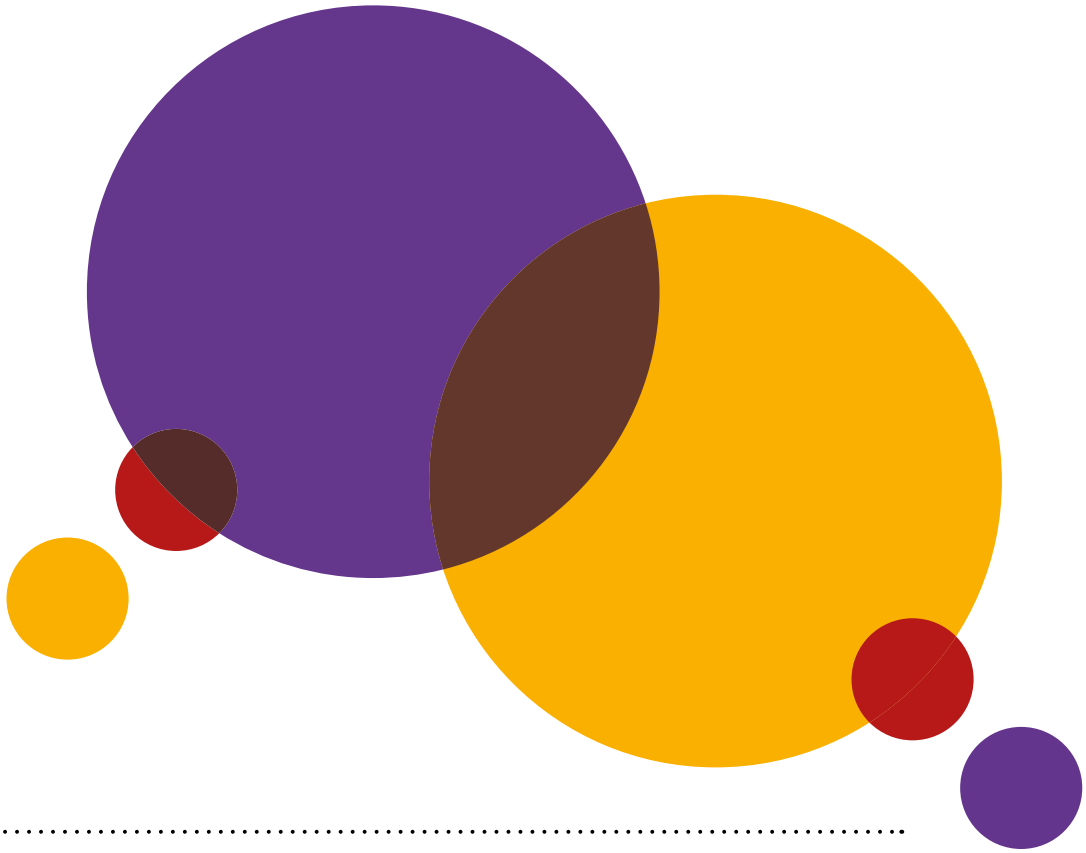
ATTC
Advanced Therapy Treatment Centres



Guidance

Establishing shared care Advanced Therapy Medicinal Product (ATMP) trials within or across NHS Trusts/Health Boards

Issue Date
July 2026

Review Date
July 2028

Version
1.0

Funded by
UKRI Innovate UK
NIHR | National Institute for Health and Care Research

Coordinated by
CATAPULT Cell and Gene Therapy

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Introduction

1. Purpose of this document

1.1 To provide guidance to research delivery teams on the key steps to establish shared care ATMP trials (either within or across NHS Trusts/Health Boards). It aims to support the creation of smooth and efficient processes, so clear lines of responsibility are in place across the trial timeline.

1.2 To identify that a communication and escalation process may need to be established between all parties, so issues which could impact set up/participant recruitment/trial delivery/treatment are shared, and mitigating actions are put in place as soon as possible.

1.3 To support acceleration of the ATMP trial process, especially within the context of the UK government target (2025), to complete set up within 150 days: Guidance on detailed definitions and processes for site-level performance reporting – ukcrd.org

1.4 This document advises on where additional communication/action is required to establish a shared care ATMP trial. It does not act as a Standard Operating Procedure covering all aspects of the trial timeline/process and its content is made available under a Creative Commons Attribution-Non-Commercial 4.0 International license: https://creativecommons.org/licenses/by-nc/4.0/. Whilst it does not include specific advice on requirements regarding the handling/storage of ATMP/ATiMPs, the Regulatory Advice Service for Regenerative Medicines (RASRM) is a useful single point of access for joined up regulatory advice on issues such as chain of identity or chain of custody.

1.5 If using this guidance to establish a shared care trial across more than one NHS Trust/Health Board, be aware of the contractual and Principal Investigator (PI) oversight arrangements required. See the Integrated Research Application System (IRAS) guidance here for full details: https://www.myresearchproject.org.uk/help/hlpinterventional.aspx#Background. In addition see 'Set Up', paragraph 2.3 below, on determining appropriate contractual arrangements and levels of PI oversight. This document supports the HRA guidance when considering appropriate PI oversight and contractual arrangements to deliver interventional health care research across more than one 'Trial Location', as defined by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

2. Who should use this document?

2.1 Those involved in the set up of ATMP clinical trials from NHS Trusts/Health Boards, universities, clinical trial units and other related organisations including personnel from:

- Non-clinical and clinical study teams
- Research and Development/Innovation teams (Research)
- Support departments eg, Pharmacy and Stem Cell Laboratories
- Designated Individuals

2.2 It aims to support NHS Trusts/Health Boards wishing to embed, or further improve, current practice in relation to shared care ATMP trials.

