Archiving of Clinical Trial Data and Essential Documentation

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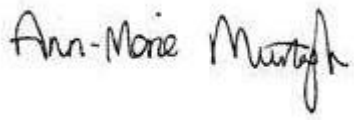
Approved by	Ann-Marie Murtagh, Director KHP-CTO  30/12/2025
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CHANGE HISTORY			
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9th Nov 2010	2.0	Transfer to King's Health Partner Livery and minor amendment to archiving process. Glossary update.	Jackie Powell
26th Feb 2013	3.0	Review of archiving process. Administrative change from JCTO to KHP-CTO.	Jackie Powell
10th Oct 2013	4.0	Amended to include archiving of traceability documentation for ATMPs.	Jackie Powell
28th Nov 2016	5.0	Update of Glossary terms, scheduled review, and inclusion of section on considerations for archiving electronic data (section 4.3) and adjustment of section 4.5 to apply only to paper data and documentation.	Jackie Pullen
8th May 2017	6.0	Amendment of section 4.5 to apply to paper and electronic data.	Jackie Pullen
1st Oct 2018	6.1	Minor amendment to include trials managed by KHP-CTO.	Jackie Pullen
26th Jun 2020	6.2	Minor amendment to clarify scope and administrative changes.	Jackie Pullen
27th Sep 2022	6.3	4.1.3 updated as per imminent new guidelines and current practice.	Jackie Pullen
16 Oct 2025	7.0	Scheduled review to clarify details of current process Amending retention period to 25 years in line with UK Clinical Trial Regulations coming into force April 2026.	Ann-Marie Murtagh
19 Dec 2025	7.1	Addition of procedure for TMF destruction for Clinical Trials Sponsored or Co-Sponsored by Partner Trusts.	Ann-Marie Murtagh

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1.0 BACKGROUND AND PURPOSE

The purpose of this SOP is to define the local procedure for archiving 1) essential documents for commercially sponsored Research Studies hosted by the Partner Trusts, and 2) essential documents for Clinical Trials that are Sponsored or Co-Sponsored by the Partner Trusts; and for these essential documents' subsequent transfer to archive as required by GCP and the Regulations.

2.0 SCOPE

The KHP-CTO are responsible for archiving the following which are in scope for this SOP:

1. Essential documents for all commercial Research Studies hosted by the Partner Trusts (to be filed in ISFs).

2. Essential documents for all Clinical Trials that are Sponsored or Co-Sponsored by the Partner Trusts (to be filed in TMFs).

3. Participant source data (e.g. patient medical records) for commercial Research Studies that are hosted by the Partner Trusts.

With respect to Trial Locations for Clinical Trials that are Sponsored or Co-Sponsored by the Partner Trusts **that are outside** of the Partner Trusts; the archiving process will be specific to that Trial Location. The KHP-CTO will maintain oversight for archiving at these Trial Locations on behalf of the Partner Trusts. This oversight will include assurance that the Trial Location adheres to local SOPs, GCP and the Regulations.

The R&D Departments at the Partner Trusts are responsible for the following and so these are <u>not in scope</u> for this SOP:

1. Essential documents for all non-commercial Research Studies that are hosted by the Partner Trusts (to be filed in ISFs).

2. Essential documents for all non-commercial Research Studies (excluding Clinical Trials) that are Sponsored or Co-Sponsored by the Partner Trusts (to be filed in TMFs).

3. Participant source data (e.g. patient medical records) for non-commercial Research Studies that are hosted by the Partner Trusts.

3.0 PROCEDURE

Retention of essential documents must safeguard participant well-being, data integrity, and allow traceability. All essential documents in scope must be archived in accordance with this SOP. This applies irrespective of the format in which the essential documents are generated i.e. digital or physical.

3.1 Retention of essential documents in the ISF for commercially sponsored Research Studies hosted by the Partner Trusts

ICH GCP E6 (R2) states it's the responsibility of the Sponsor to inform the PI at the Trial Location as to when the ISF need no longer be retained.

If the study documentation indicates the ISF need no longer be retained:

- If the Sponsor has given the PI permission to destroy the ISF, the KHP-CTO may destroy the ISF.

- If the Sponsor has not given the PI permission to destroy the ISF, the KHP-CTO should ask the Sponsor for permission to destroy the ISF.

