Advanced Therapy Treatment Centres

ATMP Clinical Trials Landscape Across the UK

A deep dive into how the ATTC network supports ATMP clinical trials across the UK

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1. Executive summary

Advanced therapy medicinal products (ATMPs) (gene therapies, somatic cell therapies, and tissue-engineered products) offer transformative potential for diseases previously considered untreatable [1] [2]. Yet the pathway from laboratory to patient remains exceptionally challenging. Complex supply chains, short product shelf lives, patient-specific manufacturing, novel toxicity profiles and specialised clinical handling create delivery requirements fundamentally different from conventional medicines [2] [3] [4].

Despite these complexities, the UK has positioned itself as one of the world's leading environments for ATMP clinical development. Nearly 200 ATMP trials are currently active, a portfolio that has grown by over 21% since 2020, with 57% of all European ATMP trials including UK participation [5]. The MHRA (Medicines and Healthcare products Regulatory Agency) is globally recognised as a progressive regulator supported by a national health system, world-class academia and committed government investment in necessary ecosystem support. One such commitment is the Advanced Therapy Treatment Centre (ATTC) network, established in 2018 to address the complex challenges of delivering ATMPs to patients, with initial funding through the UK Research and Innovation (UKRI) Medicines Manufacturing Challenge, managed by Innovate UK. Since 2024, the network has focused on accelerating ATMP clinical trials through a ~£18m National Institute for Heath and Care Research (NIHR) funded programme, overseen by Innovate UK and coordinated by Cell and Gene Therapy (CGT) Catapult. In close collaboration with the NIHR and the devolved equivalents' research infrastructure, the network aims to ensure the UK maintains its position as a globally attractive location for ATMP clinical research [6].

The ATTC network operates across the NHS as a coordinated group of clinical delivery centres, working with academia and industry to overcome barriers to advanced therapy delivery. It comprises of four regional hubs:

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

This report outlines how the UK is building institutional readiness to bridge the gap between scientific innovation and clinical delivery, and how the ATTC network is enabling this through a coordinated, collaborative approach. As a result, the UK is becoming not only an attractive place to develop ATMPs, but one where they can be delivered to patients reliably.

2. ATMPs – A Different Type of Challenge

Advanced therapies are fundamentally different from conventional medicines, creating delivery challenges for standard clinical trial infrastructure. These challenges span five core dimensions, as illustrated in figure 1.

The ATTC network conducted a UK-wide survey, collecting data from 17 NHS sites (Nov 2024–Jan 2025).

This highlighted key opportunities to address key challenges and accelerate ATMP trials: centralisation, collaboration, capacity, education, awareness, flexibility and standardisation. These challenges are not scientific or regulatory, but operational: driven by site variability, workforce gaps, and inconsistent governance, requiring a coordinated, system-level response [7]. These findings now underpin a targeted ATTC network action plan.

Key opportunities for acceleration of ATMP Trials

National Centralisation and Collaboration

Having a coordinated approach with collaboration between the NHS, regional networks, regulators and industry sponsors

Widespread Process Standardisation

Establishing consistent national protocols, templates, and best practices

Increased System Capacity

Sufficient infrastructure, staffing, and resources are required to handle the growing volume and complexity of ATMP treatments

Workforce Capability Gaps

Clinical, pharmacy, laboratory, and data skills for ATMP delivery are not covered in standard training. Each site must build capabilities before participating

Broader Stakeholder Awareness

Increasing awareness among clinicians and patients about ATMP availability, patient identification and referrals

Figure 1: Core enablers for accelerating ATMP clinical trial

3. The UK Ecosystem: End-to-end Capability for ATMP Development

The UK offers sponsors an increasingly rare asset: end-to-end development capability within a single, connected national system. From academic discovery through translational research, GMP manufacturing, clinical trials, regulatory approval, and NHS adoption, the components exist to take an advanced therapy from bench to bedside.

