

Delivery Plan for Advanced Therapies in Wales



2025 - 2029

Endorsed by Welsh Government
and ATW Programme Board

Co-ordinated by



Advanced
Therapies
Wales

Therapiau
Datblygiedig
Cymru

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Foreword

The delivery of Advanced Therapies to the people of Wales and beyond and the associated benefits will transform care and treatment. A revolution in healthcare organisation and delivery is now upon us and we must be ready for it. Working in collaboration with citizens, patients, professionals and stakeholders, we will exploit the opportunity to deliver these ground breaking therapies in innovative ways to advance treatment outcomes, reduce suffering and transform lives.

Encompassing a diverse array of treatments often referred to as cell or gene therapies, these therapies, including Advanced Therapies Medicinal Products (ATMPs), hold the potential to radically change pathways of care and outcomes. This opportunity extends to rare diseases where effective treatments are often unavailable.

The innovative therapies we've long spoken of as being "on the horizon" are now a reality and their effective deployment into practice calls for a comprehensive and iterating whole-system approach which includes developing the skills, ways of working, capabilities and capacity of our people, our facilities and infrastructure as well as a strengthened collaborative approach to working with citizens, partners and stakeholders across public and private sectors as well as academia.

This Delivery Plan sets the vision, the approach, organisation and priorities to enable us to be successful in our shared endeavour and bring the benefits to bear for all. The Delivery Plan for Advanced Therapies in Wales (2025-29), marks a crucial juncture in the journey that commenced in Wales back in 2017 and guides our partnership, building on strong foundations whilst enabling the acceleration of skill, knowledge and practice acquisition as we seek to build a sustainable model for the future.

The collaborative nature of the delivery model outlined in the plan is critical to our success. It describes collaborating with and operating within the global ecosystem and recognises that we cannot be successful alone. By working together we can build a community of practice, support and enablement that will initiate, sustain and motivate us to deliver, realise the full opportunity, alongside creating opportunities for economic prosperity and development here in Wales.

This is an exciting proposition, fuelled by cutting edge research and development, clinical trials, pharmaceutical and manufacturing innovation, active patient and public partnership and collaboration, enabled by talented clinicians and multidisciplinary teams, academics and 3rd sector partners. We are embarking on a challenging but purposeful journey with the very real prospect of a step change in population health outcomes and a revolution in healthcare delivery and efficiency. We call upon you to get involved, support and champion our collective mission.



Jeremy Miles MS
Cabinet Secretary for
Health and Social Care



Suzanne Rankin
Senior Responsible Officer
Advanced Therapies Wales

Executive summary

Advanced Therapies is the collective term for a novel class of biological medicines that are based on genes, cells or tissue. They offer ground-breaking opportunities for the treatment of disease and injury with the potential to improve clinical outcomes across a range of disease indications, including rare diseases where there are currently no or limited treatment options available.

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.

Statement of Intent

In April 2019 Welsh Government launched the SOI for Advanced Therapies. It sets out the Welsh Government's vision and strategic approach for developing the Advanced Therapies sector in Wales.

-  Public involvement and engagement
-  Clinical pathways
-  Regulatory compliance, quality and safety
-  Workforce development
-  Estates
-  Informatics and information governance
-  Research and innovation
-  Hosting and commissioning
-  Strategic partnerships

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.

"Respecting inclusivity of patients and members of the public from a wide range of diverse backgrounds, values them and places them at the heart of programme delivery."

Public and Patient Involvement & Engagement representative

"Patients and the public can help to plan the delivery of a new treatment by the NHS to make sure that it is available equally to all patients who need it throughout Wales."

Public and Patient Involvement & Engagement representative

Goals

This Delivery Plan is centred around four key goals, which are considered fundamental to the delivery of our vision for Advanced Therapies in Wales.

Goal 1



Nurturing the Advanced Therapies ecosystem in Wales

Goal 2



Developing pathways for healthcare delivery of Advanced Therapies

Goal 3



Cultivating Advanced Therapies research capacity and capability

Goal 4



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

Themes

The successful delivery of the four goals are reliant on the cross cutting development of the three themes.



Patient and public involvement and engagement

Theme 1



Workforce development

Theme 2



Strategic partnerships

Theme 3

Key dependencies

Critical success factors for addressing challenges identified in the Delivery Plan.

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

Securing funding for Advanced Therapies infrastructure and service delivery requirements

Existing NHS Wales Pharmacy infrastructure including aseptics and other associated programmes

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

Apheresis capacity across Wales and the UK

Regulatory compliance for working with or administering Advanced Therapies

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

Developing a fully integrated human tissue pathway

Introduction

Advanced Therapies is the collective term for a novel class of biological medicines that are based on genes, cells or tissue. They offer ground-breaking opportunities for the treatment of disease and injury with the potential to improve clinical outcomes across a range of disease indications, including rare diseases where there are currently no or limited treatment options available. Some of these therapies have been investigated and evaluated in clinical trials and are now being licensed for use in the standard care setting. Often complex in delivery, they offer new treatment opportunities, but also require new clinical pathways or modified ways of delivery to all patients including children, teenagers and young adults.

Advanced Therapies

An Advanced Therapy Medicinal Product (ATMP) comes under four clearly defined classifications, the term Advanced Therapies describes broader innovative therapies, as well as including those that meet the distinct criteria of the four ATMP classifications -

- Gene Therapies**
involve the transfer of genetic material into the cells of a patient's body to treat the underlying cause of a specific disease. This may involve genome editing technology to alter the patient's DNA.
- Somatic Cell Therapies**
involve the transfer of intact, live cells into a patient to help lessen or cure a disease. The cells may originate from the patient's own cells (autologous) or from a donor (allogenic).
- Tissue Engineered Products**
involve regenerating, replacing or repairing human cells, tissues or organs to restore or establish normal function. Current examples of these therapies use the patient's own cells (autologous) for therapy manufacture.
- Combined Therapies**
involve cells or tissues that have been combined with one or more medical device(s).

