Advanced Therapy Treatment Centres

How ATTCs drive innovation in support of routine delivery of ATMPs

Discover more

Advanced Therapy Treatment Centres

How ATTCs drive innovation in support of routine delivery of ATMPs

- Consortia working with industry partners
- Training and education
- Institutional readiness
- Patient and public engagement

This pathway is purely illustrative and other pathways exist that may generate nuances.

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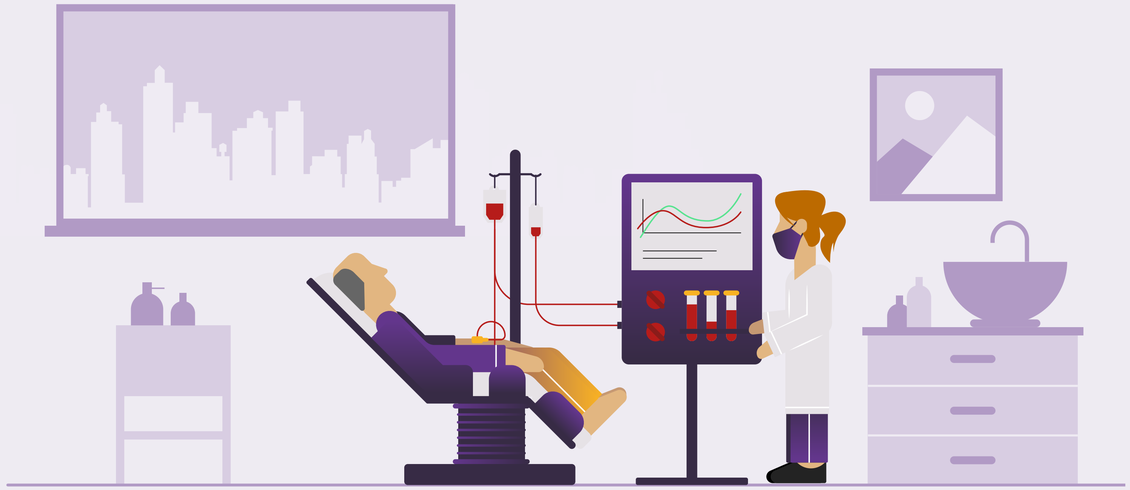
Procurement of starting materials

There are many units across the UK collecting (procuring) cells from patients to be used as a starting material for advanced therapies. Different working practices between units and varying requirements from manufacturers give rise to an increased risk of non-compliance for both sets of stakeholders. Apheresis is the most commonly used to procure cells. As part of the SAMPLE project experts from NHS clinical apheresis units and processing facilities, ATMP and equipment manufacturers, and regulatory bodies were brought together to agree a set of standard approaches to mononuclear cell collection, processing and storage, labelling and traceability, transport and logistics, quality management, audit and regulatory compliance.

See the case study to understand more about how the collection and processing of samples has been standardised across Manchester for all major cancer types.



