

Year One Annual Report

Delivery Plan for Advanced Therapies in Wales



September 2024 - August 2025

Co-ordinated by



Advanced
Therapies
Wales

Therapiau
Datblygiedig
Cymru

Introduction

Welcome to the first Annual Report of the **Delivery Plan for Advanced Therapies in Wales**. We have outlined activity and progress made over the last year, from the plan's endorsement in September 2024 by the Advanced Therapies Wales (ATW) Programme Board and its subsequent launch in January, once endorsed by Welsh Government.

We've highlighted successes and challenges along with the ongoing work associated with each Goal and Theme, and would like to thank our teams, collaborators and our patient and public partners for their help and dedication. The contents of the following pages demonstrate the impact of our collective contributions and we look forward to engaging many more of you as we continue to shape a dynamic, inclusive ecosystem moving forward into year two.



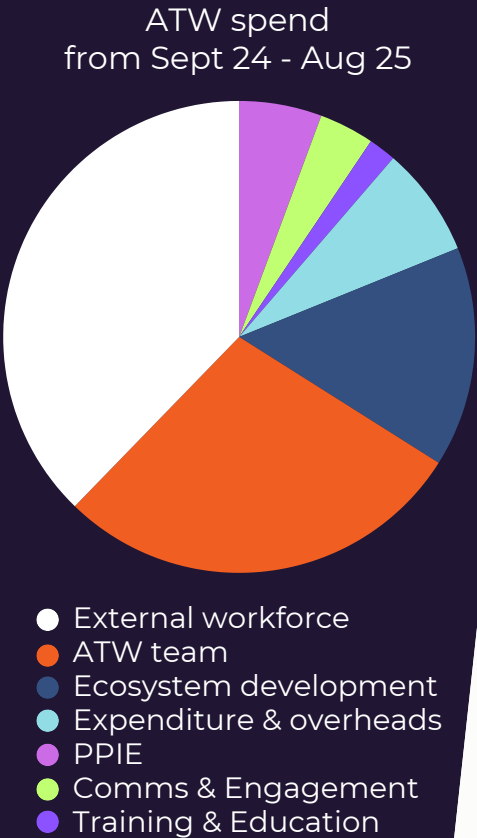
Advanced Therapies Wales (ATW) is the only programme of its kind in the UK, and this innovative approach has generated the ability to garner systemwide and strategic support in this rapidly growing advanced therapy medicinal products (ATMPs) field, creating a single point to coalesce expertise and offer national support.

With an annual budget of £0.5 million, the programme works across Wales to support the development and adoption of a wide range of advanced therapies, but does not cover the cost of the therapies themselves. Our funding supports a range of activities and substantive posts, including the core team and externally commissioned specialist roles embedded across health boards to enable ATMP delivery.

We act as a central hub, bringing together resources, coordinating activities, and nurturing collaboration across the sector, maintaining strong links with both Welsh & UK Governments developing end-to-end NHS pathways. We also support research, serving as a key interface for industry and commercial partners.

ATW co-leads the Midlands and Wales Advanced Therapy Treatment Centre (MW-ATTC) with University Hospitals Birmingham NHS Foundation Trust as one of four UK centres, making up the Advanced Therapy Treatment Network (ATTC). Coordinated by Cell and Gene Therapy Catapult (CGT Catapult) and the National Institute for Health and Care Research (NIHR), the ATTC has a UK-wide remit to accelerate advanced therapy clinical trials within the NHS, to strengthen trial readiness, to build workforce capacity and capability that enhances the UK's attractiveness as a location, aligning activities with [NHS England's 10 year health plan](#). The overall allocation is £17.9 million from 2024–2028, with MW-ATTC receiving £3.3 million, of which £1.3 million comes to Wales.

MW-ATTC is leading the Public and Patient Involvement and Engagement (PPIE) workstream. The aim is to address the current gap in ATMP-specific PPIE activity by raising public awareness, promoting equitable access, and co-developing a patient charter to support greater understanding and participation in ATMP clinical trials.