Putting the patient and public voice at the heart

"Patients and the public have an important role in ensuring that the public are engaged and informed about new treatments. They can also help to plan the delivery of a new treatment by the NHS to make sure that it is available equally to all patients who need it throughout Wales.

They also have a vital role to play in research from an early stage onwards to test that any new drug or treatment is safe and provides a positive outcome for patients, with manageable side effects. This fulfils the brief of doing research "with the patient rather than for the patient."

Julie Hepburn

*Advanced Therapies Wales Programme Board
lay person stakeholder representative*

"Patients and public members have a powerful voice to influence the development and delivery of new treatments for Advanced Therapies. They are valuable critical friends offering a wealth of experience, especially lived experiences. Their contributions cast fresh outlooks, to help guide researchers and health care providers to ensure information is communicated in easily understood ways. Respecting inclusivity of patients and members of the public from a wide range of diverse backgrounds, values them and places them at the heart of programme delivery."

Adele Battaglia

*Advanced Therapies Wales Programme Board
lay person stakeholder representative*

Advanced Therapies in Wales... the story so far

Good foundations and successes

Following successful initiatives at a local and UK level in relation to interest and ambition to develop and deliver Advanced Therapies, in 2019 the Welsh Government demonstrated its commitment to supporting the Advanced Therapies sector in Wales with the publication of the Statement of Intent (SOI) for Advanced Therapies, and the development of the Advanced Therapies Wales national programme.

Cardiff and Vale University Health Board’s haemato-oncology team treated the first patient in Wales to receive Chimeric Antigen Receptor T-cell (CAR-T) therapy in November 2019 and continue to build their patient CAR-T portfolio, along with undertaking their research work. In June 2022, the neurosurgical team in Cardiff were one of five sites worldwide to deliver the UniQure Phase I/II gene therapy trial in Huntington’s Disease, successfully delivering the gene therapy directly into the brain in three patients treated to date (March 2024).

The COVID-19 pandemic saw a hiatus in progressing Advanced Therapies activity. This prevented non-COVID clinical trials opening and resulted in a deceleration of NICE appraisals for new therapies. However, sector activity is now moving at pace in Wales and the rest of the UK. The Velindre Cancer Centre and Cardiff and Vale UHB have resumed building their patient facing clinical trial portfolios across a range of disease sites including non-blood cancers. Cardiff University in collaboration with Cardiff and Vale UHB continue their pioneering work in neurological and neurodegenerative disease. The Welsh academic life sciences continue to build on existing activity, knowledge and interest in pre-clinical, and bench to bedside translational cell and gene research.

Recently, funding for a second stage of the UK Advanced Therapy Treatment Centres was secured, focusing on clinical trial acceleration, with Midlands and Wales continuing to lead on the regional activity of the Midland-Wales Advanced Therapy Treatment Centre (MW-ATTC).

Statement of Intent

In April 2019 Welsh Government launched the SOI for Advanced Therapies. The SOI sets out the Welsh Government’s vision and strategic approach for developing the Advanced Therapies sector in Wales.

The SOI aims to

- Provide a vision for a strategic approach to harness the benefits from emerging and transformative Advanced Therapies.
- Create a sustainable platform to enable NHS Wales to provide patients with equitable access to emerging Advanced Therapies.
- Explore how this sector can contribute to the objectives of the Welsh Government’s A Healthier Wales: Our Plan for Health and Social Care in Wales.
- Deliver our full potential in the UK and international development of Advanced Therapies.
- Support strategic partnerships and collaboration between NHS Wales and academic and industry partnerships in order to harness the potential of Advanced Therapies to improve disease outcomes, well-being and prosperity for the people of Wales.

