

ATTC Network Impact Report

March 2022



Funded by



Coordinated by



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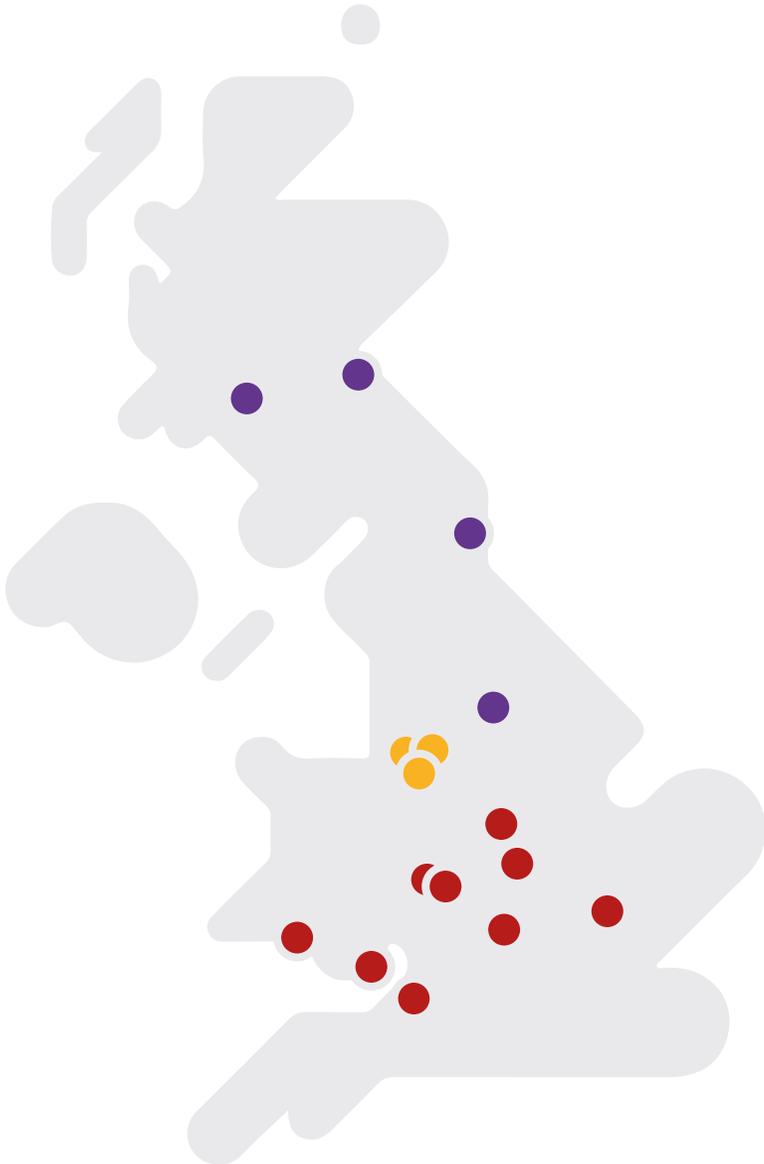
 Looking to the future

 iMATCH Spotlight

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The ATTC network, coordinated by Cell and Gene Therapy Catapult, was founded in 2018 to find innovative solutions to the unique and complex challenges associated with delivery of pioneering advanced therapy medicinal products (ATMPs)

Coordinated by the Cell and Gene Therapy Catapult (CGT Catapult) and funded by Innovate UK, the world-first programme consists of a system of connected UK Advanced Therapy Treatment Centres (ATTC) and spans across three core hubs:

- Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC)
- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- Midlands-Wales Advanced Therapy Treatment Centre (MW-ATTC)

The network involves over 800 people across industry, the NHS and public sector who work together to develop the necessary processes and infrastructure required to increase patient access to these potentially life-changing medicines.

The ATTC network has demonstrated impact across six core areas through industry led innovative solutions

These wide ranging impacts have been made possible through £37 million of funding received from Innovate UK and £8 million investment from industry across the 3 centres.

1

Commercial growth and attractiveness

The ATTC network has improved the UK's global reputation for ATMP supply and adoption, attracting greater inwards investment to grow the UK ATMP pipeline

2

Engagement and collaboration

The ATTC network, as the final segment in the supportive UK ecosystem for ATMP, has facilitated diverse collaboration across stakeholder groups

3

Leader in international standards and best practices

The network's focus on standardisation, covering the entire ATMP supply pathway, has cemented the UK's international reputation and promotion of global best practice

4

Clinical trials and patient access

Patient access to ATMPs has increased as a result of ATTC trial support, increasing the attractiveness of the UK for the conduct of clinical trials

5

Manufacturing, supply chain and logistics

ATTC network improvements to supply chain and logistics processes have increased patient access to ATMPs and made the UK more attractive to manufacturers

6

Education and workforce

The ATTC network has played a huge role in upskilling the UK ATMP workforce and has created multiple educational resources to support UK institutions in ATMP delivery

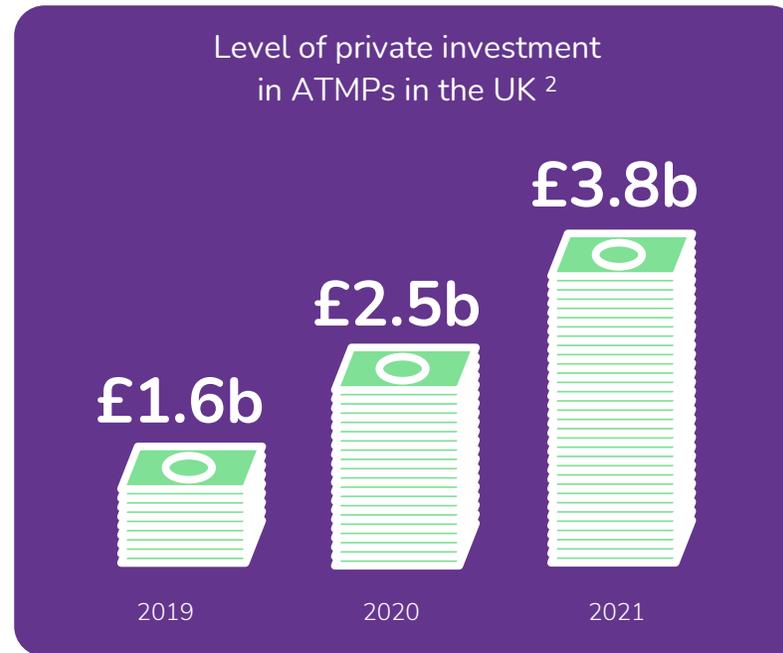
The ATTC network plays a key role in the UK ecosystem to enable ATMP adoption increasing commercial attractiveness of the UK and bringing with it a sustained increase in private investment

Individual organisations within the network have capitalised on this growth in order to expand their products and services. Not only has the ATTC network helped to scale product development within their partner organisations, it has also helped their partners to deploy these products within the wider health system to increase adoption.