3.1 The UK Leading the Way in Europe

The global market for advanced therapy clinical trials is increasingly competitive. Europe's share of CGT trials has declined over the past decade as China and the United States have expanded capacity through regulatory reform, public investment, and streamlined pathways. Markets such as Australia and South Korea have also grown their presence, with Australia in particular offering consistently short application-to-first-patient timelines. Trial set-up timelines have lengthened across most Western European markets. The EFPIA–IQVIA assessment of the European clinical trial ecosystem (2024) confirms that site activation and patient enrolment, rather than regulatory approval speed, are the principal factors determining how quickly trials get underway [8]. However, the UK has continued to grow the number of trials in ATMPs.

The UK is well-positioned due to its combination of specialised capabilities: strong Contract Development and Manufacturing Organization (CDMO) support; coordinated, centralised manufacturing hubs (including the MHRA-licensed CGT Catapult centres in Stevenage and Braintree); a progressive regulatory environment; a data-rich health system with advanced genomic capability to identify and refer patients; leading academic-clinical expertise; and a growing manufacturing base. Together, these create a connected ecosystem that enables close coordination across manufacturers, clinicians, regulators, and supply chains supporting efficient delivery of complex therapies.

For advanced therapies, the critical question is not whether the ecosystem components exist, but whether the health system is operationally ready to deliver them.

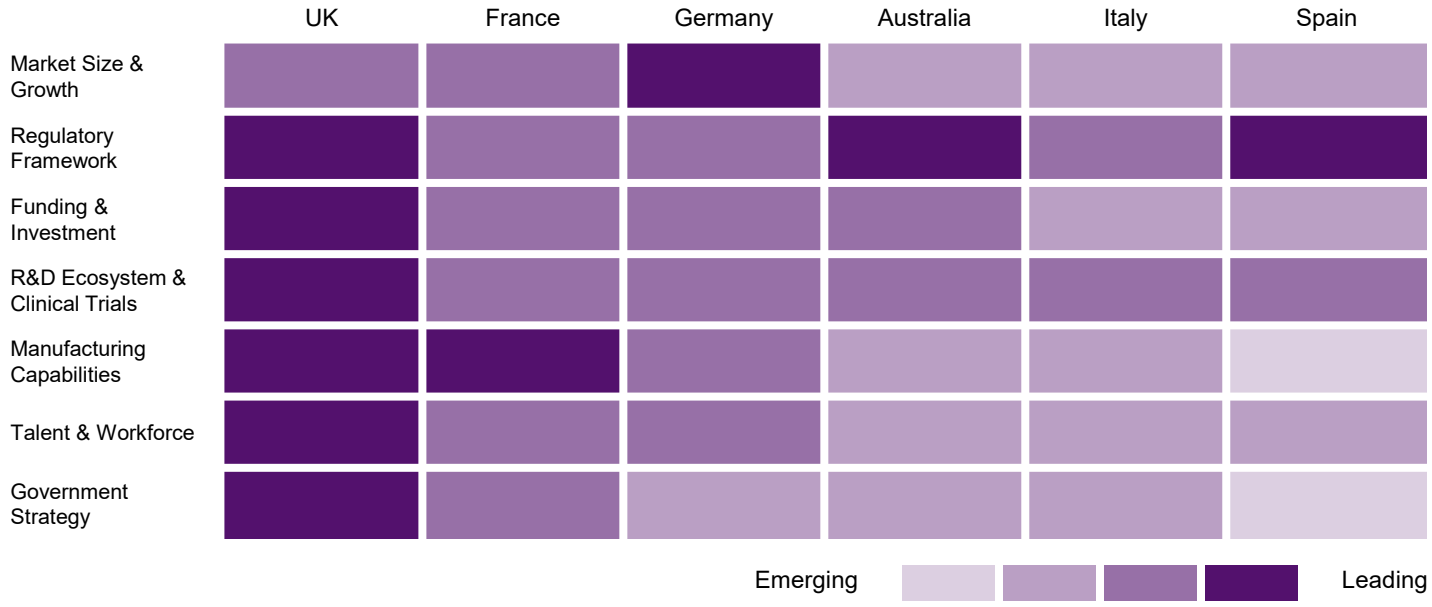

Figure 2: Indicative positioning of six national CGT ecosystems. Ratings are directional, not absolute