2.3 It may also help inform Sponsors (commercial & non commercial)/Contract Research Organisations (CROs), involved in the set up and delivery of shared care ATMP trials.

3. Definition of key terms

Key terms used within this document are defined below.

3.1 Shared care ATMP trial:

A clinical trial where participant care/treatment is provided under one trial protocol but needs to be delivered via collaborative working across more than one clinical care specialty team (referred to as 'specialty team' throughout this document). This collaboration can either be within one, or across more than one NHS Trust/Health Board.

3.2 The main NHS Trust/Health Board:

The specialty team/s at the NHS Trust/Health Board with overall responsibility for the participant's underlying medical condition.

3.3 The delegated specialty team:

A specialty team (within the same, or a different NHS Trust/Health Board) requested to enter a shared care trial by the main NHS Trust/Health Board. If agreed by all parties, the delegated specialty team subsequently agrees to deliver identified aspects of the trial protocol.

3.4 Designated Individual (DI):

In the context of UK ATMP trials, the Designated Individual is the person responsible for ensuring requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), under the appropriate site-specific Human Tissue Authority (HTA) licence (Human Application) are implemented. Please note nation specific provisions or processes may be in place. The DI authorises and supervises the licensed activity or activities and has primary (legal) responsibility to ensure:

- that suitable practices are used in undertaking the licensed activity or activities
- that other persons working under the licence are suitable persons to participate in the licensed activities
- that the conditions of the licence are complied with
- that the conditions of third-party agreements are complied with, and
- that all information relating to licensable activities is available for tracing donations, up-to-date and correct and held securely.

The above list of responsibilities is not exhaustive, and DIs should refer to paragraphs 1-4 of the:

HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment | Human Tissue Authority

Further information and details on requirements of a DI or for establishments storing tissue under the terms of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), can be located at:

How licensing works under the Human Tissue Quality and Safety Regulations | Human Tissue Authority

4. When should it be used?

4.1 This document should be referred to from submission of an expression of interest, or the beginning of the feasibility process, for an ATMP study where involvement from another specialist team(s) within the same, or another NHS Trust/ Health Board is required to deliver the trial.

4.2 It is advised that colleagues from all NHS Trusts/ Health Boards who could be involved in delivering the trial, should be contacted and involved prior to submission of feasibility and any site qualification visit.

5. How should it be used?

5.1 A summary of this document can be accessed via the 'Flowchart on Establishing Shared Care ATMP trials' which follows. This flowchart includes links which navigate the reader to more detailed information on aspects of the trial timeline.

5.2 Additionally, the 'Contents Page' above includes links which navigate the reader to detail on the establishment of a shared care ATMP trial, from pre-set up to long term participant follow up.

PRE SET UP

Identify an additional specialty team required & establish contact

Main NHS Trust/Health Board specialty team is notified of a new ATMP trial

Main NHS Trust/Health Board specialty team identifies an additional delegated specialty team (in same/other NHS organisation) is required to deliver protocol.

Clinical Trial Manager (CTM) at main NHS Trust/Health Board notified of potential shared care trial. Clinical Research Facility (CRF) to lead/be involved from outset.

Is a DI & HTA licence required?

If so, who will provide DI oversight and hold HTA licence?

If an NHS DI: identify who will support.

If a sponsor/CRO/other organisation's DI: governance checks with NHS Research team(s) required.

DI(s) to be fully engaged throughout. Responsibilities stated & documentation agreed.

Is a working relationship in place with the additional delegated specialty team?

Yes

Is the additional specialty in the same NHS Trust/Health Board?

Yes

Contact additional internal specialty **Principal Investigator (PI), Research team & Disease area Clinical Trial Manager (CTM)** to identify interest in taking part.

No

Contact additional specialty **PI, Research Team shared email inbox, disease area CTM** to identify interest in taking part.