~£74m

NHS income received from commercially sponsored ATMP trials p.a. ¹



“ ATTC network has helped boost the UK’s reputation internationally for investments through the inclusive approach Cell and Gene Therapy Catapult has taken – NHS England ³ ”

“ The ABPI welcomes the work undertaken by the ATTC network to drive standardisation and alignment across the UK’s ATMP ecosystem. These ongoing efforts are vital to maintain the UK’s position as a leading destination for ATMP manufacturers – ABPI ⁴ ”

3 products commercialised through the ATTC network ⁵

14 ATMP enabling products adopted into clinical practice ⁵

The value driven through multi-stakeholder collaboration within the ATTC network has improved UK's reputation globally in the ATMP arena

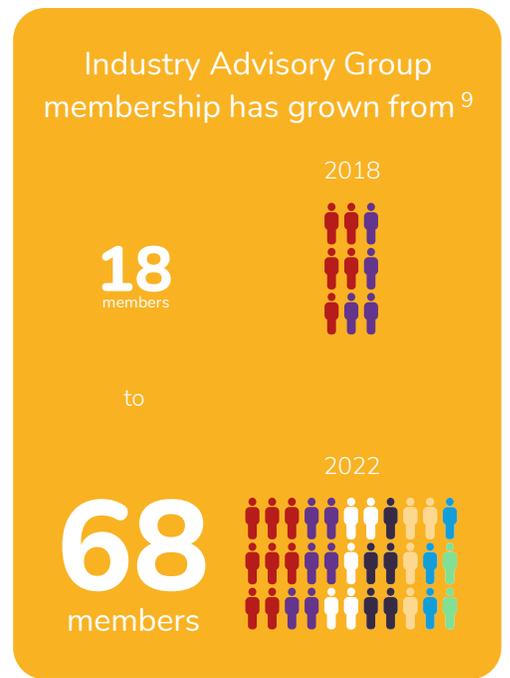
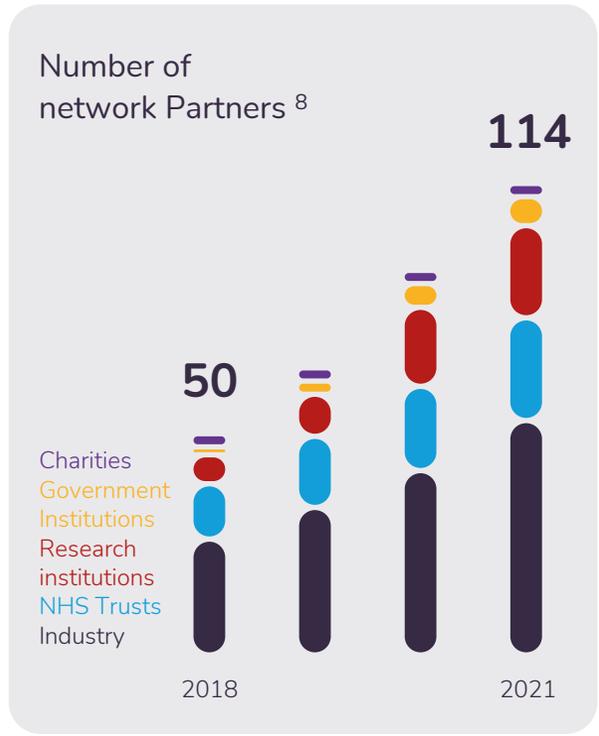
The ATTC network has dramatically increased the UK's reputation for advanced therapies as it provides the structure for organisations to develop and commercialise their treatments quickly.

The strength of the network is exemplified by its strong Industry Advisory Group. Through an open forum, the NHS and the Industry members have worked to identify barriers and jointly provide practical fit-for-purpose solutions, suitable to both industry and the NHS.

The depth and breadth of ATTC network partnerships in the UK shows the level of reach and influence that has been achieved over four years.

“The Industry Advisory Group is an essential expert network to ensure companies are able to navigate challenges and barriers speedily as we bring innovative, but at times complex, treatments to the UK market – **Gilead** ⁶”

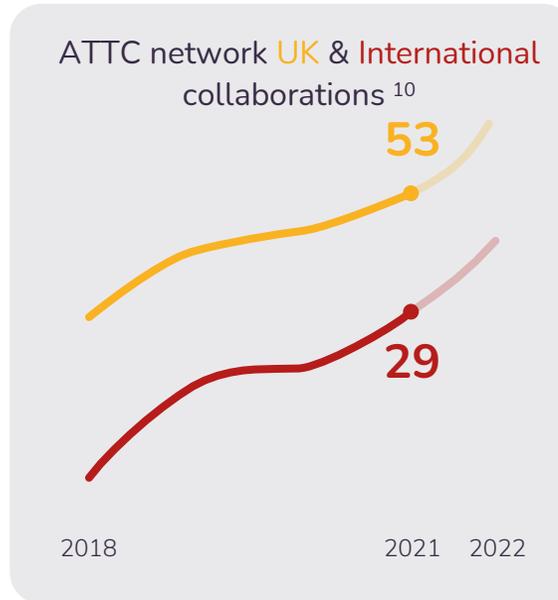
“The ATTC network is an exemplar for how industry can collaborate with the NHS and service providers to support delivery of care to patients – **Autolus** ⁷”



The ATTC network has bridged the gap between commercial, clinical, academia and government by giving all stakeholders a seat at the table

The ATTC network has enabled collaborations across the ATMP ecosystem with increasingly diverse stakeholders including pharmaceutical companies, biotechnology SMEs, NHS, academia, research organisations, logistics providers, regulators, charities and many more. The close and productive collaborative framework created by the ATTC network has increased convening power, and the network is now recognised as an informed, neutral third party between government and industry, acting as a conduit for industry concerns.

Engaging with such a large cross-section of stakeholders is seen as unique to the UK when compared against other markets. This is being recognised by other markets globally who want to emulate the ATTC network's approach, structure and resulting success.



75%

of survey respondents collaborated with organisations through the ATTC network that they would not have previously ¹¹

“The ATTC network has played a pivotal role in facilitating support from the MHRA to industry through creating new forums for discussion and dissemination. They have also contributed to augmenting regulatory support mechanisms such as ILAP*, acting as a conduit for industry feedback on the process - MHRA ¹²”

The ATTC network is internationally recognised and other countries have expressed interest in implementing similar systems ¹³



17,787

Number of times the NHS Readiness Toolkit has been accessed across

43 countries ¹⁴



The ATTC network has developed the NHS readiness toolkit to aid treatment centres in the delivery of ATMPs to patients

The ATTC network has created a common platform for ATMP industry and healthcare stakeholders, from what was previously a highly fragmented landscape.

Through pan-industry and NHS collaboration, materials and resources have been developed to accelerate the efficient adoption of ATMPs by the NHS.

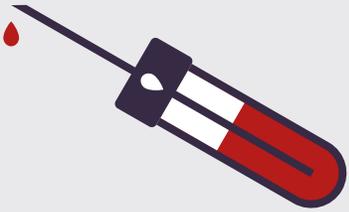
The ATTC network's role in dissemination of knowledge within the UK and internationally has increased the UK's reputation as a leader in ATMPs.