Vision

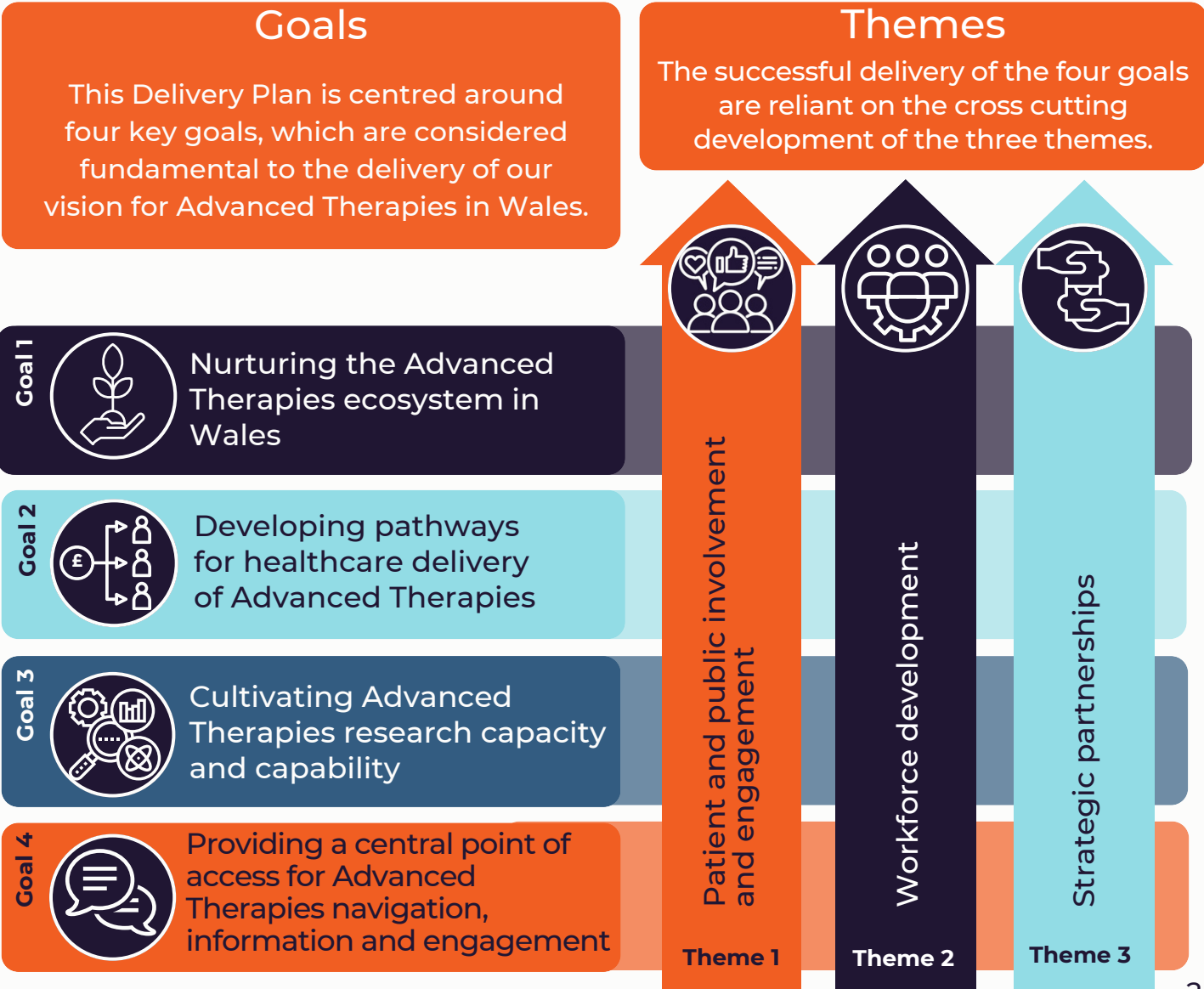
Working together within the Advanced Therapies global ecosystem, to deliver the benefits of these therapies to improve the health, wellbeing and prosperity of the people of Wales.

"I'd like to say how good I think the Delivery Plan is, really thorough, easy to digest, with accessible information, focused and ambitious. A helpful and much-needed roadmap"

Strategic approach

The development and delivery of the Advanced Therapies sector in Wales is multifaceted. To achieve the goals of the SOI, coordinated collaboration and engagement with key stakeholders and partners is required (including NHS organisations, academia, industry and others) to establish an effective pathway to enable efficient delivery of these therapies.

Ensuring alignment and contribution to regional and national policies, objectives and ambitions is vital to successful delivery.





Nurturing the Advanced Therapies ecosystem

Supporting growth in the Advanced Therapies ecosystem through enhancing and aiding opportunities for development and increased awareness.



Completed - 1
On plan - 7

Risk status **GREEN**
Social media posts 36

Goal 1

Key Activities

1. Translational research funding

ATW provided £24,000 to the Advanced Therapies Multi-Disciplinary Research Group (MDRG), who awarded grants to four small-scale projects through a competitive process which are due to report back with results in January 26. Co-hosted with Cardiff Experimental Cancer Research Centre (ECMC) and the Advanced Neurotherapies Centre (ANTC), the group has grown to 143 members from academia, health, and industry with the monthly meetings exploring three rotating themes: Neurology, Oncology, and Regenerative Medicine.

2. Regional and National collaboration

A Quarterly Regional Meeting, co-led by ATW and MW-ATTC was launched. Comprising of NHS and university partners from Cardiff and Vale University Health Board (CAVUHB), Velindre University NHS Trust (VUNHST), and institutions in Oxford, Nottingham, Leicester, Cambridge, Southampton, Bristol and Birmingham. The meetings provide an opportunity to share intelligence on clinical trials, align regional efforts, and escalate risks to the ATTC network. Despite receiving no direct funding, partners are engaged, reflecting a strong sense of shared purpose.

3. Funding clinical roles

ATW and MW-ATTC jointly funded key clinical posts including: Consultant ATMP Pharmacist, Research Nurse in Neurodegenerative Indications, ATMP Clinical Trials Manager, Clinical Lead, and Specialist Registrar in Neurosurgery.