Learn more about the recommendations

Case study

Supporting and building the supply chain for advanced therapies

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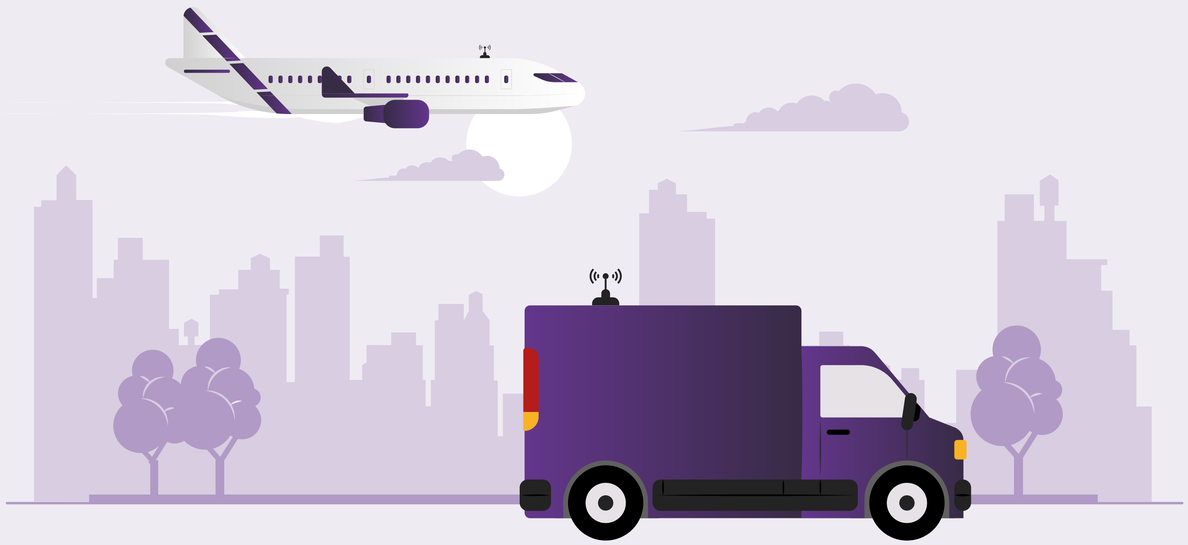
Never has the performance of the supply chain been so integral to the safe and effective treatment of patients. From the beginning of each patient's journey, we are working with supply chain specialists to track and trace the patient donation (the starting material for many cell and gene therapies), transport to the manufacturer and the subsequent return of the medicinal product from the manufacturer to the hospital.

Delivery of many of these treatments is time-critical and their success relies on an integrated and transparent supply chain (which can be enabled by the use of technology such as existing Radio Frequency Identification technology) to maintain the chain of custody. This ensures that all steps of the supply chain can be delivered in a timely fashion resulting in the best patient care.

Building strong interactions between supply chain partners and the NHS ensures the secure and smooth movement of products and data across the collaborators.

To understand how we have worked to simplify the data transfer process follow the link.

More about the work of TrakCel and their learnings from being involved in the ATTC programme can be found using the link on the opposite page.



Data transfer process

TrakCel's ATMP white paper

Video of TrakCel and NA-ATTC collaboration

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Manufacture

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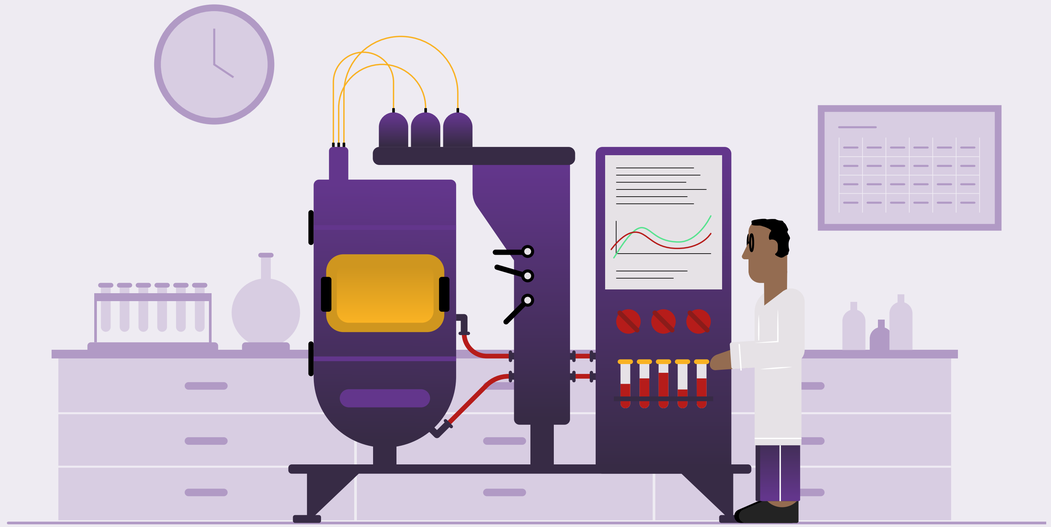
Although advanced therapies offer great promise, they also present significant challenges, including the exacting requirements of their preparation, manufacture and formulation. These involve a complex series of steps requiring specialist manufacturing techniques and compliance with strict regulations to ensure the quality and safety of the therapy. These novel medicines vary in character and each manufacturer completes these steps in slightly different ways.