No

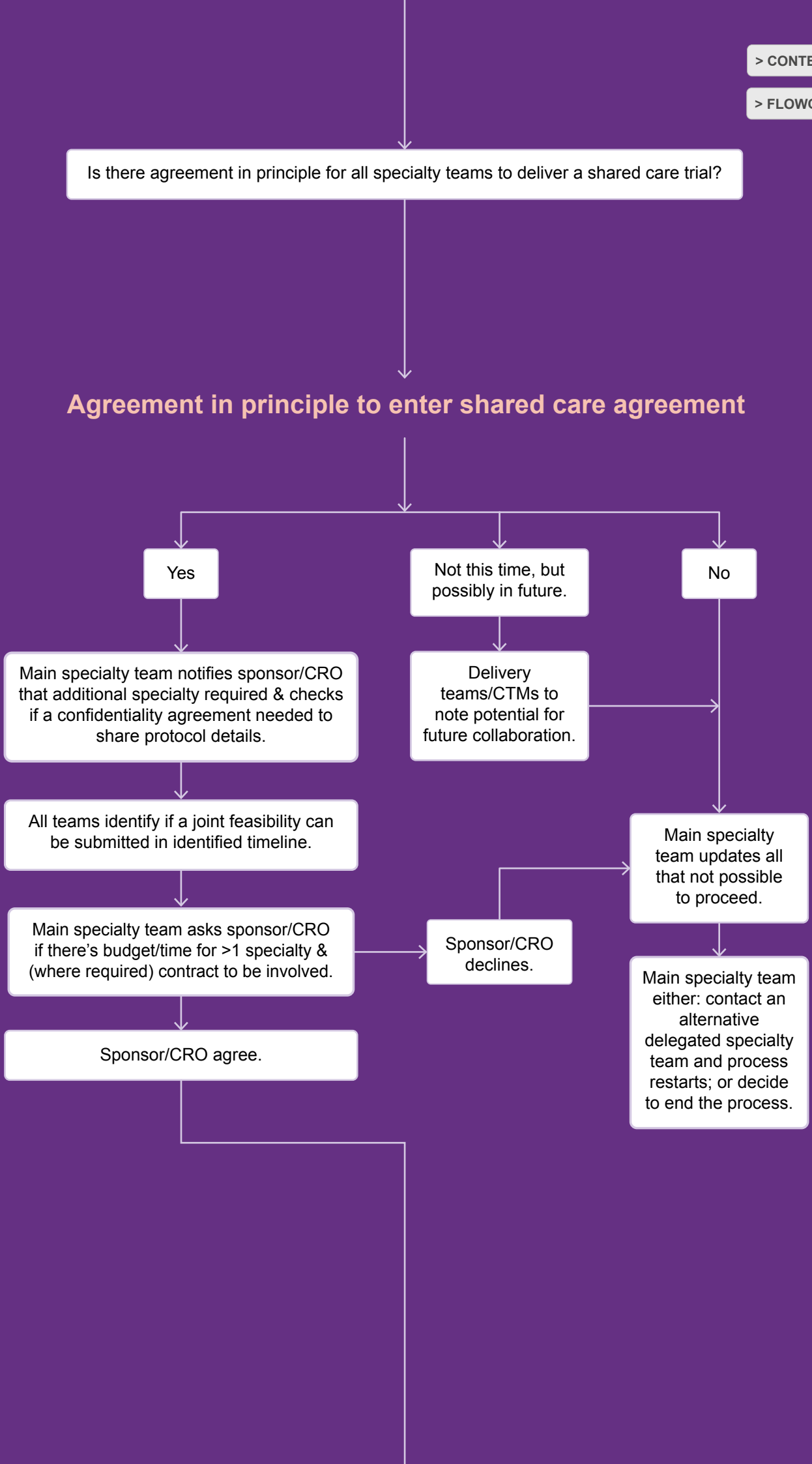
Is the additional specialty in the same NHS Trust/Health Board?

Yes

Contact additional internal **PI and Research team** to identify interest in taking part.

No

Contact additional **PI and Research team shared email inbox** to identify interest in taking part.


Is there agreement in principle for all specialty teams to deliver a shared care trial?
Agreement in principle to enter shared care agreement
Yes
Not this time, but possibly in future.
No
Main specialty team notifies sponsor/CRO that additional specialty required & checks if a confidentiality agreement needed to share protocol details.
Delivery teams/CTMs to note potential for future collaboration.
All teams identify if a joint feasibility can be submitted in identified timeline.
Main specialty team updates all that not possible to proceed.
Main specialty team asks sponsor/CRO if there's budget/time for >1 specialty & (where required) contract to be involved.
Sponsor/CRO declines.
Main specialty team either: contact an alternative delegated specialty team and process restarts; or decide to end the process.
Sponsor/CRO agree.

Completion of feasibility by all specialties

Feasibility received.

Agree who & how it will be completed across specialty teams.

Agree timescale for joint completion. Can sponsor/CRO set up/delivery times be met?

Are there any concerns impacting set up within the 150 day target?

Consider capacity and capability issues within/across NHS Trusts/Health Boards.

Are there any barriers to set up/delivery? How will they be addressed?
Identify local ATMP approval/safety committee process(es).

Will teams meet sponsor/CRO prior to submission of feasibility? Consider issues to be discussed.

Submission of joint feasibility confirms agreement in principle across all specialties

SET UP

Continue regular communication

Establish regular communication within/across NHS Trusts/Health Boards during set up and delivery on:

- respective responsibilities
- capacity and capability
- risks & mitigation
- participant recruitment
- management of participant identifiable information & clinical trial data
- the shared care study scheme of delegation
- contractual and financial arrangements (inc. standard of care)
- governance and approvals
- site selection – letter of intent
- audit and monitoring arrangements
- site qualification visit
- site initiation visit planning.

TRIAL OPENS

Continue regular communication

Following green light, continue regular communication within/across NHS Trusts/Health Boards to maintain oversight & management of operational issues/risks.

Site activation: where dates vary across specialty teams communicate regularly to ensure recruitment & treatment trial locations are set up in collaboration.
(Important to meet 60 day set up and 30 day recruitment target).

Participant recruitment and consent: ongoing communication required to ensure protocol timelines can be met; there is capacity to recruit; risks are managed.

Participant referral, treatment & progress: ensure systems in place for delivery team personnel across NHS Trusts/Health Boards to:

- book, record, view participant tests/treatment dates
- view participant safety cards (inc. out of hours contacts)
- share information on participant progress
- monitor performance against protocol/manage risks.

Data ownership, entry, access & transfer: responsibilities to be outlined, data to be entered securely into eCRF & participant notes where activity occurs. Participant data to be transferred between NHS Trusts/Health Boards using encrypted method.