SOI Thematic Domains



Public involvement and engagement



Clinical pathways



Regulatory compliance, quality and safety



Workforce development



Estates



Informatics and information governance



Research and innovation



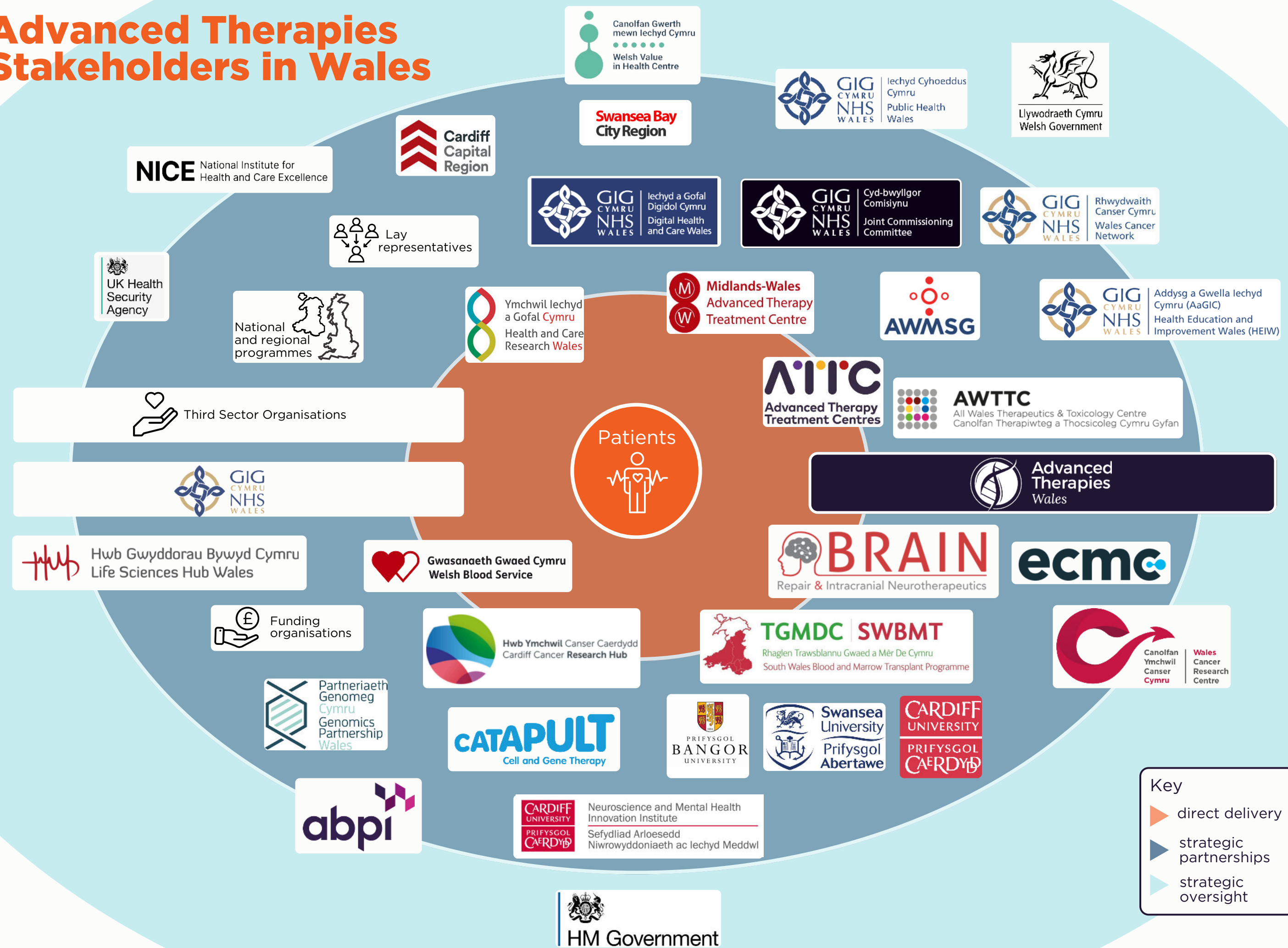
Hosting and commissioning



Strategic partnerships

For more information on the Statement of Intent - Welsh Government - www.gov.wales - 09th April 2019 - Written Statement: Precision Medicine

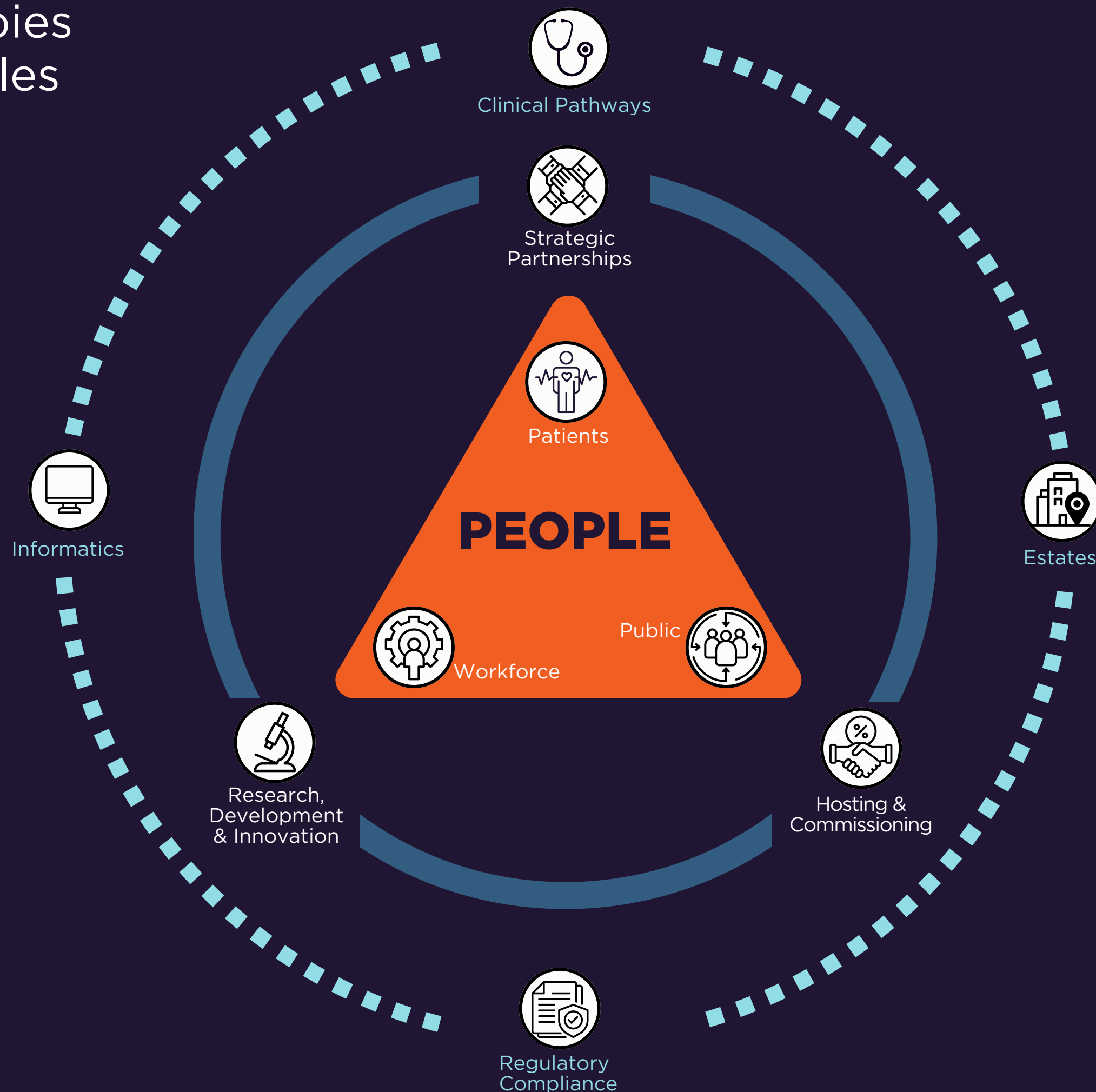
Advanced Therapies Stakeholders in Wales



