Archiving of Clinical Trial Data and Essential Records

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Contents

1. BACKGROUND AND PURPOSE

The purpose of this SOP is to define the local procedure for archiving 1) Essential Records and Source Records for commercial Research Studies hosted by the Partner Trusts, 2) Essential Records for Clinical Trials (CTIMPs) that are Sponsored or Co-Sponsored by the Partner Trusts; and for these records' subsequent transfer to archive as required by ICH GCP E6 (R3), and the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (the Regulations).

Regulation 31A of the Regulations (with respect to New Rules Trials) mandates retention of Essential Records for at least 25 years after EoT, or longer if required for Marketing Authorisation purposes.

ICH GCP E6 (R3) requires Essential Records to be complete, legible, and readily available for inspection throughout the retention period.

2. SCOPE

This table shows the records that the KHP-CTO are, and are not, responsible for:

	Non-Commercial Research			Commercial Research
	Sponsored by the Partner Trusts		Hosted by the Partner Trusts	Hosted by the Partner Trusts
	Clinical Trials	Non-Clinical Trial Research Studies	All Research Studies	All Research Studies
Essential Records	**KHP-CTO** responsible for archiving TMF and Partner Trust-ISFs	**Partner Trust R&D Dept**. responsible for archiving TMF and Partner Trust-ISFs (Partner Trust can use the KHP-CTO's Iron Mountain account at cost)	**Partner Trust R&D Dept**. responsible for archiving Partner Trust-ISFs (Partner Trust can use the KHP-CTO's Iron Mountain account at cost)	**KHP-CTO** responsible for archiving Partner Trust-ISFs
Source Records	**Partner Trust R&D Dept**. responsible for archiving Partner Trust-Source Records, if so requested (Partner Trust can use the KHP-CTO's Iron Mountain account at cost)	**Partner Trust R&D Dept**. responsible for archiving Partner Trust-Source Records, if so requested (Partner Trust can use the KHP-CTO's Iron Mountain account at cost)	**Partner Trust R&D Dept**. responsible for archiving Partner Trust-Source Records, if so requested (Partner Trust can use the KHP-CTO's Iron Mountain account at cost)	**KHP-CTO** responsible for archiving Partner Trust-Source Records, if so requested

For Clinical Trials Sponsored by the Partner Trusts, with respect to Trial Locations outside the Partner Trusts:

- The Trial Locations are responsible for archiving the ISFs (and Source Records if so requested)
- The KHP-CTO will maintain oversight of ISFs archived by these Trial Locations, and provide assurances that the Trial Locations adhere to local SOPs, GCP and the Regulations

3. PROCEDURE

3.1 Archiving ISFs for commercial Research Studies hosted by the Partner Trusts

Task	Responsibility	Activity
1	Principal Investigator or delegate	Upon receipt of written Sponsor approval to archive the Investigator Site File (ISF), contact the KHP-CTO Commercial Team and let them know. Email: KHPCTOcommercial@kcl.ac.uk
2	Commercial Trials Facilitators	Send the **KHP-CTO Study Closure & Archiving Email** to the Principal Investigator or delegate
3	Principal Investigator or delegate	When the actions in the **KHP-CTO Study Closure & Archiving Email** are completed: • Ensure archiving fees are included in a Request for Invoice (RFI) • Confirm the Sponsor or Contract Research Organisation (CRO) approves the RFI • Send the RFI (approved by the Sponsor or CRO) to the KHP-CTO Finance team at finance-khpcto@kcl.ac.uk • Contact the KHP-CTO Commercial Team to book an archiving appointment by emailing: KHPCTOcommercial@kcl.ac.uk Please note, the **KHP-CTO Study Closure & Archiving Email** contains the **KHP-CTO Clinical Trial Archive Document** template (see Related Templates) which you'll need later.
4	Commercial Trials Facilitators	Forward the request from the Principal Investigator or delegate to the Operations Manager.

5	Operations Manager or delegate	Agree a mutually convenient date with the PI (or delegate) for completion of final archiving activities.