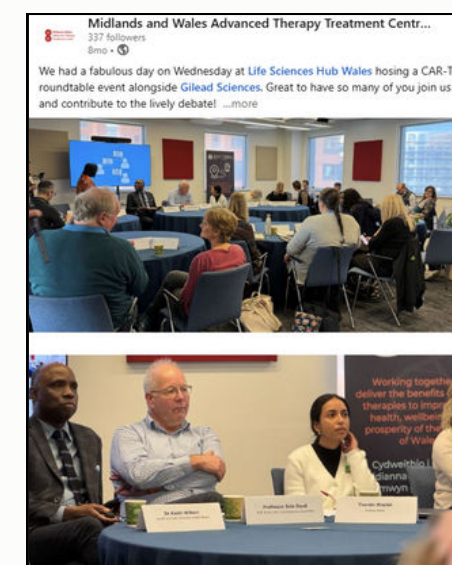
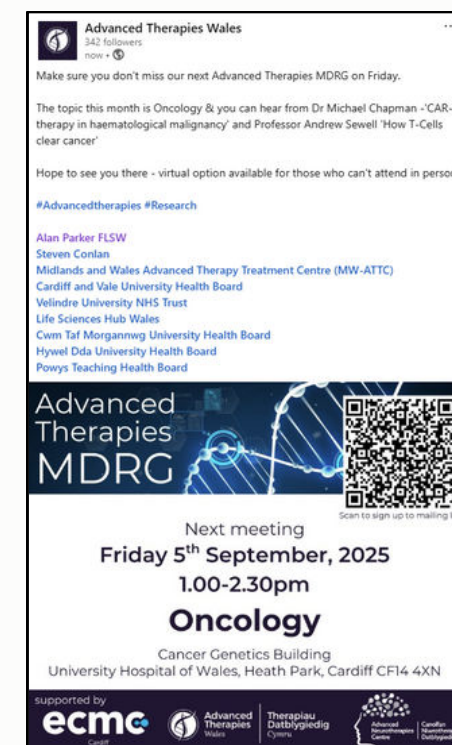
ATW has created the UK's first national Advanced Therapies Clinical Expertise Forum, which will formally convene 2025-26. Members include specialists in nursing, oncology, haematology, apheresis, regulatory affairs, and workforce planning and will be funded sessionally, with roles reviewed and rotated annually. The forum will provide advice on service design, workforce planning, business cases, regulatory compliance and infrastructure development.

4. Pharmacy readiness

ATW has engaged in national work led by the Welsh Government Chief Pharmacy Officer to assess pharmacy service preparedness for ATMPs. This informs Welsh Government decision-making and ensures alignment with the Medicines and Healthcare products Regulatory Agency's 2025 Point of Care Manufacture guidelines. Findings will be published in the 2026 Annual report, with clear recommendations to strengthen pharmacy infrastructure and workforce readiness across Wales, aligning with national and regional initiatives such as the Translational Advanced Medicines Service (TrAMS).

5. Patient engagement

ATW has hosted a series of roundtables with MW-ATTC, Gilead Sciences, and Life Sciences Hub Wales. They have brought together clinicians, researchers, policymakers, and patient advocates to address topics including CAR-T delivery, Good Manufacturing Practice (GMP) facility planning, trial inclusivity, and specialist training. Each has generated actionable recommendations that now guide programme priorities.



6. Case Study

Therapeutic Apheresis Services

Apheresis services are critical to the delivery of advanced therapies. An Apheresis Review commissioned by ATW in 2023 identified significant gaps in infrastructure and workforce capacity across the nation. The review set out recommendations for an All-Wales service model to address these limitations and enhance national readiness. ATW convened a collaborative project in 2024 involving health boards, clinicians, and patients to refine and progress preferred options for a sustainable future model.

Endorsed by the ATW Programme Board and the Regional and Specialised Services Provider Planning Partnership, the project ensures alignment with national priorities and addresses both current and anticipated service needs.

Importantly, the approach is holistic, extending beyond ATMPs to strengthen the wider strategic and financial case for investment.

To capture consensus on a preferred service model, targeted clinician and patient engagement days are planned for 2025. Our approach has gained national recognition and has been endorsed as a blueprint for potential replication across the UK, both for the initial review and for proposed future service provision.

Challenges

- Sustaining small and large-scale projects relies on securing long-term funding beyond the typical one-year cycle.
- Ambition to establish a GMP facility in Wales, will require substantial cross-sector investment supported by long-term policy planning.
- Consistent engagement and production of robust, evidence-based insights within an evolving healthcare landscape at a time when finance, capacity, and resources are extremely constrained across key partner organisations.

Next 12 months

- Draft paper for GMP facility to define objectives and resources
- Repeat MDRG funding initiative
- Recruit for roles of Advanced Therapies Clinical Expertise Forum
- Develop outline business case for Therapeutic Apheresis Service
- Develop clinical expertise forum to enhance clinical leadership
- Develop business case for aseptic staff - Hemgenix delivery
- Develop business case to enable adoption of Spherex
- Visit Miltenyi Biotec to expand Prodigy platform capability
- Support aligning local research with system-wide readiness



Developing pathways for healthcare delivery of Advanced Therapies

Supporting institutional readiness to ensure timely healthcare delivery through innovative collaborations.



● Completed - 1
● On plan - 7
● Scheduled - 3

Risk status **GREEN**
Social media posts 4

Goal 2

Key Activities

1. National coordination

In June 2025, ATW and the NHS Wales Joint Commissioning Committee (NWJCC) signed a Memorandum of Understanding which formalises collaborative arrangements developed over recent years, enabling cross-sector expertise to work together more effectively.

2. Delivery to patients

Currently, 14 therapies have been approved by the National Institute for Health and Care Excellence (NICE) for 17 indications. In Wales, three haemato-oncology therapies are delivered through the South Wales Blood and Marrow Transplant Team (SWBMT) at CAVUHB, where more than 100 patients have now received Chimeric Antigen Receptor T-Cell (CAR-T) treatment. Not all therapies are available in Wales, and some Welsh patients receive treatment elsewhere in the United Kingdom.

