Delivering the National Advanced Therapies Vision for the UK

Assessing progress made and priority areas of future focus

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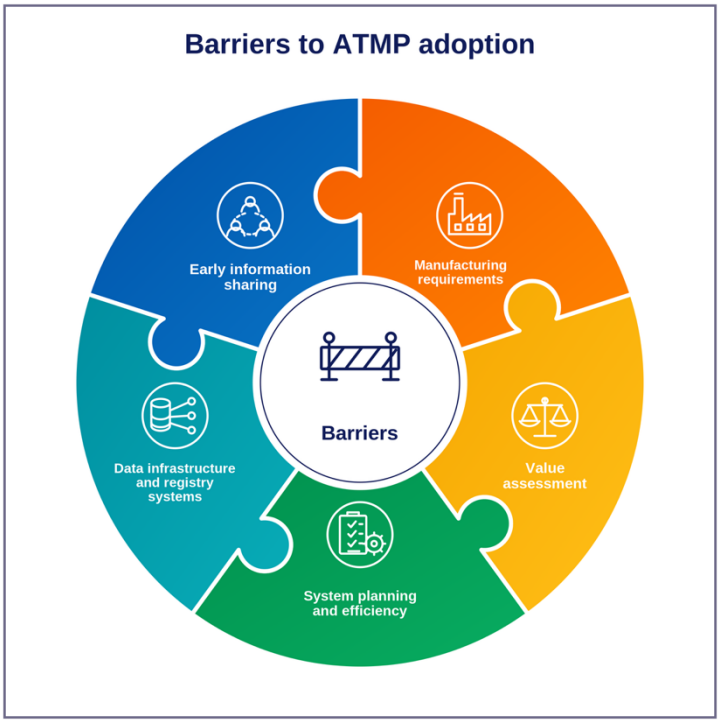
Executive summary

Cell and gene therapies, also known as advanced therapy medicinal products (ATMPs), have the potential to transform outcomes for patients with debilitating or life-shortening diseases. By targeting the underlying cause of disease, many of these therapies offer the prospect of long-term benefit or potential cure, changing the way some conditions are treated.

Four years on from publication of the 2022 report, *National Cell and Gene Therapy Vision for the UK*, important progress has been made across the UK in expanding access, increasing clinical trial activity, and strengthening NHS delivery capability. However, barriers remain across the pathway that must be resolved to safeguard the UK's leadership position in this area.

As the number of ATMPs coming to market continues to increase, and as the NHS prepares to deliver new treatments in a growing number of therapy areas, a nationally coordinated approach is required to oversee continued progress. This report highlights where progress has been made against the five barriers to ATMP delivery outlined in the 2022 publication and where further action is required. It calls for a government-supported National Advanced Therapies Vision for the UK to provide a clear roadmap for delivery.



Barrier	Progress made	Areas of priority focus
Manufacturing requirements	The UK's manufacturing base has been strengthened, including through investment in domestic capacity and growth in the manufacturing workforce.	It is important that ongoing barriers to investment identified by manufacturers are addressed, alongside continued investment in the manufacturing capacity, infrastructure and workforce needed to support the delivery of future advanced therapies.
Value assessment	Patient access to ATMPs has been facilitated by adapting assessment and reimbursement approaches for innovative therapies, including the introduction of innovative payment model pilots for ATMPs and the increase in NICE's cost-effectiveness thresholds.	It is important that future reform ensures health technology assessment (HTA) processes are better suited to ATMPs, including the recognition of long-term health and societal benefits, novel endpoints and the development of more flexible and innovative payment approaches, such as outcomes-based models.
System planning and efficiency	Delivery capacity across the UK has been expanded, supported by the work of the ATTC network and funding from the NIHR, alongside activity by the NHS in each of the four nations and improved system planning through national coordination and information-sharing.	Capacity will need to increase further to meet anticipated demand, with infrastructure and workforce constraints addressed. This includes expanding apheresis capacity through nationally coordinated capacity planning. It is important that regional variation in ATMP referrals is reduced by improving the consistency and speed of referral pathways.
Data infrastructure and registry systems	Progress has been made in strengthening data infrastructure across the UK, including the development of the Health Data Research Service in England, initiatives such as DataLoch in Scotland, and increased use of real-world evidence to support research and evaluation.	Challenges in data collection and integration will need to be addressed. This should include setting out how the Health Data Research Service will improve the use of data to support evaluation, long-term monitoring and future ATMP regulatory and commissioning decisions.
Early information sharing	Early engagement and horizon scanning has been strengthened through the NHS England ATMP programme and the Advanced Therapy Wales coordination programme.	Links between horizon scanning, real-world evidence collection, and engagement between manufacturers and the NHS on service planning should be strengthened.