6	Principal Investigator or delegate	Ensure the ISF:
		• Contains the Pharmacy Site File (PSF)
		• Does not contain:
		  ○ Essential Records that should go into the TMF only; nor
		  ○ Source Records
		
		Ensure all documents in the ISF are secured using document clips where appropriate.

7	Operations Manager or delegate	Gather materials required for preparation of hard-copy records: • Iron Mountain boxes (branded) • Iron Mountain incoming records jacket • Archive box labels
8	Operations Manager or delegate	Visit the PI (or delegate) for completion of final archiving activities, and bring the materials required for preparation of hard-copy records. Prepare hard-copy records for archiving: • Make reasonable efforts to remove plastic wallets (ink may adhere to plastic over time, reducing legibility) • Make reasonable efforts to remove metal clips and staples (these may rust and damage records) • Ensure all pages are hole-punched
9	Principal Investigator or delegate	If electronic records are to be **uploaded to a Sponsor-controlled repository** and there's no expectation of maintaining a local copy: • Upload the electronic records to the Sponsor-Controlled repository; and • Notify the Named Archivist.
10	Named Archivist or delegate	If electronic records are to be **uploaded to a Sponsor-controlled repository** and there's no expectation of maintaining a local copy, ensure that:

		• The details are noted on EDGE • Access remains reasonably available • Access is appropriately restricted by the Sponsor • The process for obtaining timely access is documented (e.g. for audit, inspection or transparency requests)
11	Principal Investigator or delegate	If there's an expectation that **a local copy of the electronic records must be maintained**, these must be downloaded to storage media to be placed in Iron Mountain boxes: • High-quality, durable storage media should be used • Two separate forms of storage are recommended (e.g. an external hard drive and a USB device) • **Please note**, Iron Mountain will not accept storage devices containing a power source • The media must meet Sponsor contractual requirements (if applicable) • Any requirement for periodic data integrity checks should be documented in the **KHP-CTO Clinical Trial Archive Document** • File formats should align with UK Data Service recommended preservation formats (see Related Documents) • Any passwords required to access the device or files must be clearly recorded in the **KHP-CTO Clinical Trial Archive Document**
12	Principal Investigator or delegate	Place hard-copy records and electronic records (if there's an expectation that a local copy of the electronic records must be maintained) in the boxes: • Use Iron Mountain branded boxes only • Do not overfill boxes • Lids must sit flush with box sides and handholds must remain usable • Sign and date the **KHP-CTO Clinical Trial Archive Document** for each box to confirm the box contents are accurately described
13	Operations Manager or delegate	Sign and date the **KHP-CTO Clinical Trial Archive Document** for each box to confirm the box contents are accurately described Place the original signed **KHP-CTO Clinical Trial Archive Document** inside each box and retain a copy

		Secure the lid using cable ties to indicate tamper evidence Save a copy of the signed **KHP-CTO Clinical Trial Archive Document(s)** to EDGE and the SharePoint.
14	Principal Investigator or delegate	Store sealed boxes in a secure, access-restricted location pending collection
15	Operations Manager or delegate	Arrange collection with Iron Mountain. Update EDGE to reflect the ISF has been archived.
16	Principal Investigator or delegate	Facilitate access for Iron Mountain personnel to collect the boxes.

3.2 Destruction of ISFs for commercial Research Studies hosted by the Partner Trusts

Task	Responsibility	Activity
1	Named Archivist	Track retention periods and any periodic review requirements in accordance with the study contract and applicable regulatory requirements.
2	Named Archivist	If required for audit, inspection, legal, regulatory or periodic review purposes, arrange recall of archive boxes in accordance with the recall process (see Section 3.7 below).
3	Named Archivist or delegate	At the end of the contractual retention period, contact the Sponsor in a timely manner to request written approval for destruction of the ISF (unless otherwise specified in study contract).
4	Named Archivist or delegate	On receipt, save the Sponsor's written approval for destruction on EDGE and on the SharePoint.
5	Named Archivist or delegate	If the Sponsor requires continued ISF retention, ask the Commercial Trials Contracts Manager to: • Arrange for the study contract to be amended to extend the retention period; and

		• Ensure appropriate funding arrangements are agreed for extended storage.
6	Named Archivist or delegate	Upon receipt of the Sponsor's written approval for destruction: • Arrange for Iron Mountain to destroy the ISF; or • Recall the ISF from archive and dispose of it in the confidential waste. Update EDGE to reflect the ISF has been destroyed.