“ I believe the ATTC network is an essential bridge for the NHS to work directly with industry to accelerate adoption of highly complex products – Leeds Teaching Hospitals NHS Trust ¹⁵ ”

The ATTC network's standardisation projects and resources now cover the entire ATMP pathway

As a result, ATMP manufacturers, NHS staff and supporting industry have a wide range of resources available to ensure best practice is delivered in every aspect of patient delivery in the UK.

1 Apheresis & starting material procurement



2 Manufacturing



3 Logistics & shipping



4 Clinical trials & setup



8 NHS service readiness



7 Pharmacy



6 Regulatory & HTA



5 Patient administration



The ATTC network's standardisation projects and resources now cover the entire ATMP pathway

ATTC via its website, provides an excellent "one-stop" means of accessing information on Advanced Therapies – Velindre University NHS Trust ¹⁶

1 Apheresis & starting material procurement

Example documents

- Apheresis guidance document
- ISBT 128 labelling project and standard label roll out

2 Manufacturing

Example documents

- Procurement site readiness checklist
- Manufacturing and preparation toolkit

3 Logistics & shipping

Example documents

- Tracking and Storage Considerations
- Addressing issues for ATMP logistics

4 Clinical trials & setup

Example documents

- Advanced Therapies Clinical Trials Toolbox
- Model Clinical Trial Agreement & Guidance

8 NHS service readiness

Example documents

- NHS Readiness Toolkit
- White Paper: NHS Institutional Readiness

7 Pharmacy

Example documents

- Cell therapy, Gene therapy and tissue engineered product pharmacy guidance (PWG)
- Out-of-specification ATMP guidance for healthcare

6 Regulatory & HTA

Example documents

- HTA Guide
- Reimbursement Considerations for ATMPs
- Micro Costing Analysis Toolkit

5 Patient administration

Example documents

- The CAR-T-Cell Therapy Clinical Trial Journey Guide
- Non-cellular GMO therapies: a visual guide

“ I firmly believe that work associated with process standardisation of starting material collection would not have been possible without the work of the ATTC - TrakCel ¹⁷ ”

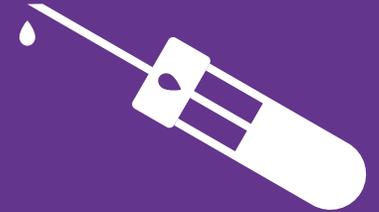
22,549

views of pharmacy resources co-developed with the Pan-UK Pharmacy Working Group ¹⁸

The ATTC network alongside the Pan-UK Pharmacy Working Group (PWG) have developed a comprehensive suite of pharmacy resources which standardise pharmacy approaches to ATMP handling

The ATMP guidance and checklist resources can be used to aid the implementation of ATMPs, allowing for consistency in governance, clinical and operational aspects for pharmacies across the country.

Case study



The SAMPLE project is a cross-network collaboration to drive standardisation of starting material procurement for apheresis within the UK

A significant variation in working practices between different clinical apheresis units (CAUs) has allowed for unnecessary complexity and therefore inefficiency in apheresis collection. To simplify the procurement protocol across manufacturers, the ATTC network devised Project SAMPLE as a means to analyse the end-to-end procurement process, generate and test new guidance and ultimately promote adoption of a standardised collection process across manufacturers, clinical apheresis groups and regulators.

The ATTC network is currently supporting 92 clinical trials within the UK, with a key emphasis on building regional access to clinical trials

In line with the UK government's levelling up agenda, the ATTC network has supported a high proportion of advanced therapy trials across various UK regions, ensuring greater options for patients across the country. This has led to new clinical trial capabilities and increased workforce demand within these areas as increasing numbers and sizes of trials are conducted. The increase in number of commercial trials has also led to increased industry investment.

“The ATTC network is drawing our attention to the UK as a potentially preferred country in which to perform clinical trials
– AstraZeneca ¹⁹”

Distribution of ATTC network supported trials across the UK ²⁰

-  UK Levelling up agenda priority 1 & 2 locations
-  ATTC supported clinical trials



ATTC network representation in global ATMP trials has more than doubled since the programme began

Despite the global pandemic limiting trial activities in many markets, the presence of the ATTC network has allowed the UK to continue to grow its clinical trial activity.

More than half of UK trials are supported by the ATTC and they have grown the UK's global share, making the UK an epicentre for clinical research for advanced therapies.



“The ATTC has set the standard for the establishment of world-class ATMP clinical trial ecosystem across key UK NHS centres. These standardised processes, coupled with an integrated infrastructure and targeted training increase our ability in the UK to treat patients with ATMPs at pace and volume – Avacta ²²”

* This has reduced from 7% in 2020 due to the addition of new data to Alliance of Regenerative Medicine Global data

As a result of the ATTC network there is new clinical trial capacity and trial capabilities being built within the UK

As a result of ATTC network support, the UK has increased advanced therapy clinical trial capacity, through supporting numerous UK centers to host their first advanced therapy trials.

The work in clinical trial acceleration and preparedness increases the reputation of the UK in the research and clinical trial area, making the UK a more attractive place to conduct trials. This has been noted by a number of ATMP developers, despite the UK being perceived as more complex and expensive to conduct trials than other markets.



Where we were 4 years ago vs where we are today illustrates the impact of the ATTCs. 4 years ago we had no Cell Therapy trials live and today we are a commissioned provider of CAR-T services with 2-3 patients per month and a growing portfolio of ATIMP trials

– Leeds Teaching Hospitals NHS Foundation Trust ²³



63%

of manufacturers surveyed used the ATTC network or their resources whilst conducting ATMP clinical trials ²⁴

Case study

ATTC network helps Birmingham Children's Hospital to host their first ATMP trial

As a result of the collaboration with MW-ATTC and sharing of essential knowledge regarding ATMP clinical trials, access to ATMP clinical trials in Birmingham Children's Hospital has been accelerated. As a result, they have been approached by new companies looking to partner on future ATMP trials.

ATTC network driven improvements and efficiencies gained in manufacturing and supply chain processes have made the UK a more attractive place to manufacture ATMPs

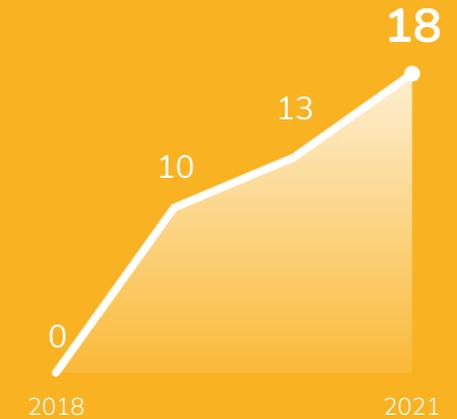
This is demonstrated by the growth in international manufacturers looking to set up manufacturing locations within the UK since network inception. The collaborative and open approach of the ATTC network and their efforts to improve the UK infrastructure has resulted in inward investment to the UK, with three manufacturers having now set up core facilities in the UK and more in the pipeline.

