Advanced Therapy Treatment Centres

Advanced Therapy Clinical Trials

Capability Framework

Skills for Health

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Contents

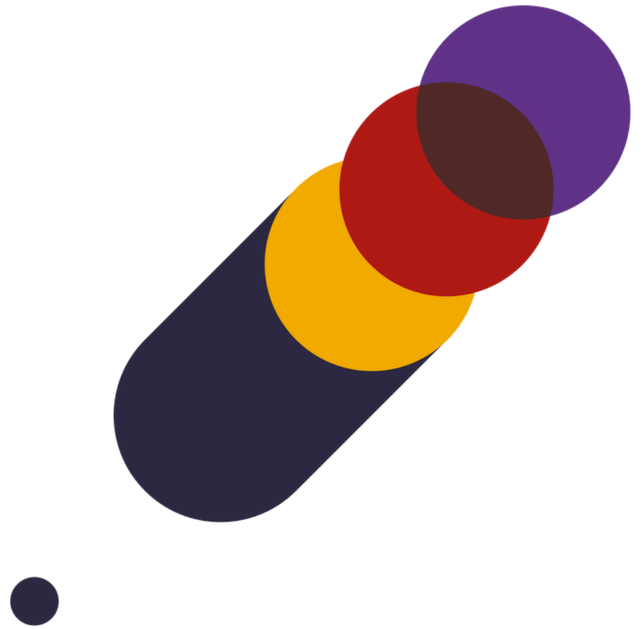
Introduction and background

Advanced Therapy Medicinal Products (ATMPs) represent a significant development in modern medicine. Unlike conventional medicines, ATMPs use genes, cells, or engineered tissues to modify biological processes. Many are personalised or patient-specific, often manufactured or prepared for individual patients rather than produced at scale.

While scientifically transformative, ATMPs introduce delivery considerations that differ from traditional clinical trials. These products frequently depend on tightly controlled handling, storage, timing, and transport conditions. Safe trial delivery therefore relies on coordinated practice across clinical, pharmacy, laboratory, and operational functions.

ATMP trials commonly operate across multiple regulatory and governance frameworks, including Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), research governance requirements, and clinical risk management processes. Some therapies, particularly those involving genetically modified organisms may also require biosafety oversight. In addition, many ATMP pathways involve complex procurement, starting-material collection, and Human Tissue Act (HTA) considerations.

As ATMP research activity expands, variation has emerged in organisational readiness, operational models, and workforce familiarity. Experience from feasibility assessments, operational learning, and stakeholder engagement indicates that challenges are rarely confined to specialist clinical knowledge alone.



Frequently observed issues include:

- Differing familiarity with regulatory and approval pathways.
- Unclear ownership of chain-of-identity and chain-of-custody processes.
- Variability in confidence with toxicity management and escalation.
- Inconsistent expectations around multidisciplinary coordination.
- Variable early involvement of pharmacy and laboratory services.
- Infrastructure and logistics constraints.
- Role ambiguity across organisational interfaces.

These considerations highlight the need for a shared capability reference that supports consistent understanding of the factors contributing to safe and effective ATMP trial delivery.

At present, no single national resource describes the capabilities uniquely associated with ATMP clinical trial activity. This framework has therefore been developed to provide a coherent, system-level reference point that organisations and practitioners may use to inform planning, reflection, and capability development.

The framework complements existing professional, regulatory, and research governance structures. It does not replace or reinterpret statutory or sponsor requirements.

Statements of support

We welcome this publication as a pivotal resource for strengthening and harmonising the UK's capacity to deliver high quality research in advanced therapy medicinal products (ATMPs). This framework reflects a shared commitment across the health and research landscape to ensure that patients, clinicians, research teams and sponsors benefit from a coherent, nationally aligned approach to developing the skills and expertise required to lead in this rapidly evolving field.

Joint statement from:

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

HSC Public Health Agency
Research and Development

NHS SCOTLAND
NHS RESEARCH SCOTLAND

NIHR | National Institute for Health and Care Research

ATMPs represent a transformative opportunity for improving patient outcomes and positioning the UK as a global leader in cutting edge clinical research. Realising this potential requires a workforce that is confident, capable, and supported by a clear, structured development pathway. This framework provides a practical, accessible guide that helps organisations and individuals understand the capabilities needed to deliver safe and efficient advanced therapy trials. It also supports greater consistency across the UK, ensuring that research teams - regardless of geography or organisational setting - can work to a shared standard of excellence.