3.3 Archiving Source Records for commercial Research Studies hosted by the Partner Trusts

Task	Responsibility	Activity
1	Principal Investigator or delegate	If there's a need to archive Source Records after the Sponsor has completed the Close Out Visit, contact the KHP-CTO Commercial Team to arrange archiving. Email: KHPCTOcommercial@kcl.ac.uk
2	Commercial Trials Facilitators	Forward the request from the Principal Investigator or delegate to the Operations Manager.
3	Operations Manager or delegate	Agree a mutually convenient date with the PI (or delegate) for completion of archiving activities.
4	Principal Investigator or delegate	Ensure the Source Records do not contain Essential Records that should go into the ISF or TMF. Ensure all documents in the ISF are secured using document clips where appropriate.
5	Operations Manager or delegate	Send materials required for preparation of Source Records to the PI (or delegate): • Iron Mountain boxes (branded) • Iron Mountain incoming records jacket • Archive box labels • Blank **KHP-CTO Clinical Trial Archive Documents** (see Related Templates)

6	Principal Investigator or delegate	Prepare Source Records for archiving: • Make reasonable efforts to remove plastic wallets (ink may adhere to plastic over time, reducing legibility) • Make reasonable efforts to remove metal clips and staples (these may rust and damage records) • Ensure all pages are hole-punched
7	Operations Manager or delegate	Visit the PI (or delegate) for completion of archiving activities.
8	Principal Investigator or delegate	Place Source Records in the boxes: • Use Iron Mountain branded boxes only • Do not overfill boxes • Lids must sit flush with box sides and handholds must remain usable • Sign and date the **KHP-CTO Clinical Trial Archive Document** for each box to confirm the box contents are accurately described
9	Operations Manager or delegate	Sign and date the **KHP-CTO Clinical Trial Archive Document** for each box to confirm the box contents are accurately described Place the original signed **KHP-CTO Clinical Trial Archive Document** inside each box and retain a copy Secure the lid using cable ties to indicate tamper evidence Save a copy of the signed **KHP-CTO Clinical Trial Archive Document(s)** to EDGE and the SharePoint.
10	Principal Investigator or delegate	Store sealed boxes in a secure, access-restricted location pending collection
11	Operations Manager or delegate	Arrange collection with Iron Mountain. Update EDGE to reflect that Source Records have been archived.
12	Principal Investigator or delegate	Facilitate access for Iron Mountain personnel to collect the boxes.

3.4 Destruction of Source Records for commercial Research Studies hosted by the Partner Trusts

Task	Responsibility	Activity
1	Named Archivist	Track retention periods. Retain the Source Records for the same retention period as the corresponding ISF.
2	Named Archivist	If required for audit, inspection, legal, regulatory or periodic review purposes, arrange recall of archive boxes in accordance with the recall process (see Section 3.7 below).
3	Named Archivist or delegate	When the Sponsor provides written approval for destruction of the ISF that corresponds to the Source Records: • Arrange for Iron Mountain to destroy the Source Records; or • Recall the Source Records from archive and dispose of them in the confidential waste. Update EDGE to reflect the Source Records have been destroyed.

3.5 Archiving TMFs and Partner Trust-ISFs for Clinical Trials sponsored by the Partner Trusts

Task	Responsibility	Activity
1	Clinical Research Associate	Upon requesting the TMF and Partner Trust-ISF from the Chief Investigator or delegate, ensure the Chief Investigator or delegate provides an inventory with the documents. The inventory should provide a brief description of each document, and should use the document definitions starting on page 74 of ICH GCP E6 (R3) in (See ICH GCP E6 (R3) in Related Documents).
2	Clinical Research Associate	Ensure the End of Trial (EoT) notification (sent to the MHRA by the Chief Investigator or delegate) and the EoT acknowledgement (sent to the Chief Investigator or delegate

		by the MHRA) are saved on the SharePoint in the Clinical Trial-specific folder.

