Clinical Trial Monitoring

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Contents

1. BACKGROUND AND PURPOSE

The purpose of this SOP is to describe the monitoring procedures for Clinical Trials (CTIMPs) sponsored by KHP, that are overseen by the KHP-CTO.

Monitoring is defined as the act of overseeing the progress of a Clinical Trial, and ensuring it's conducted, recorded and reported in accordance with the protocol, SOPs, Good Clinical Practice (GCP), and The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (the 'Regulations').

Monitoring has an integral role in the quality control of a Clinical Trial, and it's specifically designed to verify that:

- The rights, safety and well-being of participants are protected.
- The reported Clinical Trial data are accurate, complete and verifiable from Source Records.
- The Clinical Trial is conducted in compliance with the approved protocol, any Modifications, GCP, and the Regulations.

The following Principles of ICH GCP E6 (R3) have been used to prepare this SOP:

- Principle 6: 'Quality should be built into the scientific and operational design and conduct of clinical trials.'

- Principle 6.2: 'Factors critical to the quality of the trial should be identified prospectively. These factors are attributes of a trial that are fundamental to the protection of participants, the reliability and interpretability of the trial results and the decisions made based on those trial results. Quality by design involves focusing on critical to quality factors of the trial in order to maximise the likelihood of the trial meeting its objectives.'

- Principle 7.4: 'Trial processes should be operationally feasible and avoid unnecessary complexity, procedures and data collection. Trial processes should support the key trial objectives. The sponsor should not place unnecessary burden on participants and investigators.'

2. SCOPE

This SOP applies to all Clinical Trials (CTIMPs) sponsored by KHP, that are overseen by the KHP-CTO.

In exceptional circumstances, delegate monitors may be appointed by the KHP-CTO to conduct monitoring activities. For the purposes of this SOP, delegate monitors appointed by the KHP-CTO are included in the definition of Clinical Research Associate (CRA).

The following activities <u>are not</u> within the scope of this SOP:

- Monitoring activities carried out by the CRAs at the start of the Clinical Trial. These are described in **KHP-CTOSOP 13.0: Study Set-Up and Initiation of an Investigator Site.**
- Monitoring activities carried out by the CRAs at the end of the Clinical Trial. These are described in **KHP-CTOSOP 16.0: Investigator Site Close-out Procedure.**
- Monitoring activities carried out by the:
    - Chief Investigator and/or Sponsor Team
    - Principal Investigator and/or Trial Location Team
    - DMEC committee members
    - R&D Depts.

3. PROCEDURE

3.1 Training Clinical Research Associates

Task	Responsibility	Activity
3.1.1	Non-Commercial Trials Manager or delegate	Employ a sufficient number of CRAs to deliver the required monitoring activities for the Clinical Trials managed by the KHP-CTO. Ensure CRA job description and person description templates are regularly updated, so CRAs with the appropriate skills and experience can be recruited when required.

3.1.2	Non-Commercial Trials Manager or delegate	Ensure that each CRA receives the training appropriate to their role:
		• Mandatory KCL training
		• Mandatory KHP-CTO training
		• EDGE training
		• SAE training
		• Clinical Trial-specific training, including:
		  ○ Reading and confirming their understanding of the CTA Submission Package and any Modification submission packages, if applicable
		  ○ Clinical Trial-specific systems training, if applicable

3.1.3	CRA	Complete all required training prior to undertaking monitoring activities. Maintain a personal training record and training file Ensure personal training record and training file are kept up to date at all times.

3.2 Developing the Monitoring Plan

Task	Responsibility	Activity
3.2.1	sCRA or delegate	Complete a Risk Assessment (see Related Templates section below) for the Clinical Trial during protocol development and no later than first site initiation. The Risk Assessment should incorporate the following with respect to monitoring: • Identification and assessment of Critical-to-Quality (CtQ) factors, critical data and processes. • Determine a monitoring approach based on the above factors that is proportionate to the objective, purpose, design, size, complexity, blinding, endpoints, and risks of the Clinical Trial.
3.2.2	CRA	Following completion of the Risk Assessment, develop the Monitoring Plan (see Related Templates section below) for the Clinical Trial: • Use the approved Monitoring Plan template • Determine the format of monitoring visit –'remote, on-site or hybrid' suitable for the trial based on risk assessment and availability of remote access to electronic medical records for each site. • Where remote monitoring is planned, confirm that the Trial Location has sufficient capacity, capability, and permissions to support remote access to relevant systems and records to enable the CRA to perform the monitoring activities described in the Monitoring Plan. To assess the feasibility of remote monitoring with the Trial Location, see section 3.7.
3.2.3	sCRA	Review the completed Risk Assessment and Monitoring Plan for adequacy, proportionality, and regulatory compliance. Record approval of the Risk Assessment and Monitoring Plan in the TMF.
3.2.4	CRA	During the conduct of the Clinical Trial, review and update the Risk Assessment as appropriate to reflect emerging risks or changes to the Clinical Trial. Where changes to the Risk Assessment are identified, review and if necessary, update the Monitoring Plan. Triggers for review of the Risk Assessment and subsequent review of the Monitoring Plan may include, but are not limited to: • Updates following Modifications, Urgent Safety Measures (USMs), or updates to the Reference Safety Information (RSI);

		• Trends identified through monitoring findings, deviation reports, or suspected or confirmed Serious Breach reports; • Changes to site capacity, capability, or willingness to support remote monitoring activities.
3.2.5	sCRA	Review and approve updates to the Monitoring Plan. This review is normally undertaken by the line manager of the individual who drafted the update. Record approval of the updated Monitoring Plan in the TMF.