3.2 Retention of essential documents in the TMF for Clinical Trials Sponsored or Co-Sponsored by the Partner Trusts

TMFs should be retained:

- 30 years after Last Participant Follow-Up (LPFU) for ATMPs

- 25 years after LPFU for Clinical Trials (excluding ATMPs) that:
    - Support or are intended to support a Marketing Authorisation
    - Involve novel mechanisms of action
    - Involve vulnerable populations (i.e. paediatric populations)
    - Involve reproductive risk or germline exposure
    - Have Trial Locations in non-UK countries where those countries have longer regulatory retention periods
    - Involve medical devices or combination products

- 5 years after LPFU for all other Clinical Trials

3.2.1 Conflicting TMF Rention Periods in Study Documentation

Minimum retention periods for TMFs may be stated in the following study documents listed below. The minimum retention periods stated in this SOP supersede any minimum retention periods listed in these documents.

- The protocol
- The Informed Consent Form
- The Participant Information Sheet
- The Clinical Trial-specific SOPs
- The approved IRAS form
- The approved amendment tools

3.3 External Archiving Services

The KHP-CTO has a contract with an external company for archiving services. If a Partner Trust has archiving requirements that are not the KHP-CTO's responsibility, the Partner Trust may use this service if they have no archiving facilities of their own. Partner Trusts using this service must ensure access to archived documents is restricted, protected from unauthorised changes, and the lifecycle of these documents (collection through to disposal) must be governed to ensure integrity, traceability and authenticity.

To use this service, Partner Trusts must procure authorisation from the Named Archivist within the KHP-CTO.

3.4 Archiving Arrangements for Participant Source Data

The KHP-CTO are responsible for archiving participant source data (e.g. patient medical records) for commercial Research Studies that are hosted by the Partner Trusts. The KHP-CTO are not responsible for archiving participant source data for non-commercial Research Studies that are hosted by the Partner Trusts.

The KHP-CTO has a contractual arrangement with an approved external archiving provider for the long-term storage of participant source data generated or retained for commercial research hosted by the Partner Trusts.

Where a Trial Location identifies that participant source data must be archived:

1. The Trial Location Team will inform the Named Archivist or delegate at the KHP-CTO about their requirement to archive participant source data.

2. The Named Archivist or delegate will send the materials required for archiving (i.e. the barcodes, archive clips, archiving boxes) to the Trial Location Team.

3. The Trial Location Team is responsible for the content and structure of the participant source data to be stored in the archival boxes.

4. During the archival process, The Trial Location Team will restrict access to the participant source data to authorised personnel only, to protect against unauthorised access, alteration, loss, or destruction.

5. Once the above actions are complete, the Trial Location Team should inform the Named Archivist or delegate, and arrange for the Named Archivist or delegate to visit the Trial Location.

6. The boxes will be sealed by the Named Archivist or delegate using archive cable ties. This will ensure unauthorised attempts to open the boxes will be evident.

7. Barcode(s) stickers will be stuck to the boxes where clearly visible.

8. The Named Archivist or delegate will arrange collection of the boxes with the external company and ensure MATTS/EDGE are updated.

3.5 Electronic Data Archiving

The use of electronic systems for various Research Study-related activities (i.e. data management, statistical analysis, reporting, trial management), means that electronic data also needs to be retained. The electronic data may be held on a server or other media (e.g. a USB stick).

It is recommended that more than one copy of any electronic data is retained (i.e. a copy is placed on a back-up server, or a copy is placed on back-up media stored in a separate location).

Consideration should be given to storing the electronic data in different formats on different types of media, or on the same media from different manufacturers.

Access to archived electronic data must be restricted, protected from unauthorised changes, and its lifecycle (collection through to disposal) must be governed to ensure integrity, traceability and authenticity.

It's important that access to electronic data is maintained until expiry of the retention period. If it's identified that electronic data stored on certain media may deteriorate or become obsolete, the transfer of this electronic data to new media should be undertaken.

The process of transferring electronic data from one media to another will be documented to confirm all electronic data have been transferred and can be accessed from the new media.

3.6 Preparation for Archiving

Before archiving, it's important to assess the contents of the ISF or TMF for any records that could be disposed of, and for any records requiring special attention to ensure they don't deteriorate i.e. photographs should be placed into acid-free folders or sleeves.