3. Horizon scanning

Over the last year publication of the Horizon Scanning Snapshot has been established. Produced every six months, it supports planning and NHS readiness. ATW has worked with the All-Wales Therapeutics and Toxicology Centre (AWTTC) and the NWJCC to create this document, which provides early intelligence on therapies nearing market entry and awaiting NICE approval. The snapshots have become a key resource for commissioners, clinicians, and service planners, and are published each March and September.

4. Practicalities of adoption

The ATW Adoption working group is now co-chaired by Professor Iolo Doull of NWJCC and Vicky Le Grys of CAVUHB. The group helps healthcare providers implement NICE recommended therapies and identifies the resources needed for consistent delivery in standard care settings.

ATW has also facilitated the introduction of gene therapy for haemophilia by convening multidisciplinary progress meetings led by the ATMP Consultant Pharmacist, who identified and addressed implementation challenges and supported readiness across pharmacy, clinical, and commissioning teams.

ATW has also collaborated with colleagues at VUNHST and Welsh Blood Service (WBS) to develop models of care that enable more local delivery of complex therapies with specialist support and explored service expansion to meet current unsustainable demand and growing future needs.

5. System wide collaboration

ATW and the AWTTC have jointly developed a governance proposal to support the integration of complex and novel therapies into routine practice, enabled by the creation of the "Coalition of the Willing," a national multi-stakeholder working group. This UK first, working on mapping of the complex therapy pathway, has produced a national proposal for introducing complex therapies into standard care in Wales. It addresses evolving requirements by providing a modified whole-system pathway that meets governance, infrastructure, regulatory, and workforce needs including service redesign, national policy, and capital planning.

SPECIALITY	ABBREVIATED INDICATION	THERAPY	ATMP TYPE	CLINICAL INFORMATION	NICE REF
Haemato-oncology	Acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	Administration via specialist team	GS247
Dermato-oncology	Previously treated unresectable or metastatic melanoma	Lifilecet	Anticancer drug	Administration via specialist team	GS253
Dermatology	Severe eczema associated with dysmorphic features	Bemegrener gepaprevac	Small molecule	Administration via specialist team	GS253
Neuromuscular	Duchenne muscular dystrophy in children < 7 years	Exon-skipping therapy	Gene therapy	Administration via specialist team	GS257
Neuro-oncology	High-grade glioma	DCVax-L	Cell-based therapy	Administration via specialist team	GS259
Neuromuscular	Spatial muscular atrophy	Onasemnogene APOB protein	Gene therapy	Administration via specialist team	GS265

SPECIALITY	ABBREVIATED INDICATION	THERAPY	ATMP TYPE	NICE REF	PUBLISHED
Haemato-oncology	Acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS247	March 2025
Haemato-oncology	Acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS248	March 2025
Haemato-oncology	Diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS249	March 2025
Haemato-oncology	Multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS250	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS251	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS252	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS253	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS254	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS255	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS256	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS257	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS258	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS259	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS260	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS261	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS262	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS263	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS264	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS265	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS266	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS267	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS268	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS269	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS270	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS271	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS272	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS273	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS274	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS275	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS276	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS277	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS278	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS279	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS280	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS281	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS282	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS283	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS284	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS285	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS286	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS287	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS288	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS289	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS290	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS291	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS292	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS293	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS294	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS295	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS296	March 2025
Haemato-oncology	Relapsed and refractory acute myeloid leukaemia (AML)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS297	March 2025
Haemato-oncology	Relapsed and refractory acute lymphoblastic leukaemia (ALL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS298	March 2025
Haemato-oncology	Relapsed and refractory diffuse large B-cell lymphoma (DLBCL)	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS299	March 2025
Haemato-oncology	Relapsed and refractory multiple myeloma	Chimeric Antigen Receptor T-Cell (CAR-T)	Gene therapy	GS300	March 2025



Challenges

- Limited dedicated resources. ATW working with Health Boards and partners to address workforce allocation and operational support. Gaps in pharmacy and aseptic services, being targeted through investment and service redesign.
- Cleaning and linking datasets to develop more integrated digital systems, supporting timely decision-making to enable real-time data sharing and collaboration.
- Coordinated planning across Health Boards, commissioners and clinical teams required to reduce fragmentation.

Next 12 months

- Develop an innovative commissioning support model for efficient movement through to delivery.
- Prepare paper on pharmacy readiness for ATMPs
- Continued coordination of national complex pathway solutions, moving to proof of concept stage.
- Continued facilitation and support to contribute to and/or develop multidisciplinary clinical solutions.
- Digital needs- articulating the ask
- Launch open access version of ATMP Commissioning Dashboard

6. Case Study

Advanced Therapies Commissioning Dashboard

Developed by the ATMP Outcomes Programme at NWJCC, the Advanced Therapies Commissioning Dashboard has been launched.

It provides a clear picture of access to advanced therapies in Wales, showing how many have been commissioned with demographic insights into who is receiving them. This is building understanding and will highlight potential barriers or inequalities.

Retrospective data on diffuse large B-cell lymphoma patients in Cardiff has been analysed, which is the main group eligible for CAR-T therapy, ahead of an all-Wales rollout. Early findings indicate patients present at an older age compared to international benchmarks. Scoping on innovative payment models to support sustainable commissioning has also begun.

The dashboard will be expanded to capture clinical and patient-reported outcomes, enabling real-world evaluation of their impact. It will also explore what information matters most to the public, with the aim of creating a transparent, open-access version. This work will contribute to a case study for the ATMP Coordination group led by the UK's Department of Health and Social Care.