Introduction

This year marks four years since the publication of our report calling for a National Cell and Gene Therapy Vision for the UK.[1] The report called for a government-driven action plan, covering the whole of the UK, that would safeguard the UK's global leadership in advanced therapies.

Whilst such a UK government action plan has not been established since our document was published, important progress has been made against the areas set out. In response to the 2022 report, the Office for Life Sciences (OLS) introduced a coordination group on ATMPs involving experts from across the sector to consider how our recommendations can be delivered.[2]

Despite this progress, important barriers remain across the advanced therapies pathway in the UK, from translation and commercialisation through to manufacturing, approval and NHS adoption. Addressing these barriers will be important both to patient access and to maintaining the UK's position as a leading environment for advanced therapy research, development and investment, supporting wider government ambitions for life sciences innovation and economic growth. This report evaluates progress that has been made against our recommendations since 2022 and sets out areas where further progress is required to safeguard the UK's leadership.

Following engagement with key stakeholders from across the UK's advanced therapies sector through two workshops, we assess progress made in resolving the five barriers to ATMP adoption identified in the previous report:

1. Manufacturing requirements
2. Value assessment
3. System planning and efficiency
4. Data infrastructure and registry systems
5. Early information sharing

In this report, the term advanced therapies is used to refer collectively to advanced therapy medicinal products (ATMPs), including cell and gene therapies and tissue-engineered products. However, this report predominantly focuses on cell and gene therapies, reflecting the scope and focus of the evidence and examples discussed. The title of this progress report reflects the increasing breadth of advanced therapies both in development and approved for use by the NHS since publication of the original National Cell and Gene Therapy Vision in 2022.

The Cell and Gene Therapy Catapult has welcomed the collaborative approach to engagement from each of the four UK nations in supporting and enhancing the UK's ATMP sector. We look forward to working with officials in each nation and wider system partners to

consider how the challenges outlined in this document can be resolved and existing areas of progress built on further.

The case for a nationally coordinated Advanced Therapies Vision

ATMPs are innovative treatments that have the potential to transform outcomes for patients with serious, debilitating and life-limiting conditions. Unlike many conventional medicines, they are often designed to target the underlying cause of disease and can provide long-term benefit, and in some cases potentially curative outcomes, following a single administration.[3] Research from the Office for Health Economics (OHE) and the Cell and Gene Therapy Catapult estimates that widening access to ATMPs in four exemplar indications could create health benefits exceeding £20 billion over 10 years. These benefits can include improved patient quality of life and overall survival rates, as well as non-health outcomes such as job creation and investment in research and development.[4]

Unlike many conventional medicines, ATMPs rely on complex manufacturing processes, specialist infrastructure and a highly skilled workforce. Their delivery requires coordination between government, the NHS, regulators, industry and academia, from early-stage research and clinical trials through to manufacturing, assessment and patient care.

As the number of approved ATMPs continues to grow, and as advanced therapies expand into new therapy areas and larger patient populations, progress in one part of the pathway can increasingly be limited by barriers at other stages. This includes the translational research pathway, where academic sponsorship of early-phase clinical trials, access to research infrastructure and good manufacturing practice (GMP) capacity for first-in-human studies are all important. Funding is also needed to bridge the gap between grant support and commercial investment and bring new therapies forward. A National Advanced Therapies Vision for the UK would help to coordinate action across the whole pathway, ensuring the UK can continue to develop new treatments as well as deliver them to patients.

The UK Rare Diseases Framework offers a model that could be taken forward to deliver this work: a nationally coordinated strategy setting out priorities and objectives, which are then taken forward by the four UK nations. This would provide sufficient flexibility to build on the important work already underway across the four nations:

- **England**: an ATMP coordination group has been established to support planning across different parts of the system.
- **Wales**: the Delivery Plan for Advanced Therapies in Wales sets the vision, approach, organisation and priorities to enable Wales to deliver on the potential of advanced therapies, running until 2029.[5]
- **Scotland**: progress has included the expansion of specialist delivery capability and investment in data infrastructure, including initiatives such as the Accelerated National

Innovation Adoption (ANIA) Pathway and DataLoch, to support research, innovation and service planning.
- **Northern Ireland**: patients benefit from UK-wide advanced therapy delivery pathways and specialist referral arrangements, helping to ensure access to approved therapies despite the absence of local delivery centres for some treatments.