If records are assessed as being likely to deteriorate, the records should be copied to a suitable media so they don't deteriorate.

If any essential documents are supposed to go into the TMF/ISF but it's been decided they'll be archived separately to the TMF/ISF; the location of these essential documents must be documented in the TMF/ISF.

In the case of electronic data, if it's been transferred to a new media for archiving, the transfer should be validated and fully documented so it can be subjected to an audit. This ensures it can be demonstrated that there's been no loss of, change to, or corruption of the electronic data or metadata, and authenticity has been maintained.

Ensure all the essential documents are archived:

1. For the TMF, this includes (but is not limited to) pharmacy records, laboratory records, statistics documentation, correspondence between the KHP-CTO and sponsor.

2. For the ISF, this includes (but is not limited to) confirmation of capacity and capability at the Trial Location, the delegation of duties log, current and superseded protocols and amendments.

The CI or their delegate is responsible for addressing any issues identified with the contents of the TMF prior to archiving.

The PI or their delegate is responsible for addressing any issues identified with the contents of the ISF prior to archiving.

When a Sponsor Team/Trial Location Team requests archiving for the TMF/ISF, the following procedure applies:

1. The Named Archivist or delegate will send the materials required for archiving (i.e. the Clinical Trial Archive Document template, barcodes, archive clips, archiving boxes) to the Sponsor Team/Trial Location Team.

2. If requested by the CI/PI, the Named Archivist or delegate will visit the Sponsor Team/Trial Location Team to assess the archiving requirements.

3. Before archiving TMFs for Clinical Trials Sponsored or Co-Sponsored by the Partner Trusts, the Named Archivist or delegate will confirm that the close-out visit has been completed, the database has been locked, and the Clinical Study Report has been finalised and published.

4. Before archiving ISFs for commercial Research Studies hosted by the Partner Trusts, the KHP-CTO Commercial Trial Facilitators will ensure the study is closed, and the Sponsor has confirmed that archiving can proceed.

5. The Sponsor Team/Trial Location team will prepare the physical records and electronic data (on the appropriate media) for archiving by:

5.1 Removing documentation from any lever arch file(s) (physical records only).

5.2 Removing all paperclips or bulldog clips (physical records only).

5.3 Placing paperwork onto blue archive clips (physical records only).

5.4 Packing physical records and electronic data (on the appropriate media) in the standard archiving boxes with lids. **Please note**, where the Sponsor Team and the Trial Location Team are located at the same Trial Location, the ISF and TMF can go into the same box as long as they are clearly separated.

6. If, under exceptional circumstances, the KHP-CTO have agreed to take responsibility for archiving participant source data (e.g. patient medical records) for a non-commercial Research Study; the Trial Location Team must archive these records in a separate box and the content must be clearly labelled.

7. Once the above actions are complete, the Sponsor Team/Trial Location Team should inform the Named Archivist or delegate, and the Named Archivist or delegate will review the records in the boxes and complete the Clinical Trial Archive Document (see Section 4.1).

8. The original Clinical Trial Archive Document will be filed in the TMF/ISF. A copy of the Clinical Trial Archive Document will be given to the CI/PI for their records. A copy of the Clinical Trial Archive Document will be retained for the KHP-CTO's records.

9. The boxes will be sealed by the Named Archivist or delegate using archive cable ties. This will ensure unauthorised attempts to open the boxes will be evident.

10. Barcode(s) stickers will be stuck to the boxes where clearly visible.

11. The Named Archivist or delegate will arrange collection of the boxes with the external company and ensure MATTS/EDGE are updated.

3.7 Retrieval of Archived Boxes

Archived boxes may be retrieved from the external company per the Document Retrieval Process Map (see Section 5.2):

Essential documents must be available at all times for inspection by regulatory bodies in accordance with the Regulations.

Essential documents may be retrieved to meet research transparency expectations.

Only the Named Archivist can instigate the retrieval of an archived box. The CI/PI must send a written request to the Named Archivist for the retrieval of an archived box. Telephone requests will not be accepted. The required box(es) will be identified by the Named Archivist or delegate, and arrangements will be made with the external company so the box(es) will be sent by courier to the CI/PI.

3.8 Re-Archiving Retrieved Boxes

Prior to re-archiving retrieved boxes, if any records have been added/removed, a new Clinical Trial Archive Document must be prepared and filed in the TMF/ISF.