The inclusion of manufacturers in the planning and execution of the ATTC programme is an unprecedented collaboration aimed at building solutions that benefit all partners, addressing the entire ATMP supply chain. An example of this type of collaboration was one between MW-ATTC's ATMP manufacturing partners, including Orbsen and Rexgenero, the supply chain provider Thermo Fisher Scientific and the University of Birmingham which examined the growing issue of pre-production consumable management and storing for manufacturers. To find out more please see the case study on kitting services opposite.

In addition, the Manufacturing and Preparation Toolbox produced by the NA-ATTC addresses areas with high rates of variation across the advanced therapies manufacturing sector and provides standardised analytical templates and techniques to ensure quality is maintained.

To find out more please see the case study on the toolkit opposite.



Kitting Services for ATMP Manufacturers

Development of a Manufacturing and Preparation Toolbox

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Supporting and building the supply chain for advanced therapies

Once an ATMP has been manufactured, the ultimate success of the treatment is dependent on the timely delivery of a viable product to the patient and having a robust supply chain is critical to this. As part of this chain, the final delivery step from arrival at the hospital to administration to the patient is equally important and it is vital that on arrival at a hospital this last leg of the journey (“the last 100m”) is completed quickly whilst maintaining the chain of custody.

The last 100m

Standardising processes used in hospitals to handle ATMPs

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These therapies are transformative but are complex and disruptive for the NHS to deliver. In order to drive down complexity, reduce the risk of error and maximise resource utilisation it is necessary to standardise processes.

Examples of standardisation projects being driven through the ATTC network include standardisation of the collection of patients cells and tissues, standardised labelling, model agreements and pharmacy procedures for the handling and dispensing of ATMPs.

For simplicity, it is favourable for all pharmacies across the country to treat ATMPs the same way. By having the same procedures to follow, best practice can easily be shared throughout the UK. An added benefit to this is that companies can work across the UK in a more streamlined manner easing the process of bringing these life changing medicines to patients.

All ATMPs have specific storage, handling and dispensing instructions that must be followed to ensure that the quality and safety of products are maintained. Pharmacists are responsible for ensuring that the ordering, storage, reconstitution and dispensing of ATMPs are in line with their product specifications, patient clinical needs and protocols when the products are offered as part of a clinical trial.

The Specialist Pharmacy Service has worked closely with the ATTC network to create a series of guidance documents to standardise the UK approach to ATMPs, more can be found via the link on the opposite page.

Standardising pharmacy approaches

See the interview

Specialist Pharmacy Service

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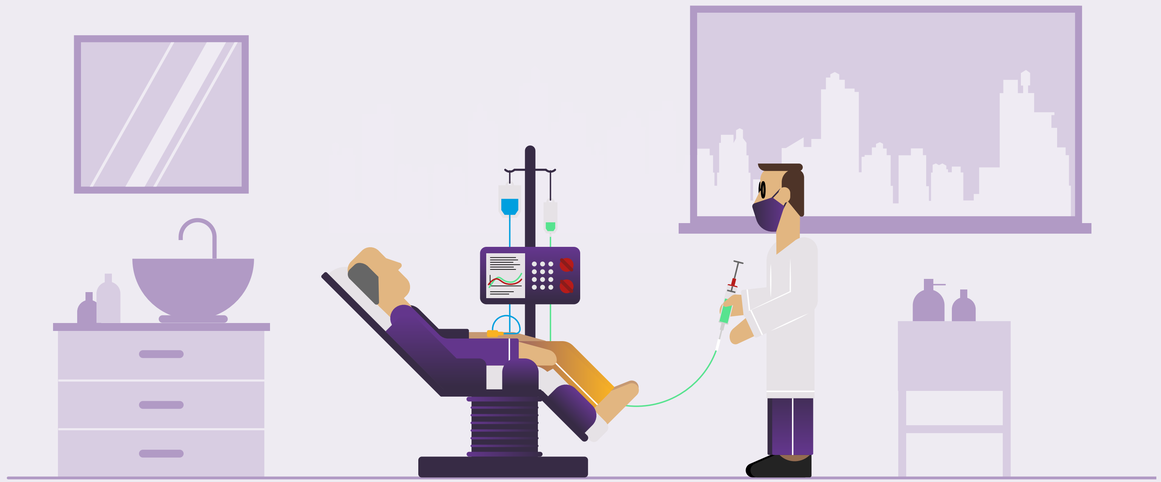
Delivery to patient