3	Clinical Research Associate	Review the TMF and Partner Trust-ISF.
		
		The TMF and Partner Trust-ISF can go into the same box, **but they must be kept separate**
		
		Ensure the TMF:
		• Contains the Sponsor File (SF)
		  ○ The files in the TMF and SF do not need to be de-duplicated
		• Does not contain:
		  ○ Essential Records that should go into the Partner Trust-ISF only; nor
		  ○ Source Records
		
		Ensure the Partner Trust-ISF:
		• Contains the Partner Trust-Pharmacy Site File (PSF)
		  ○ The files in the Partner Trust-ISF and Partner Trust-PSF do not need to be de-duplicated
		• Does not contain:
		  ○ Essential Records that should go into the TMF only; nor
		  ○ Source Records

4	Clinical Research Associate	For Essential Records that are missing from the TMF or Parter Trust-ISF, make a reasonable effort to locate the Essential Records. If the missing Essential Records cannot be located within 15 calendar days, please include a file note in the TMF or Partner-Trust ISF to clearly record: • The nature of the missing Essential Records; and • The fact that the missing Essential Records were not available at the point of archiving. The archiving process for the TMF and Partner-Trust ISF must continue, despite the missing Essential Records.
5	Clinical Research Associate	Once the TMF and Partner Trust-ISF review is complete, inform the Operations Manager and provide the contact details for the person currently in possession of the TMF and Partner Trust-ISF (the CRA, the CI, or the CI's delegate).

6	Clinical Research Associate	Record the archiving fees in the Clinical Trial-specific invoicing spreadsheet on the SharePoint.
7	Operations Manager or delegate	Agree a mutually convenient date with the person currently in possession of the TMF and Partner Trust-ISF for completion of final archiving activities.
8	Operations Manager or delegate	Gather materials required for preparation of hard-copy records: • Iron Mountain boxes (branded) • Iron Mountain incoming records jacket • Archive box labels • Blue document clips (recommended but not mandatory) • Blank **KHP-CTO Clinical Trial Archive Documents** (see Related Templates)
9	Operations Manager or delegate	Visit the person currently in possession of the TMF and Partner Trust-ISF, and bring the materials required for preparation of hard-copy records. Prepare hard-copy records for archiving: • Make reasonable efforts to remove plastic wallets (ink may adhere to plastic over time, reducing legibility) • Make reasonable efforts to remove metal clips and staples (these may rust and damage records) • Ensure all pages are hole-punched • Secure documents using blue document clips where appropriate
10	Chief Investigator or delegate	If electronic records must be archived, these must be downloaded to storage media to be placed in Iron Mountain boxes: • High-quality, durable storage media should be used • Two separate forms of storage are recommended (e.g. an external hard drive and a USB device) • **Please note**, Iron Mountain will not accept storage devices containing a power source • Any requirement for periodic data integrity checks should be documented in the **KHP-CTO Clinical Trial Archive Document**

		• File formats should align with UK Data Service recommended preservation formats (see Related Documents) • Any passwords required to access the device or files must be clearly recorded in the **KHP-CTO Clinical Trial Archive Document**
11	Person currently in possession of the TMF and Partner Trust-ISF (the CRA, the CI, or the CI's delegate)	Place hard-copy records and electronic records (if applicable) in the boxes: • Use Iron Mountain branded boxes only • Do not overfill boxes • Lids must sit flush with box sides and handholds must remain usable • Sign and date the **KHP-CTO Clinical Trial Archive Document** for each box to confirm the box contents are accurately described • Place the original signed **KHP-CTO Clinical Trial Archive Document** inside each box and retain a copy locally • Secure the lid using cable ties to indicate tamper evidence • Store sealed boxes in a secure, access-restricted location pending collection Contact the Operations Manager to arrange collection by Iron Mountain. Give copies of the signed **KHP-CTO Clinical Trial Archive Document(s)** to the Operations Manager.
12	Operations Manager or delegate	Arrange collection with Iron Mountain. Save a copy of the signed **KHP-CTO Clinical Trial Archive Document(s)** to EDGE and the SharePoint. Update EDGE to reflect the TMF and Partner Trust-ISF have been archived.
13	Person currently in possession of the TMF and Partner Trust-ISF (the CRA, the CI,	Facilitate access for Iron Mountain personnel to collect the boxes.