Progress since the 2022 National Cell and Gene Therapy Vision for the UK

The 2022 report set out how the number of ATMPs coming to market was expected to rise significantly in the coming years. The UK has since made progress in ensuring many of these treatments have been made available to patients. By mid-2026, across the UK:[6]

- 3,500 patients have received an ATMP.
- 20 products have received marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) in 28 indications.
- 15 ATMPs are being delivered to patients in 17 indications in England. In Scotland, recent high-profile examples of ATMPs approved by the Scottish Medicines Consortium include treatments in sickle cell disease and haemophilia B.[7]

The number of ongoing ATMP clinical trials in the UK has also continued to increase – rising to 193 trials in 2025, up from 178 in 2022, reflecting sustained investment in the UK's ATMP sector.[8]

The national coordination group on ATMPs, initially organised under the Department of Health and Social Care (DHSC) and now coordinated through the OLS, has played an important role in facilitating this progress. Bringing together stakeholders from across government, the NHS, regulators and industry, the group has supported horizon scanning, system planning and coordination across the ATMP pathway, helping to align stakeholders on upcoming therapies and the associated service, workforce and infrastructure requirements. It has also provided a forum for sharing best practice and identifying cross-system challenges, including those related to capacity and delivery.

Learnings from the NHS's delivery of CAR-T

Whilst this report uses examples of several different ATMPs being delivered across the UK to illustrate the issues outlined, CAR-T is predominantly referenced, with examples included across the five barriers reflecting learnings from delivery to date. The NHS in England was the first health system in Europe to make CAR-T available, with Scotland following soon after. As a result, CAR-T provides a useful exemplar for understanding the practical challenges of manufacturing, assessment and delivery of ATMPs at scale. CAR-T is also diversifying into non-oncology indications, with the expansion of advanced therapies into chronic conditions also creating potential challenges where they are used alongside existing long-term treatments.

The global CAR-T Vision

The 2025 global CAR-T Vision sets out an international roadmap to improve patient access to CAR-T cell therapies. It was developed by a coalition of clinical, policy, patient and system experts, and proposes solutions to resolve many of the barriers outlined in this progress report – improving awareness and referral pathways, expanding system capacity and infrastructure, and developing sustainable and innovative funding models.

The global vision provides an important blueprint for the development of a National Advanced Therapies Vision for the UK, allowing the UK to align with emerging international best practice while retaining the flexibility to develop actions tailored to the structure, needs and specific delivery challenges of each of the UK nations.

The remainder of this document focuses on barriers to the delivery of ATMPs, from manufacturing to assessment and patient uptake, exploring both how they have been resolved since the 2022 report was published, and where additional work needs to be targeted to fully unlock the potential of ATMPs in the UK.

Resolving barriers to patient access to ATMPs

1 Manufacturing

ATMPs, both those that involve the extraction and manipulation of a patient's cells, as well as in vivo therapies in which the therapy is directly delivered to cells inside the patient's body, pose a unique set of manufacturing challenges, with strict requirements on storage, handling and staff training.

Unlike small molecule drugs, the individualised nature of many ATMPs makes large-scale, standardised manufacturing more complex and resource-intensive, often requiring specialist manufacturing centres. For some ATMPs, manufacturing is closely linked to the patient's clinical

status and prior treatments, meaning that production and delivery must take place within a defined and time-sensitive treatment window.

Limited manufacturing capacity can restrict the number of patients who can be treated at any one time, contribute to delays in treatment initiation and place pressure on clinical pathways – creating variation in access. The 2022 report highlighted a number of considerations for ATMP manufacturing, including the need to expand the workforce to keep pace with growing demand and to further develop domestic manufacturing capacity to support supply and minimise delays in treatment initiation. Areas of progress in addressing these considerations include:

- The MHRA has recognised the need for a new framework for decentralised manufacturing, including point of care and modular manufacturing approaches, which applies across a range of medicines, including ATMPs. This world-first framework supports manufacturing outside of centralised facilities and closer to patients that will support the development of future models in which personalised therapies can be prepared and delivered more flexibly.[9]
- In 2024, the Government introduced a new Life Sciences Innovative Manufacturing Fund, supported by £520 million for 2025-2030. This covers support for the manufacturing of new medicines,[10] and one company has already received funding to support the development of new gene therapies – with R&D supported by a mix of public and private funding.[11] The Government's 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) Investment Programme also includes manufacturing as one of three areas of focus for investment.
- The UK's manufacturing workforce and infrastructure have continued to develop. The 2024 Cell and Gene Therapy Catapult manufacturing survey found there are now 2,195 full-time equivalent (FTE) roles in ATMP manufacturing, compared to 1,696 in 2022 – an increase of 29%. The survey also highlighted continued growth in manufacturing and quality control (QC) space across the UK. As of the end of 2024, there were 32 MHRA-licensed GMP facilities in the UK, an increase from 29 in 2022.[12]

In Wales, work is underway to support implementation of decentralised manufacturing approaches, including reviews of manufacturing capability, therapeutic apheresis and pharmacy preparedness requirements for advanced therapies.[13]

Alongside growth in commercial manufacturing, academic and NHS-based manufacturing facilities continue to play an important role in the UK's advanced therapies ecosystem, particularly in supporting early-stage development and translational research. Maintaining this capability will be important in supporting new therapies to progress from research into clinical development.