Source: CGT Catapult Annual Reviews (2024, 2025) and UK ATMP Clinical Trials Database; BIA UK Cell and Gene Therapy Leadership Report; OHE/CGT Catapult economic impact analysis; ABPI Unlocking ATMPs report; Fraunhofer IZI and BIH Charité (Germany National Strategy for Gene and Cell-Based Therapies); Genopole/Genother, France 2030, AP-HP (France); AIFA and Nature National Centre for Gene Therapy coverage (Italy); RARE IMPACT country assessments (France, Spain); ARI-0001 hospital exemption literature (Spain); AusBiotech Cell and Gene Catalyst and National CGT Plan, TGA, Australian Genomics, Novotech (Australia); Alliance for Regenerative Medicine; Novotech Global CGT Clinical Trial Landscape 2024; EMIS/Arizton Europe Cell and Gene Therapy Market; European Commission Advanced Therapies; European Parliament EPRS study (2026); EFPIA Clinical Trials report; OECD Corporate Tax Statistics (2025); MHRA, TGA and CTIS regulatory performance data; EU Clinical Trials Register; ClinicalTrials.gov; CGT Catapult analysis.

Note: Countries rated *Leading*, *Strong*, *Developing*, or *Emerging* per dimension, combining quantitative indicators with qualitative institutional evidence. Heatmap is unweighted; each dimension rated independently, and the "Leading count" reflects breadth of competitive advantage rather than a score. The UK is the only benchmarked country publishing national-level ATMP trial, manufacturing, and workforce data; no equivalent resource exists for the other five countries, creating a structural data asymmetry. Cross-country trial counts are directional given variation in database definitions, registration practices, and ATMP classification criteria by jurisdiction. Ex-UK venture capital figures compiled from press releases and are indicative rather than comprehensive. Ratings reflect balance of evidence as of March 2026 and are intended to inform sponsor decision-making, not to produce a definitive country ranking.

3. The UK Ecosystem: End-to-end Capability for ATMP Development

3.2 A Growing Clinical Trial Portfolio

The UK's ATMP clinical trial portfolio has expanded consistently over the past decade, increasing from 154 ongoing trials in 2020 to 193 in 2025, representing an increase of more than 21%. This growth continued through a period when Europe's share of cell and gene therapy trials has steadily decreased from 25% in 2013 to 10% in 2023 [9]. UK sites now host 9% of all global ATMP trials and take part in 57% of all European trials. These shares directly indicate where industry chooses to locate its most advanced clinical programmes. [5] [10]

Looking at the trial pipeline, gene therapies accounted for the largest share in 2025, making up more than 80% of ongoing trials. The portfolio remains concentrated in early-phase innovation with 56% of trials in Phase I or Phase I/II. 42 active Phase III trials demonstrate a pipeline that is progressing as well as growing. Oncology remains the leading therapeutic area at 35%. [5] See figure 3 for a further breakdown. Approximately 80% of UK ATMP trials are commercially sponsored, which has remained roughly stable since 2020, and above the European average. [5] [8] This concentration of registration-focused studies signals strong industry confidence in the UK as both a research base and a viable route to approval and patient access.

The ATTC network is strengthening the UK's position as a leading destination for ATMP clinical trials by investing in operational infrastructure that directly connects sponsors to trial-ready NHS sites. Two key new resources - the ATTC Site Delivery Hub and the Signposting Directory - aim to reduce barriers in trial set-up and site selection. The Site Delivery Hub provides a single front door to understand the networks footprint, allowing users to explore ATMP capabilities at each site within the network. This provides sponsors with insights to a national network of 55 ATMP delivery sites across England (78%), Scotland (15%), and Wales (7%) [11], supporting faster and more efficient site identification for clinical trials. Complementing the Hub, the Signposting Directory offers structured, user-friendly access to the broader UK ATMP ecosystem, including NIHR infrastructure, regulatory bodies (MHRA, NICE, SMC), funding opportunities, specialist logistics, apheresis, and manufacturing networks. Together, these tools put the network's mission into practice by transforming fragmented site-level expertise into a nationally coordinated, standards-driven system, building on the existing clinical trials toolkit of >120 resources across eight key domains.