With an expected increase in the delivery of ATMPs, the UK, as a global leader, must plan and prepare for this scale-up. This requires a co-ordinated, system-led change to ensure the effective and efficient delivery of these complex therapies by the NHS in a way that meets the needs of patients.

This is being done through system standardisation, for example, the development of standardised tools (e.g. costing tools and model clinical trial agreements) as well as increasing capability through workforce development and physical infrastructure expansion. This is all required in order to support the delivery of these therapies ‘at scale’.

An example of how physical infrastructure is being developed is the implementation of a 50-fold increase in capacity of cell storage facilities at The Christie Hospital. This was specifically designed for ATMPs to allow for future scale-up for providing ATMP treatments.



Case study

See the interview

Unique consortia of industry partners collaborating to support the ATMP community

The ATTC network facilitates a unique collaboration of partners across the ATMP landscape. This includes those from industry, academia, healthcare providers, government agencies and regulatory bodies that has led to a single, respected voice.

The ATTC network has facilitated huge advances in the way healthcare organisations can work together effectively and at speed which has resulted in treatment with ATMPs becoming a reality for patients both in the UK and abroad. The network benefits from strong support from an experienced Industry Advisory Group (IAG) which provides expert knowledge on issues with cross-border trade, regulatory approvals, reimbursement and commissioning. The support of the IAG has been invaluable for the development of standards overcoming complex, sector-specific barriers in areas such as procurement of starting materials, clinical trial set-up and management and logistics.

The IAG industry partners have benefitted from a deep understanding of the requirements for the adoption of ATMPs by the NHS. The NHS equally benefits from an advanced view of new products in development. This means that the pipeline of new ATMPs is continually considered and planned for, ready for controlled and more expedient delivery to waiting patients.

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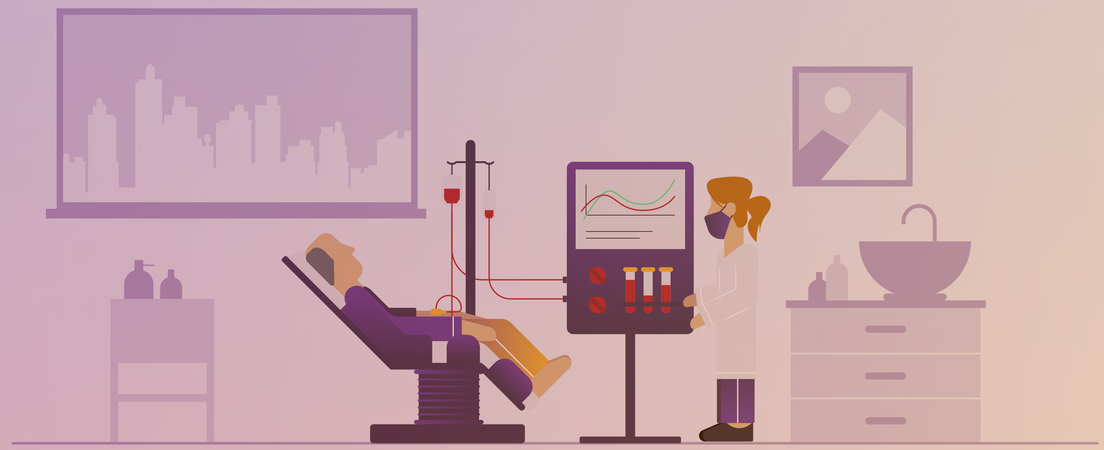

Training and Education

The ATTC network recognised a major issue to clinical adoption was a lack of ATMP training for NHS staff. The ATTC network and London Advanced Therapies (LAT) have worked with experts across the country, Health Education England and e-Learning for Health to develop a series of e-Learning modules to address this problem. The modules take the learner from the basics of cell and gene therapy through to a more in-depth look at products currently being delivered through both commissioned treatments and clinical trials.