Adverse Event (AE) management & safety reporting: systems to record AEs should be in place and PI medical cover established for ATMP trial and disease related events.

Inspection, audit & modifications: systems should be in place to communicate within or across specialty teams on these issues.

CLOSE OUT

If the trial was across more than one NHS Trust/Health Board, each should close out independently. There should be clarity on whether:

joint/separate archiving should be undertaken, or

if all records should be returned to sponsor.

Long term follow up: this should be agreed within/across NHS Trusts/Health Boards in line with standard of care or protocol requirements.

APPENDICES

Appendix 1: Outline email for contacting an additional specialty team, to identify interest in establishing a shared care ATMP trial.

Appendix 2: Feasibility checklist & record of agreement for ATMP trials.

Appendix 3: Shared care study specific scheme of delegation for ATMP trials.

Appendix 4a: Participant management across NHS Trusts/Health Boards (CAR-T).

Appendix 4b: Participant management across NHS Trusts/Health Boards (TIL).

Appendix 5: Referral template for an ATMP trial.

Pre Set Up

Step 1:

Identify that an additional delegated specialty team is required to deliver the ATMP trial

1.1 The main NHS Trust/Health Board delivery team receives notification of a new ATMP trial and it is identified an additional delegated specialty team (from within their own organisation, or another NHS Trust/Health Board) is required for successful delivery of the trial.

1.2 The delivery team at the main NHS Trust/Health Board should confirm with their disease area Clinical Trial Coordinator/Manager, that another delegated specialty team may be needed, and there is potential for a shared care ATMP trial to be established. Where a Clinical Research Facility (CRF) is required to deliver the trial protocol, this should be identified at the earliest opportunity. Dependent on local practice, the CRF will lead/be involved throughout the process.

1.3 The delivery team at the main NHS Trust/Health Board must clarify if a DI and HTA licence is required for successful delivery of the trial and in order to comply with regulatory/statutory requirements. If there is any uncertainty, the HTA should be contacted, to provide assurance that the correct regulatory framework is in place. Where a licence and DI is required:

1.3.1 The delivery team at the main NHS Trust/Health Board should agree which organisation(s) is responsible for ensuring the appropriate HTA licence is in place, that the DI has oversight of all related agreements/ activities, and contact the DI(s) to identify their availability and capacity to support. There should also be consideration of whether the HTA licence needs to be varied to include tissue requirements of the trial. Checks to ensure the trial protocol is compliant with Regulations, and that any training has/can be satisfactorily completed, should be factored into potential set up timelines. Where a HTA licence variation is required, a request should be initiated at the earliest opportunity and time critical requirements highlighted. The timescale to process a variation may not be compatible with the agreed set up timeline.

1.3.2 Where the sponsor wishes to use their own HTA licence and associated DI, the delivery team (specifically the PI and DI within the NHS Trust(s)/Health Board(s)), should discuss potential delegation of this responsibility with their respective Research Team(s), to identify if it is acceptable within local governance arrangements to proceed on this basis. Other HTA licensing models for ATMPs may be applicable. In all cases the role and responsibilities of the DI must be agreed.

1.3.3 The DI(s) should be fully engaged and involved throughout the trial process to ensure all Human Tissue legislation and associated regulations continue to be met.

1.3.4 The assigned Stem Cell Laboratory Manager and the DI (where they are not the same person) should consider which accompanying documentation may be required, for example handling manuals or starting material quality technical agreements.

1.3.5 See Appendix 2 ‘Feasibility checklist & record of agreement for ATMP trials’ for more detail re: Stem Cell Laboratory and DI considerations.

1.3.6 DI(s) responsibilities should be discussed, agreed and clearly stated within Appendix 3 ‘Shared care study specific scheme of delegation’. Appendix 3 does not replace compliance with the International Council for Harmonisation Good Clinical Practice (ICH GCP) E6 guidance regarding maintaining a record of delegation.

1.3.7 Considerations noted in 1.3.1 – 1.3.6 above can run in parallel with activities noted in Step 2 below.

Step 2:

Establish contact with an additional specialty team

2.1 Where the main NHS Trust/Health Board delivery team **has an established working relationship** with the additional specialty team and:

2.1.1 all teams required to deliver the trial are **located in the same NHS Trust/Health Board**, contact should be made as soon as possible with the additional internal PI, Research team and disease area Clinical Trial Manager, to identify if there is interest/potential in their taking part in the ATMP trial as a delegated specialty team.

2.1.2 the additional specialty team is **located in another NHS Trust/Health Board**, contact should be made as soon as possible with the additional external PI, relevant Research Team shared inbox and disease area Clinical Trial Manager, to identify if there is interest/potential in their taking part in the ATMP trial as a delegated specialty team.

2.2 Where the main NHS Trust/Health Board delivery team **does not have an established working relationship** with the additional specialty team and:

2.2.1 all teams required to run the trial are **located in the same NHS Trust/Health Board**, contact should be made as soon as possible with the additional internal PI and Research team, to identify if there is interest/potential in their taking part in the ATMP trial as a delegated specialty team.

2.2.2 the additional specialty team is **located in another NHS Trust/Health Board**, contact should be made as soon as possible with the external PI and via their Research Team shared inbox, to identify if there is interest/potential in their taking part in the ATMP trial as a delegated specialty team.