The retrieved boxes will then be dispatched to the external company in compliance with Section 3.5 above.

3.9 TMF Destruction

Task	Responsibility	Activity

1	Non-Commercial Trials Manager or delegate	On the first Monday in June (the annual review point), commence reviewing the archived TMFs using the Iron Mountain online interface.
		
		Identify if any Clinical Trials have met the following minimum retention periods (use the protocols to work out which minimum retention periods apply):
		
		• 30 years after Last Participant Follow-Up (LPFU) for ATMPs
		
		• 25 years after LPFU for Clinical Trials (excluding ATMPs) that:
		  ○ Support or are intended to support a Marketing Authorisation
		  ○ Involve novel mechanisms of action
		  ○ Involve vulnerable populations (i.e. paediatric populations)
		  ○ Involve reproductive risk or germline exposure
		  ○ Have Trial Locations in non-UK countries where those countries have longer regulatory retention periods
		  ○ Involve medical devices or combination products
		
		• 5 years after LPFU for all other Clinical Trials

2	Non-Commercial Trials Manager or delegate	For those Clinical Trials with a minimum retention period of 5 years, and that have met this minimum retention period; check with the CRAs to see if the Clinical Trials have: • Had a history of significant safety signals or SUSARs; and/or • Undergone regulatory inspection

		If so, the minimum retention period for these Clinical Trials will switch to 25 years. If this is the case, an EDGE note must be made.
3	Non-Commercial Trials Manager or delegate	For those Clinical Trials where the minimum retention periods have been met (taking **Step 2** into account), check the EDGE notes to see if there's a reason why the TMFs have not yet been destroyed.
4	Non-Commercial Trials Manager or delegate	If the EDGE notes reflect there's a reason why the minimum retention periods have been met for Clinical Trials and the TMFs have not yet been destroyed, write to the following individuals and ask if the reason still applies: • CI • Research Manager at the Sole Sponsor/NHS Co-Sponsor • Sole Sponsor/NHS Co-Sponsor R&D Dept. Representative Add an EDGE note with the outcome. If the EDGE notes reflect there isn't a reason why the minimum retention periods have been met for Clinical Trials and the TMFs have not yet been destroyed, write to the following individuals and ask if there's any **pending or active regulatory or legal action with respect to the Clinical Trials:** • CI • Research Manager at the Sole Sponsor/NHS Co-Sponsor • Sole Sponsor/NHS Co-Sponsor R&D Dept. Representative Add an EDGE note with the outcome.
5	Non-Commercial Trials Manager or delegate	If no response is received from any of the individuals listed in **Step 4** within 30 calendar days, it should be assumed that there is no pending nor active regulatory nor legal action with respect to the Clinical Trials. Add an EDGE note with the outcome and go to **Step 7**. If any responses are received from any of the individuals listed in **Step 4** within 30 calendar days, and there's no indication of pending nor active regulatory nor legal action with respect to the Clinical Trials; add an EDGE note with the outcome and go to **Step 7.** If any responses are received from any of the individuals listed in **Step 4** within 30 calendar days, and there's an indication of pending or active regulatory or legal action with respect to the

		Clinical Trials; add an EDGE note with the outcome and go to **Step 6.**
6	Non-Commercial Trials Manager or delegate	Create/update the EDGE notes to record the reasons why the minimum retention periods have been met for the Clinical Trials and the TMFs have not yet been destroyed. List/update the names, phone numbers and email addresses for the following individuals in the EDGE notes: • CI • Research Manager at the Sole Sponsor/NHS Co-Sponsor • Sole Sponsor/NHS Co-Sponsor R&D Dept. Representative Take no further action with respect to the Clinical Trials referred to in this **Step 6** until the next annual review point.
7	Non-Commercial Trials Manager or delegate	If the TMF has not yet been archived, ask the CRA to arrange for it to be disposed of in the confidential waste. If the TMF has been archived, contact Iron Mountain to instruct them to dispose of the TMF. • Create an EDGE note to record this instruction • Upload a copy of the correspondence with Iron Mountain to EDGE
8	CRA	Upon receipt of the instruction from the Non-Commercial Trials Manager or delegate per **Step 7**, work with the Sponsor Team to arrange for the TMF to be disposed of in the confidential waste. • Create an EDGE note to record completion of this task

4.0 RELATED TEMPLATES

4.1 Clinical Trial Archive Document

5.0 RELATED DOCUMENTS

5.1 Archiving Process Map

5.2 Document Retrieval Process Map

Appendix 1

GLOSSARY

Advanced Therapy Medicinal Product (ATMP) - A type of Clinical Trial involving a medicine based on genes, cells, or engineered tissues that is intended to treat, prevent, or diagnose disease by modifying biological functions at a cellular or genetic level.