The above actions, enabled through a mix of public and private investment, have helped to further enhance the UK's domestic manufacturing sector and protect it from external shocks. This growth is key to safeguarding UK leadership in ATMPs and ensuring it is well placed to deliver future advances in treatment.

Despite these advances, there remain several unresolved challenges facing the UK manufacturing sector. Wider challenges facing the UK commercial environment for life sciences companies, outlined in more detail in the value assessment section, have translated into investment decisions. These decisions risk reversing growth in the UK manufacturing sector, with investment instead going to international peers.[14,15]

The UK's ability to attract and deliver ATMP clinical trials is also important to its future competitiveness. As well as supporting research and investment, trial sites provide opportunities to develop operational expertise, build workforce capability and understand the infrastructure and capacity that may be required as therapies move into routine care. The Life Sciences Sector Plan acknowledged that "for too long, the UK's offer for those looking to scale and invest in the sector has been internationally uncompetitive".[16] Continuing to support manufacturing growth will require action to improve the UK's attractiveness as a destination for life sciences investment and ATMP clinical trials, alongside ongoing investment in the manufacturing capacity, infrastructure and workforce needed to support the development and delivery of advanced therapies. Future growth will also depend on supporting the UK manufacturing sector to adopt new technologies, including advances in automation, digital technologies and AI, to enable the development of the next generation of advanced therapies.

2 Value assessment

ATMPs have a number of characteristics that pose challenges to traditional assessment and reimbursement processes. These can include a high upfront cost, the lack of long-term certainty on safety, efficacy and cost-effectiveness and the fact they are often administered only once.[3] The 2022 report outlined these challenges in further detail and called for government coordination to systematically review the appropriateness of the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium's (SMC) existing methods and processes for ATMPs, to ensure the UK remains at the forefront of their delivery.

ATMPs can also generate benefits that extend beyond traditional healthcare outcomes, including impacts on productivity, participation in education and employment and wider economic activity. Research undertaken by the Office for Health Economics, with input from the Cell and Gene Therapy Catapult, has highlighted the importance of considering these broader system-level impacts when assessing the value of ATMPs.[4] As the number of approved therapies grows, there is an opportunity to consider whether existing assessment frameworks sufficiently capture these wider benefits alongside direct health outcomes.

Whilst the characteristics of ATMPs pose particular challenges to HTA bodies, many of these challenges are not unique to advanced therapies. They reflect wider questions facing health systems as healthcare innovation increasingly includes preventative, precision and individualised therapies with long-term, system-wide impacts, often accompanied by uncertainty. The 10 Year Health Plan for England sets out direction towards prevention, earlier intervention and working towards long-term health outcomes.[17] This creates a growing need to

consider whether existing value assessment approaches adequately capture benefits that may accrue over a long period or beyond the healthcare system. These challenges can be particularly acute for advanced therapies, given their potential to involve substantial upfront costs alongside health, societal and economic benefits realised over a longer period of time.

Some progress has been made in recognising these challenges, reflected by the continued expansion in the number of ATMPs recommended for use across the UK. The 2024 VPAG agreed between the UK Government and industry recognised challenges in the assessment of these therapies and included a commitment to deliver two innovative payment model pilots to explore the practicalities of outcomes-based agreements for ATMPs. The first pilot has been used to support managed access to the gene therapy for haemophilia B, while further work is ongoing to develop and test outcomes-based payment approaches for other ATMPs.[18]

In 2024, the first gene therapy was made available through the Innovative Medicines Fund (IMF) for adults with severe haemophilia B. Approval of the therapy was supported through a managed access agreement linked to one of the innovative payment model pilots introduced under the 2024 VPAG.[19] This arrangement illustrates how outcomes-based payment models can be utilised to enable reimbursement approaches for high-cost, one-off therapies, while additional evidence on long-term outcomes data is collected. It is available at eight specialist centres across six NHS regions.

In 2024, the first approved gene-editing therapy was made available on the NHS in England for patients with transfusion-dependent beta thalassaemia.[20] The therapy was made available through the IMF under a managed access agreement while additional evidence on long-term outcomes is collected. It is available to eligible patients at seven specialist NHS centres across the country and the therapy is manufactured in the UK.