The network has also delivered a series of educational webinars to build knowledge across the NHS, academia and industry.

The network has developed the modules to address specific current and future challenges to adoption. One such area is around shipment and storage of products at ultra-low or cryogenic temperatures and three interlinked resources have been created to address this:

- An exemplar risk assessment for the receipt of products at ultra-low temperatures
- An e-learning module on the Safe Use of Low Temperature Transport Vessels
- A template competency assessment checklist, supported by assessor guidance notes

More information can be seen in the case study.

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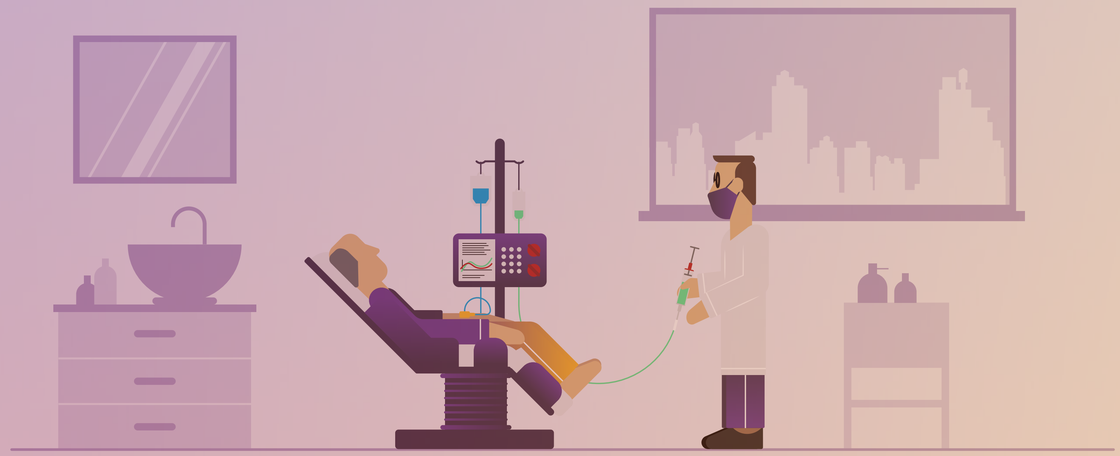

Access to webinars ›
e-learning platform ›
Case study ›
Testimonial ▶

Supporting the rapid adoption of advanced therapies across the NHS

To accelerate adoption and ensure the spread of learning throughout and outside of the ATTC network, the network has created the Advanced Therapies NHS Readiness Toolkit. The UK is represented in 9% of global ATMP clinical trials, with the ATTC network supporting over half of those. Roll-out of this toolkit across the UK health service strengthens its leading position and enhances the readiness of hospitals nationwide to adopt ATMPs and to rapidly set up clinical trials with such therapies. The availability of this new toolkit means NHS staff can easily access the resources they need to evaluate their organisation's readiness and establish the necessary infrastructure for delivery of advanced therapies.

The NA-ATTC has developed a questionnaire for use by clinical sites with aspirations to deliver ATMPs. It allows NHS clinical sites to self-assess their own Institutional Readiness (IR) for adoption of ATMPs, both through clinical trials and licensed medicines.

Read more about a cost effective and efficient solution for compliant storage and integration of data and documents used in early phase clinical trials as well as the impact the ATTC network has had to accelerate clinical trials.

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Discover the Advanced Therapies NHS Readiness Toolkit ›

Access the Site Assessment Questionnaire ›

Accelerating access to ATMP clinical trials - case study ›

Data science to support clinical trials - case study ›

Patient and public engagement

ATMPs are significantly different to conventional medicines and some of the key differences can impact both patients and their families. Advanced therapies have the potential to cure life-threatening diseases and though often it is the patient's own biological material that is used, there can be side-effects e.g. a range of immunological responses that you might similarly expect from organ transplantation. Ensuring general understanding of both the benefits and risks associated with developing and delivering ATMPs is imperative.