Advanced Therapies Ecosystem in Wales

The Advanced Therapies ecosystem in Wales places people at the centre, as they form our three cornerstones.

The purpose of this Delivery Plan is to set out agreed and shared goals, collected from across the Advanced Therapies ecosystem in Wales and beyond, to coalesce ambition, resources and opportunities to accelerate patient access to these treatments.



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.

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.

Model pathway



The goals

This Delivery Plan captures the steps required to progress the development of the Advanced Therapies sector across Wales, over the next five years.

It is written on behalf of the Welsh Advanced Therapies community, with delivery of the plan coordinated and facilitated through the ATW Programme, strategic partnerships, and continued stakeholder engagement.

This Delivery Plan is centred around four key goals, which are considered fundamental to the delivery of our vision for Advanced Therapies in Wales.

Goal 1

Nurturing the Advanced Therapies ecosystem in Wales



Goal 2

Developing pathways for healthcare delivery of Advanced Therapies



Goal 3

Cultivating Advanced Therapies research capacity and capability



Goal 4

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



Nurturing the Advanced Therapies ecosystem



Goal alignment to SOI

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

Goal Objective

Nurturing a dynamic ecosystem to attract investment and activity in Wales. Developing an innovative environment, we aim to support Welsh ambition with Wales playing an integral part in developing the Advanced Therapies ecosystem through collaboration with Health & Care Research Wales (HCRW), educational institutions, centres of excellence and industry.

Goal Deliverables

- Build on capacity and capability in the Advanced Therapies sector in Wales by supporting pharmacy, apheresis and stem cell processing activities in Wales to enhance service development.
- Establish transparent funding processes for small and medium scale projects to support the ecosystem.
- Maintain a continuous line of communication with policy and decision-makers to raise awareness of infrastructure requirements and address barriers to progress.
- Act as a centralised resource centre, providing sector guidance, information dissemination, and efficient signposting.

Critical partners to achieve delivery



Developing pathways for healthcare delivery of Advanced Therapies



Goal alignment to SOI

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

Goal Objective

Developing expertise in hosting and commissioning, ensuring seamless implementation and delivery of Advanced Therapies as they become available through NICE recommendation for NHS adoption. Support the identification of requirements and resources to enable standard care delivery.

Goal Deliverables

- Inform the community of Advanced Therapies coming to market and NHS requirements to deliver them.
- Identify innovative commissioning models for delivery of Advanced Therapies in Wales.
- Support Welsh NHS institutional readiness, capacity and capability to deliver Advanced Therapies.
- Develop a commissioning strategy for Wales.
- Support NHS Wales to facilitate the implementation of NICE recommended Advanced Therapies, with commitment to equitable access for Welsh patients.
- Support the development of the requisite connected IT environment for Advanced Therapies delivery and monitoring outcomes.

Critical partners to achieve delivery



Cultivating Advanced Therapies research capacity and capability



Goal alignment to SOI

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

Goal Objective

Driving innovation in research, fostering an environment that encourages the delivery of Advanced Therapies research in Wales, nationally and internationally.

Goal Deliverables

- Support Advanced Therapies research activity and expertise, develop sector research interest, knowledge and skill-set.
- Promote the delivery of Advanced Therapies research being developed in Wales.
- Facilitate opportunities for research investment and funding to develop infrastructure, capacity and capability in clinical trials in Wales.
- Engage with initiatives that promote industry engagement, partnerships and collaboration.

Critical partners to achieve delivery



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



Goal alignment to SOI

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

Goal Objective

The Advanced Therapies sector in Wales is multifaceted requiring engagement with a wide range of stakeholders, partners, patients and the public. Effective communication is pivotal to successful programme delivery. We are committed to equality, diversity and inclusion.

Goal Deliverables

- Develop a communication and engagement strategy to raise awareness of the ATW programme and delivery objectives.
- Promote awareness and access to those interested in or already working within the ecosystem of Advanced Therapies.
- Share sector intelligence, horizon scanning and updates.
- Promote sector development and generate interest.