Fiona Thistlethwaite, Medical Oncology Consultant and iMATCH Director

Acknowledgements

We are indebted to the Advanced Therapy Clinical Trials Expert Reference Group chaired by Uta Griesenbach, Professor of Molecular Medicine, Imperial College London and Fiona Thistlethwaite, Medical Oncology Consultant and iMATCH Director, The Christie NHS Foundation Trust for sharing their expertise and time to inform the design and content of the Framework.

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Thanks to the Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC) programme team at The Newcastle upon Tyne Hospitals NHS Foundation Trust for commissioning this work on behalf of the ATTC network – led by Finn Willingham and supported by Kelsie Thomas and Catherine van Niekerk.

Who this framework is for

ATMP clinical trials require contribution from a broad range of roles and services. Capability for successful delivery is distributed across the system rather than located within any single professional group. This framework is relevant to any role or function that contributes to the design, preparation, delivery, oversight, or follow-up of ATMP clinical trials. This may include:

Clinical practitioners involved in patient assessment, administration, monitoring, and escalation.

Pharmacy services responsible for product receipt, storage, preparation, verification, release, and controlled handling.

Laboratory, cellular therapy, and bioscience services supporting starting-material management, sample handling, processing activities, and chain-of-identity controls.

Trial management and operational roles coordinating feasibility, governance processes, documentation, quality oversight, and data management.

Governance, assurance, and organisational leadership functions, including research offices, quality and safety roles, risk management, procurement, and sponsor liaison.

Manufacturing and technical partners whose work interfaces with NHS delivery pathways, including local manufacture or processing facilities where relevant.

The framework is also relevant to organisational leaders and managers. ATMP trials often involve low patient volumes but complex operational, governance, and workforce implications. Understanding these capability considerations supports realistic planning and resource alignment. The framework does not prescribe capability ownership by role or profession. Instead, it offers a shared reference point to support role-appropriate interpretation within different organisational contexts.

Overview of the framework

The framework is organised around the typical lifecycle of ATMP clinical trial activity. This structure reflects how ATMP studies are commonly experienced in practice. The lifecycle comprises five interconnected Dimensions:

Initial sponsor engagement: Exploring feasibility, infrastructure, and service readiness considerations.

Trial set-up: Governance processes, risk assessment, pathway design, and multidisciplinary planning.

Trial delivery: Product handling, administration, monitoring, documentation, communication, and toxicity management considerations.

Trial close-out: Reconciliation, reporting, learning capture, and archiving activities.

Long-term follow-up: Ongoing surveillance, data integrity, late-effects monitoring, and patient support considerations.

Each Dimension outlines capability considerations relevant to that phase of trial activity. These are expressed to support understanding of safe and effective practice rather than define prescriptive requirements. The framework is guided by four design principles:

Evidence-informed: Shaped by operational experience, stakeholder engagement, and established national guidance.

Nationally coherent: Providing a consistent reference point while recognising variation in local models and contexts.

Multidisciplinary and role-relevant: Applicable across professional groups and organisational functions.

Adaptive and future-focused: Intended to evolve alongside scientific, regulatory, and service developments.

How to use the framework

This framework is intended to support reflection, dialogue, and planning rather than function as a compliance instrument.

For individuals, it may provide a structured way to consider role-relevant knowledge, responsibilities, and development needs. Practitioners may use the framework to inform supervision discussions, professional reflection, or learning planning.

For teams and services, the framework offers a shared language for examining capability dependencies, clarifying assumptions, and supporting multidisciplinary coordination. It may inform induction, service design, or workforce planning conversations.

For organisations, the framework can inform feasibility discussions, governance planning, and quality improvement activity. It may assist services in considering infrastructure, processes, and coordination factors associated with ATMP trial readiness.

