









Increasing capacity to deliver advanced therapy trials

The challenge

Advanced therapies offer unprecedented promise across many disease areas where there is currently a high unmet need. With an expected increase in delivery of advanced therapy medicinal products (ATMPs), the UK has the opportunity to secure its position as a global hub in this area. In order to achieve this, scale up activities must be put in place to efficiently and effectively meet the delivery needs of the NHS. Whilst there are potential therapeutic advantages for patients coming from these newer therapies, they pose many challenges to healthcare systems that limit the ability to deliver these currently as hospitals do not have key equipment with spare capacity and new governance procedures need to be implemented.

The solution

Bringing together the various improvements across the iMATCH project are resulting in an overall increase in capacity for running cell and gene therapy trials across Manchester. These increases in capacities are detailed below.

The results

- Enhanced capacity for apheresis by providing further skilled nurses across both Manchester trusts (Manchester University NHS Trust and The Christie NHS Trust) and by purchasing and commissioning a further apheresis machine at The Christie.
- Robust governance structure has been implemented to give oversight of all ATMP trials being run
- A 50-fold increase in capacity of cell storage facilities at The Christie hospital, specifically designed for ATMPs, to allow for future scale up of providing ATMP treatments.
- Harmonising policies and procedures between pharmacy and pathology for the receipt, storage and issue of ATMPs allows both departments to work together to establish a workable, robust clinical governance framework for safe storage, release and administration of ATMPs across hospital sites in Manchester.
- Safer patient management by defining the pathways for patients receiving ATMPs, establishing a standardised process for the identification, recruitment and management of patients receiving ATMPs.

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- Comprehensive staff training to educate staff on these new medicines, how they work and the management of side effects.
- Sharing of best practice across the two trusts in the iMATCH consortium, learning from each other's experience and developing a good practise approach to ATMP delivery.
- The Christie Clinical Research Facility (CRF) has applied for JACIE accreditation, a European wide body overseeing haematopoietic stem cell transplantation and cellular therapy. If approved this would be the first CRF in the world with this standard allowing for the delivery of more ATMP clinical trials to patients at this hospital.

Making further impact

Adopting ATMPs to existing NHS services is undoubtedly a challenge with several obstacles to overcome. The successful delivery of this Manchester wide programme will be the considerably increased capability to effectively deliver advanced therapies to patients in the North West. There is a significant increase expected in patient numbers due to the anticipated number of trials and approvals of ATMPs. The Accelerated Access Collaborative (AAC) has undertaken a horizon scan of ATMP developments and conclude there are 30 ATMPs expected to undergo NICE assessment in the next 3 years¹. The infrastructure, governance and skilled personnel that the iMATCH programme is putting in place will enable the hospitals involved to safely treat more patients whilst promoting a culture of best practice across the region to support this expected increase.

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¹ <u>https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/01/aac005-atmps.pdf</u>