Critical partners to achieve delivery

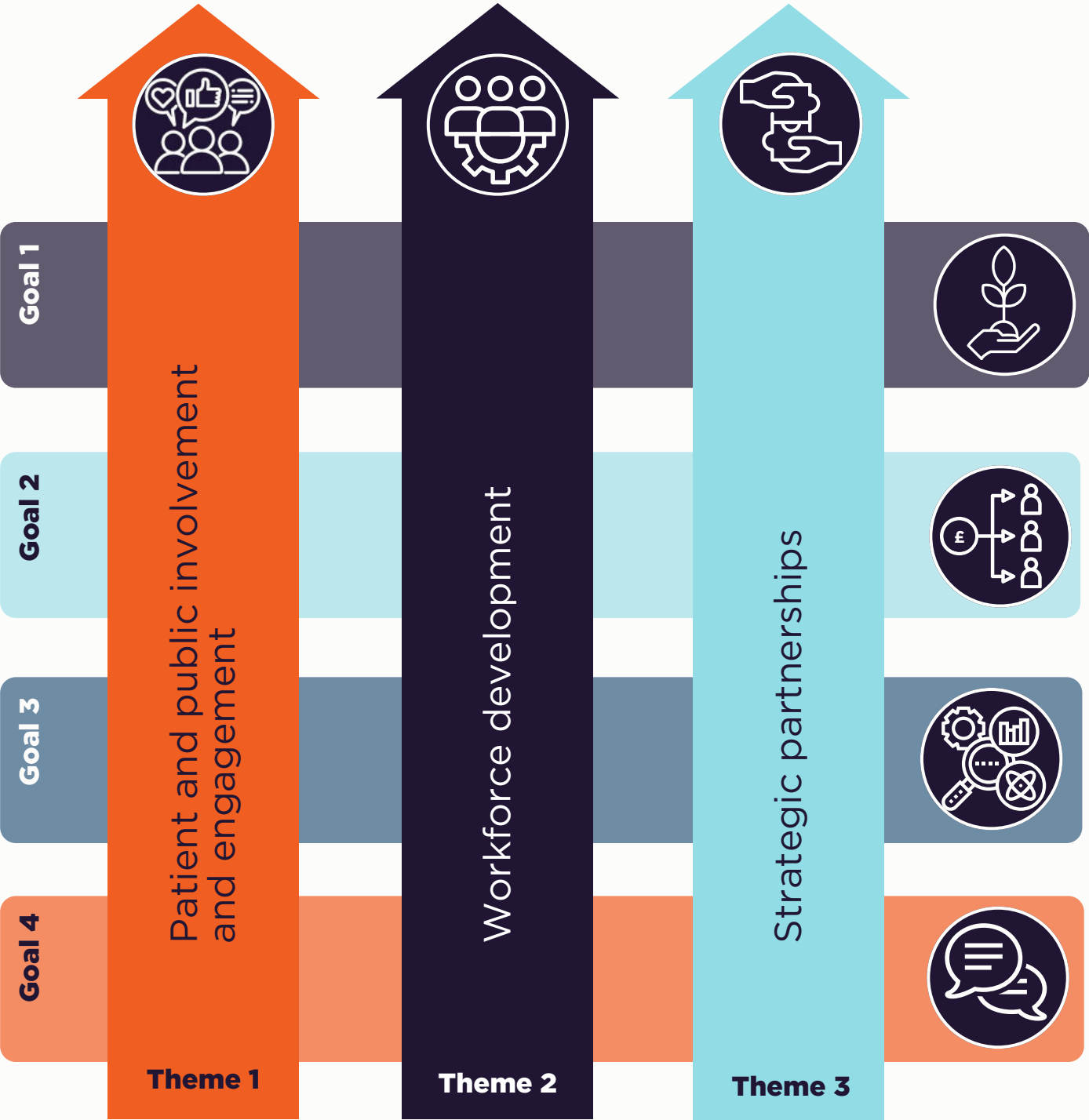


Key themes

The successful delivery of the four goals are reliant on the cross cutting development of three themes. These are:

- Theme 1 - Patient and public involvement and engagement
- Theme 2 - Workforce development
- Theme 3 - Strategic partnerships

They intersect with each of the goals, and play a key role in ensuring intended outcomes are achieved.



Theme 1

Patient and public involvement and engagement

We are committed to placing patients and the public at the centre of programme endeavours, ensuring their voices contribute to shaping the trajectory of the of Advanced Therapies sector in Wales. We will engage with patients and members of the public from a diverse range of backgrounds, share experiences of patients and public members to raise awareness of Advanced Therapies and establish a range of PPI activities to ensure equality, diversity and inclusion needs are met. We will respect the contributions made and experiences shared by our lay person stakeholder representatives to help inform and shape programme delivery.

Theme 2

Workforce development

We will support local and national initiatives to create a skilled and empowered workforce capable of delivering cutting-edge Advanced Therapies. This includes supporting the identification of workforce training needs, understanding workforce requirements for delivering Advanced Therapies and facilitating access to training opportunities and resources. We will ensure Welsh representation at UK wide workforce development strategic platforms. We are committed to supporting workforce development to deliver against our future needs and ambitions.

Theme 3

Strategic partnerships

The Advanced Therapies Wales Programme operates within the Welsh Government's Precision Medicine portfolio, alongside Genomics, Pathology, and Imaging. Close collaboration with these programmes ensures information sharing, resource pooling, and the dissemination of best practices and lessons. Together we will identify innovative, forward thinking and collaborative opportunities and projects to meet future service needs and ambitions. A robust relationship with the academic sector, specifically Higher Education, is integral to the success of Advanced Therapies development in Wales. The Programme has initiated engagement with major Universities in the region. Industry engagement is supported by Life Sciences Hub Wales, which identifies Advanced Therapies as a key strategic priority.

Key dependencies

These key dependencies form the bedrock for addressing key challenges identified in the Delivery Plan, but are significant and far reaching in their impacts and solutions required. The Advanced Therapy community recognises these significant dependencies, and will have involvement in positively influencing them.

They are considered fundamental to the successful delivery of Advanced Therapies in Wales, and are identified as part of the response in the Goals and Themes where appropriate.