In 2025, the same therapy was subsequently approved for use through the IMF in patients with severe sickle cell disease. The therapy is delivered through specialist NHS centres in London, Manchester and Birmingham.[21]

Whilst not specific to ATMPs, the increase in NICE's cost-effectiveness thresholds (that NICE uses in evaluations of new medicines) from £20,000–£30,000 to £25,000–£35,000 may allow greater flexibility in decision-making, particularly where treatments demonstrate high value but are associated with greater uncertainty, as is often the case for ATMPs. NICE says this increase will allow them to recommend an additional 3-5 new medicines or indications per year.[22]

However, a range of challenges continue to limit UK health technology assessment (HTA) systems' ability to recommend new treatments, limiting patient access to new treatments and affecting industry confidence in the UK commercial environment:

- The IMF was created to help address some of the challenges with demonstrating cost-effectiveness for innovative non-cancer medicines, including ATMPs, by providing time-

limited access while further evidence is gathered. However, whilst it was used to approve the above gene therapies in thalassaemia, sickle cell disease and haemophilia B, these remain the only treatments that have been approved through the IMF, and there has been a significant underspend on budget. In both 2023/24 and 2024/25, NHS England spent £2 million on drugs funded through the IMF, which equates to approximately 0.6% of its £340 million budget.[23]

- ATMPs have not clearly benefitted from the introduction of NICE's severity modifier in 2022 in the way that was hoped, with challenges around uncertainty affecting the weighting under the modifier that committees are likely to apply to an ATMP. A recent analysis suggested that 78% of all appraised treatments do not qualify for the severity modifier.[24]
- Non-submissions, where companies choose not to submit a treatment or indication to NICE for assessment, and withdrawals post-submission, have risen for ATMPs. The 2022 report called on NICE and the SMC to examine how their appraisal processes need to be updated to account for the fact ATMPs (outside of those used for ultra rare diseases) are evaluated via the same routes as treatments with significantly larger patient populations. This will help to restore industry confidence in the commercial environment for new ATMPs, following recent non-submissions to NICE.

The NHS in England was the first health system in Europe to make CAR-T available, and at the end of 2025 a new CAR-T therapy was approved for use by NICE in leukaemia. However, some CAR-T products have faced barriers to access. For example, one company did not submit evidence to NICE for a CAR-T therapy in lymphoma, citing concerns about demonstrating cost-effectiveness. The appraisal was subsequently terminated, despite the therapy being available in some other European countries, including France.[25,26]

A recent NICE appeal relating to the disclosure of the NHS England CAR-T tariff (which refers to the non-treatment costs of delivering CAR-T on the NHS) highlighted the challenges associated with transparency of some of the cost inputs used in NICE appraisals, illustrating the importance of clear and predictable assessment processes for innovative therapies.[27]

While there has been ambition to explore more flexible and innovative payment approaches for ATMPs – such as phased or annuity-based payment models, where costs are spread over time and linked to patient outcomes – these approaches have yet to be widely implemented in practice. Such models have the potential to support more sustainable adoption of one-off, high-cost therapies by aligning payment more closely with long-term value and helping to manage affordability within existing budgets.

Lowering the discount rate used by NICE for ATMPs could help address some of these challenges. Discounting reflects the principle that health benefits and costs occurring in the future are valued less than those occurring today. NICE typically applies a 3.5% annual discount rate to both costs and health effects, which can particularly affect the assessed value of ATMPs where benefits are expected to accrue over long periods. Applying a lower discount rate of 1.5% to ATMPs would better recognise their potential long-term benefits and more

closely align with HM Treasury Green Book guidance, which applies a 1.5% annual discount rate to policies that impact health or life outcomes. Additional challenges can arise where advanced therapies are used as an add-on in combination with another treatment. In these cases, the cost and value of the advanced therapy cannot be considered in isolation from the other treatments required, potentially increasing the overall cost of treatment and creating additional complexity in demonstrating cost-effectiveness.

Future reform of HTA and reimbursement should include accelerated work to explore how outcomes-based reimbursement models can be applied to ATMPs, better reflecting their one-off, high-cost nature and linking payment to long-term patient outcomes. In parallel, there is an opportunity to strengthen early access pathways. While the Early Access to Medicines Scheme (EAMS) provides a route for earlier patient access ahead of formal NICE appraisal, it does not provide routine NHS funding. Exploring options for time-limited funded early access, particularly for high-cost ATMPs, could help bridge the gap between regulatory approval, managed access and routine commissioning, enabling patient access while further evidence on effectiveness and value is generated.

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3 System planning and efficiency

Our 2022 report outlined how, as the next generation of ATMPs are brought to market, the NHS will need to consider whether existing system and infrastructure capacity is sufficient to meet rising demand. The delivery of ATMPs requires highly specialised infrastructure, coordinated multidisciplinary care, robust safety systems and significant clinical capacity across a concentrated network of accredited centres.

The DHSC's response to this recommendation was welcomed, stepping up a coordination group that has had a specific focus on horizon scanning and system planning and efficiency. That coordination group, alongside other work, has helped to strengthen the UK's capacity and infrastructure for delivering approved ATMPs:

- **Ongoing centre expansion**. Across the UK there has been an expansion in the hospitals delivering ATMPs to patients. This has been supported by the work of the Advanced Therapy Treatment Centre (ATTC) network, which has played an important role in developing capability, sharing best practice and supporting the geographical spread of delivery centres across the UK.