Cultivating Advanced Therapies research capacity and capability

Supporting research and innovation acceleration in Wales, nationally and internationally to increase capacity and capability.



Completed - 1
On plan - 12

Risk status **GREEN**
Social media posts 109

Goal 3

Key Activities

1. Knowing our strengths

ATW has commissioned a mapping and review exercise of advanced therapies research in Wales, covering both pre-clinical studies and clinical trials. It will highlight current strengths and gaps, identify opportunities for growth, inform strategic planning, and help shape research priorities. Insights will also feed into broader infrastructure assessments, including requirements for GMP facilities and align with the UK Government's [Life Sciences Sector Plan](#).

2. Sharing learning

In addition to the previously mentioned Advanced Therapies MDRG, ATW provides collaborative research space with The Research, Development and Innovation Working Group, chaired by Professor Steve Conlan of Swansea University. The group meets quarterly providing a platform for knowledge sharing, building trial capacity, and promotes collaborative research opportunities.

3. Research activity support

ATW funds the ATMP Consultant Pharmacist who supports clinical research delivery, as well as other posts involved in advanced therapies research centres. This includes funding consultant time and a research nurse at the ANTC, who have been leading first-in-human trials for Huntington's disease. Funding has also supported trial administrators for the Cardiff Cancer Research Hub (CCRH) and cystic fibrosis studies to facilitate early-phase advanced therapy trials.

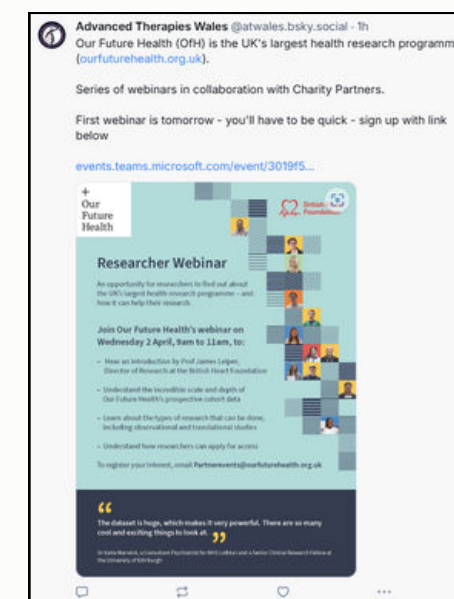
ATW further supported pre-clinical research, awarding a £10,000 grant to PhD student Rosie Mundy at the Wales Applied Virology Unit at Cardiff University for her work on the Ad10 viral platform, which has already resulted in a [published paper](#).

4. Achieving shared goals

Through the Wales Cancer Industry Forum, which includes a patient representative, ATW has partnered with AstraZeneca to incorporate industry insights into pathway mapping. The programme also collaborates with partners through initiatives such as roundtables with Gilead Sciences, also maintaining strong relationships with Amgen, Cytiva, and the Association of the British Pharmaceutical Industry (ABPI). ATW has also aligned with the wider United Kingdom ecosystem by implementing recommendations from the Lord O'Shaughnessy review to strengthen commercial trial delivery and through engagement with the ATTC Industry Advisory Group.

5. Research intelligence and information

ATW has helped develop a process for open trial recruitment and site selection. Working with colleagues in Health and Care Research Wales (HCRW) and ATTC network, opportunities are shared across Wales, with dedicated support provided to clinical teams in site selection to widen engagement. Connecting with other national and funded research initiatives in Wales has enabled increased collaboration and value for money. There is regular engagement with the ANTC, Cardiff ECMC (both adult and paediatric), SWBMT Team, CCRH, Betsi Cadwaladr University Health Board (BCUHB) Clinical Trials Unit and many other specialist teams.



6. Case Study

Activity Snapshot Advanced Therapy investigational Products (ATiMPs)

The Advanced Therapy Investigational Medicinal Products Clinical Trial Activity Snapshot has been launched. Produced collaboratively by ATW, CAVUHB, and VUNHST, using data from CGT Catapult database, with input from the Research, Development and Innovation Working Group and HCRW.

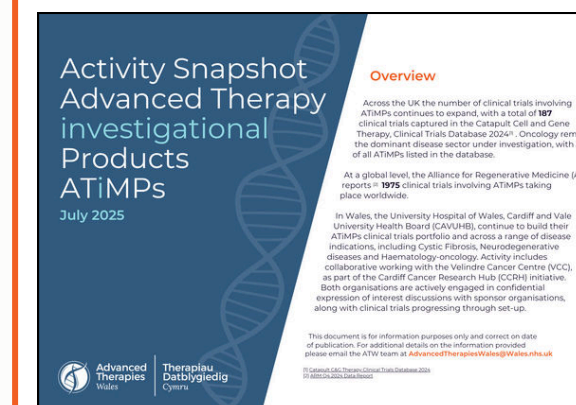
The bi-annual snapshot, provides an up-to-date overview of open and follow-up clinical trials across Wales, helping stakeholders identify strengths, gaps, and opportunities. It has supported planning, provided transparency and enhanced equitable patient access. Joint authorship ensures the data is accurate, relevant, and directly useful to research teams and partners, making it a valuable tool for strengthening research capacity.

