
Cross-Specialty Coordination to Accelerate CAR-T Trial Start-Up in NHS Lothian: AUTO1-MS1 Case Study

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The Challenge

The AUTO1-MS1 trial represented one of NHS Lothian's most complex Advanced Therapy (ATMP) study startups to date, requiring coordinated input from Haematology, Neurology, Scottish National Blood Transfusion Service (SNBTS), Pharmacy, Data Management, Research & Development (R&D), and clinical services. The trial successfully opened in 92 days (from full document set received to site activation) and the first patient was recruited 5 days after activation.

This case study describes the practical challenges encountered, the collaborative solutions delivered, and the system-level learning that can be applied across the ATTC network.

Navigating Complexity in a Multisite, Multispecialty ATMP Trial

Successful site activation of the study required the alignment of different clinical specialties operating across geographically separate sites (Western General Hospital for Haematology, Royal Infirmary of Edinburgh for Neurology and Apheresis, and the Jack Copland Centre for cell receipt/storage). This inherent structural separation introduced natural challenges in scheduling, pre-screening, work-up procedures, and cross-team communication.

During study set-up, teams faced unclear laboratory pathways, contracting and budget bottlenecks due to changes in deadlines to meet sponsor requirements and challenges in establishing where responsibility sat across Haematology, Neurology, Apheresis, Pharmacy, and R&D. The setup required intense cross-specialty coordination and rapid adaptation to evolving trial requirements.

Despite these challenges, teams reported a shared sense of enthusiasm, motivation, and ownership over delivering the trial successfully — a critical culture factor for ATMP readiness.

The Solution

How Multidisciplinary Teams Overcame Barriers

Across all departments, a clear theme emerged: the solution to complexity is early engagement with all departments during feasibility, tight communication loops, and adaptive problem-solving. NHS Lothian has recently assembled a disease agnostic ATMP Working Group (ATMP Lead

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Consultant, Data Manager, ATMP Research Nurse, Clinical Nurse Manager and ATMP Quality and Product Manager) to support the set-up and running of ATMP trials. This group was instrumental in moving the study trial set-up forward in a timely manner.

Key elements included:

- NHS staff from all the relevant specialities attended, the meeting chaired by the ATMP research nurse.
- Weekly CAR-T meetings and additional small-group “micro-meetings” accelerated problem-solving and reduced the burden of email traffic, particularly between research nurses, neurology, haematology, pharmacy, and SNBTS.
- SNBTS representation (SNBTS are different legal entity to NHS Lothian) at feasibility meetings ensured apheresis and storage processes were correctly understood and aligned.
- Agile responses reviewing manuals, ensuring rapid approvals and alignment with sponsor expectations.
- Clinical pharmacy aligned trial-related SOP updates with local processes to avoid repeating work for future studies.
- Neurology and Haematology teams worked together to harmonise expectations despite operating from different geographical sites.
- Research nurses coordinated closely with Clinical Nurse Specialists and clinical services to map the CAR-T work-up alongside trial requirements, identifying where role clarity was lacking.
- Any feedback or questions for the sponsor from these weekly meetings was fed back to the Sponsor.

Proposed process improvements included:

- Closer review of apheresis processes and documentation mapped out in the trial protocol and Apheresis manual prior to trial launch.
- Encouragement for sponsors to review delegation log requirements to reduce administrative delays.
- Ensuring department approvals are tailored according to information available.

These suggestions reflect a maturing ecosystem where teams are not only solving problems but also shaping the system for more efficient ATMP delivery in the future.

The Results

Strengthening NHS Lothian’s ATMP Readiness

Even within the constraints of a complex, evolving setup process, the trial team demonstrated resilience and adaptability.

Strengths included:

- Strong interdisciplinary collaboration.

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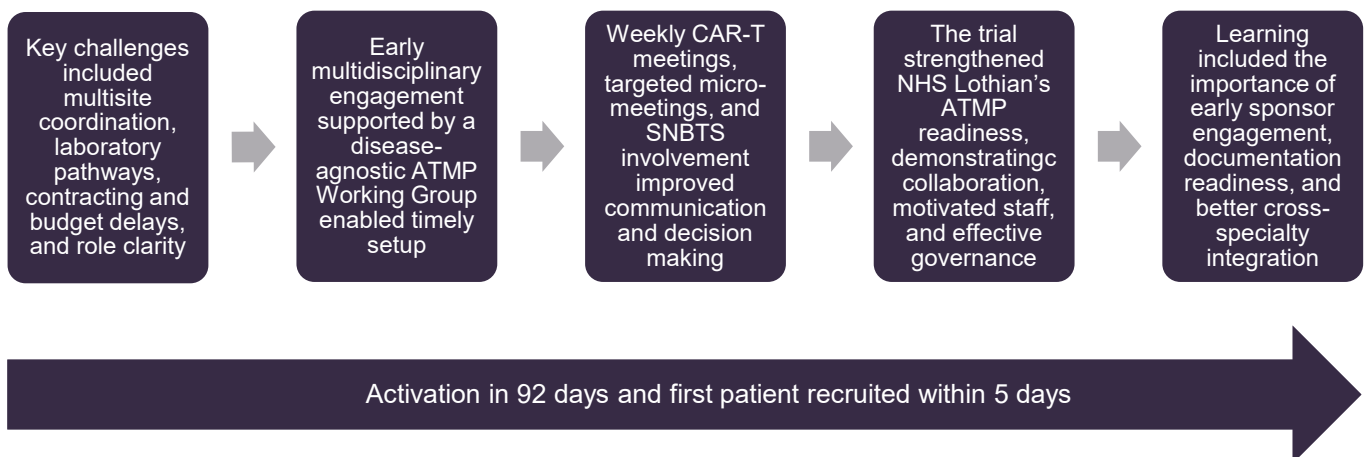


- Teams consistently described communication as clear, supportive, and efficient, with weekly meetings providing structure and transparency.
- Engaged and motivated staff.
- Ward staff demonstrated high enthusiasm and completed GCP training promptly and therefore increasing their career development opportunities.
- Research nurses and clinical teams expressed commitment to seeing the trial succeed.
- Robust governance sequencing during set up.

Insights from the study directly inform broader ATTC themes, including:

- Earlier sponsor engagement.
- Improved documentation readiness.
- More seamless integration between specialty teams.

Each of these will contribute to shorter, smoother start-up timelines for future ATMP trials.



Wider Impact

A Model of Learning Through Complexity

This trial is a strong example of how NHS Lothian's workforce adapts to the unique operational pressures of ATMP trials: multisite coordination, and complex clinical pathways. Despite these challenges, teams demonstrated exceptional collaboration, proactive problem-solving, and a shared commitment to safe, efficient trial delivery. This case study highlights that the real strength of an ATMP-capable Health Board lies not merely in its processes, but in the culture, communication, and relationships that allow those processes to work. The study has provided valuable insights that will strengthen upcoming ATMP trial setups — not only in Lothian, but potentially across the entire ATTC network.

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