	or the CI's delegate)	

3.6 Destruction of TMFs and Partner Trust-ISFs for Clinical Trials sponsored by the Partner Trusts

Task	Responsibility	Activity
1	Named Archivist	Track retention periods and any periodic review requirements in accordance with the study contract and applicable regulatory requirements.

2	Named Archivist	**Old Rules Trials:**
		Use the protocol and the following instructions to establish which minimum retention period applies:
		• 30 years after End of Trial (EoT) for ATMPs
		• 25 years after EoT 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. populations that can't give informed consent)
		  ○ 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 EoT for all other Clinical Trials
		New Rules Trials:
		Use the protocol and the following instructions to establish which minimum retention period applies:
		• 30 years after End of Trial (EoT) for ATMPs
		• 25 years after EoT for Clinical Trials (excluding ATMPs)

3	Named Archivist	Document the retention period for the TMF and ISF on EDGE.

4	Named Archivist	If required for audit, inspection, legal, regulatory or periodic review purposes, arrange recall of archive boxes in accordance with the recall process (see Section 3.7 below).
5	Named Archivist or delegate	**Old Rules Trials** For a Clinical Trial with a minimum retention period of 5 years, at the end of the retention period; check with the CRAs to see if the Clinical Trial has: • Had a history of significant safety signals or SUSARs; and/or • Undergone regulatory inspection If so, the minimum retention period for this Clinical Trial will switch to 25 years. If this is the case, the retention period for the TMF and ISF must be updated on EDGE.
6	Named Archivist or delegate	When the retention period has been met, write to the following individuals and ask if there's any **pending or active regulatory or legal action with respect to the Clinical Trial:** • 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.
7	Named Archivist or delegate	If no response is received from any of the individuals listed in **Step 6** within 30 calendar days, it should be assumed that there is no pending nor active regulatory nor legal action with respect to the Clinical Trial. Add an EDGE note with the outcome and go to **Step 9**. If any responses are received from any of the individuals listed in **Step 6** within 30 calendar days, and there's no indication of pending nor active regulatory nor legal action with respect to the Clinical Trial; add an EDGE note with the outcome and go to **Step 9.** If any responses are received from any of the individuals listed in **Step 6** within 30 calendar days, and **there is** an indication of pending or active regulatory or legal action with respect to the Clinical Trial; add an EDGE note with the outcome and go to **Step 8.**

8	Named Archivist or delegate	Update the EDGE notes to record the reasons why the minimum retention period has been met for the Clinical Trial and the TMF and ISF 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 TMF and ISF for the Clinical Trial until the next annual review point.
9	Named Archivist or delegate	Contact Iron Mountain to instruct them to dispose of the TMF and ISF. Create an EDGE note to record this instruction Upload a copy of the correspondence with Iron Mountain to EDGE

3.7 Recall of records from Iron Mountain

Task	Responsibility	Activity
1	Named Archivist	Upon receipt of a request to recall archived records, assess whether recall is appropriate. Requests must be made in writing and clearly state the scope, purpose, and required timeline. Where this information is unclear or incomplete, clarification must be obtained before a decision is made. If records were omitted in error from the TMF or ISF, sending a new consignment to archive may be more appropriate than recalling previously archived boxes. Document the request on EDGE.
2	Named Archivist	If the request is not approved, document the decision and rationale on EDGE and notify the requestor in writing.
3	Named Archivist	If the request is approved, document the decision and rationale on EDGE and notify the requestor in writing.