  In the case of CAR-T, there is now a delivery centre in every region in England, alongside one in Cardiff and three in Scotland.[28,29] In haemophilia, NHS England has established eight haemophilia ATMP treatment hubs, also covering every region of England.[30]

- **Strengthening system planning.** The ATTC network's NHS Readiness Toolkit has helped Trusts and Health Boards assess their preparedness across facilities, workforce, governance and clinical pathways – reducing variation in local understanding of operational

requirements and supporting more consistent planning. The toolkit has been accessed more than 32,000 times across 81 countries globally, reflecting its value in supporting system readiness for ATMP delivery. It has also helped to identify existing capability across a wider network of clinical sites, including those involved in clinical trials and early access programmes, supporting a more coordinated approach to scaling ATMP delivery. The Delivery Plan for Advanced Therapies in Wales includes a commitment to "utilise horizon scanning intelligence to inform NHS Wales on Advanced Therapies coming to market", and two Horizon Scanning Snapshots have been published to support planning for new therapies.[13]

- **Accelerated commercial trial set-up.** The NIHR Industry Hub provides a single, nationally coordinated point of contact to support sponsor-site collaboration. This approach recently supported the rapid activation of an early-phase CAR-Treg trial in autoimmunity through collaboration between the UK Clinical Research Facility (UKCRF) Network, the ATTC network, the BioIndustry Association (BIA) and the Arthritis Therapy Acceleration Programme (A-TAP). The trial achieved a start-up time of 113 days from regulatory filing to first participant screening, around two months ahead of comparable European sites.[31] This demonstrates a scalable approach that enhances clinical trial delivery and strengthens the UK's growing global competitiveness in trial setup for advanced therapies.
- **Evolving commissioning guidance**. Based on learnings to date, some parts of the ATMP delivery process are now increasingly being delivered closer to home at local referral centres, as opposed to exclusively at specialist delivery centres. For some ATMPs, there are now opportunities to move many aspects of patient follow up carried out in delivery centres closer to home. This aligns with the direction and 'shift' of the 10 Year Health Plan, while recognising that there are limits to which elements of ATMP delivery can be safely carried out in the community.

In CAR-T, many centres are increasingly exploring how to roll out ambulatory models of care, with elements of the pathway already being delivered in outpatient settings in a number of cases. In June 2026, the Cell and Gene Therapy Catapult and ATTC network brought together partners across the system to consider how ambulatory CAR-T delivery can be safely expanded and standardised across the NHS. The workshop found broad agreement that many elements of the CAR-T pathway can be delivered in outpatient settings for selected patients. Discussion also identified significant variation between centres and the need for further development of workforce, infrastructure, monitoring arrangements and patient support. Work is now underway to build on these findings and develop a more standardised approach to support ambulatory CAR-T delivery across the NHS.

These examples point to important work being carried out across the system to apply learnings to date to prepare for the future of ATMP delivery. However, there are several areas where this work needs to be accelerated, and challenges with infrastructure and capacity across the system mean that the benefits of ATMPs are currently not being felt equally across the system:

- **Centre expansion** will need to go further to meet existing patient demand for many approved ATMPs. Specialist centres in many regions are at capacity, though in future will likely need to expand provision in new indications and new therapy areas.

  We have heard how some recently approved CAR-T centres are already at capacity and referring patients to centres further away from where patients live. This adds to the already long distances patients often need to travel for treatment; around 50% of CAR-T patients travel over 50km for treatment and a quarter travel over 100km.[32] The absence of a delivery centre in Northern Ireland requires patients there to travel to England to receive treatment.

- **Capacity and infrastructure**. Our previous report outlined how many ATMPs have a particularly complex manufacturing process. In the case of CAR-T each treatment is individually manufactured following the extraction of a subset of the patient's white blood cells, a process known as apheresis. It noted that to support the increased delivery of ATMPs, capacity within specialist centres will need to be expanded to support the increased demand on the apheresis process. In future, additional cell-based ATMPs in development that require apheresis may also be approved. However, shortages in apheresis capacity and the specialist apheresis workforce continue to be highlighted by local centres as a challenge in managing patient numbers, with apheresis at risk of becoming a bottleneck due to the number of other clinical services and treatments that rely on it. A recent review of apheresis capacity by an expert working group commissioned by the DHSC validates these concerns. It highlights a growing concern of the impact on capacity that will be created by new ATMPs becoming available over the next few years, and signals the need for a strategic, nationally co-ordinated approach to capacity planning.[33]
- **Variation in referral pathways and patient identification**. Variation in referral pathways alongside low awareness of approved ATMPs in some referral centres means that some patients who may be eligible for an ATMP are either never referred to a treatment centre or are referred too late to then receive it. Variation in the way multidisciplinary team (MDT) meetings are carried out can also contribute to regional inequalities by making it more, or less, likely for patients in some regions to access ATMPs. The commitment in the National Cancer Plan to modernise MDT working is welcome and should include a focus on how referral pathways can be streamlined and standardised.[34]