“The ATTC network has enabled the UK CGT industry to accelerate solutions to CGT specific delivery challenges. The network is globally respected and a number of countries look to replicate similar supportive structures”
– Autolomous ²⁵

3 ATMP Manufacturers have been attracted to set up in the UK ²⁶

“A phase 2 ATTC project is critical to ensuring the continued and rapid development of a supply chain that is able to meet the projected volumes, without which the supply chain is likely to be a brake on the sector’s expansion – Thermo Fisher Scientific ²⁷”

Number of manufacturers expressing interest in setting up in the UK 2018-2021 ²⁶



“ Having the ATTC network in place has provided a greater level of all round understanding and has put the patient at the heart of what we do
– World Courier ²⁸ ”

The ATTC network has undertaken a number of pivotal projects with Cytiva, World Courier and Orbsen Therapeutics among others, to streamline logistics processes related to ATMPs

The streamlining of logistics processes has driven the growth of international manufacturers choosing to set up bases within the UK. This rise in ATMP manufacturers re-locating ultimately leads to increasing the skilled workforce within the UK required for advanced therapy production, transportation and administration. As a result, UK patients to have earlier access to a broader range of advanced therapy options.

Case study



Cytiva’s collaborations with the ATTC network have allowed them to launch products in a significantly faster timeframe

Cytiva has worked across the ATTC network, collaborating with NA-ATTC to identify barriers associated with cryogenic shipping and to ultimately enable the accelerated commercial launch of the VIA Capsule™ (a smart LN2-free cryogenic shipping solution for cell therapies) which was supported by the MW-ATTC regional network. This work allowed Cytiva to form a long standing relationship with World Courier, facilitating the safe and effective delivery of cell products to patients across the globe. Cytiva are also in the process of setting up a Cell Therapy Hub at NHS Lothian, which will utilise the VIA Capsule and another of its devices - the VIA Thaw, a system to safely determine thaw endpoint without waterborne contamination risks, to ensure safe access to ATMP therapies.

With the development of new ATMP supply chains, the ATTC network is supporting more patients to access advanced treatments than ever before

The streamlining of UK supply chain infrastructure along with increased capability for developing and transporting live products has allowed advanced therapies to be delivered to more UK patients.

In addition, the resources, guidance and capabilities developed through the ATTC network can be applied in numerous other healthcare contexts demonstrating the broad applicability of this specialist knowledge and infrastructure.

Number of patients receiving ATMP treatment through the ATTC supply chain network ²⁹

> 300

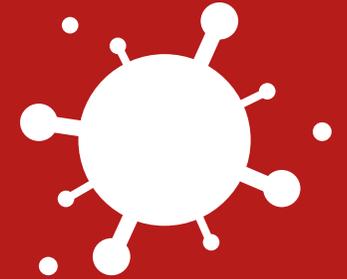
2021

23

procedures and processes adopted nationally affecting the entire patient journey ³⁰



Case study



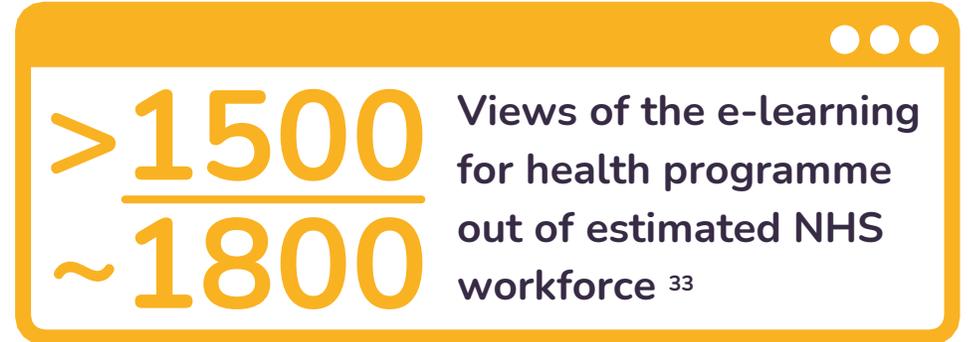
COVID-19 applications of ATTC logistics guidance

As a result of the work produced by the ATTC network, the logistics and handling guidance developed for ATMPs was utilised in the context of other innovative technologies during the global pandemic. The dry ice handling documents were used for aiding in the transportation of the Pfizer vaccines across the UK to help accelerate the Covid vaccination rollout.

The ATTC network has played a major role in upskilling the UK workforce by developing training modules and hosting learning events for healthcare staff and supporting industries

Through these education and training initiatives, the ATTC network is building the UK expertise and in-house knowledge of ATMP treatments and their administration.

By honing these skills within the UK, this in turn makes the country more attractive for companies to launch their products, creating a cyclical increase effect.



71%

of survey respondents from key UK public sector organisations have used ATTC network educational materials ³²

Case study

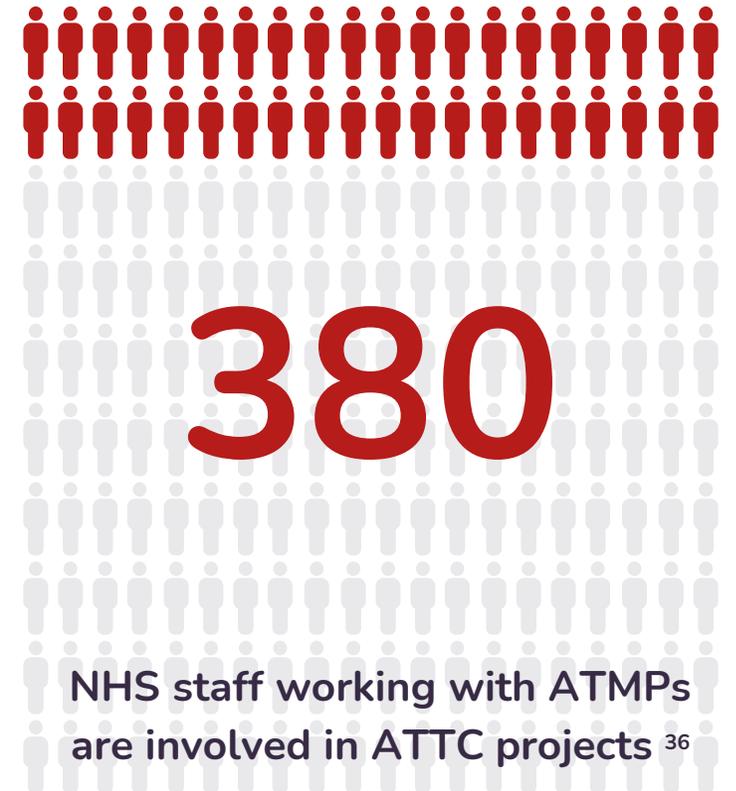
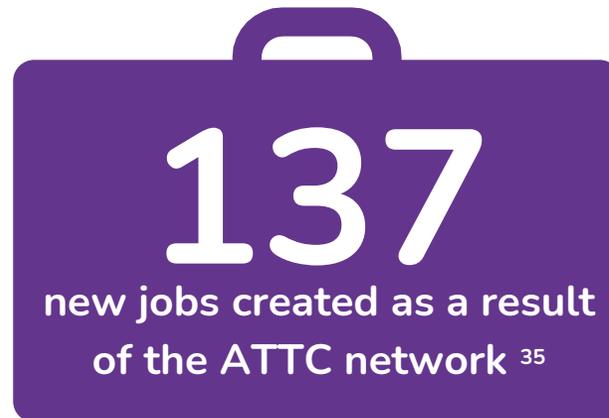
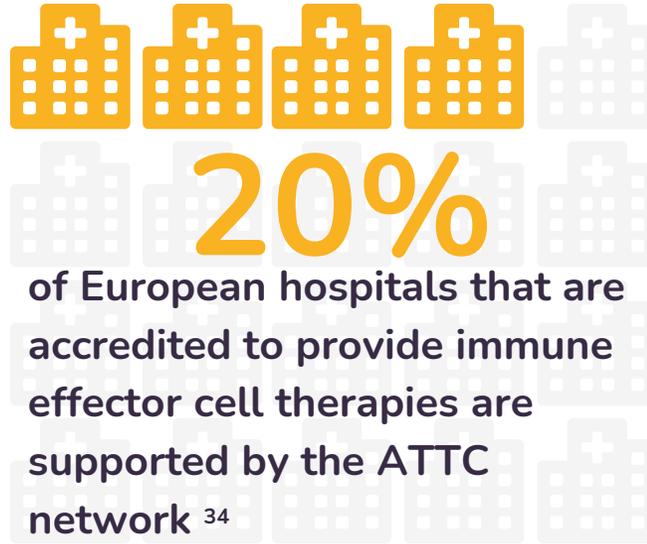
The E-learning for Health programme

