Advanced Therapy Treatment Centres

Skills for Health

Advanced Therapy Medicinal Products Clinical Trials Capability Framework

Draft for Consultation

Coordinated by CATAPULT Cell and Gene Therapy

Delivered by Innovate UK

NIHR | National Institute for Health and Care Research

Contents

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Introduction and Background

Advanced Therapy Medicinal Products (ATMPs) represent one of the most significant developments in modern medicine. Gene therapies, cell-based interventions and tissue-engineered products are heralding new treatment possibilities for conditions where conventional approaches have offered limited benefit. Their translation into routine health service delivery, however, requires a new set of organisational and workforce capabilities.

ATMPs differ fundamentally from traditional medicines. They are often bespoke or patient-specific, biologically active at the point of administration, and reliant on precise timing, temperature control, complex transport arrangements and specialist storage conditions. They interact with multiple regulatory domains:

- Good Manufacturing Practice (GMP)
- Good Clinical Practice (GCP)
- Biosafety oversight
- Research governance
- Clinical risk management.

They can generate acute or late-onset toxicities requiring escalation beyond standard trial frameworks and long-term follow-up extending many years after treatment.

As interest, availability and commercial pressure around ATMP trials continue to grow, the UK health system faces a dual opportunity and challenge: expanding access to innovation, while maintaining patient safety, equity, and operational resilience.

National policies and industry strategies emphasise the importance of improving UK capability to host and grow ATMP trials. Yet local readiness varies, with some organisations delivering high volumes of ATMP activity, and others struggling to navigate sponsor engagement, governance pathways, workforce preparation, or technical delivery.

Learning from feasibility reviews, near-misses, operational delays, training needs analyses and stakeholder consultation suggests that capability gaps are frequently multifactorial. They relate not only to specialist clinical knowledge, but also to variation in familiarity with regulatory expectations and approval pathways; inconsistent involvement of pharmacy and laboratory services at early stages; limited operational ownership of chain-of-custody and product receipt processes; varying comfort with toxicity management and escalation routes; unclear roles between sponsors, R&D offices, trial teams and governance leads; and variable expectations around multidisciplinary communication and oversight.

These realities underscore the need for a shared, system-wide capability reference that supports safe, scalable trial delivery and enables the NHS to keep pace with the evolving ATMP landscape.

This framework has therefore been developed to:

- articulate the ATMP-specific capabilities underpinning safe delivery at each stage of the clinical trial lifecycle
- provide a consistent language and structure that can be used across clinical, pharmacy, laboratory and governance teams
- support organisations to assess readiness, develop their workforce, and align operating models
- complement existing national resources, including the NIHR Research Delivery Competency Framework (by defining what is unique to ATMP delivery rather than replicating generic research competencies
- offer a forward-looking reference that can evolve as therapies, evidence bases and operational models develop.

It does not prescribe programmes of learning, competency sign-off processes or governance structures. Instead, it establishes shared expectations of capability, giving organisations and individuals flexibility to determine how best to develop, assess and embed these within their own context.

In doing so, it contributes to the wider aim of strengthening the UK's ability to deliver cutting-edge therapies safely, consistently and at scale, supporting both patient benefit and strategic national ambitions in regenerative medicine, life sciences innovation and research performance.

Who is this framework for?

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Overview of the Framework

The framework is organised around the full lifecycle of an ATMP clinical trial. This reflects the natural flow of activity experienced by sites, rather than imposing an abstract capability taxonomy.

The lifecycle comprises five interconnected Dimensions:

1. **Initial Sponsor and Other Stakeholder Engagement:** early operational dialogue and capability exploration to ensure site feasibility, appropriate representation and realistic expectation setting.
2. **ATMP Trial Set-Up:** governance approvals, multidisciplinary planning, contract and data readiness, risk assessment, pharmacy/lab preparation, documentation control and emergency planning.
3. **ATMP Trial Delivery:** product receipt, verification and administration; monitoring and escalation; documentation and deviation management; communication and psychosocial support.
4. **ATMP Trial Close-Out:** reconciliation, product return/destruction oversight, reporting, quality learning capture, archiving and handover to long-term pathways.
5. **ATMP Trial Long-Term Follow-Up:** safety surveillance, registry coordination, late toxicity monitoring, psychosocial support, information sharing and data integrity.

Each phase sets out capability expectations framed enabling clarity in what practice should look like without mandating how capability is attained.

The framework is underpinned by four design principles:

- **Evidence-informed:** shaped by operational learning, stakeholder feedback, consultation, and relevant national sources.
- **Nationally consistent:** providing a single reference point to support harmonisation across organisations.
- **Role-relevant, multidisciplinary and adaptable:** able to be applied across professional groups, seniority levels and evolving therapy modalities.
- **Future-focused and iterative:** recognising the need for ongoing review as science, regulation and service capability evolve.

Mapping capabilities to the lifecycle makes the framework intuitive and practically usable. It allows organisations to orient workforce development to the specific demands of each stage and helps individuals to understand how their role contributes to the broader delivery ecosystem.

How to use the Framework

The framework is intended to be lived, rather than merely read. Its value lies in shaping thinking, prompting conversation and guiding decisions across the system. When brought into routine practice, it helps individuals reflect on their responsibilities, assists teams to plan capability, and enables organisations to understand what must be in place for safe and effective ATMP trial delivery.