4	Named Archivist	Submit a recall request to Iron Mountain for the relevant box(es). Boxes may be recalled to the KHP-CTO, the Chief Investigator (or delegate), or the Principal Investigator (or delegate), as appropriate and proportionate to the purpose of the recall.
5	Named Archivist or delegate	Provide the person making the request with the **KHP-CTO Clinical Trial Archive Document** (see Related Templates) for completion.
6	Named Archivist or delegate	Send materials required for preparation of hard-copy records to the person making the request: • Iron Mountain incoming records jacket • Archive box labels • Blue document clips (recommended but not mandatory)
7	Any person	If Essential Records are found to be damaged, incomplete, illegible, or otherwise inaccessible at any time during the retention period, consider whether this constitutes a potential serious breach. Refer to **SOP 6.0 Notification of Serious Breach**, as retention and accessibility of Essential Records is a regulatory requirement.
8	Person making request	Ensure recalled records are stored securely at all times and access is restricted to authorised personnel. Maintain a clear record of any changes made to the contents of the recalled box(es), including: • Records added • Amendments made to existing records • Records removed (with justification).
9	Person making request	Notify the Named Archivist when the recalled records are ready to be returned to archive.
10	Person making request	Prepare additional and/or amended hard-copy records for archiving:

		• Make reasonable efforts to remove plastic wallets (ink may adhere to plastic over time, reducing legibility). • Make reasonable efforts to remove metal clips and staples (these may rust and damage records). • Ensure all pages are hole-punched. • Secure documents using blue document clips where appropriate.
11	Person making request	Treat returned box(es) as a new archiving consignment. For each box: • Do not overfill boxes. Lids must sit flush with box sides and handholds must remain usable. • Sign and date a new **KHP-CTO Clinical Trial Archive Document** to confirm the box contents are accurately described. • Place the original signed **KHP-CTO Clinical Trial Archive Document**. inside the box and retain a copy locally. • Secure the lid using cable ties to indicate tamper evidence. • Store sealed boxes in a secure, access-restricted location pending collection. Treating returned box(es) as a new consignment ensures a clear audit trail, documents the period during which records were outside the archive, and confirms that appropriate checks were performed prior to re-archiving.
12	Named Archivist or delegate	Arrange collection with Iron Mountain. Save a copy of the signed **KHP-CTO Clinical Trial Archive Documents** to EDGE and the SharePoint. Update EDGE to reflect that the records have been re-archived.
13	Person making request	Facilitate access for Iron Mountain personnel to collect the boxes.

3.8 External Archiving Services

The KHP-CTO has a contract with an external company (Iron Mountain) for archiving services. If a Partner Trust has archiving requirements that are not the KHP-CTO's responsibility, the Partner Trust may pay the KHP-CTO to use this service at cost.

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.

4. RELATED TEMPLATES

- KHP-CTO Clinical Trial Archive Document
- KHP-CTO Study Closure & Archiving Email

5. RELATED DOCUMENTS

SOPs

- SOP 6.0 Notification of Serious Breach

Other Documents

ICH GCP E6 (R3)
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

MHRA 'GXP' Data Integrity Guidance and Definitions
https://assets.publishing.service.gov.uk/media/5aa2b9ede5274a3e391e37f3/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf

NHS Records Management Code of Practice
https://transform.england.nhs.uk/information-governance/guidance/records-management-code/records-management-code-of-practice/

Schedule of Retention Periods for Research Data
https://www.kcl.ac.uk/assets/aboutkings/business-assets/pdf/retention/research-data.pdf

UK Data Service Consent for Data Sharing
https://ukdataservice.ac.uk/learning-hub/research-data-management/ethical-issues/consent-for-data-sharing/

UK Data Service Recommended Formats for Data Sharing

https://ukdataservice.ac.uk/learning-hub/research-data-management/format-your-data/recommended-formats/

6. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
09 Nov 2010	2.0	Transfer to King's Health Partner Livery and minor amendment to archiving process. Glossary update.	Jackie Powell
26 Feb 2013	3.0	Review of archiving process. Administrative change from JCTO to KHP-CTO.	Jackie Powell
10 Oct 2013	4.0	Amended to include archiving of traceability documentation for ATMPs.	Jackie Powell
28 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
08 May 2017	6.0	Amendment of section 4.5 to apply to paper and electronic data.	Jackie Pullen
01 Oct 2018	6.1	Minor amendment to include trials managed by the KHP-CTO.	Jackie Pullen
26 Jun 2020	6.2	Minor amendment to clarify scope and administrative changes.	Jackie Pullen
27 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 to account for UK Clinical Trials Regulations taking effect on 28 Apr 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
09 Apr 2026	8	• SOP template updated • Updates to account for UK Clinical Trials Regulations taking effect on 28 Apr 2026	Ann-Marie Murtagh

7. GLOSSARY

Advanced Therapy Medicinal Product (ATMP) - 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.