Launched in partnership with Health Education England, the programme is targeted at healthcare and academic professionals to support their learning on both the fundamentals and clinical adoption of advanced therapies. The 5 learning modules cover gene, cell and CAR-T therapies along with logistics and transportation safety considerations.

Increased workforce knowledge on ATMPs has ultimately led to a greater ability for UK centres to deliver advanced therapies to patients

Upskilling the UK workforce is a critical step in enhancing the UK's ability to treat patients with advanced therapies. In addition to creating and funding new skilled roles, the ATTC network has engaged a greater number of healthcare staff in both ATMP research and adoption.

ATTC network sites now make up a large proportion of European sites for administration of CAR T therapies, demonstrating how the UK is now leading the way within Europe on advanced therapy adoption.



The ATTC network has supported the ATMP Patient Engagement Working Group to engage patients and spread awareness of advanced therapies

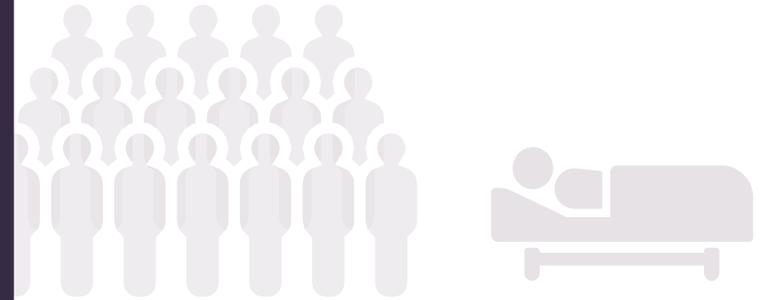
Greater patient engagement and transparency within the development process will improve trial recruitment and retention, increase trial credibility and ultimately improve uptake of advanced therapies.



The ATTC network has collaborated with NHS England, EuroGCT, Genetic Alliance UK and other partners to promote patient and public involvement and engagement (PPIE) across the ATMP pathway

Close collaborations with national and international partners include the following key activities:

- Developing resources for patients and clinicians, signposting trusted information to patients
- Holding various educational events for patients and carers
- Conducting academic research to assess the public understanding of ATMPs, their broader perceived value and support for high-cost treatments
- Developed a digital Patient Reported Outcomes solution to enable patients to monitor their experiences of ATMP treatment in real time outside of healthcare settings and to optimize PPIE in ATMP trials



“Cell and Gene therapies hold significant promise for treating patients. The ATTC network is supporting innovation, and helping drive collaboration to support rapid development and adoption of new therapies for patient benefit”

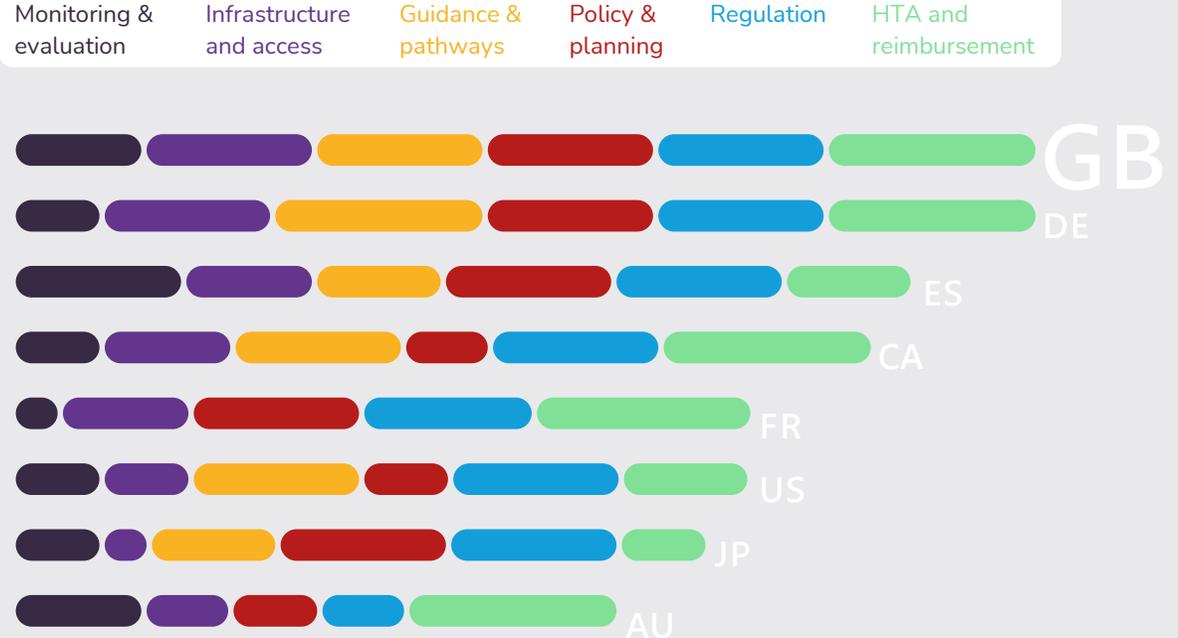
– Anthony Nolan Charity ³⁷

New analysis of market readiness shows the UK is a global leader in Cell and Gene Therapy adoption readiness

As a result of the widespread impact generated by the ATTC network, the UK is scored as a leading market, however other markets such as Germany and Spain are keeping pace.