Key dependency	Challenge	Impacts	
		Goal	Theme
Balancing commissioning Advanced Therapies treatment delivery in Wales or commissioning outside for highly specialised disease indications	Resource requirements dependent on patient population numbers		
Securing funding for Advanced Therapies infrastructure and service delivery requirements	NHS readiness, Commissioning, Business case development	   	
Existing NHS Wales infrastructure including pharmacy and it's associated programmes	Facilities for storage, monitoring, thawing and preparation of Advanced Therapies including staffing levels and expertise	   	
Availability of in-patient and out-patient facilities to deliver Advanced Therapies in the standard care setting or clinical trial space	Clinical delivery may require access to isolation rooms with ensuite facilities/air flow systems, close monitoring/follow-up, access to critical care and/or psychological support	   	
Apheresis capacity across Wales and the UK	Starting materials for some types of Advanced Therapies, particularly CAR-T products which have the greatest demand for apheresis services	  	
Regulatory compliance for working with or administrating Advanced Therapies	Burdensome and challenging permission process often involving multiple agencies. Where applicable maintenance of accreditation standards and requirements i.e. JACIE, MHRA & ILAP	 	
Ability to increase the number of clinical trials involving Advanced Therapies being undertaken in Wales	NHS capacity and capability, clinical expertise and interest, streamlined local NHS study set-up, NHS staffing shortages, technical, logistical and organisational shortfalls	   	
Developing a fully integrated human tissue pathway	Including cell path capacity, transport and integrated digital systems	   	

The Advanced Therapies Wales (ATW) Programme



The purpose of the ATW Programme is to provide a central point for supporting the co-ordinated delivery of actions identified in this plan.

The ATW Programme is funded by Welsh Government. Along with the Genomics, Pathology and Imaging programmes, it forms an integral part of the Welsh Precision Medicine portfolio.

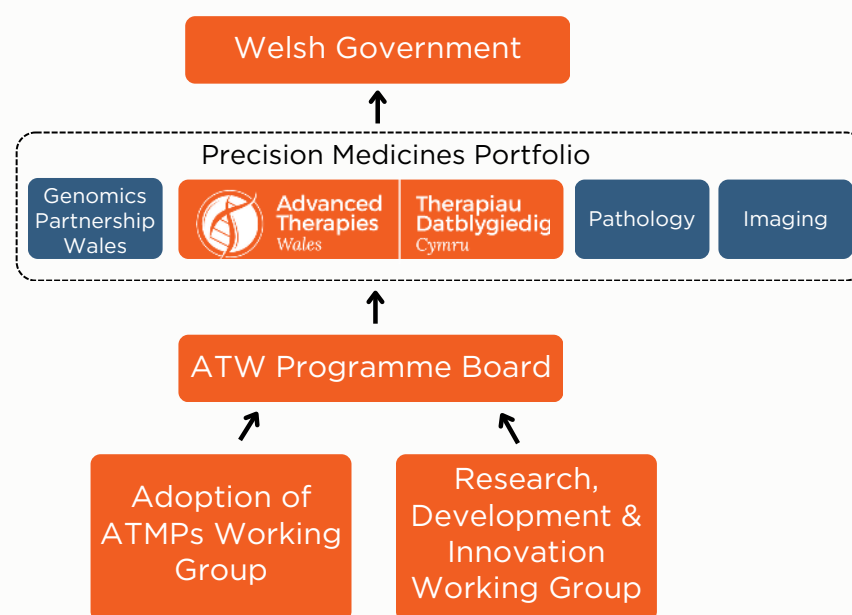
The ATW programme is overseen by the ATW Programme Board, chaired by the Senior Responsible Owner (SRO) Suzanne Rankin, who is also Cardiff and Vale University Health Board's CEO. The Board includes representatives of the key stakeholder organisations and partners invested in research and delivery of Advanced Therapies in Wales, and includes Patient and Public Involvement (PPI) representatives as core members. The secretariat is provided by the ATW Programme team.

Funding for Advanced Therapies treatments is allocated through specific funding streams managed by the NHS Wales Joint Commissioning Committee.

The governance arrangements draw together the community for developing the Advanced Therapies landscape in Wales, and provides an accountability framework for monitoring Programme delivery.



Governance structure



The Advanced Therapies Wales Programme is hosted by Velindre University NHS Trust

Our continued role in Advanced Therapy Treatment Centres



**Midlands-Wales
Advanced Therapy
Treatment Centre**



Coordinated by
CATAPULT
Cell and Gene Therapy

During the period March 2018 to March 2022, Wales was one of three UK regional centres forming the £30m Advanced Therapy Treatment Centres (ATTC) network.

These were:

- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- Midlands-Wales Advanced Therapy Treatment Centre (MW-ATTC) comprising Birmingham, Bristol, Cambridge, Cardiff, Leicester, Nottingham and Swansea
- Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC) comprising Edinburgh, Glasgow, Leeds and Newcastle

Coordinated by Cell and Gene Therapy Catapult (CGTC), the primary objective of the programme was to investigate, understand, map and develop potential solutions to the unique and complex logistical, operational and clinical challenges of bringing Advanced Therapy Medicinal Products (cell and gene therapies) into the NHS and making them available to patients.

The MW-ATTC was led by Birmingham, and in Wales was hosted by the Welsh Blood Service (Velindre University NHS Trust), and was aligned with the activity of the Advanced Therapies Wales programme.

In spring 2024, reflecting the success of the 2018-22 programme, and the ongoing UK commitment to a continued network approach, £18m of funding until 2028 was secured by Cell and Gene Therapy Catapult (CGTC) via Innovate UK for the ATTC programme to recommence, with the existing centres and a fourth centre, London, to be included into the network.

The focus of this next stage of the programme will be on increasing activity and access of clinical trial delivery of ATMPs. Workstreams identified for this include acceleration of clinical trials, workforce development, and data collection. MW-ATTC will continue to participate as a core centre in the network, and will lead on patient and public involvement.

The programme will continue to be operated within an NHS operational framework with key links and collaborations with industry partners.