Capability may be evidenced through multiple mechanisms depending on organisational context. Examples may include:

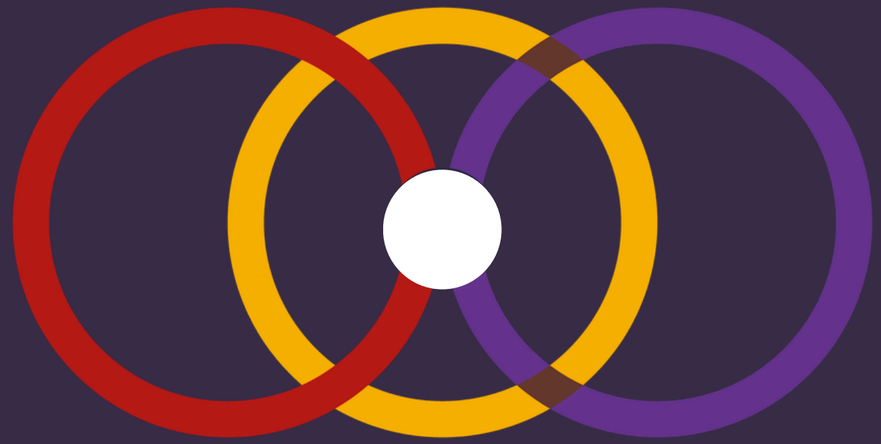
- Structured professional discussion or supervision.
- Participation in simulations or scenario exercises.
- Demonstration through operational practice.
- Targeted learning or experiential development.
- Contribution to multidisciplinary planning or review.

In practice, the framework is most valuable when applied to real scenarios. For example, services preparing for ATMP studies may use it to consider escalation pathways, pharmacy support models, starting-material logistics, or long-term follow-up arrangements.

Use of the framework is intended to complement existing sponsor and regulatory governance arrangements rather than introduce new obligations.

Dimension 1

Initial sponsor and other stakeholder engagement



Capabilities

1.1: Engaging with ATMP trial site team to maximise site capability & readiness.	The individual will be able to: • Demonstrate an understanding of own organisation's research and development processes. • Establish positive working relationships with the research and development department. • Coordinate activities across internal teams (including for example Operational Group for Advanced Therapies, study handlers, clinical trial coordinators, pharmacy, labs) prior to sponsor contact, ensuring consistent messaging and readiness. • Interpret complex and sensitive information and share information using methods to maximise understanding. • Use problem solving skills to resolve issues and challenges in a timely manner.
1.2: Working with the community of ATMP trial sites to accelerate site readiness.	The individual will be able to: • Identify key opinion leaders and wider stakeholders in the field and work collaboratively with them to assess protocol feasibility and identify potential challenges. • Engage with other ATMP trial sites, proactively sharing with and learning from the community to accelerate trial readiness. • Assimilate large volumes of complex information to predict potential operational or feasibility risks and propose mitigation strategies.

Capabilities

1.3: Engaging the sponsor and building relationships to optimise ATMP trial set up and delivery.	The individual will be able to: • Establish communication structures and frequency with the ATMP trial sponsor. • Clarify roles, responsibilities and timelines with the ATMP trial sponsor. • Proactively manage expectations with sponsors to protect timelines, recognising the significance of site selection visit in the timeline. • Identify initial risks to patient recruitment, timelines, manufacturing slots or early logistical issues that may impact ATMP trial set-up and delivery. • Navigate the international, UK and local government context in collaboration with the project sponsor, signposting onwards as appropriate. • Communicate effectively and professionally with the project sponsor using methods that instil confidence. • Use leadership skills when liaising and negotiating with the project sponsor.

Dimension 2

ATMP trial set-up

Capabilities

2.1 Upholding professional and technical standards and supporting others to do the same.	The individual will be able to: • Apply an in-depth knowledge of legislation, policies, international, national and local SOPs consistently to working practices. • Confidently share good clinical practices with others. • Explain own role and responsibilities in relation to the ATMP trial, limitations to own competence and authority and how to seek additional guidance and support. • Act as a role model for others in the multidisciplinary team in ATMP trials, providing support and direction appropriately. • Work effectively as part of the multidisciplinary team, providing leadership, supervision and line management as required by the role.
2.2 Conducting preliminary feasibility assessments to maximise ATMP trial viability and safety.	The individual will be able to: • Describe the potential impact of conducting feasibility assessments on managing viability and safety when setting up ATMP trials. • Work collaboratively with pharmacy and laboratory teams, proactively engaging them from the outset of testing. • Map the patient pathway for feasibility to ensure patient safety considerations are included from the outset. • Assess critical pathway steps: referral, screening, collection, manufacturing timelines to identify early barriers. • Conduct relevant feasibility assessments with the pharmacy and laboratory teams. • Interpret and utilise data from the feasibility assessments to adapt plans and practices. • Liaise with the biosafety officer and others in the health and safety team as required to establish suitability of the ATMP.