Active Clinical Trials Snapshot, 2025

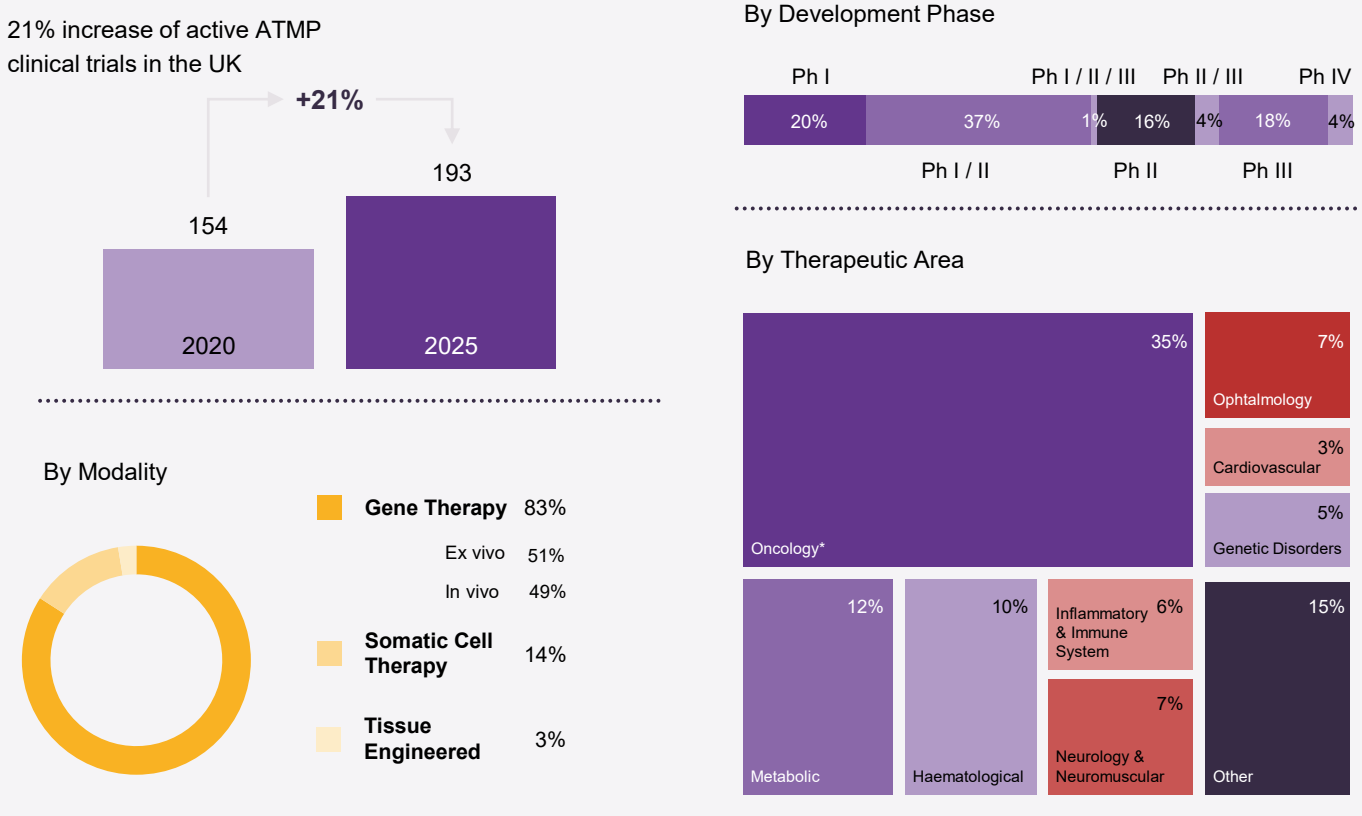

Figure 3: Active clinical trials snapshot, 2025 [5]. **blood & solid tumours.*

3. The UK Ecosystem: End-to-end Capability for ATMP Development

3.3 Progressive Regulation and Government Commitment

While system readiness and clinical adoption networks address the delivery, sponsors can only move as fast as the regulatory and reimbursement environment allows. Published on 16 July 2025, the Life Sciences Sector Plan (LSSP) seeks to make the UK the most attractive place in the world to develop and deploy new treatments. By 2030, the UK will be one of the top three fastest places in Europe for patient access to medicines and medtech [12] [13]. This includes reducing clinical trial set-up times to under 150 days, through implementation of the O'Shaughnessy recommendations and updated NIHR governance [14]. The Welsh government has also endorsed the Delivery Plan for Advanced Therapies in Wales, which outlines themes of PPIE (Patient & Public Involvement and Engagement), workforce development and strategic partnership.