The opportunity to align and coordinate ATTC activity with the Delivery Plan is timely and complimentary. With shared goals and corresponding areas of focus, it allows for a greater level of integration between the MW-ATTC and ATW programmes than the previous 2018 to 2022 model, which will allow for more significant progress to be made to ensure delivery across the Advanced Therapy ecosystem.

Appendix

The following pages constitute the working document of the Advanced Therapies Wales Program the working document of the Advanced Therapies Wales Programme team.

The goal and theme deliverables and success factors contained within will be reviewed and updated on an annual basis to reflect the rapidly developing nature of the Advanced Therapies ecosystem.

Synchronisation, timeframes and milestones will be monitored and managed within the ATW Programme.



- i Goal 1 - Nurturing the Advanced Therapies ecosystem in Wales**
- iii Goal 2 - Developing pathways for healthcare delivery of Advanced Therapies**
- v Goal 3 - Cultivating Advanced Therapies research capacity and capability**
- vii Goal 4 - Providing a central point of access for Advanced Therapies navigation, information and engagement**
- ix Key themes**

Co-ordinated by



**Advanced
Therapies**
Wales

**Therapiau
Datblygiedig**
Cymru

January 2025



Goal 1

Nurturing the Advanced Therapies ecosystem

Goal Deliverables

- Build on capacity and capability in the Advanced Therapies sector in Wales by supporting pharmacy, apheresis and stem cell processing activities in Wales to enhance service development.
- Establish transparent funding processes for small and medium scale projects to support the ecosystem.
- Maintain a continuous line of communication with policy and decision-makers to raise awareness of infrastructure requirements and address barriers to progress.
- Act as a centralised resource centre, providing sector guidance, information dissemination, and efficient signposting.

Success Measures

- **Progress milestones achieved towards the feasibility of a gene therapy manufacturing facility located in Wales.**
- **Increase expertise to support and deliver Advanced Therapies (i.e. pharmacy, apheresis, stem cell processing, clinicians and nursing) from NHS mainstreaming, digital infrastructure to specialised clinical delivery.**
- **Number of successful collaborations (including medium and large scale projects, capital investment etc.) initiated, supported or funded, and facilitated by the ATW Programme**

Goal alignment to SOI

-  Public involvement and engagement
-  Clinical pathways
-  Regulatory compliance, quality and safety
-  Workforce development
-  Estates
-  Informatics and information governance
-  Research and innovation
-  Hosting and commissioning
-  Strategic partnerships

To achieve success we will...

Develop a funding application and approval process to fund small scale projects that will support sector development, subject to resources.



Support medium to large scale projects through a business case approach to signpost to funding opportunities.



Share and disseminate information on funding opportunities available to the ecosystem in Wales.



Support and collaborate with sector initiatives to develop Advanced Therapies capacity and capability in Wales.



Identify centres of excellence in Wales and promote expertise development across Wales.



Maintain a line of communication to policy and decision makers to raise awareness of identified infrastructure requirements and barriers to progress.



Act as a resource centre for sector guidance, information, and signposting.



Collaborate with stakeholders to support the progression of the ambition for a Gene Manufacturing facility in Wales.



Goal activities



Goal 2

Developing pathways for healthcare delivery of Advanced Therapies

Goal Deliverables

- Inform the community of Advanced Therapies coming to market and NHS requirements to deliver them.
- Identify innovative commissioning models for delivery of Advanced Therapies in Wales.
- Support Welsh NHS institutional readiness, capacity and capability to deliver Advanced Therapies.
- Develop a commissioning strategy for Wales.
- Support NHS Wales to facilitate the implementation of NICE recommended Advanced Therapies, with commitment to equitable access for Welsh patients.
- Support the development of the requisite connected IT environment for Advanced Therapies delivery and monitoring outcomes.

Success Measures

- **Completion of a commissioning strategy and pathways for delivering Advanced Therapies in Wales.**
- **Inclusion of Advanced Therapies provision in all Welsh health board's IMTPs, clinical service plans/strategies.**
- **Increase in the number of Welsh patients receiving treatment with NICE recommended Advanced Therapies. To include patients accessing treatment at specialist centres outside of Wales.**

Goal alignment to SOI

- Public involvement and engagement
- Clinical pathways
- Regulatory compliance, quality and safety
- Workforce development
- Estates
- Informatics and information governance
- Research and innovation
- Hosting and commissioning
- Strategic partnerships

To achieve success we will...

Collaborate in the development of innovative and streamlined commissioning pathways for Advanced Therapies.



Utilise horizon scanning intelligence to inform NHS Wales on Advanced Therapies coming to market and/or pending NICE review and the requirements to deliver them.



Identify known or potential barriers to clinical delivery of Advanced Therapies in NHS Wales.



Map the capacity and capability of the current NHS infrastructure to deliver Advanced Therapies for investment identification.



Support the development of specific referral pathways and tertiary commissioning for the delivery of NICE recommended Advanced Therapies.



Co-ordinate mapping of the commissioning process from NICE recommendation to clinical delivery.



Scope an optimal approach for the development of collaborative informatics and business intelligence.



Collaborate with the NWJCC ATMP Outcomes Programme in the development of an outcome-based, value for health care model.



Provide a bespoke impact assessment for Advanced Therapies that are likely to be delivered in Wales.



Identify potential funding opportunities and enhance sector infrastructure through collaboration.



Support NHS Health Boards through the business case process for NWJCC commissioning.



Use informatics for retrospective and prospective analysis of patient outcomes to inform service planning and commissioning decisions.



Support identification of IT architecture for safe information exchange within the Advanced Therapies landscape.



Support identification of IT architecture and measure actual resource use versus anticipated use in the Advanced Therapies delivery landscape to link outcomes to resources.