Capabilities

2.3 Securing approval for ATMP research activity.	The individual will be able to: • Demonstrate an in-depth understanding of the approval processes and standards/accreditations, which may include HTA and Joint Accreditation Committee of ISCT and EBMT (JACIE), that will apply to the ATMP trial. • Complete the relevant approval applications and submit valid applications as necessary in line with ATMP trial requirements. • Prepare for attendance at committee meetings, including the preparation of presentation materials as appropriate to the local context. • Defend/justify an application and provide clarification information as required. • Respond to any conditions or requests for further information arising in collaboration with the multi-disciplinary team.
2.4 Defining and establishing ATMP trial governance, accountability, reporting and escalation structures.	The individual will be able to: • Demonstrate an understanding of the organisational context in which the ATMP trial will be operating, including key roles and responsibilities. • Demonstrate an understanding of the frameworks and accreditations that are required to support consistency, compliance and safety in ATMP trial delivery, including any project management frameworks. • Demonstrate an in-depth understanding of the principles of ATMP Good Clinical Practice. • Locate and understand site readiness process documents and ensure that they are appropriately validated and accessible to all staff. • Establish and communicate clear reporting mechanisms for safety events, quality concerns, deviations, chain of custody issues / operational issues; and define escalation pathways.

Capabilities

- Establish and communicate clear reporting mechanisms for safety events, quality concerns, deviations, chain of custody issues / operational issues; and define escalation pathways.
- Ensure data can be captured consistently and accurately according to trial protocols and in compliance with regulatory requirements.
- Facilitate multidisciplinary meetings and discussions to prepare sites for ATMP trial initiation.
- Facilitate the delivery of the ATMP trial through all stages of the research process using recognised project management systems as per individual site set-up and local guidelines.

2.5 Liaising with commissioners, sponsors and contracting teams to ensure that ATMP trial contracts and finance agreements are in place.

The individual will be able to:

- Work in line with the NHS standing financial instructions and the National Contract Value Review as they apply to the ATMP trial.
- Demonstrate an understanding of budgetary controls and the potential impact of high-cost ATMP products and procedures on budget.
- Identify and liaise with key individuals in the commissioning process, including the ATMP trial sponsor, research and development, contracting and finance teams.
- Respond promptly to requests for information and any deviations from the NHS standing financial instructions, escalating as appropriate.
- Confirm agreement for the ATMP trial to commence from the sponsor as per the contracting arrangements.
- Provide budgetary oversight throughout the duration of the ATMP trial, including long-term follow up.

Capabilities

2.6 Completing clinical and ATMP-specific technical risk assessments and ensuring mitigation plans in place.

The individual will be able to:

- Select the appropriate tools and techniques for identifying, evaluating and mitigating risks in ATMP trials.
- Systematically identify and evaluate potential risks that relate to patient safety, timelines, data integrity, resources, trial design and compliance with regulations.
- Mitigate risks by identifying and documenting control measures and work with the multi-disciplinary team to make adaptations to ATMP trial processes if needed.
- Liaise with the biosafety officer to establish and document frequency for review of risks and mitigation plans.