The MHRA has delivered on this ambition: 99% of clinical trial applications, including ATMPs, are now completed within the 60-day statutory period, with average approval times falling to 41 days (down from 91 days pre-2023 reforms) [15]. When compared with the EU Clinical Trials Information System (CTIS) statutory maximum of 156 days, this gives the UK a significant speed advantage [8] [15].

The MHRA is also synchronising licensing and value assessment decisions with the National Institute for Health and Care Excellence (NICE) through a new joint MHRA-NICE pathway [16].

Separately, the introduction of Modular Manufacture and Point of Care Regulations (effective July 2025) makes the UK the first country with a dedicated legal framework for medicines manufactured in a decentralised manner. While not ATMP-specific, this is directly relevant to advanced therapies where manufacturing proximity to patients may confer significant advantage [17].

The National Contract Value Review (NCVR) now serves as the standard costing framework for ATMPs and early oncology trials [18]. The UK's cost-effectiveness threshold, previously £20,000–£30,000 per Quality-Adjusted Life Year (QALY), rose to £25,000–£35,000 from April 2026 with added modifiers for broader value factors [19] [20]. This adjustment could improve the probability of favourable NICE recommendations for high-cost advanced therapies, particularly one-time therapies with significant upfront costs. These commitments are embedded in the Life Sciences Sector Plan and the 10-Year Health Plan and taken together represent a coordinated dismantling of multiple access barriers.

4. Building Institutional Readiness

ATMPs introduce fundamentally different clinical, operational, and logistical challenges for an NHS that was originally designed around the delivery of standardised, mass-produced medicines. Pharmacy handling, clinical administration, governance, risk assessment and logistical pathways must all be specifically configured before a sponsor's first shipment can be received. Developing this capability on a site-by-site basis has therefore been slow, inconsistent, and heavily reliant on local expertise and individual clinical champions.

The ATTC network has supported site readiness by helping move it beyond a purely local capability and by encouraging more consistent standards across a network of sites with increased visibility for sponsors.

In its first phase (2018–2022), the network worked across industry, academia, and the health system to build ATMP treatment capability within the network and lay strong foundations for future ATMP delivery. This included the creation of 80 highly skilled jobs [21].

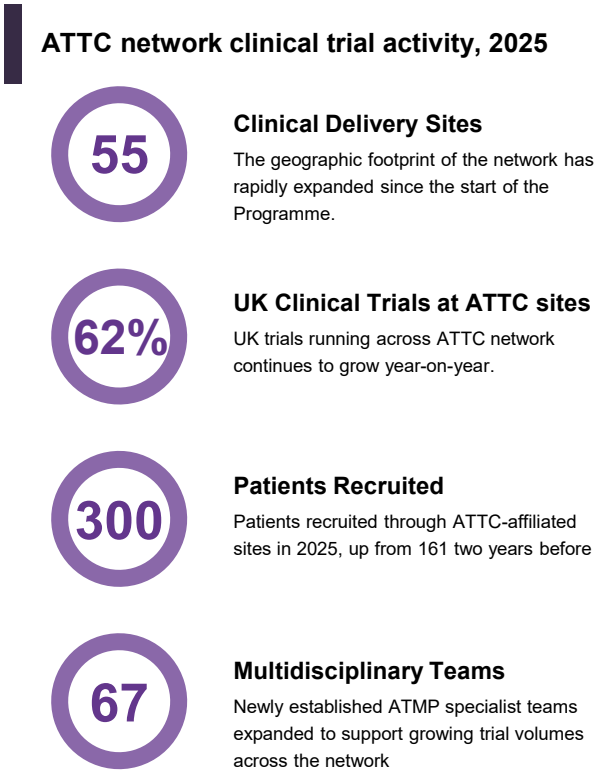

Figure 4: ATTC impact on the UK clinical trial landscape, Phase II 2025

4. Building Institutional Readiness

4.1 Standardising Processes to Remove Bottlenecks

For sponsors running multi-centre ATMP programmes, variation between sites is one of the most persistent sources of delay. Nationally coordinated standardisation work has addressed this by building shared processes — SOPs, guidelines, workforce training, readiness assessment frameworks, and data reporting standards — that make trial set-up more repeatable across the system.