An essential component of the safe use and public acceptance of ATMPs relates to trusted communication and education. Obtaining valuable feedback and listening to patients' and carers' experiences, particularly around communication and information sharing, will have a massive impact on future clinical adoption of ATMPs.

The CAR T-Cell Therapy Clinical Journey Guide has been created for people who are either considering enrolling in or are already enrolled in a CAR T-cell therapy clinical trial.

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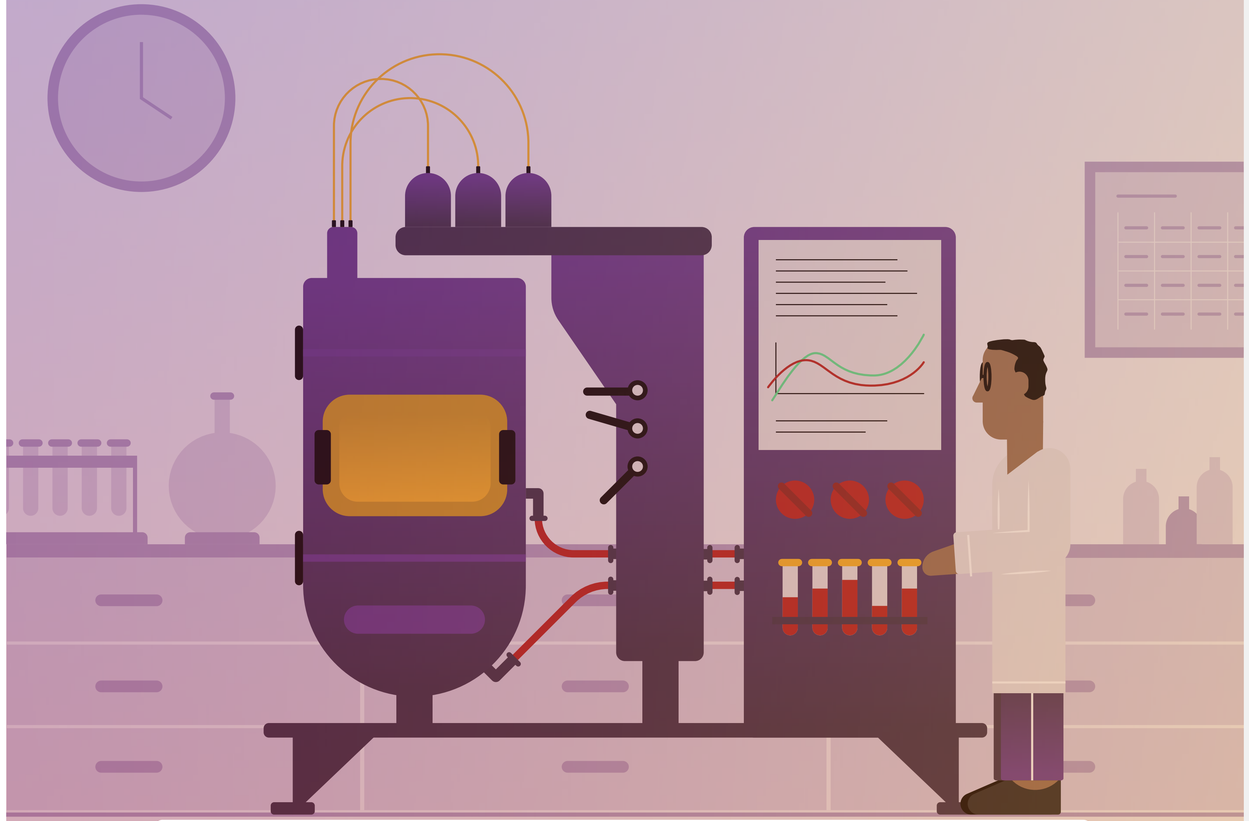

Learn more about our work with patients ›

Access webinars ›

CAR T-Cell Therapy Clinical Journey Guide ›