2.7 Establishing pharmacy and cellular therapy/ stem-cell laboratory readiness and chain-of-custody arrangements.

The individual will be able to:

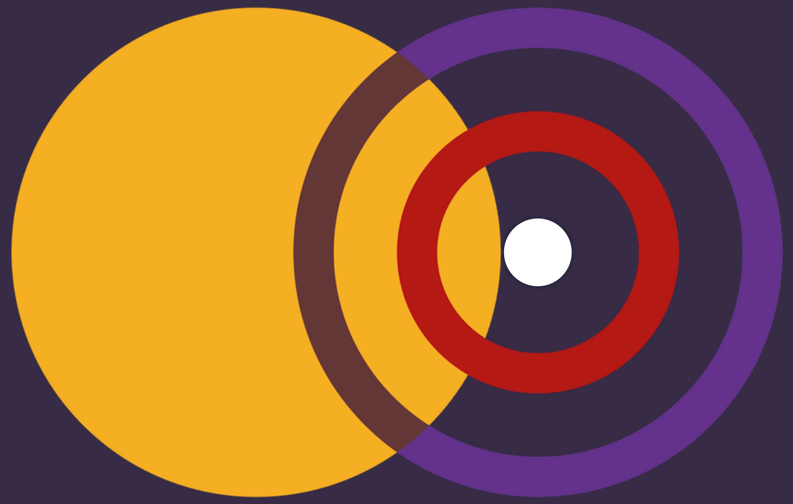
- Demonstrate an understanding of the significance of chain of custody in ensuring integrity of samples, traceability and regulatory compliance.
- Liaise with relevant teams to confirm that procurement and storage requirements can be met for ATMPs.
- Establish the availability of appropriate infrastructure, including clinical space for delivery, storage and disposal of ATMP trial products.
- Establish and confirm courier arrangements and cold-chain procedures for ATMP products.
- Demonstrate an understanding of contingency plans and the actions to take in the event of excursions in the cold-chain.
- Establish and confirm arrangements for the safe return, reconciliation or destruction of ATMP investigational products.
- Monitor systems for ATMP product transport as per sponsor and local site policy requirements.

Capabilities

2.8 Testing processes and procedures to optimise ATMP clinical trial study design and maximise safety.	The individual will be able to: • Demonstrate an understanding of the significance of testing in simulated environments in the ATMP trial set-up phase. • Identify risk factors and if necessary, work with the multi-disciplinary team on the of design valid simulation activities and environments to test processes and procedures. • Interpret results of simulation activities and make recommendations to adapt and optimise processes and procedures. • Source equipment and resources identified as a requirement as an outcome of testing, and any associated logistical challenges. • Escalate emerging safety issues, making recommendations for modifications in the study design and/or establishing mitigation plans. • Reflect on learning arising from testing and liaise with others in the multidisciplinary team to update processes and procedures.
2.9 Recruiting appropriate patients to the ATMP trial.	The individual will be able to: • Identify potential participants and conduct screening interviews using standardised tools. • Recruit appropriate patients according to the ATMP trial protocol. • Facilitate the early engagement with patient representatives where possible.

Dimension 3

ATMP trial delivery



Capabilities

3.1: Receiving, verifying and reconciling ATMPs at site, maintaining full chain of custody.	The individual will be able to: • Receive ATMP products at pre-defined, secure and controlled areas, adhering to the relevant SOPs. • Verify that ATMP products have been maintained within validated temperature ranges throughout transit and that products and labelling are complete and undamaged. • Reconcile the received ATMP products with the anticipated delivery information from the manufacturer and report any discrepancies. • Record information at each step of the process and ensure that the ATMP products are transferred to the appropriate secure storage facility for onward use. • Transfer ATMP products promptly to validated, secure storage equipment or controlled environments, while ensuring that correct setup of environmental monitoring and alarms are in place. • Conduct formal handover to authorised personnel (e.g., pharmacy, clinical team, cell processing lab) following local SOPs. • Build resilience in the chain of custody arrangements by training staff across departments in the receipt and handling of ATMP products, running simulation exercises to test and modify cross-cover plans.
3.2 Preparing ATMPs.	The individual will be able to: • Demonstrate an understanding of the principles of gene editing, cell manipulation, cell preparation and genetically modified organisms as they apply to a specific ATMP. • Demonstrate an understanding of the specific occupational health hazards when handling ATMPs. • Prepare ATMPs for administration according to specific and temperature sensitive procedures.

Capabilities

- Use aseptic techniques to prevent contamination of the product, following biosafety and infection-control practices appropriate to the ATMP type.
- Recognise any ATMP-specific risks that may affect blinding (e.g., product appearance, handling requirements) and follow mitigation strategies to minimise the chance of inadvertent disclosure.
- Adhere to waste management, cleaning and decontamination procedures following ATMP preparation in accordance with biosafety, environmental and regulatory requirements.