Challenges

- Sustained engagement from stakeholders essential to ensure mapping and review process progresses. It may also highlight workforce and infrastructure gaps that will require investment or policy action.
- Ensuring that horizon scanning and mapping outputs are thorough and reliable is critical for informing future planning and strategic decision-making. Collaboration with industry and academic partners remains vital, though resource intensive.

Next 12 months

- Utilise information in the research baseline review to develop appropriate model for Wales and publish.
- Support continuing research collaboration in advanced therapies by facilitating and funding activity where possible
- Identify new activity or developments to ensure that the Welsh offer can be capitalised upon.
- Continue to provide intelligence and information to enhance capitalisation of opportunities and collaborative working.





Providing a central point of access for Advanced Therapies navigation, information and engagement

Developing high quality, up to date and easily accessible information to support navigation of the Advanced Therapies landscape.



Completed - 1
On plan - 4

Risk status **GREEN**
Social media posts 135

Goal 4

Key Activities

1. Committed resources

The ATW Communication and Engagement Strategy has been developed. It outlines how the programme will produce targeted communications, stakeholder engagement, and inclusive messaging. To support this work, a full-time Communications Officer post has been funded until March 2026.

2. Increasing visibility and online presence

Social media activity has increased, and the new ATW website is being developed. It is being designed as a central access point and resource hub with dedicated pages covering all stakeholder groups. Targeted social media and media campaigns have helped grow the audience. Post information is captured and aligned to the goals and themes in the delivery plan. Targeted emails on events and funding opportunities are shared to relevant stakeholders, as well as the distribution of the Horizon Scanning Snapshot and the ATiMP Activity Snapshot.

3. Engagement

ATW has developed and maintains a calendar of events, and now coordinates monthly MDRG meetings. The Advanced Therapies Annual Conference in London has become a regular fixture and in 2025, ATW joined with Life Sciences Hub Wales for a joint stand. ATW and MW-ATTC hosted a roundtable on patient and family perspectives. Professor Liam Gray also attended as a clinical representative.

Events hosted

- Delivery Plan launch
- ATTC & Gilead Sciences CAR-T workshop
- ATW Symposium

Events with stand or presentations

- Friends of Cymru Sickle Cell and Thalassaemia Day
- Genomics Strategic Workforce plan launch
- UK Medicines Information Conference
- Precision Medicine Showcase
- Velindre Medical Engagement Day
- Advanced Therapies UK Congress
- HCRW Faculty Showcase
- Glen Wells Visit
- Velindre Working Together Conference
- MediWales Connects Conference

Events attended

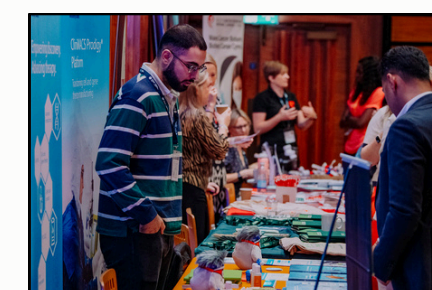
- Drug Discovery Conference
- HCRW Conference
- Wales Rare Care Centre for Wales
- UCL Advanced Therapies Symposium
- Advanced Therapies Integrates North
- Advanced Neurotherapies Centre launch
- NHS Wales Confederation Conference
- Wales Cancer Research Conference (sponsor)
- Wales Scientific Advisory Committee Conference
- Huntington's Disease Centre Summer Event
- Scientific Showcase Advanced Cellular Therapy
- UK Clinical Research Facility (UKCRF) and Biomedical Research Centres (BRC) Conference
- Resilience Launch

Next 12 months

- Grow ATW online presence and platforms to enable signposting, support and easy access to information.
- Increase reach and visibility to promote activity of the community, both online and in person.
- Process and share outputs from Symposium roundtable reports and develop next steps for each.
- Continually assess and develop approach to remain useful, relevant, and innovative.

Challenges

- Sustaining engagement with diverse stakeholders requires ongoing coordination, resources, and considerable time.
- Developing and maintaining responsive digital infrastructure to support a centralised access point requires forging strong links and progressing NHS Wales' digital maturity.
- Collecting and integrating robust evaluation and feedback from engagement activities to inform future planning of relevant, value-added activities.



4. Case Study



3rd ATW national Symposium

Launched in 2023 as a small stakeholder event, it has matured into a flagship annual gathering for clinicians, researchers, industry, patients, and policymakers. The 2025 event saw an almost two-fold increase in delegate registrations, highlighting its expanding reach and influence.

The theme of patient and public involvement and engagement took centre stage this year and included a patient speaker. There was a 'lessons learned' session from the Infected Blood Inquiry emphasising the importance of patient involvement in achieving fully informed consent. In the afternoon four workshop discussions were held which focused on different areas of work within the delivery plan.

This year poster displays and stands were a new feature and all feedback received was positive. The event was recognised as a catalyst for new collaboration and a model of inclusive practice.

"Congratulations on yesterday's event, very impressed with the range of speakers, presentation content and the networking"



Patient and public involvement and engagement



Theme 1

Key Activities

1. Representation

ATW have retained their two lay-representatives on the programme board until March 2027. They have provided valuable insight in preparation and review of documentation and producing content for the new ATW website.



2. Raising the patient and public voice

ATW have collaborated closely with patient advocate Jemin Popat, who brings lived experience of beta thalassemia with his expertise as an entrepreneur and presenter. The partnership began in November 2024 when ATW presented at an event organised by the charity Friends of Cymru Sickle Cell and Thalassaemia, inspiring a shared commitment to rethinking patient engagements. Since then, Jemin has presented at the ATW Symposium 2025, the Cross-Party Group on Medical Research, and MediWales Connects 2025, supported by ATW through honoraria. Building on this collaboration, a documentary-style video project is being developed with Jemin to share lived experiences, highlight the challenges of navigating rare conditions, and showcase the life-changing potential of advanced therapies.