Case Report Form: A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.

Chief Investigator (CI) – The overall lead researcher for a Research Study (Outside the UK the term 'Coordinating Investigator', 'Principal Investigator' or 'Investigator' may be used for the overall lead researcher for a Research Study). Chief Investigators are responsible for the overall conduct of a Research Study.

Clinical Research Associate (CRA) – The staff member(s) employed by the KHP-CTO who are responsible for the initiation phase, routine phase, and close down phase of a Clinical Trial.

Clinical Study Report (CSR) – A Clinical Study Report is a comprehensive, regulatory-standard document that provides a complete and structured account of a Clinical Trial's methods, conduct, results, and conclusions. It includes all analyses — efficacy, safety, and protocol deviations — and is used by regulators, Sponsors, and auditors to verify the integrity and outcomes of the Clinical Trial. Academic publication cannot double as a Clinical Study Report, a journal article does not meet the regulatory requirements for a Clinical Study Report. A funder report cannot double as the Clinical Study Report, a funder report does not meet the regulatory requirements for a Clinical Study Report.

Clinical Trial aka **Clinical Trial of an Investigational Medicinal Product (CTIMP)** - Any investigation in human participants (other than a non-interventional trial) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products and/or to identify any adverse reactions to one or more such products and to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety and/or efficacy of those products. For the avoidance for all doubt, ATMPs are considered Clinical Trials.

Clinical Trial Archive Document – The form which must be completed for each box sent to archive. The form contains details of the study, investigator, archivist and box contents. A copy should be present in each box archived, with a copy held at the Trial Location and the original held at the KHP-CTO.

Co-Sponsors – Two organisations that take responsibility for the initiation, management and financing (or arranging of the financing) in relation to a Clinical Trial. The Co-Sponsors agree how the sponsor functions for the Clinical Trial are divided between themselves and document this accordingly.

Commercial Trials Facilitator (CTF) - The staff member(s) employed by the KHP-CTO who support commercially sponsored Research Studies hosted by the Partner Trusts.

End of Trial (EoT) – The end of the trial as defined in the protocol. The end of the trial is typically expressed as a condition-based event, not a predetermined date.

Good Clinical Practice (GCP) - An international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding participants and ensuring Clinical Trials produce reliable, scientifically valid results.

ICH GCP E6 (R2) - The internationally recognised ethical and scientific quality standard for the design, conduct, recording and reporting of Clinical Trials, providing assurance that participants' rights, safety and well-being are protected and that trial data are credible. The principles of ICH GCP E6 (R2) are incorporated into the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), and are legally binding for Clinical Trials in the UK.

Investigator Site File (ISF) – The Trial Location-specific set of essential documents held at the Trial Location by the Principal Investigator, demonstrating how the trial was conducted at that particular location and that the investigator complied with the protocol, sponsor instructions, and GCP.

King's Health Partners (KHP) – King's Health Partners brings together research, education and clinical practice across three NHS Foundation Trusts - Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust and South London and Maudsley NHS Foundation Trust - and a world-leading university, King's College London.

King's Health Partners Clinical Trials Office (KHP-CTO) – The department established by KHP to 1) undertake the governance, contracting and financial management for commercial research hosted by KHP, and 2) undertake the monitoring and regulatory compliance for non-commercial Clinical Trials sponsored by KHP.

Last Participant Follow-Up (LPFU) - The date on which the final Clinical Trial-related follow-up activity is completed for the last remaining participant in the study. This is defined in the protocol. Please note, depending on the protocol and regulatory notifications, it is possible for LPFU to occur **after** EoT.

Marketing Authorisation – A regulatory approval granted by the competent authority that permits a medicinal product to be placed on the market, confirming that its quality, safety, and efficacy have been adequately demonstrated.