France's recent announcement of their 2030 Healthcare Innovation strategy shows a pledge of €7 billion of spending overall, with €2.8 billion targeted for advanced biotherapies, and aims to double the number of jobs in the sector³⁸. If the UK is to maintain its position, build on the achievements to date and maximise impact, the ATTC network must continue to expand in order to ensure that UK patients can gain early access to innovative medicines.

Comparison of country readiness scores for Cell and Gene Therapy Adoption



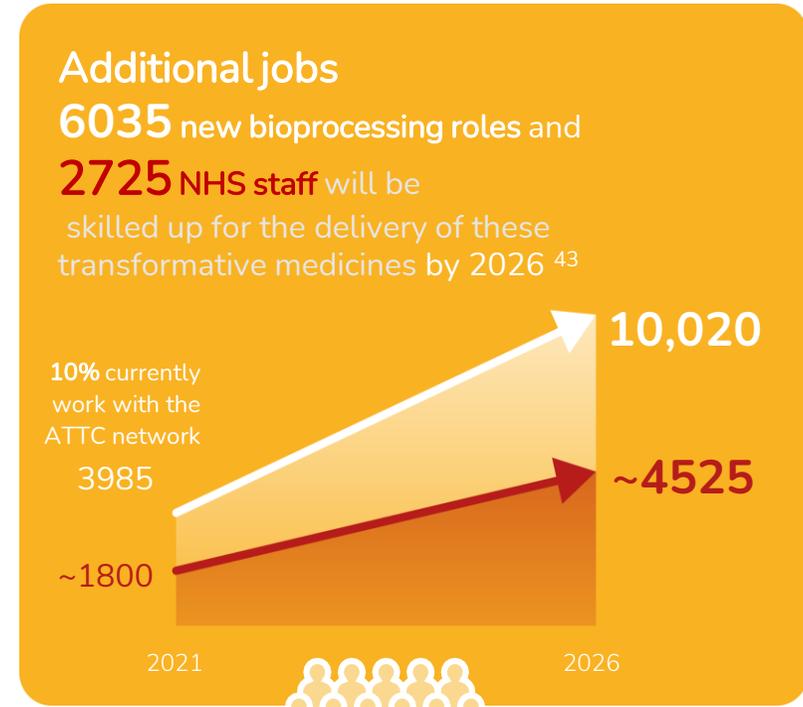
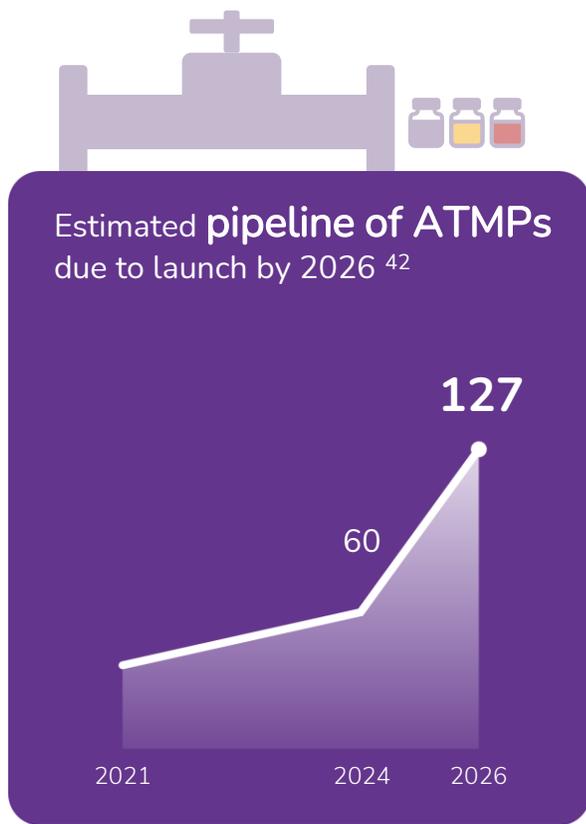
Raw data provided by the Economist (each category ranked out of 5)³⁹

“If the UK is to retain its leading role in the development of innovative treatments like cell and gene therapies, it is essential that we are able to deliver these life-changing treatments to the patients who need them. The ATTC network will have an increasingly important role to play in ensuring the NHS has the capacity and capability to deliver these new treatments – UK BioIndustry Association (BIA)⁴⁰”

In order for the UK to keep pace with the forecasted pipeline growth in advanced therapies and the associated workforce demands, the ATTC network must continue their work in the field

The advanced therapy pipeline is forecasted to increase dramatically by 2026, and the number of skilled jobs required to meet these ambitions is forecasted to grow by 151%. The ATTC network currently works directly with ~10% of the total industry workforce and this is predicted to grow as the sector develops further.

The UK Life sciences vision has pledged to invest 2.4% of Gross Domestic Product (GDP) in Research and Development (R&D) by 2027⁴¹. £40 million has been invested in the ATTC network to date, but advances in other European markets mean that the UK must sustain its growth in order to deliver this pipeline and meet the skills demand to continue the progression of advanced therapy research and adoption.

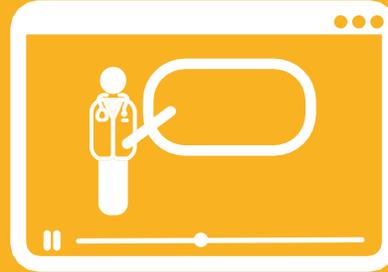


£15m per year Investment will be needed for the next 3 years, in order to sustain the advances of the ATTC network and invest in exemplar projects to maintain momentum



Cutting-edge technology to monitor patients is supported by iMATCH

To safely manage patients receiving ATMPs and identify those at risk of deterioration, iMATCH planned the trial of a wearable technology designed to measure patient vital signs, and flag evolving toxicities. The device was tested in the COVID-19 setting, for which it was shortlisted in the NIHR CRN Greater Manchester's Evening of Excellence 2021. A spin-off study has also since been initiated to look at applications within CAR T-cell therapy, with potential additional commercial funding of £500k anticipated.



New clinical scenario training video aids early toxicity intervention

MW-ATTC and iMATCH have collaborated to produce a new clinical scenario training video (based on Pan-UK Pharmacy Working Group guidance) to support the management of cytokine release syndrome (CRS) following CAR T therapy. The training video will support healthcare professionals to recognise CRS presentation and aid the diagnosis and clinical management of what is a life threatening toxicity requiring early and rapid intervention.

“Because of the [iMATCH] infrastructure and collaboration agreements in place, funding was secured, protocols were written and the first patients were recruited all within 4 months of concept creation”

– The Christie ⁴⁴



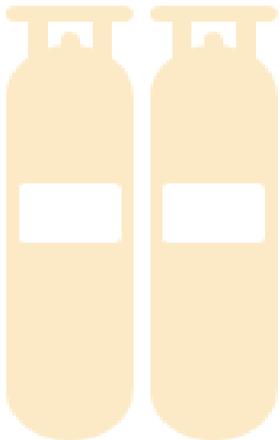
Clinical Trials Acceleration Team support NHS Institutional Readiness in Manchester

The iMATCH Clinical Trial Acceleration Service was designed as a multidisciplinary team to support NHS Institutional Readiness for the adoption of ATMPs across Greater Manchester. This is being achieved through the streamlining and standardisation of set-up documents, costs templates and contract documents, with an overall aim of continuing to up-scale ATMP delivery within iMATCH, the ATTC network and beyond.