3. Practical considerations

ATW has established a strong partnership with Kerry-Ann Holder, Consultant Clinical Psychologist and Head of Service for Children, Young People and Family Psychology at CAVUHB, who also presented at the 2025 Symposium. Kerry-Ann highlighted a lack of structured psychological support for patients, families, and staff in the ATMP pathway, recognising it should be included in service design. A proposal for a large-scale research project with Cardiff University's Doctorate in Clinical Psychology programme has been developed, to inform a Psychology Strategy for Advanced Therapies in Wales, addressing this currently unmet need.

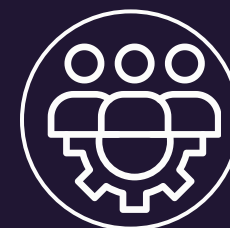


4. Partnership working

ATW and MW-ATTC have worked with ATMP Engage and Genomics Partnership Wales to align public involvement with national priorities. They attended the July 2025 Genomics Café to present ongoing work on the Equity of Access for ATMPs report and the Raising Public Awareness of ATMP strategy, alongside co-producing the ATMP Patient Charter.

Next 12 months

- Host patient and clinician engagement events for Apheresis Report.
- Monitor progress of Equity of Access Report and continue stakeholder events.
- Develop and launch documentary-style video project with patient advocates.
- Explore additional community-based engagement initiatives, with a focus on amplifying voices of underserved or underrepresented groups.
- Develop and launch the Advanced Therapies Engagement Network, which will meet tri-annually.
- Publish draft Patient Charter for ATMPs



Workforce development



Theme 2

Key Activities

1. Cytiva manufacturing workshop

In December 2024, a two day CAR-T manufacturing workshop was delivered by Cytiva at WBS hosted by ATW. It provided hands-on training for 14 delegates across pharmacy, clinical, and nursing roles. ATW supported logistics, venue provision, and delegate engagement.

"The hands-on demo was really good. Plenty of time for questions. It was exciting and very useful to see the background production pathways."

2. Partnerships in precision medicine

ATW and Health Education and Improvement Wales (HEIW) have co-designed a long-term workforce model for advanced therapies alongside the Genomics Workforce Plan activity. This includes funding a Clinical Lead and Digital Technologist role to support capacity building.

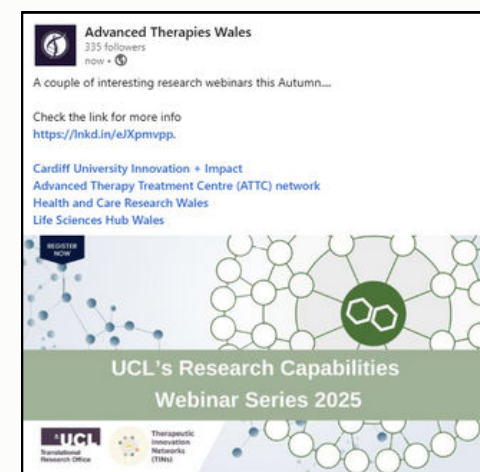
3. Expanding understanding

ATW has funded several learning visits including: NHS Blood and Transplant by pharmacy teams, and to CAVUHB to learn more about maintaining Qube equipment. There was a scoping visit to Exmoor's GMP facilities which has informed planning for a potential Welsh facility. The 2025 Symposium also featured a dedicated training and education roundtable, which generated actions for workforce planning and education.



4. Supporting clinical trial set-up

Professor Thistlethwaite, Director of the Innovate Manchester Advanced Therapy Centre Hub (iMATCH) delivered a session on Tumour-Infiltrating Lymphocytes (TILs) and T-Cell toxicity management to CCRH and wider stakeholders. This supported the set-up of the TILs clinical trial at CCRH.



Next 12 months

- Delivery of 2nd Cytiva manufacturing workshop in Swansea
- Recruit HEIW clinical lead for workforce development
- Expand delivery of targeted training opportunities, including advanced therapy workshops and online learning modules, to equip multidisciplinary teams with the specialist skills required for both clinical and research delivery.
- Strengthen workforce planning in collaboration with national partners to identify gaps, support the development of career pathways, and build sustainable models for training, recruitment, and retention.