For practitioners, the framework offers a way to explore their own development. Rather than prescribing training, it invites people to consider whether they feel confident in the knowledge and behaviours expected at different stages of an ATMP trial. It supports clinicians, pharmacists, laboratory practitioners and trial managers to understand how their expertise contributes to the wider ecosystem, and where further experience, supervision or exposure may be valuable as they move into new responsibilities.

At service level, the framework acts as a shared reference point. By describing capability across the trial lifecycle, it becomes a language through which multidisciplinary teams can surface assumptions, highlight gaps and plan for improvement. Leaders may find it helps to articulate where capability is well embedded and where it needs strengthening; for example, whether critical functions such as pharmacy support, operational escalation or emergency preparedness are consistently available across operating hours. In this way, the framework supports workforce planning, role clarity and induction for those entering the ATMP field.

For organisations, the framework can be woven into wider governance and planning processes. It can assist in early sponsor conversations, helping services test their readiness before accepting a trial and revealing where development may be needed before activation. It can inform service design, assurance systems and quality improvement, particularly when closing out a trial and reflecting on lessons learned. Over time, it has the potential to influence strategic workforce planning and investment decisions, offering a structured way of thinking about capability and maturity in ATMP activity.

The framework also has value beyond organisational boundaries. For sponsors, regional research networks and system partners, it provides a consistent basis for dialogue about expectations, roles and pathways to readiness. It can underpin benchmarking, facilitate collaboration, and support national alignment in how capability is understood.

Ultimately, the framework is most powerful when applied to real situations. A service preparing for a CAR-T study, for example, may use it to examine whether it has sufficient cross-cover arrangements at weekends, or whether escalation pathways are clearly rehearsed.

Dimension 1. Initial Sponsor and Other Stakeholder Engagement	
Capability	**The individual will be able to:**
1.1: Engaging with ATMP trial site team to maximise site capability & readiness	• 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 (Operational Group for Advanced Therapies, study handlers, CTCs, 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	• 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.
1.3: Engaging the sponsor and building relationships to optimise ATMP trial set up and delivery.	• 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. • Explain the international, UK and local government context to 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	
Capability	**The individual will be able to:**
2.1 Upholding professional and technical standards and supporting others to do the same.	• 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 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.	• Describe the potential impact of conducting feasibility assessments on managing viability and safety when setting up ATMP trials. • Work collaboratively with the 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 bottlenecks. • 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 to establish suitability of the ATMP.

2.3 Securing approval for ATMP research activity.	• Demonstrate an in-depth understanding of the approval processes 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.	• Demonstrate an understanding of the organisational context in which the ATMP trial will be operating. • Demonstrate an understanding of the frameworks 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. • 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.	• Work in line with the NHS standing financial instructions and the NCVR as they apply to the ATMP trial.

	• Demonstrate an understanding of budgetary controls and the potential impact of high-cost ATMPs 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.
2.6 Completing clinical and ATMP specific technical risk assessments and ensuring mitigation plans in place.	• 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 stem-cell laboratory readiness and chain-of-custody arrangements.	• Demonstrate an understanding of the significance of chain of custody in ensuring integrity of samples, traceability and regulatory compliance. • Liaise with pharmacy and stem-cell laboratory teams to confirm that storage requirements can be met for ATMPs. • Assess clinical space for delivery, storage and disposal of ATMP trial products. • Establish and confirm courier arrangements and cold-chain procedures for ATMPs. • 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 transport as per sponsor and local site policy requirements.
2.8 Testing processes and procedures to optimise ATMP clinical trial study design and maximise safety.	• 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 design of 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	• Identify potential participants and conduct screening interviews using standardised tools. • Recruit appropriate patients according to the ATMP trial protocol.

Dimension 3. ATMP Trial Delivery	
Capability	**The individual will be able to:**
3.1: Receiving, verifying and reconciling ATMPs at site, maintaining full chain of custody.	• Receive ATMPs at pre-defined, secure and controlled areas, adhering to the relevant SOPs.

	• Verify that ATMPs have been maintained within validated temperature ranges throughout transit and that products and labelling are complete and undamaged. • Reconcile the received ATMPs with the anticipated delivery information from the manufacturer and report any discrepancies. • Record information at each step of the process and ensure that the ATMPs are transferred to the appropriate secure storage facility for onward use. • Transfer ATMP produs 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.	• 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. • 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.	• 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.
3.4 Providing patient information and securing valid consent.	• 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.	• Demonstrate an understanding of the ATMP escalation threshold 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. • 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.
3.6 Documenting ATMP trial activities contemporaneously and maintaining audit readiness.	• 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.

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Dimension 4. ATMP Trial Close-Out	
Capability	**The individual will be able to:**
4.1: Conducting data cleaning and reconciliation, ensuring completeness of essential documents.	• 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.	• 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.	• Work in line with local protocols, standards and legislation that apply to the archiving, storage and retention of ATMP trial documentation. • 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.	• 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.	• 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	
Capability	**The individual will be able to:**
5.1 Maintaining registries and long-term data collection to monitor outcomes and late effects of ATMPs.	• Demonstrate an awareness of the significance of long-term data collection

	• Coordinating with national and international registries, ensuring data integrity and compliance with regulatory expectations and ensuring that data is managed safely when patients move between ATMP trial sites. • 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.	• 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.
5.3 Providing sustained counselling, psychosocial support and health literacy resources for patients and families.	• 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.	• Recognise the different needs and levels of understanding of the scientific community, ATMP trial participants, 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.

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