Analysis undertaken through England's Rare Diseases Action Plans identified variation in uptake across treatments in highly specialised services, including some ATMPs, with 3 of the 16 measured geographies having uptake below expected levels. Where unexpected variation was identified, providers were asked to develop action plans to address inequities and improve access.[35]

Additionally, the barriers patients face in receiving an ATMP, including those created by the travel and accommodation costs associated with receiving treatment at a specialist delivery centre, can be prohibitive for some patients. These barriers can increase the burden on patients

and families, who also require clear, accessible information and appropriate psychological support throughout the treatment pathway. Future work around service design should recognise the important role that carers and family members play in supporting treatment decisions, adherence to follow-up requirements and ongoing recovery.

Commitments in the National Cancer Plan to review and modernise MDT working and introduce a new travel fund for young people living with cancer and their families are welcomed in responding to some of these challenges.[34] However, the need here is significant, and Anthony Nolan is calling for a national patient travel fund to be established to support travel and accommodation costs for accessing treatment. In response to these challenges, some charities have established dedicated travel and accommodation support programmes for patients receiving advanced therapies, to address costs that would otherwise create barriers to access.

Delivering the above will also require workforce upskilling and, where relevant, shortages to be addressed. ATMP delivery requires highly skilled staff – from apheresis nurses, stem cell technologists and specialist pharmacists to clinical nurse specialists and cell therapy coordinators. Many centres continue to operate with shortages across these roles, affecting referral timelines and increasing pressures on existing staff. It will also be important that a strong clinical-academic pipeline is maintained, including clinician-scientists and researchers who can support translation, evidence generation and the development of new advanced therapies.

Important progress has already been made in developing workforce capability. The Advanced Therapy Treatment Centre (ATTC) network and the Cell and Gene Therapy Catapult have played a key role in supporting workforce development, including the development of a skills and capability framework in partnership with Skills for Health, and the provision of free, accessible education and training resources for NHS staff. These initiatives provide a strong foundation for building the workforce required to support future ATMP delivery.

In England, the forthcoming 10 Year Workforce Plan is an important opportunity to build on this progress, setting out measures to address remaining workforce gaps while increasing awareness of ATMPs across the wider healthcare workforce.

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4 Data infrastructure and registry systems

The accessibility of data across the system is vital in capturing patient experience, verifying long-term efficacy claims, assuring long-term safety and informing routine clinical practice. The 2022 report outlined the data challenges that exist across the ATMP adoption pathway, from reimbursement – given the immaturity of the data available at the time a product is assessed by NICE – to ongoing patient monitoring and patient experience.

The creation of the new Health Data Research Service (HDRS) in England could play a key role here, delivering a single point of access to health data for research purposes from multiple sources.[36] The 2025 Life Sciences Sector Plan refers to the HDRS as a unified service across existing data assets that will resolve system fragmentation.[16] Recent analysis of the UK health data ecosystem has highlighted the complexity of the existing health data landscape and the role the HDRS will play in enabling coordination across data infrastructure and services.[37] The HDRS provides an opportunity to link patient data across care settings, and support the generation of the real-world evidence needed to resolve uncertainty in HTA (particularly at the conclusion of managed access agreements where ATMPs are then reassessed), monitor long-term safety and durability and inform future commissioning decisions.

It should also further accelerate the setting up of new ATMP clinical trials, through integrating health data into clinical trials platforms. The HDRS will provide a single-entry point for NHS data in England with standardised commercial agreements, data access approvals and accredited research environments. A National Advanced Therapies Vision for the UK, if introduced, would help to set out how the HDRS will address the challenges around data collection and sharing for ATMPs specifically.

Alongside developments in England, important progress has also been made across the devolved nations in strengthening health data infrastructure. In Scotland, the Digital Health and Care Innovation Centre (DHI) and DataLoch are working to standardise and automate systems for the collection of real-world evidence, and support the use of linked health and social care data for research and innovation.[38] Initiatives such as those detailed above demonstrate the broader opportunity across the UK to improve access to linked, real-world data to support clinical research, long-term follow up and evaluation of advanced therapies. Alongside this, the DHSC's ATMP data working group is seeking to address challenges in data collection and integration across the pathway. In Wales, plans are underway to expand the Advanced Therapies Commissioning Dashboard, which provides real-time data on access and demographics, to include clinical and patient-reported outcomes data.[13]

The commitments around HDRS are welcomed, alongside NHS England's ongoing work to support ATMP research and strengthen data collection. It is now important for the Government to set out clearly how HDRS and related data reforms will be applied to advanced therapies specifically, to ensure the UK's data infrastructure develops alongside advances in treatment delivery and adoption.