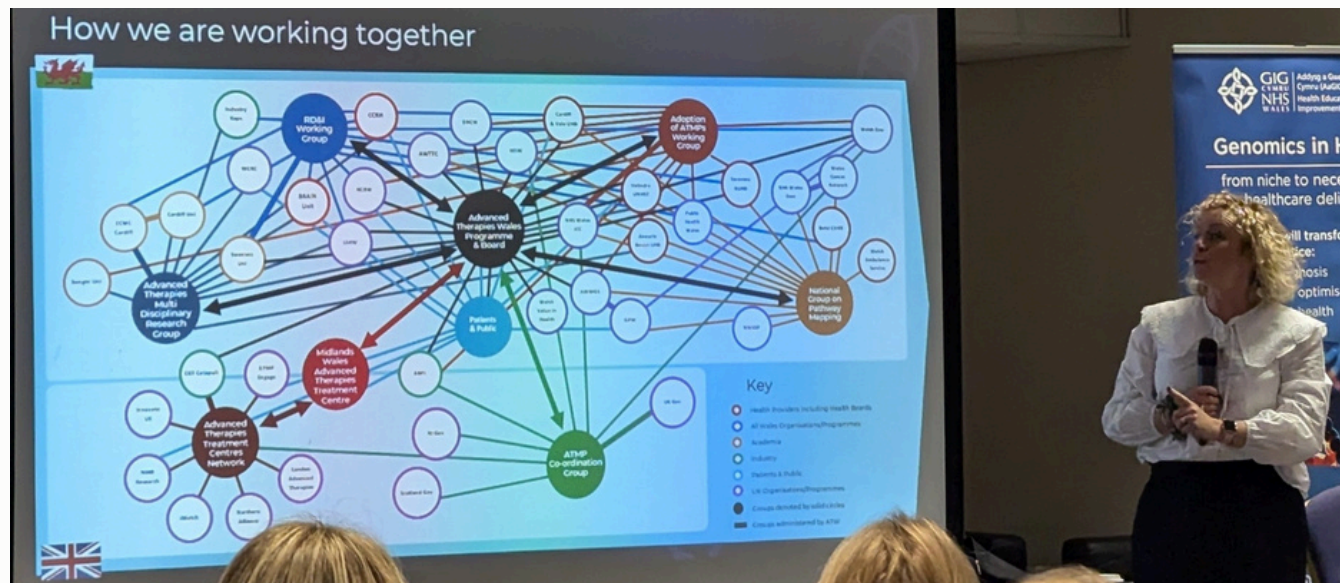


Strategic partnerships



Theme 3

Key Activities



1. Partnership working

ATW's Relationship with Life Sciences Hub Wales (LSHW) has strengthened, holding a joint stand at Advanced Therapies UK Conference in London, with LSHW representing both partners at Advanced Therapies Integrates Conference in Edinburgh and British Society of Gene and Cell Manufacturing Conference to maintain UK wide visibility.

2. Industry engagement

ATW hosted a roundtable with Gilead Sciences to address inequities in CAR-T delivery. The outcomes were widely shared and followed up at the ATW Symposium. The programme also contributed to the Genomics, Precision Medicine and Advanced Therapies (GPMAT) group through the Wales Cancer Industry Forum, and has supported initiatives such as Quick DNA (QuicDNA), a liquid biopsy project.

3. Regional and national conversations

ATW supported Wales' input into the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG), securing recognition for ATMPs within national funding. Collaboration with AWTC and NWJCC has extended horizon scanning and adoption pathways. There has been UK wide participation with Department for Health and Social Care through the UK ATMP Co-ordination Group enabling regular dialogue with colleagues in Scotland and Northern Ireland. Collaboration with CAVUHB on CAR-T and Huntington's disease trials, with VUNHST on pioneering TIL therapies, also been involved in establishing Cardiff Cancer Research Partnership, and development of Cardiff Health Partners, exploring infrastructure requirements.

Next 12 months

- Continue to collaborate with the Welsh Government, AWTC, and national stakeholders to shape policy, funding, and adoption pathways for emerging therapies.
- Strengthen regional engagement with health boards and clinical teams to expand trial delivery, enhance coordination, and embed innovative service models.
- Work with TrAMS programme to develop aseptic hub planning
- Work with BCUHB and SBUHB to strengthen early-phase therapy support.

Key dependencies update

Balancing commissioning Advanced Therapies treatment delivery in Wales or commissioning outside for highly specialised disease indications

The ATMP Outcomes Programme is underway, being led by NWJCC and is key to addressing this dependency. Resource requirements dependent on patient population numbers.

Securing funding for Advanced Therapies infrastructure and service delivery requirements

Apheresis service review and paper outlining the requirements for a GMP facility in Wales and pharmacy considerations are underway with partners, business cases to follow.

Existing NHS Wales Pharmacy infrastructure including aseptics and other associated programmes

Infrastructure reviews underway as above, with targeted investment proposals and workforce planning with HEIW and local pharmacy leads.

Availability of in-patient and out-patient facilities to deliver ATMPs in standard care setting or clinical trial space

Site readiness assessments being conducted, with recommendations feeding into capital planning and service redesign managed through the ATW Adoption of ATMP's working group. Psychological support plan to be developed in 2025/26.

Apheresis capacity across Wales and UK

Following apheresis service review and paper outlining requirements, preferred service model development underway to prepare outline business case.

Regulatory compliance for working with or administering Advanced Therapies

ATW supporting with shared learning from early adopter sites and updated guidance. Specialist lead in ATW clinical expertise forum. Infrastructure reviews underway, with targeted investment proposals and workforce planning with HEIW and local pharmacy leads.

Ability to increase the number of clinical trials involving Advanced Therapies being undertaken in Wales

ATW supporting ATTC network in the clinical trial acceleration, streamlined study set-up processes with HCRW and R&D leads.

Developing a fully integrated human tissue pathway

"Coalition of the Willing," a national multi-stakeholder working group established. National oversight panel due to be in place by end of 2026.



Conclusion

There has been significant progress for the advanced therapies sector in Wales over the last year, driven by a shared commitment to innovation, equity, and collaboration. Across the goals and cross-cutting themes, tangible outcomes have been delivered which lay the foundations for future work. This progress reflects the collective effort of many. **ATW and MW-ATTC extend our sincere thanks to all the individuals and teams who have contributed to delivering these achievements.**