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

Clinical Research Associate (CRA) – A staff member employed by the KHP-CTO who conducts monitoring activities for a Clinical Trial, including but not limited to the initiation phase, routine phase, and close down phase. Delegate monitors (appointed in exceptional circumstances) are included in this definition.

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. Includes clinical trials of ATMPs.

Close Out Visit (COV) - A monitoring visit conducted at the end of a Clinical Trial at a Trial Location to confirm that all Clinical Trial activities have been completed in accordance with the protocol and regulatory requirements. It typically includes verification that essential documents are complete and archived, investigational

product accountability is resolved, outstanding data queries are addressed, and any remaining HBS are managed or disposed of appropriately.

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 Contracts Manager – A member of the KHP-CTO Commercial Team with various duties, including arranging for commercial study contracts to be amended.

Commercial Trials Facilitator (CTF) – A member of the KHP-CTO Commercial Team with various duties, including monitoring the KHPCTOcommercial@kcl.ac.uk inbox.

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

Essential Records - These are records that permit and contribute to the evaluation of the conduct of a Clinical Trial in relation to the compliance of the Principal Investigator and the Sponsor with Good Clinical Practice (GCP) and the Regulations and the reliability of the results produced. For a full list of the records considered to be Essential Records, see ICH GCP E6 (R3) Appendix C.

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 (R3) – The International Council for Harmonisation – Good Clinical Practice, Guideline E6 (Revision 3). This is an internationally recognised ethical and scientific quality standard for the design, conduct, oversight, recording, and reporting of Clinical Trials.

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

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 oversight for non-commercial research sponsored by KHP.

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.

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 individual formally designated by KHP to be responsible for the oversight, control, and long-term preservation of Essential Records and Source Records for which the KHP-CTO is responsible.

New Rules Trial - A Clinical Trial where the application to approve it is submitted after 28 April 2026.

Old Rules Trial – A Clinical Trial where the application to approve it is submitted before 28 April 2026.

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.

Pharmacy Site File (PSF) aka **Pharmacy File (PF)** - The primary location for storing pharmacy-related Essential Records at Trial Location level.

Principal Investigator (PI) – The individual at a Trial Location who has primary responsibility for the conduct of the Clinical Trial at that Trial Location.

Regulations – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).

Research & Development Department (R&D Dept.) – The NHS department at a Trial Location that's responsible for research and development at that Trial Location.

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.

Source Records - Original documents or data (which includes relevant metadata) or certified copies of the original documents or data, irrespective of the media used. This may include participants' medical/health records/notes/charts; data provided/entered by participants (e.g., electronic patient-reported outcomes (ePROs)); healthcare professionals' records from pharmacies, laboratories and other facilities involved in the Research Study; and data from automated instruments, such as wearables and sensors.

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

Sponsor File (SF) - The primary location for the KHP-CTO to store hard-copy documentation about a Clinical Trial. The SF may contain Essential Records, but the SF is not the primary location for storing Essential Records. Any Essential Records stored in the SF will be duplicated in the TMF.

Sponsor Team – The team selected by the CI to undertake the sponsorship functions of the Clinical Trial.

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.

Suspected Unexpected Serious Adverse Reaction (SUSAR) - A Serious Adverse Reaction to an IMP that is unexpected, meaning that the nature or severity of the reaction is not consistent with the applicable product information according to the RSI.

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 Master File (TMF) - A standard filing system which contains all essential documents which individually and collectively permits the evaluation of the conduct of a Clinical Trial and the quality of the data produced. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular Clinical Trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside Case Report Forms and Source Records.