MATTS – Stands for MedSciNet Active Trial Tracking System. This is the research management system used by the KHP-CTO to undertake their delegated responsibilities.

Medicines & Healthcare products Regulatory Agency (MHRA) – The UK government agency responsible for regulating medicines, medical devices, and Clinical Trials. In the context of Clinical Trials, the MHRA i) acts as the licensing authority for Clinical Trials, ii) reviews the scientific, quality, and safety aspects of a Clinical Trial application, iii) issues CTAs, iv) oversees GCP and GMP inspections, v) monitors pharmacovigilance and safety reporting, and vi) enforces compliance with UK medicines legislation.

Named Archivist – The named individual at the KHP-CTO who's ultimately responsible for ensuring archiving requirements are met.

Non-Commercial Trials Manager – The most senior member of the KHP-CTO Non-Commercial Team.

Partner Trusts – Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

Principal Investigator (PI) - The individual primarily responsible for the conduct of a Research Study at a Trial Location.

Regulations – Statutory Instrument 2004 No. 1031 – Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), and Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products, retained by virtue of the European Union (Withdrawal) Act 2018.

Research & Development Department (R&D Dept.) – The NHS department responsible for confirmation of capacity and capability for all clinical research.

Research Ethics Committee (REC) – A national independent body consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and well-being of human subjects involved in a Clinical Trial, and to provide public assurance of that protection by, among other things, expressing an opinion on the Clinical Trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform Clinical Trial participants and obtain their informed consent.

Research Study - Any health or social care research study (including Clinical Trials) involving patients, their data, or their tissue. Research studies include those involving NHS patients, NHS service users, NHS staff, NHS facilities, NHS data, or NHS-held tissue, as well as certain non-NHS settings where the research raises comparable ethical or legal considerations.

Sponsor - The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging of the financing) of a Research Study. Note: The Regulations allow for two or more persons or bodies to take on responsibility for Sponsor functions.

Sponsor Team – The team selected by the CI to undertake the sponsorship functions of the Research Study.

Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis upon which Quality Systems and Processes are conducted and monitored against.

Statutory Instrument (SI) - A legal document made by a Minister or other authority under powers given by an Act of Parliament, which has the force of law.

Trial Location - means a hospital, health centre, surgery or other establishment, or facility or premises at or from which a Clinical Trial, or any part of such a Clinical Trial, is conducted.

Trial Location Team - The team selected by the PI to undertake the Trial Location functions of the Research Study.

Trial Master File (TMF) – Is the sponsor-held collection of essential documents that, taken together, allow regulators to assess whether a Clinical Trial was properly designed, authorised, conducted, monitored, and reported in accordance with GCP and the Regulations. It is the sponsor's formal record of overall trial compliance and governance.

Appendix 2

BACKGROUND FOR TMF RETENTION PERIODS IN THIS SOP

The following clauses from The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) have been used to prepare this SOP:

- *2 (1) "conditions and principles of good clinical practice" means the conditions and principles specified in Schedule 1;*

- *28 (1)* ***No person shall (a) conduct a clinical trial****; or (b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),* ***otherwise than in accordance with the conditions and principles of good clinical practice****.*

- *31A (7)* ***The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial…***

Please note, Schedule 1 in The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (Conditions and principles of good clinical practice and for the protection of clinical trial subjects) does not restate the requirements listed in ICH GCP E6 (R2). However, the MHRA decide how the conditions and principles of good clinical practice are interpreted, and since 2016, the MHRA have been using ICH GCP E6 (R2) to make their interpretation.

Therefore, the following clauses from ICH GCP E6 (R2) have been used to prepare this SOP:

- *4.9.5. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12)*

- *5.5.11. The sponsor specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or if needed by the sponsor.*

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products has also been used to prepare this SOP as it was assimilated into UK law by virtue of the European Union (Withdrawal) Act 2018. The relevant clauses are:

- *Article 15, Traceability, 1. The holder of a marketing authorisation for an advanced therapy medicinal product shall establish and maintain a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging,*

storage, transport and delivery to the hospital, institution or private practice where the product is used.

- *Article 15, Traceability, 4. The marketing authorisation holder shall keep the data referred to in paragraph 1 for a minimum of 30 years after the expiry date of the product, or longer if required by the Commission as a term of the marketing authorisation.*