Results:

Outcome	Value delivered
Cross-Trust trial set-up enabled	NCA and MFT delivered recruitment, specialist CAR T-cell treatment and follow-up through one shared participant pathway.
Governance and contracting strengthened	NCVR, documentation, biosafety governance, contracting and oversight requirements were clarified across both NHS organisations.
First European recruitment achieved	Early alignment between clinical, research, governance and sponsor teams supported effective feasibility and set-up and delivery.
Participant safety supported	Responsibilities, handover points, communication routes and escalation processes were defined across recruitment, treatment and follow-up, reducing ambiguity and supporting patient safety
Supported wider ATMP trial delivery	The same model has subsequently been used to successfully set up further ATMP clinical trials, showing its scalability beyond the original study.
Reusable model and standardised resources produced	The collaborative approach generated guidance, a process flowchart, participant pathway, templates and materials to support a structured approach for future adoption of shared care ATMP trials by other NHS organisations.

Wider Impact:

Learning from the development of local guidance was used to inform a wider ATTC network consultation, enabling experience from iMATCH NHS organisations to be tested, broadened and strengthened through input from subject matter experts and delivery teams across the network.

This collaborative review translated local practice into UK-wide guidance that can be adapted by other organisations planning shared care arrangements for complex advanced therapy studies across disciplines, services or NHS organisations.

The UK-wide guidance, [*Establishing shared care Advanced Therapy Medicinal Product \(ATMP\) trials, within or across NHS Trusts & Health Boards*](#), is available through the ATTC network NHS Readiness Toolkit. It supports sites to consider roles and responsibilities, communication routes, governance requirements, Principal Investigator oversight, participant handovers and safety monitoring from the outset of trial planning.

By creating a reusable resource, the work has contributed to the ATTC network's wider aim of accelerating safe and efficient advanced therapy trial delivery across the UK. It reduces duplication between sites, supports earlier identification of operational risks, and gives sponsors and NHS organisations greater confidence in shared care models. This ultimately allows for trials to be delivered at sites that otherwise wouldn't be set up or available to patients locally.

The shared care model has already supported further ATMP clinical trial set-up by NCA and MFT, demonstrating lasting system value for more consistent, scalable and participant-centred delivery of advanced therapy research.