2.3 An email template for use when contacting an additional specialty team, to identify interest in establishing a shared care ATMP trial is attached. (Appendix 1). It is useful to build and maintain a list of Research Team and disease area specific shared email inbox addresses for the NHS Trusts/Health Boards where shared care trials are likely to be established.

Step 3:

Establish if there is agreement in principle for all specialty teams, within/across the NHS Trust(s)/ Health Board(s), to deliver a shared care ATMP trial

3.1 If there is agreement in principle to enter a shared care arrangement between all Research parties involved:

3.1.1 The main NHS Trust/Health Board specialty team is advised to inform sponsor/CRO that an additional delegated specialty is needed to deliver the trial. They should enquire whether a confidential disclosure agreement is needed to share protocol details with another specialty team, so arrangements can be established as required.

3.1.2 There should be discussion as soon as possible on whether a joint feasibility can be submitted within the sponsor/CRO's timeline for completion, especially where a new collaboration is required. If a response is not received from an NHS Trust/Health Board in the agreed timeframe, it is assumed that they do not wish to enter into a shared care agreement.

3.1.3 The main NHS Trust/Health Board should clarify with the sponsor/CRO whether:

a) there is sufficient budget to facilitate a shared care approach

b) additional time can be provided for the NHS Trust(s)/Health Board(s) to coordinate submission of a joint feasibility

c) sponsor/CRO agrees to enter contractual agreements with more than one specialty team//NHS Trust/Health Board as appropriate.

3.1.4 If sponsor/CRO agrees to a shared care approach and the stipulations in 3.1.3 can be met – go to Step 4.

3.1.5 If sponsor/CRO does not agree to a shared care approach the main NHS Trust/Health Board specialty team should update all teams and sponsor/CRO as soon as possible that it is not possible to proceed and the process ends.

3.2 If it is not possible to enter a shared care agreement for the ATMP trial at that time, but there is potential to do so in the future:

3.2.1 this can be noted by all teams (within or across the NHS Trust(s)/Health Board(s)). Thereby keeping channels of communication open to facilitate future discussion on potential collaboration between the organisations.

3.2.2 The main NHS Trust/Health Board should update all teams as soon as possible that it is not possible to proceed at this time.

3.2.3 The main NHS Trust/Health Board should discuss if it is still possible to establish a shared care trial, i.e., where an alternative delegated specialty team can be identified, or if other options on a way forward are available.

3.2.4 If a shared care option is still possible, return to step 2.

3.2.5 If a shared care option is not possible, the process ends.

3.3 If it is not possible to enter a shared care agreement for the ATMP trial, for the foreseeable future:

3.3.1 The main NHS Trust/Health Board should update all teams as soon as possible that it is not possible to proceed at this time.

3.3.2 The main NHS Trust/Health Board should discuss if it is still possible to establish a shared care trial, i.e., where an alternative delegated specialty team can be identified, or if other options on a way forward are available.

3.3.3 If a shared care option is still possible, return to step 2.

3.3.4 If a shared care option is not possible, the process ends.

Step 4:

Receipt and completion of the ATMP trial feasibility proforma, by all specialty teams

4.1 Representatives from all CRF(s), specialty and Research teams (within or across the NHS Trust(s)/ Health Board(s)) and any other staff who may be involved in the ATMP trial process, should be included in discussions as soon as possible regarding completion of the feasibility proforma. It should be clarified within/across the NHS Trust(s)/ Health Board(s) which combination of personnel are best placed to lead on completion of the feasibility proforma. This can be decided locally, as appropriate.

4.2 There should be agreement on how the feasibility proforma will be completed eg, via email or online meeting as appropriate, to meet the required response timescale.

4.3 The timescale for completion of the feasibility proforma (especially if it is to be completed by more than one NHS Trust/Health Board) should be agreed by all parties. Consideration should also be given to whether the NHS Trust(s)/Health Board(s) can meet the sponsor/CRO's expected set up/ delivery timelines, especially if sponsor/CRO have made contact following site initiation of this trial elsewhere. All parties should operate within clear and agreed escalation pathways to ensure barriers are addressed swiftly and set up is accelerated.

4.4 It should be clarified as soon as possible if there are any issues or concerns which might impact set up within the government's 150 day target. The main NHS Trust/Health Board usually maintains oversight and tracking of performance against this target.

4.5 Dependent on local practice and the timescale sponsor/CRO has requested for the feasibility to be submitted, the NHS Trust(s)/Health Board(s) can either discuss:

- **essential elements** of potential capacity and capability to deliver the trial. (See a guide on issues to discuss in Appendix 2, 'Feasibility checklist & record of agreement for ATMP trials')

Or,

- **more detailed issues** on potential capacity and capability to deliver the trial. (See 'Set Up' paragraph 2.2.1 below and Appendix 3, 'Shared care study specific scheme of delegation for ATMP trials' for more information). Appendix 3 does not replace compliance with the ICH GCP E6 guidance regarding maintaining a record of delegation.

4.6 There must be mutual agreement on which PI/ delegated medical practitioner will provide oversight wherever clinical judgement is exercised in relation to a participant, for each aspect of trial delivery, within or across the NHS Trust(s)/Health Board(s) as appropriate. Where responsibility for the underlying condition and the investigational product sit in different specialty teams, a PI should be named for each, with agreement on who leads where attribution of an adverse event is uncertain.