3.3 Administering ATMPs.

The individual will be able to:

- Demonstrate an understanding of the underlying biology of the specific ATMP and the therapeutic application of the product.
- Rigorously follow chain of identity procedures to ensure that the correct ATMP is matched to the correct patient throughout the entire preparation and administration process.
- Use specialised equipment safely, such as laminar flow hoods, controlled-rate freezers, monitored storage units, thawing devices, and infusion pumps when handling and administering ATMPs as per local SOPs and policies.
- Follow biological containment procedures in the event of ATMP spillage or accidental exposure.
- Work collaboratively and seamlessly within the multidisciplinary team, using handover and safety-critical communication protocols.
- Follow the agreed deviation, excursion, escalation pathways and risk management arrangements and support quality investigations following events.

Capabilities

3.4 Providing patient information and securing valid consent.

The individual will be able to:

- Communicate with patients and ATMP trial participants, using methods and pace relevant to the individual's needs and wishes.
- Offer accessible and accurate patient information resources and maintain resource currency when significant new information becomes available.
- Interpret complex and technical information relating to ATMPs and use professional judgement when sharing information with patients.
- Respond to questions and requests for further information, escalating and signposting to others as necessary.
- Engage patient support networks appropriate to the individual's needs and wishes.
- Obtain initial valid consent prior to accepting the patient onto the ATMP trial and re-affirm consent at times when significant new information becomes available.
- Ensure consent and information processes are fully documented, version-controlled and accessible.

3.5 Monitoring patients closely for ATMP-specific toxicities.

The individual will be able to:

- Demonstrate an understanding of the ATMP reporting and escalation protocols in the event of patient deterioration.
- Monitor patients closely, using standardised tools and techniques to undertake assessments and grade toxicities.
- Escalate safely and promptly in the event of deterioration or a clinical emergency.
- Communicate effectively with patients, providing psychosocial support and reassurance alongside clinical monitoring.

Capabilities

- Provide advice and guidance to the patient and their family on recognising signs and symptoms of toxicity and the action to take, reinforcing safety-netting information.
- Work collaboratively within the multidisciplinary team to ensure coordinated, safe patient monitoring and prompt response to clinical changes.
- Ensure mechanism in place to identify patient has had ATMP if presenting to another medical team or hospital, for example, an electronic patient record flag or alert card.

3.6 Documenting ATMP trial activities contemporaneously and maintaining audit readiness.

The individual will be able to:

- Use electronic data capture systems and Clinical Trial Management Systems that include comprehensive, time-stamped audit trails to manage and secure electronic records in compliance with regulations.
- Recognise any deviation from the approved protocol or SOPs and report it promptly in accordance with site and sponsor requirements.
- Assess the impact of a deviation on patient safety, data integrity, and regulatory compliance and contribute to correcting issues and preventing future occurrences.
- Work in line with the agreed Quality Management Systems, participating in internal audits and quality control checks to identify and address potential issues before external inspections.
- Ensure compliance with governance, safety reporting and sponsor requirements throughout delivery.

Dimension 4

ATMP trial close-out

Capabilities

4.1: Conducting data cleaning and reconciliation, ensuring completeness of essential documents.	The individual will be able to: • Demonstrate an understanding of the significance of using standardised data formats and terminologies in ATMP trials. • Systematically compare data between the electronic clinical databases and external sources, including lab data and manufacturing data using technology to automatically identify inconsistencies where possible. • Resolve discrepancies promptly, maintaining comprehensive documentation of all data handling, cleaning procedures, and changes for audit readiness and transparency.
4.2 Managing the return, reconciliation or destruction of ATMP investigational products.	The individual will be able to: • Work in line with the scheme of delegation that supports the safe return, reconciliation or destruction of ATMP investigational products, including the agreed ways of working with the pharmacy team. • Segregate returned/used investigational products from unused stock to prevent inadvertent use. • Perform reconciliation of the quantity of investigational product dispensed, used, and returned/destroyed, identifying and promptly reporting any discrepancies to the sponsor. • Manage the return of used or partially used containers from participants to the trial site or pharmacy, following sponsor-specific or site-specific procedures. • Follow established procedures for on-site destruction (if permitted) or prepare the investigational product for off-site destruction.
4.3 Finalising archiving and storage of ATMP trial documentation.	The individual will be able to: • Work in line with local protocols, standards and legislation that apply to the archiving, storage and retention of ATMP trial documentation.