Key resources to aid in standardisation can be found in the NHS Readiness Toolkit which has been accessed over 32,000 times across 81 countries. This covers eight domains: governance, business and financial planning, quality assurance, operational delivery, clinical practice, education and training, long-term follow-up, and clinical trials [21].

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

The AUTO1-MS1 CAR-T trial is a complex, multi-specialty ATMP study that traditionally carries long start-up timelines. NHS Lothian, an ATTC network affiliated site, compressed this by engaging Neurology, Haematology, Pharmacy, Research Nursing, Governance, and SNBTS apheresis services at feasibility stage, rather than sequentially after approvals.

A disease-agnostic ATMP Working Group, supported by weekly CAR-T meetings and targeted "micro-meetings," resolved bottlenecks around apheresis pathways, contracting, SOP alignment, and role clarity in parallel with governance review. Weekly meetings also created a structured sponsor feedback channel, while research nurses and Clinical Nurse Specialists jointly mapped the full CAR-T work-up end-to-end.

The coordinated model strengthened NHS Lothian's broader ATMP readiness, improved interdisciplinary collaboration, and is now being applied to subsequent ATMP trial set-ups. [23]

92 days	5 days to first	6+ specialties
to site activation	patient recruited	aligned in parallel

Figure 5: NHS Lothian AUTO1-MS1 CAR-T trial — key start-up performance metrics

4.2 Developing the Workforce

Standardised sites and processes can only deliver results with the right workforce capability. Specialist workforce development is central to building institutional readiness. Over 5,000 professionals [24] have been trained at ATTC sites or using ATTC developed training, supported by 73 learning modules and training packages, 13 of which are hosted on the NHS England e-learning for healthcare Hub [21].

Training and education have always been an important part of the network's work, ensuring a workforce that is ready to deliver ATMPs now and in the future. In addition to the development of training resources, the network also regularly brings together multi-stakeholder groups to work collaboratively on specific aspects of ATMP delivery. For example, the network is currently working to curate and disseminate best practice examples for Chimeric Antigen Receptor T-cell therapy (CAR-T) delivery within autoimmune indications – a relatively new area of development for ATMPs that has introduced new challenges in delivery at NHS sites. The network has brought together clinicians and industry to share best practice and collectively tackle known challenges in this area, via a national webinar and an in-person event, which took place in May 2026.

Developed with Skills for Health and an Expert Reference Group comprising of NHS subject matter experts from across the UK, the Advanced Therapy Clinical Trials Capability Framework provides a structured roadmap for coordinated learning, service design, governance, workforce development, and quality improvement across the ATMP sector. Following public consultation, the framework was published in May 2026 [25]. Building on this, a national ATMP clinical trial training programme is in development. This will standardise NHS staff preparedness for advanced therapy trials, giving sponsors confidence in a consistent baseline capability across sites and allowing trial-specific training to focus on protocol requirements rather than fundamentals [26].

4.3 National Clinical Infrastructure and Geographic Reach

Advanced therapies have historically been concentrated in a small number of highly specialised urban centres, requiring patients to travel significant distances to access potentially life-changing treatments.

4. Building Institutional Readiness

The ATTC network has worked to expand the geographic footprint of ATMP-ready infrastructure, with 62% of all active UK ATMP clinical trials having at least one ATTC-affiliated site [5]. The ATTC network provides coordinated coverage across this geography. The network has sought to partially address the challenge of patient access and inequity through its geographic expansion — a critical foundation as the field moves from rare-disease applications toward higher-prevalence conditions requiring more delivery sites [5] [12]. The ATTC network is also advancing equity of access by enabling targeted initiatives and co-developing a national strategy to address variation in ATMP access across the UK. Whilst progress is being made in this area, it is recognised that more needs to be done to ensure patient access to these often life changing therapies.

Wales has built infrastructure and capability through deliberate investment to deliver ATMP clinical trials at national scale, providing end-to-end bench to bedside experience with globally recognised expertise in complex neurodegenerative trials.