Goal activities



Goal 3

Cultivating Advanced Therapies research capacity and capability

Goal Deliverables

- Support Advanced Therapies research activity and expertise, develop sector research interest, knowledge and skill-set.
- Promote the delivery of Advanced Therapies research being developed in Wales.
- Facilitate opportunities for research investment and funding to develop infrastructure, capacity and capability in clinical trials space in Wales.
- Engage with initiatives that promote industry engagement, partnerships and collaboration.

Success Measures

- **Increase in the number of opportunities resulting in research collaborations and partnerships being undertaken in Wales (led or participatory including academia, NHS and industry) involving Advanced Therapies.**
- **Increase in the number of research projects related to Advanced Therapies initiated and taking place in Wales.**
- **Improvement of NHS clinical trials infrastructure in Wales with the capacity and capability to deliver Advanced Therapies.**

Goal alignment to SOI

- Public involvement and engagement
- Clinical pathways
- Regulatory compliance, quality and safety
- Workforce development
- Estates
- Informatics and information governance
- Research and innovation
- Hosting and commissioning
- Strategic partnerships

To achieve success we will...

Map and monitor Advanced Therapies research activity in Wales, including pre-clinical and clinical trials.



Review Advanced Therapies research capacity and capability in Wales, identifying infrastructure and workforce needs.



Collaborate with stakeholders to agree on a priority focus for Advanced Therapies research in Wales.



Share research horizon intelligence to inform stakeholders of the evolving Advanced Therapies research sector.



Facilitate industry partnerships through networking, signposting, and industry engagement.



Disseminate information to stakeholders on research funding calls and other investment opportunities for the sector.



Support the translational research environment in Wales, developing pathways to support commercial and academic 'First in Human' Clinical Trials.



Support clinical teams with the site selection process upon request.



Collaborate with stakeholders to promote open recruitment for clinical trials involving Advanced Therapies in Wales for all Welsh patients.



Maximise opportunities to promote the Advanced Therapies research sector in Wales, such as through media stories and conferences.



Support the expansion of Advanced Therapies expertise in Wales.



Work with stakeholders to support Welsh investigator-led Advanced Therapies research.



Align with UK Clinical Research Delivery Programme (CRDP) which incorporates the recommendations following the Lord O'Shaughnessy review on commercial clinical trials.



Goal activities



Goal 4

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

Goal Deliverables

- Develop a communication and engagement strategy to raise awareness of the ATW programme and delivery objectives.
- Promote awareness and access to those interested in or already working within the ecosystem of Advanced Therapies.
- Share sector intelligence, horizon scanning and updates.
- Promote sector development and generate interest.

Success Measures

- **Increase in the use of ATW programme's website and social media platforms for generating the sharing of sector knowledge and information, updates and signposting.**
- **Increase communication and engagement activity to raise awareness of the ATW programme and the Advanced Therapies sector in Wales to professionals, patients and public. (i.e. presentations, conference stand attendance, media outputs etc.)**

Goal alignment to SOI

-  Public involvement and engagement
-  Clinical pathways
-  Regulatory compliance, quality and safety
-  Workforce development
-  Estates
-  Informatics and information governance
-  Research and innovation
-  Hosting and commissioning
-  Strategic partnerships

To achieve success we will...

Develop a strategy for communication and engagement that supports programme goals and objectives.



Share and disseminate sector intelligence, horizon scanning, funding opportunities, and updates through media resources, website and social media.



Establish an annual calendar of engagement activities and events.



Collate and evaluate feedback from engagement activities to shape future initiatives and needs.



Align PPI & E activity in collaboration with ATMP Engage to contribute to NIHR ATMP Coordinating Group.



Goal activities



Patient and public involvement and engagement

Theme 1

Maximise media opportunities to raise patient and public awareness of Advanced Therapies.

Use ATW social media platforms to provide a patient and public facing resource about Advanced Therapies.

Create an agenda of activity to raise patient and public awareness, and to obtain insight for informing ATW Programme delivery.

Ensure Welsh representation at national PPI initiatives and forums.

Develop PPI & E engagement strategies in collaboration with Genomics Partnership Wales, considering long term data capture requirements.

Retain Programme Board lay person representation and utilise their expertise to contribute to programme development and delivery.



Workforce development

Theme 2

Ensure Welsh representation at UK National initiatives that focus on workforce development.

Hold and maintain details of UK training providers in Advanced Therapies.

Promote the e-learning for health (elfh) Advanced Therapies training modules

Create an agenda of bite-size training sessions using both local and wider network knowledge and expertise.

Collaborate with and support the work of HEIW in developing the health and care workforce to support Advanced Therapies.

Promote and disseminate training & education opportunities via social media platforms.

Support local initiatives for the development of training and education materials, eg webinars, information sheets, on-line training modules etc.



Strategic partnerships

Theme 3

Develop informatics structure to collate sector intelligence, for monitoring and reporting on the evolving landscape.

Map and be aware of interest, activity, ambition, and opportunities in the Advanced Therapies sector in Wales.

Act as a resource centre to provide sector information, guidance, and signposting across the landscape.

Maximise opportunities to promote home grown sector expertise at local and national level.

Strengthen partnership with Genomics Partnership Wales to ensure there is the genomic testing capacity required to support and advance the ambitions of the Statement of Intent.

Align with the aims and objectives of the MW-ATTC.

Ensure Welsh representation at UK wide national Advanced Therapies strategic initiatives.

Engage in initiatives and /or facilitation that promote the activity of industry engagement.

Maintain a line of communication to policy and decision makers to inform on sector activity, raise awareness of opportunities and to highlight barriers to sector progress.

Raise the profile of the ATW Programme to encourage more active engagement with all of our stakeholders by attending national events, maximising networking opportunities.