4.7 It is useful to create a record of discussion/ agreement across specialty teams at this point, due to timescales between submission of feasibility and set up (if the trial location(s) are selected).

4.8 It is advised that any potential issues/barriers, highlighted following discussion on feasibility, are identified as soon as possible, and an approach to address them agreed in principle within or across the NHS Trust(s)/Health Board(s). Information on key ATMP governance and biological safety committees, within or across the NHS Trust(s)/Health Board(s), should be identified by all parties to inform timeline planning.

4.9 If prior to submission of feasibility, a meeting with sponsor/CRO is to take place regarding a shared care arrangement, there should be clarity on:

- When and how the meeting should be held?
- Which staff roles should attend?
- Whether representatives from all specialty teams should be present?
- Which documents can be shared prior to the meeting, eg, an overview of the participant pathway

4.10 Submission of a joint feasibility acts as confirmation of agreement in principle between the NHS Trust(s)/ Health Board(s) to proceed.

Set Up

1. Establish regular communication within/across the NHS Trust(s)/Health Board(s) on the ATMP trial

1.1 Good practice would include identifying key contacts from relevant departments within or across the NHS Trust(s) and establishing regular contact through set up and delivery, to ensure a shared understanding of:

- respective responsibilities relating to set up and anticipated delivery processes,
- capacity and capability
- risk management processes and any required mitigating actions
- the participant recruitment strategy

1.2 Further detail on activities in 1.1 above is outlined under 2. 'Processes/issues to consider regarding the ATMP trial' below.

2. Processes/issues to consider regarding the ATMP trial

An overview of some key processes/issues, which can be considered (as appropriate) during set up of an ATMP trial within/across NHS Trusts/Health Boards, is listed below. This is not a fully exhaustive list:

- Management of participant identifiable information and clinical trial data
- The shared care study specific scheme of delegation
- Contractual and financial arrangements including standard of care
- Governance and approvals
- Site selection – letter of intent
- Site qualification visits
- Site initiation visit planning

Please note the above are not listed in chronological order, also activities relating to each may run in parallel throughout the set up process.

Further detail on each bullet point is included in 2.1 - 2.7 below.

2.1 Management of participant identifiable information and clinical trial data

Transfer of participant data from referral to treatment trial location:

2.1.1 If required, there should be discussion and agreement on: the participant data that can be shared across NHS Trusts/Health Boards; who will have access to it (eg the named PI at each Trust/Health Board); how it will be shared using a secure and encrypted method; if there are any additional data requirements where patients from another devolved nation are being treated.

2.1.2 Information on out of hours contact details, for each point in the participant pathway, should be available within/across the NHS Trust(s)/ Health Board(s) personnel involved in the shared care trial.

Clinical trial data:

2.1.3 If required, there should be discussion with sponsor/CRO on how clinical trial data is entered into each NHS Trust/Health Board's electronic Case Report Form (eCRF).

2.2 Shared care study specific scheme of delegation

2.2.1 Dependent on local practice, there should be detailed discussion and agreement at submission of feasibility or during set up, on capacity and capability at the trial location(s) involved, regarding respective responsibilities across the shared care participant pathway.

In addition to the issues noted in Appendix 2, discussion on capacity and capability can include the following (not an exhaustive list):

- Identification of staff training requirements
- Inpatient capacity
- Clinical space: is space available at times required? Does it meet requirements on infection control, patient monitoring, emergency response, sample handing and proximity to support services?
- Collection of time critical samples: are lab facilities available; are there sample stability windows to consider; do transport arrangements need to be put in place; are contingency arrangements in place?
- Is any specific equipment needed: has it been validated/calibrated; where will it be located; who will fund and maintain it?
- Has sponsor identified any specific reporting requirements?
- Are there long term follow up requirements

2.2.2 Agreement on respective responsibilities across the participant pathway should be documented at this stage within the 'Shared care study specific scheme of delegation' (Appendix 3), which does not replace compliance with the ICH GCP E6 guidance regarding maintaining a record of delegation. Any subsequent changes should be documented using a document version control process and be available to all teams involved.

2.2.3 Sponsor/CRO should be updated regarding NHS Trust(s)/Health Board(s) responsibilities and any agreed changes.

2.2.4 Examples of participant management across NHS Trusts/Health Boards for chimeric antigen receptor T-cell therapy (CAR-T) and tumour-infiltrating lymphocytes (TIL) are included as Appendices 4a & 4b. These example pathways would need to be adapted if being used to create a shared care arrangement for other indications/technologies. They may also support NHS Trusts/Health Boards to identify the appropriate financial and contractual arrangements required to establish and deliver this trial. It may also support sponsor/CRO's understanding, regarding establishment of these arrangements, within/across NHS Trusts/Health Boards.

2.3 Contractual and financial arrangements

2.3.1 It is advised that the NHS Trusts/Health Boards involved discuss and document agreement reached on:

- which PI(s) will provide oversight at the NHS Trust(s)/Health Board(s) involved in the trial
- how agreement on PI oversight has been reached
- the 'type' of trial locations to be involved.

The types of activities taking place at each location and the level of PI oversight required to deliver the shared care trial will determine any additional inclusion of locations in IRAS ethics applications, the establishment of full site agreements or Hub and Spoke contract arrangements. The Shared care study specific scheme of delegation (Appendix 3) will work alongside these arrangements, which does not replace compliance with the ICH GCP E6 guidance regarding maintaining a record of delegation.