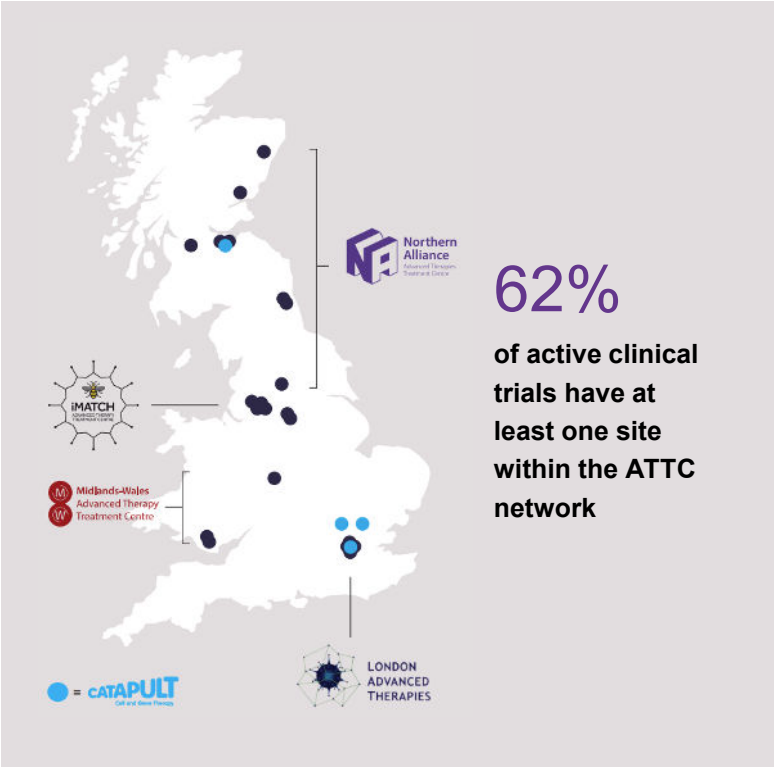

Figure 6: ATTC network presence throughout the UK

5. Achieving Impact Through Collaboration

NHS readiness cannot be built by any single organisation. It requires collaboration between the NHS, industry, academia and the wider ecosystem. This collaborative way of working is the cornerstone of the ATTC network's success to date.

5.1 Connecting Industry with the NHS

The ATTC network acts as a national driver of collaboration across the ATMP industry, strengthening the UK's position as a global hub for advanced therapies. Central to this is the Industry Advisory Group (IAG), coordinated by the CGT Catapult, which brings together ~70 organisations spanning small biotech, global pharma, CROs and suppliers. Through this forum, industry partners work collaboratively to address shared delivery challenges. This collective effort has streamlined trial logistics, standardised delivery models and supported workforce development; reducing risk, improving trial efficiency and ensuring industry perspectives are embedded in the ongoing development of the ATTC network.

Members of the IAG have worked collaboratively and in partnership with the ATTC network on a number of different projects including the development of a UK National Vision for Cell and Gene Therapy, an ATMP protocol guidance document and a set of recommendations for future-proofing the UK CAR-T patient referral pathway [27] [28].

Advanced therapy developers who are new to the field can often lack established relationships with the NHS sites that will deliver their trials. The ATTC network addresses this by acting as a conduit — providing easier access to experienced ATMP delivery sites across the NHS. The network can provide developers with insight into the expertise that is available to support delivery of their clinical trial within the UK and help to engage with those experts at an early stage. For example, the network has supported developers in early engagement with ATMP healthcare professionals, who have supported Sponsors in their clinical trial design. The impact of this has been to de-risk the operational delivery of the trial, supporting accelerated start up.

5. Achieving Impact Through Collaboration

5.2 NHS, Academic, and Ecosystem Partnerships

The ATTCs are embedded within NHS trusts and health boards, ensuring that the tools and standards they develop are operationally grounded and immediately applicable. Collaboration with NIHR and devolved equivalent infrastructure — Clinical Research Facilities (CRF), Research Delivery Network (RDN), Biomedical Research Centres (BRC), Experimental Cancer Medicine Centres (ECMC), Commercial Research Delivery Centres (CRDC) — ensures alignment between ATMP-specific support and the broader national research delivery system. Academic partnerships across the four nations provide the translational research pipeline that feeds clinical trial activity. Continual inclusion of patients in network decisions and events also means that their voice is heard. The ATTC network reinforces its commitment to patient-centred innovation by co-chairing ATMP Engage, an initiative advancing meaningful PPIE in ATMP development and delivery.