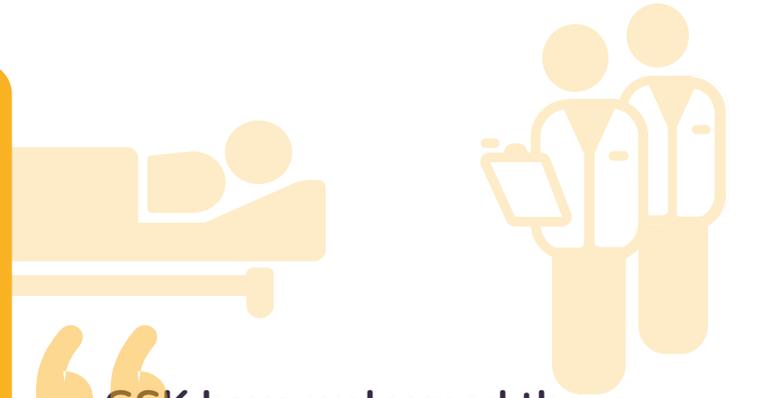
The ATTC network infrastructure in Manchester enabled selection as a first-wave CAR T provider

The Christie hospital had previously received offers for additional liquid nitrogen storage tanks, however inspections from JACIE highlighted a need to meet certain minimum space requirements. Due to ATTC support, the hospital was able to secure funding to increase their nitrogen storage capacity in line with JACIE guidance, re-locating their storage facilities in order to meet the logistics requirements. This ultimately increased the hospital's capacity for the provision of advanced therapies and ensured increased patient access to both trial and licenced medicines.



Working with large pharmaceutical companies to enhance the referral pathway to optimise patient trial recruitment

iMATCH have carried out a project at The Christie to optimise local referrals for ATMP trials across different oncology disease groups. Due to its success, the project is now being extended nationally. The extension will include interviewing key networks, charities and patient support groups to understand optimum communication channels for referral before implementing the core recommendations. Outputs will be made available across the network to enhance the ability of centres to optimise recruitment and deliver the highest level of care for patients being considered for these complex trials.



“GSK have welcomed the opportunity to support iMATCH and the ATTC on a number of important initiatives. We are confident that the innovative projects underway will result in accelerated delivery of complex cell therapies and enhanced patient access. We look forward to these projects coming to fruition and contributing to the UK's continued leadership in this field – GlaxoSmithKline ⁴⁵”

Orbsen Therapeutics relocates to the UK for MW-ATTC capabilities and support

European ATMP manufacturer, Orbsen Therapeutics, has relocated manufacturing for one of their clinical trials to Birmingham's Advanced Therapy Facility (ATF). The move can be 100% attributed to the formation of NIHR's Birmingham Biomedical Research Centre (BRC), a joint leader of the MW-ATTC, and has allowed Orbsen to expand their manufacturing capacity to execute larger randomised studies and begin commercialisation.

“We're really excited that the programme has been a success. It has allowed us to build partnerships, collaborations and expertise; not just within Birmingham, but in the wider UK cell therapy community – Orbsen Therapeutics ⁴⁶”

Trial Acceleration Programme in Cellular Therapies coordinated by the University of Birmingham



The network was initially made up of four sites at inception and has since grown to nine NHS Trusts across the region with dedicated support to facilitate accelerated ATMP trial set up and opening for both academic and commercial sponsors. The programme offers access to a large and diverse patient population of more than 20 million across the Midlands, South Wales, Bristol, Oxford and Cambridge to support reaching recruitment targets for complex trials, in particular those in rare diseases.



MW-ATTC has helped TrakCel to customise bespoke solutions for tracking therapies across the ATMP supply chain

TrakCel provides the electronic platform to arrange cellular product delivery, seamlessly integrating all elements of the supply chain to allow real-time tracking and tracing of advanced therapy location, status and condition. MW-ATTC supported TrakCel to convert their bespoke autologous system for use as an off the shelf allogeneic software solution and through use in the PELICAN clinical trial, evolved the software further to facilitate integration with other supplier applications and make more effective use of shared data. Interactions with Orbsen Therapeutics, the Cancer Research Clinical trials Unit, the ATF and clinical sites contributed largely to the development.

The predicted arrival of 31 new ATMPs between 2021 and 2023 necessitates a standardised ATMP ordering system

Horizon scanning data predicts the arrival of 31 new ATMPs between 2021 and 2023. In building upon the existing MW-ATTC Cell Orchestration Platform infrastructure, a web-based prototype system was developed standardising the Ordering and Scheduling of ATMP Treatments for the NHS to provide a singular interface for viewing and ordering ATMP products.

This is a step forward in making a standardised NHS IT system to facilitate ATMP treatments and link to cell orchestration platforms. This will allow ATMP treatments to become more mainstream

– University Hospitals Birmingham
NHS Foundation Trust ⁴⁸

>500 patients reached



via

4 different webinars

The MW-ATTC has developed a series of educational webinars to increase patient and public knowledge on ATMP therapies ⁴⁹

The MW-ATTC has reached over 500 patients to date via 4 different webinars empowering patients and the public to engage with ATMP research and potentially improving future ATMP trial patient recruitment.



MW-ATTC has developed a range of Health Economics guidance and publications to aid users with costing ATMP products

Documents developed include:

- A microanalysis costing toolkit for ATMPs
- An assessment of the cost benefits of utilising an ATMP versus the cost of standard care treatment
- White Paper, 'The Methods of Economic Evaluation of Advanced Therapy Medicinal Products'
- Economic analysis of tumour storage for a Tumour Infiltrating Lymphocyte
- Development of the UK's first Family Reported Outcome Measures Survey for ATMPs

NA-ATTC partner Autolus enables knowledge sharing and clinical trial advancement within the UK network

With NA-ATTC support, Autolus Therapeutics, a CAR T-cell therapy developer, have been able to increase patient access to ATMPs on a national level. Since the collaboration began, Autolus have invested in an extensive clinical trial programme in the UK, comprising 7 Phase I clinical studies for 5 programmes, and treated over 80 patients to date. Autolus has shared its experience via a number of channels including an event with NHS and industry colleagues to share the practical lessons learned in the set-up and delivery of CAR T clinical trials in Newcastle.

The NA-ATTC has facilitated knowledge exchange which accelerated the clinical trial programmes of our lead products and their successful conduct

– Autolus ⁵⁰

CAR-T-cell Therapy Clinical Trial Journey resource produced by Autolus and NA-ATTC

Autolus, in partnership with the NA-ATTC, have launched a comprehensive guide to support patients and carers on their CAR T journey. Accessed through the ATTC website, the guide provides educational support and advice on CAR T treatment, side effects and the trial process, as well as acting as a teaching aid for clinical staff.