Further advice on the above can be found within the 'Summary of Principles and Expectations' table at: IRAS Help – Preparing & submitting applications - Interventional Research.

2.3.2 Following agreement within/across the NHS Trust(s)/Health Board(s) on PI oversight and the type(s) of trial locations involved, it is possible to discuss with sponsor/CRO the appropriate contractual and financial arrangements required to facilitate delivery of the shared care trial.

2.3.3 The usual NHS Trust/Health Board and National Contract Value Review (NCVR) ATMP interactive costing tool and contractual processes can be utilised to establish these arrangements. Prior to finalisation of the NCVR, parties may wish to discuss costs (where the trial is delivered across more than one NHS Trust/Health Board). It is also advised that the NHS Trust(s)/Health Board(s) treating the participant review and compare its standard of care procedures, against those required in the study protocol. Thereby ensuring all procedures required (outside standard of care) are accurately costed and all parties are aware of them. For further guidance see: NCVR ATMP EP Costing Guidance v1.0 October 2024.docx

2.4 Governance and Approvals

2.4.1 Sufficient time should be identified (in the period allocated for submission of Capacity and Capability) to facilitate all relevant local ATMP governance, approval and biological safety committee considerations. This is especially important where there is more than one committee in place within or across the NHS Trust(s)/Health Board(s).

2.4.2 Sponsor/CRO should be made aware of these local committees and their operating timescales.

2.4.3 Following local approvals, Capacity and Capability can be issued.

2.5 Site Selection – Letter of Intent

2.5.1 Specialty teams within/across the NHS Trust(s)/Health Board(s) should update each other following site selection; check there is continued capacity and capability to deliver the trial; and discuss possible dates to open/recruit.

2.6 Audit and monitoring arrangements

2.6.1 NHS Trust(s)/Health Board(s) should establish all audit and monitoring requirements with sponsor/CRO, and these expectations should be clearly communicated between all parties involved.

2.7 Site Qualification Visit (SQV)

2.7.1 The NHS Trust(s)/Health Board(s) should discuss how SQVs should be facilitated with sponsor/CRO, i.e.:

- online/in person
- which personnel and speciality teams within/across the NHS Trust(s)/Health Board(s) should be present (with PI involvement being key)
- which trial location(s) within/across the NHS Trust(s) should hold the SQV.

2.8 Site Initiation Visit (SIV) Planning

2.8.1 It is advised that the NHS Trust(s)/Health Board(s) involved are aware of any SIV planning, visits that need to take place and where they will be held. The appropriate personnel and specialty teams should be present, with PI involvement being key. Progress updates should be regularly communicated within/between trial location(s).

2.8.2 Sponsor/CRO should be requested to tailor training offered, so content is delivered at SIV, in line with the NHS Trust(s)/Health Board(s) relevant and respective trial delivery responsibilities.

Trial Opens

1. Regular communication within/across the NHS Trust(s)/Health Board(s) on the ATMP trial

Following green light, regular communication within/across the NHS Trust(s)/Health Board(s) should continue, to ensure ongoing awareness and the management of any operational issues which arise within or across these NHS Trusts/Health Boards. Any cross-specialty meetings will require engagement from PIs to ensure oversight of trial activities.

2. Site activation

2.1 Where more than one NHS Trust/Health Board trial location is involved in the shared care trial, site activation dates may vary. It is especially important therefore to maintain regular communication within/across organisations so:

- updates on site activation dates can be shared
- progress to open can be discussed
- recruiting and treatment trial locations are set up in collaboration.

2.2 Regular communication is particularly important regarding those trials subject to the government's 150 day set up target, where there are 60 days to complete local set up and 30 days to recruit first participant.

3. Ongoing management and monitoring

3.1 Participant recruitment and consent

3.1.1 It is advised that the regular communication meetings include discussion on recruitment and consenting activities, to ensure protocol timelines can continue to be met. This could include involvement from all relevant disciplines within the Delivery team, including but not limited to: PIs, Clinical Trial Coordinators/Managers, Research Nurses, Research Practitioners and any other members of the delivery team.

3.1.2 There should be continued monitoring to ensure capacity to recruit or to flag any risks associated with recruitment.

3.2 Participant referral, treatment & progress

3.2.1 As the participant journey will move between specialty teams, systems should be in place to ensure all involved within or across the NHS Trust(s)/Health Board(s), can as appropriate:

- book, record and view participant visit/test/treatment dates per trial location (as this also supports advance and capacity planning)
- view participant safety cards, including out of hours contact details
- answer participant queries
- share information on participant progress, eg, clinic letters/notes, test results
- share information on the standard of care participant pathway outside of the protocol eg for follow up care
- monitor local performance against protocol recruitment and delivery requirements and manage any associated risks.

3.2.2 Refer to Appendix 5: Referral template for ATMP trials, for further advice to support efficient establishment of contact between specialty teams and provide a clinical summary of the trial participant.

3.3 Data ownership, entry, access and transfer

3.3.1. It should be agreed which location holds primary source responsibility for data on specific activities across the trial timeline.

3.3.2 There should also be agreement on the ownership of data entry and query resolution within or across the NHS Trust(s)/Health Board(s). Data should be entered securely into the sponsor/CRO's eCRF and participant's clinical notes, by the specialty team or NHS Trust/Health Board where the participant activity occurs. There should be clear expectations within or across the NHS Trust(s)/Health Board(s) on access to electronic medical records/source data.