5 Early information sharing

The 2022 UK National Cell and Gene Therapy Vision report outlined how strong collaboration and partnership working between NHS commissioners, providers and industry had been seen as key to the successful approval and delivery of ATMPs on the NHS to date, contributing towards early progress. The effective sharing of information across the system allowed for the NHS to develop service specifications quickly, with site selection and set-up for ATMPs fast and efficient. Effective early information sharing also facilitated effective commercial discussions between manufacturers, HTA bodies and payers.

NHS England has since developed a strategic approach to commissioning ATMPs, involving building horizon scanning capabilities and working with pharmaceutical companies to anticipate future demand.[2] Its ATMP programme supports service preparedness, horizon scanning and early engagement for complex new products, enabling the NHS to understand the operational and workforce requirements well before NICE issues guidance. Strong engagement between the NHS England innovative medicines team with industry on pipeline ATMPs has helped to support service readiness and capacity for newly approved ATMPs. As NHS England is merged into the DHSC, it is vital that both the strategic approach and the ATMP coordination group are retained, to protect existing expertise.

In Wales, the National Pathway Mapping for Complex Therapies Group is exploring the introduction of a new national pathway to assess what investment and reform is required for the implementation of new advanced therapies.[39] If introduced, this will help to consider wider system readiness requirements for new advanced and complex therapies, including the patient pathway and resultant implications for estates, and workforce and training requirements.

Alongside improvements in early information sharing and system planning, the MHRA has taken positive steps to support earlier regulatory engagement and access for ATMPs. This includes changes to clinical trial approvals and initiatives to reduce approval timelines and consistently meet clinical trial authorisation (CTA) targets.[40] The MHRA has also set out proposals for a more flexible regulatory framework for rare therapies, aimed at supporting earlier patient access. These proposals create an important opportunity to improve coordination between regulatory and HTA processes for rare disease therapies, including ATMPs, where evidence generation can be particularly challenging.[41]

Going forward, in our engagement we heard how links between horizon scanning, real-world evidence collection, and discussions between manufacturers and the NHS on service planning could still be strengthened. Stronger mechanisms for structured, early sharing of clinical, operational and manufacturing information will become even more important as ATMPs expand into higher-volume indications, where service planning timelines are tighter and system impact is greater. This will be required to explore how shortages in laboratory space and apheresis,

among other areas, can be overcome so that all eligible patients are able to benefit equally from newly approved ATMPs.

As advanced therapies are approved in more non-oncology indications, there is also an opportunity to apply learnings from existing ATMP delivery programmes to new therapy areas. This includes supporting specialties with less experience of delivering advanced therapies to develop referral pathways, workforce capability and clinical infrastructure, while avoiding duplication of effort across the system. Greater visibility of upcoming ATMP clinical trials and future service requirements could further support coordinated planning, maximise opportunities for patient recruitment and improve system readiness for new therapies.

The refreshed **Innovative Licensing and Access Pathway (ILAP),** which brings the MHRA, NICE and NHS England together at the clinical development stage, should create new opportunities for earlier engagement with industry and alignment on data, regulatory and commercial expectations.[42] ATMPs offer an ideal focus for the refreshed ILAP, and a narrower focus on these treatments would help to address the challenges that affected the initial pathway – notably too many eligible candidates and more limited engagement than intended as a result.

Conclusion

The 2022 report was published four years ago to call for the development of a national UK-wide vision to protect and strengthen UK leadership in ATMPs, building on early successes and addressing challenges in approval and delivery. Subsequently, important progress has been made – more ATMPs have been approved in new therapy areas and expanding indications, UK ATMP clinical trials continue to grow and more specialist centres across the UK have been approved so more patients can benefit.

However, the absence of a government-supported UK-wide vision has meant progress has been fragmented, with advances at some stages of the pathway adversely affected by challenges at other stages. This report analyses progress against the five barriers to ATMP delivery set out in the original report. Across each barrier progress has been made, from investment in manufacturing to centre expansion and the creation of a new data research service. To ensure patients continue to benefit from this progress, further reform is now required – including the handling of uncertainty in HTA, investment in infrastructure and the ATMP workforce and more consistent patient referral pathways.

A National Advanced Therapies Vision for the UK, supported by the UK Government and involving input from stakeholders across the system and four nations, would help to resolve the barriers set out and support the UK across the full advanced therapies pathway – from research, translation and commercialisation through to manufacturing and NHS delivery. This should be guided by the four principles set out in the 2022 report: collaboration between

partners, flexibility on the part of all stakeholders, putting patients' needs at the heart of decision-making and ensuring sustainability for the health system and manufacturers.

The Cell and Gene Therapy Catapult and the ATTC network, alongside partners, are committed to supporting this effort, building on the strong collaborative working and engagement that has embodied past UK leadership in ATMPs. We look forward to receiving the Government's response to this report and to working with partners to put these principles into practice and ensure the UK remains at the forefront of delivery.

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