NA-ATTC partners lead in new macrophage cell therapy study

Two partners within the NA-ATTC (University of Edinburgh and Scottish National Blood Transfusion Service) have been developing a new macrophage cell therapy for liver cirrhosis. The study was able to quickly expand to reach multiple clinical sites due to NA-ATTC's network, helping with patient recruitment and also allowing the exploration into stable transportation of starting material and therapy. Use of the ATTC network will prove vital in ensuring provision of the therapy on a national scale.

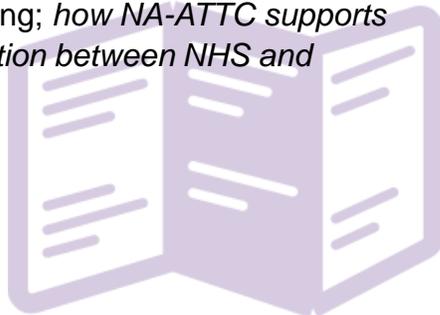
'The multidisciplinary collaboration across academic, commercial and healthcare sectors afforded by the NA-ATTC network is an excellent support for start-up companies such as RTx

– Resolution Therapeutics ⁵¹

Supporting effective collaboration between the NHS and Industry

NA-ATTC's collaborative forums have informed best practice in advanced therapy trial delivery and clinical adoption and established disease-specific clinical networks to accelerate pathways towards equitable, sustainable delivery and life-long follow up of adopted therapies. These forums – the Clinical Advisory Group, Trial Coordination Unit and Industry Advisory Group - have facilitated interactions between industry and NHS in order to accelerate update of products and services and enabled production of guidance documents and a toolkit to accelerate the adoption of ATMPs:

- Clinical Trials Toolkit
- Harmonised Working; *how NA-ATTC supports effective collaboration between NHS and Industry*



The NA-ATTC have created a 'Manufacturing and Preparation Toolkit' to enable academics and developers to understand ATMP challenges and ask questions on their manufacture and preparation



The Manufacturing and Preparation Toolkit is a compendium of documents detailing best practice and expert guidelines in relation to the manufacture of ATMPs. The purpose of the Toolkit is to disseminate learnings from the ATTC network and increase awareness of Good Manufacturing Practice (GMP) for ATMPs. Information is provided on Cell Analysis, Cell Manufacture and Pharmacy & Regulatory.

NA-ATTC drives Institutional Readiness (IR) through NHS and Industry collaboration

NHS IR for ATMPs is critical for their rapid, wide-scale adoption. The IR questionnaire developed by NA-ATTC allows NHS clinical sites to assess their readiness levels for all classes of ATMPs. In collaboration with Achilles Therapeutics, NA-ATTC has also developed learnings to aid NHS IR for T cell therapies manufactured from solid tumours.

“CGT operational pathways built in conjunction with the ATTC network will enable scale up of delivery capacity in the UK in the future – Achilles Therapeutics ⁵²”

Industry organisations working across the ATTC ecosystem



NHS collaborators / Blood Services across the ATTC Ecosystem

Charity, Government institutions and research institutions across the ATTC Ecosystem

1. ABPI (2019) Clinical trials: How the UK is researching medicines of the future [data extrapolated based on known number of commercial ATMP trials for 2019]
2. Cell and Gene Therapy Catapult (2021) Annual Review
3. Ben Doak, National Senior Programme of Care Manager, NHS England and NHS Improvement
4. Richard Torbett, Chief Executive, ABPI
5. The ATTC network, internally reported benefits data for period Oct 2020 – Sep 2021
6. Anita Ralli, Associate Director of Government Affairs, Gilead Sciences
7. Christopher Vann, Chief Operating Officer, Autolus Ltd.
8. ATTC network internal metrics
9. ATTC network internal metrics
10. ATTC network internal metrics
11. Out of a total of 8 respondents from survey sent to ATMP manufacturers without licensed / launched products, Mar 2022
12. Ian Rees, Unit Manager Inspectorate Strategy and Innovation, MHRA
13. ATTC network internal metrics
14. ATTC network internal metrics
15. Chris Herbert, Director of Operations: Research and Innovation, Leeds Teaching Hospitals NHS Trust
16. Advanced Therapies Wales (ATW), Welsh Blood Service, Velindre University NHS Trust
17. Matthew Lakelin, VP Scientific Affairs & Business Development, TrakCel
18. Specialist Pharmacy Service (2022) Summed pageviews for ATMP-related documents from the Pan-UK Pharmacy Working Group, 2019 – 2022
19. Johan Hyllner, Head of Cell Therapy Department, BioPharmaceuticals R&D, AstraZeneca
20. ATTC network internal metrics
21. ATTC network internal metrics
22. Neil Bell, Chief Development Officer, Avacta
23. Chris Herbert, Director of Operations: Research and Innovation, Leeds Teaching Hospitals NHS Trust
24. Out of a total of 8 respondents from survey sent to ATMP manufacturers without licensed / launched products, Mar 2022
25. Kwok Pang, Chief Operating Officer, Autolomous
26. ATTC network internal metrics
27. Neil Ridley, Thermo Fisher Scientific
28. Kelly Frend, Personalised Supply Chain Manager, World Courier
29. ATTC network internal metrics
30. ATTC network internal metrics

31. ATTC network internal metrics
32. Out of a total of 14 respondents from survey sent to public sector organisations, Mar 2022
33. ATTC network internal metrics. Denominator estimate extrapolated from data from: NHS workforce dataset; Statistics Wales [NHS Wales dataset], ISD Scotland National Statistics; Health and Social Care Northern Ireland Quarterly Workforce Bulletin December 2021; and proportion of staff within ATTC centres involved in ATMPs assuming the same proportion across CAR-T delivery centres, centres that conduct ATMP trials, and centres that do not host ATMP trials.
34. Figures obtained from EY analysis of JACIE database: [Immune Effector Cell therapy JACIE accredited centres](#)
35. ATTC network internal metrics
36. ATTC network internal metrics
37. Daniel Gibson, Director of Cell and Gene Therapy Services, Anthony Nolan
38. French Government (2021) Healthcare innovation strategy 2030
39. Economist Impact (2022) Cell and Gene Therapies Technical Report [in press] – data for infographic obtained from CGTs Health System Readiness scorecard
40. Steve Bates, Chief Executive Officer, UK BiIndustry Association, Mar 2022
41. HM Government (2021) Life Sciences Vision
42. Estimated Figures obtained from Horizon Scanning Operations Lead, North West Medicines Information Centre, Mar 2022
43. Cell and Gene Therapy Catapult (2021) UK Cell and Gene Therapy Skills Demand Survey Report
44. Fiona Thistlethwaite, Medical Oncology Consultant, The Christie NHS Foundation Trust
45. Joanne Rule, Medical Affairs, GSK Oncology
46. Steve Elliman, Chief Scientific Officer, Orbsen Therapeutics
47. The ATTC network, NHS readiness toolkit
48. Philip Newsome, University Hospitals Birmingham NHS Foundation Trust
49. The ATTC Network, PPIE webinar series analytics
50. Christopher Vann, Chief Operating Officer, Autolus Ltd.
51. Management, Resolution Therapeutics
52. Shreenal Patel, SVP Global Clinical Operations & Supply Chain, Achilles Therapeutics