3.3.3 Participant data transferred between NHS Trusts/Health Board should always be conveyed in an encrypted format and covered by appropriate contractual arrangements, such as Data Sharing Agreements if required.

3.4 Adverse event management and safety reporting

3.4.1 Systems should be in place to record and communicate any information regarding safety concerns or incidents, which have occurred within or across the NHS Trust(s)/Health Board(s).

3.4.2 PI(s) role in providing acute medical cover, for both ATMP trial and disease related adverse events, must be clarified and agreed prior to trial opening.

3.4.3 Where an adverse event is reportable to the HTA, the DI is legally responsible for undertaking this.

4. Inspection, audit & modifications

4.1 If an NHS Trust/Health Board involved in the shared care trial is notified by sponsor/CRO that a regulatory inspection, audit or a modification is required, it is essential this is communicated as soon as possible to all those involved within or across the NHS Trust(s)/Health Board(s).

5. Close out

5.1 If the shared care trial has taken place across more than one NHS Trust/Health Board, each should close out independently.

5.2 Sponsor/CRO should be asked to clarify with each NHS Trust/Health Board involved whether separate or joint archiving should be undertaken, or if all records should be returned to sponsor to enable:

- statistical analysis
- development of a clinical trial summary report
- dissemination of results, i.e., via recruiting trial location and in line with trial protocol

6. Long term follow up

6.1 There should be agreement within or across the NHS Trust(s)/Health Board(s), on how participants long term follow up requirements will be met. Follow up should be determined, defined and planned in line with any HTA, accreditation, regulatory, standard of care or trial protocol requirements, so compliance can be met. Any trial protocol requirements should be included in the Shared Care Study Specific Scheme of Delegation.

Acknowledgements

The following NHS Trusts within the Advanced Therapy Treatment Centre (ATTC) network, have shared their knowledge regarding the establishment of successful shared care ATMP trials, in order to produce this document:

Manchester University NHS Foundation Trust
Alison Walker, Senior Research Operational Manager
Gemma Donohoe, Clinical Trials Manager

Northern Care Alliance NHS Foundation Trust
Kathryn Slevin, Research Delivery Lead
Louise Harrison, Lead Nurse
Tracy Marsden, Lead Nurse

The Christie NHS Foundation Trust
Camille Nicholls, Senior Clinical Research Nurse
Claire Howard, iMATCH Project Manager
Colette Mann, Interim iMATCH Programme Manager
Terry Wood, Research Manager
Victoria Williams, iMATCH Programme Manager

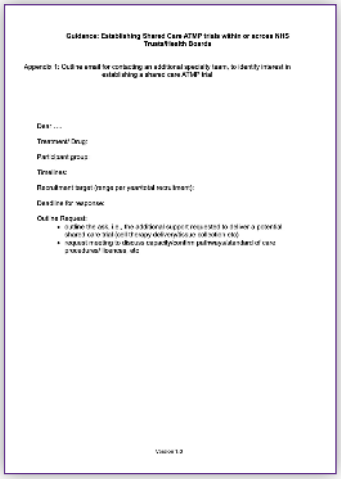
This document also includes feedback from wider ATTC network NHS Trusts and Health Boards, following a consultation period.

Appendices

Click on the thumbnail images below to download each appendix

Appendix 1:

Outline email for contacting an additional specialty team, to identify interest in establishing a shared care ATMP trial

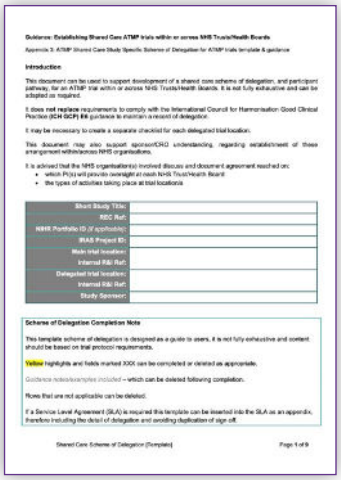


Appendix 2:

Feasibility checklist & record of agreement for ATMP trials

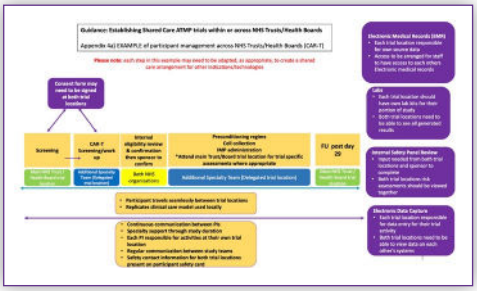
Appendix 3:

Shared care study specific scheme of delegation for ATMP trials



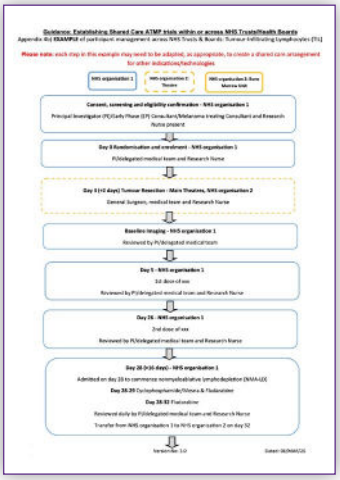
Appendix 4a:

Participant management across NHS Trusts (CAR-T)



Appendix 4b:

Participant management across NHS Trusts (TIL)



Appendix 5:

Referral template for ATMP trials