Capabilities

- Prepare ATMP trial documents for storage in secure and environmentally controlled locations.
- Establish a document inventory and procedure for retrieval that supports the extended timeframes for retaining ATMP trial data.

4.4 Capturing lessons learned and sharing best practice nationally.

The individual will be able to:

- Plan and lead close-out meetings and debriefs with ATMP trial teams, facilitating open discussion and encouraging individuals to reflect and share constructive feedback.
- Complete required regulatory and sponsor reports, addressing any outstanding safety issues or adverse events.
- Use structured formats to capture lessons learned consistently and comprehensively.
- Prepare and host ATMP trial close-out workshops, sharing complex information, lessons learned, emerging new information that may inform future ATMP trials, and best practices.
- Identify opportunities for improvement and make recommendations for change.

4.5 Providing patients with ATMP trial exit information and clear referral pathways into long-term follow-up.

The individual will be able to:

- Invite patients to participate in exit interviews designed to share information and improve understanding of the patient experience.
- Conduct sensitive exit interviews, enabling patients to express their future needs and expectations.
- Assess the need for ongoing care and support, coordinating with the multi-disciplinary team to provide future appointments and tests as required.
- Provide clear written guidelines on self-care, warning signs, and how to re-engage directly with the appropriate specialist service without a new GP referral.

Dimension 5

ATMP trial long-term follow-up

Capabilities

5.1 Maintaining registries and long-term data collection to monitor outcomes and late effects of ATMPs.

The individual will be able to:

- Demonstrate an awareness of the significance of any long-term data collection.
- Coordinate with national and international patient registries as required.
- Ensure processes are in place to safely and securely collect data, manage integrity and compliance with regulatory expectations.
- Collaborate with ATMP trials sites and organisations utilising the ATTC network to maintain consistent follow-up standards and share information effectively.

5.2 Conducting ongoing safety surveillance, reporting late adverse events and monitoring for chronic toxicities or secondary malignancies.

The individual will be able to:

- Recognise the signs and symptoms of late adverse effects, chronic toxicity or secondary malignancies relating to the ATMP, including expected timelines and risk factors.
- Work collaboratively with the multidisciplinary team and the ATMP trial sponsor to establish systems to capture long-term observational data.
- Use advanced data analysis to identify emerging trends and risks, escalating and reporting findings and contributing to the long-term safety of the ATMP, escalating concerns promptly and contributing to updates in risk mitigation strategies.
- Identify opportunities for improvement and make recommendations for change.

Capabilities

5.3 Providing sustained counselling, psychosocial support and health literacy resources for patients and families.	The individual will be able to: • Use person-centred approaches, acting with compassion and empathy when providing long-term psychosocial support for patients and families. • Communicate complex medical and scientific information related to advanced therapies using methods and pace relevant to the individual's needs and wishes, empowering patients and families in decision-making and self-management. • Identify psychological needs of patients and families through formal and informal psychosocial assessment methods. • Use cognitive behavioural techniques, and other evidence-based psychological treatments, knowing when and how to refer patients and families to specialist agencies for more intensive support.
5.4 Contributing to the dissemination of findings from the ATMP trial.	The individual will be able to: • Recognise the different needs and levels of understanding of the scientific community, ATMP trial participants, patient and public involvement (PPI) groups and the wider public. • Analyse and interpret ATMP trial results and explain their relevance to the original research question and broader medical context. • Articulate complex scientific information in a concise, accurate, and understandable manner, adjusting the format and language for the specific audience. • Contribute to the drafting of content for dissemination using a range of formats, which may include peer-reviewed scientific publications, presentations, posters, media/social media copy and plain language summaries. • Explain the ethical obligation to share results with ATMP trial participants in a timely manner, acknowledging their contribution and respecting their interest in the outcomes.

ATTC

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