Coordination by the CGT Catapult connects clinical delivery capabilities to the wider UK ecosystem, including GMP manufacturing and broader sector development. Engagement with the MHRA, NICE and the NHS ensures policy alignment across all activities.

The NIHR Life Sciences Industry Hub provides commercial sponsors with a single point of entry covering feasibility, site selection, costing, and contracting. This integrated model is what distinguishes the UK from markets where ecosystem components exist in isolation.

5.3 Environmental Shaping

A core aim of the network is to ensure that the UK is future-proofed for ATMP delivery. In the last couple of years, there has been a diversification of both technologies and target indications. To ensure that the UK health system is ready to deliver, it is important that known barriers are addressed and work continues with the wider sector to ready the healthcare system for the future clinical trial pipeline.

Industry partners are working with the ATTC network through regional roundtables convened across England and Wales over the past two years. Led by Gilead Sciences with Anthony Nolan, these cross-stakeholder discussions use CAR-T as a case study to examine variation in access to ATMPs, links to health inequalities, and to develop short, medium, and long-term recommendations.

“The specialist focus group supported by the ATTC has not only shaped our plans for first-in-human clinical trials but gave us access to an invaluable network of clinical, regulatory, and statistical experts whom we hope to continue liaising with as we move our cell therapy forward.”

— Fiona Cunningham, Senior Scientist, VascVersa

"Collaborating with Prof Thistlethwaite and her talented team, with the support of the ATTC, has been instrumental in accelerating the translation of our novel TCR-NK platform into the clinic. The expertise of the group, combined with ATTC's infrastructure and commitment to advanced therapies, aligns closely with Zelluna's mission to make next-generation, off-the-shelf cell therapies broadly accessible to patients with solid tumours who are in need of new treatment options.“

— Namir Hassan, CEO, Zelluna

“With support from the ATTC network, we were able to collaborate and brought together expertise from across the ATMP pathway to ensure our regional roundtables were grounded in frontline delivery experience, strengthening engagement and generating practical, locally relevant solutions to address variation in access. The ATTC network played a pivotal role in facilitating the meetings and ensuring we had a rich and focused discussion.”

— Anita Ralli, Director Government Affairs, UK & Ireland, Gilead Sciences

6. Conclusion and Outlook

The UK is a globally leading environment for ATMP clinical development through world-class science, a progressive regulatory framework, and committed public investment. The truly differentiating factor is the deliberate, sustained investment in institutional readiness resulting in the systematic preparation of the NHS to deliver these complex therapies to patients.

The ATTC network has been central to this transformation. Since its establishment in 2018, it has played a key role in moving the UK from a fragmented landscape of site-level expertise towards a more nationally coordinated, standards-driven system capable of delivering advanced therapies at scale. By expanding site readiness across 55 NHS sites, standardising processes that have cut variability across multi-centre trials, training over 5,000 professionals to a consistent national standard, and connecting companies with the NHS through structured industry collaboration, the network has built the operational backbone that sponsors and patients now rely on. Today, 62% of all active UK ATMP trials run through ATTC-affiliated sites, a measure of how deeply embedded this infrastructure has become in the national clinical trial landscape.

The foundations are strong. The UK has demonstrated that with the right coordination, investment, and collaboration between industry, the NHS, academia, and government, it is possible to build a national system capable of turning the promise of advanced therapies into reality for patients. The ATTC network will continue to be at the heart of that effort, driving the next phase of institutional readiness and ensuring the UK remains the destination of choice for sponsors seeking to develop, trial, and deliver the next generation of transformative medicines.

Nearly 200 active trials, over 21% growth since 2020, 80% commercial sponsorship, 57% of European ATMP trials and 55 ATTC-affiliated sites reflect the strength of a coordinated UK national system. With continued focus on institutional readiness, the UK is well positioned to lead the next phase of advanced therapy delivery, with the ATTC network enabling sponsors to engage efficiently with the UK trial ecosystem

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