3.3 Trial Location-level CRA monitoring responsibilities

Task	Responsibility	Details
3.3.1	CRA	**Communication** Act as the primary point of contact between the KHP-CTO (acting on behalf of the Sponsor) and the Principal Investigator and Trial Location Team.
3.3.2	CRA	**Correct Documentation** Ensure the correct documentation is being used by the Trial Site, in particular: • Current approved version of Investigator Brochure (IB) or Summary of Product Characteristics. • Protocol – the current protocol is the most recent version approved by the MHRA. • Participant Information Sheet(s) and Informed Consent Form(s) – the current versions are those most recently approved by the Research Ethics Committee (REC). Review the Investigator Site File (ISF), including paper and electronic records, in accordance with the Monitoring Plan.
3.3.3	CRA	**Records of Submissions** Verify that records of applications, notifications, submissions, and reports are available within the Trial Master File (TMF). Confirm that records are accurate, complete, legible, contemporaneous, and version-controlled, and clearly identify the Clinical Trial.
3.3.4	CRA	**Supplies** Verify that documents and other supplies required for Clinical Trial conduct and regulatory compliance are available at the Trial Location.

3.3.5	CRA	**Source Data Location List** Verify that the Source Data Location List accurately reflects current practice at the Trial Location. Raise an action as part of the monitoring visit follow up to update the source data location list if any inconsistencies are noted. Notes: • Information intended to be recorded on Clinical Trial worksheets but held elsewhere (e.g. participant medical records) should be monitored as Source Records. • Where calculated values are entered into Source Records (e.g. CRFs), the underlying calculation must be retained as Source Records.
3.3.6	CRA	**Capacity and Capability** Verify that the Principal Investigator has adequate qualifications, resources, facilities (including laboratories and equipment), and appropriately trained staff to safely and properly conduct the Clinical Trial, and that these remain adequate throughout the Clinical Trial.
3.3.7	CRA	**Training** Verify that individuals have completed appropriate training prior to being delegated Clinical Trial-related tasks, in accordance with the protocol and Clinical Trial documentation. Training records (e.g. GCP certificates) may be copied for Sponsor records where required by the protocol (scanned copies by email are acceptable). Where appropriate, the CRA may deliver training during monitoring visits (e.g. training for an upcoming Modification). Document any training provided in the monitoring visit report and ensure documented in the site staff log in the site training log.
3.3.8	CRA	**Delegation** Verify that Clinical Trial tasks are delegated only to individuals who are appropriately qualified by education, training, and experience. Verify that Clinical Trial activities are performed in accordance with the delegation log and not by unauthorised individuals. Focus on review of delegated tasks critical to participant safety and data integrity in accordance with the monitoring plan. For electronic systems, where possible, verify metadata in accordance with the Monitoring Plan to confirm activities were performed by appropriately delegated staff.

3.3.9	CRA	**Informed Consent** In accordance with the proportion specified in the Monitoring Plan, verify that informed consent was obtained and documented as required by the protocol and **SOP 7.0 Obtaining Informed Consent for Clinical Trials.** Consent must be obtained prior to any Clinical Trial-specific procedures unless otherwise specified in the protocol.
3.3.10	CRA	**Eligibility** Verify that participant eligibility was confirmed prior to Clinical Trial intervention. Records must confirm that, at the time of Clinical Trial entry (e.g. randomisation or first IMP administration): • All inclusion criteria were met; • No exclusion criteria were met; • Eligibility assessment was completed by the Principal Investigator or an appropriately delegated individual.
3.3.11	CRA	**Protocol Deviations** Any deviation from the approved protocol, approved Modifications, GCP, or applicable regulatory requirements identified during monitoring must be documented in the Monitoring Visit Report. Request a Corrective and Preventative Action (CAPA) as part of the visit follow up actions where necessary. A Clinical Trial deviation log must be maintained within the TMF. Follow **SOP 6.0 Notification of Serious Breach** where applicable.
3.3.12	CRA	**Source Data Verification (SDV)** Verify transcription of data from Source Records to the Case Report Form (CRF) for completeness and accuracy, in accordance with the Monitoring Plan. For data selected for verification, confirm that: • CRF entries are accurate, complete, and consistent with Source Records; • IMP accountability entries are consistent with Source Records; • Adverse Events, concomitant medications, and medical history are recorded in accordance with protocol requirements; • Protocol deviations are appropriately documented; • Participant withdrawals are documented and verifiable from Source Records.

		Note: SDV must be conducted in compliance with data protection legislation and Trial Location policies governing access to participant records
3.3.13	CRA	**Data Integrity** Where data are missing, inaccurate, or inconsistent with protocol requirements, notify the Principal Investigator or appropriately delegated individual to ensure corrections are made. The CRA must not make changes to Source Records or CRFs.
3.3.14	CRA	**Principal Investigator Oversight** For the proportion of data reviewed per the Monitoring Plan, verify that the Principal Investigator (or delegate): • Reviews laboratory results in a timely manner; • Maintains the delegation log appropriately; • Reviews Serious Adverse Event reports in a timely manner (wet ink, electronic signature, or documented email confirmation).
3.3.15	CRA	**Pharmacovigilance** Verify that Serious Adverse Event (SAE) reports are accurate, complete, and consistent with participant Source Records. Where reports are incomplete, inaccurate, or submitted outside required timelines, document a deviation and follow **SOP 6.0 Notification of Serious Breach** where appropriate. Ensure any unreported Serious Adverse Event (SAE) that is identified during a monitoring visit, are reported within 24 hours of identifying them. Ensure that the unreported SAE is recorded on the deviation log and in the monitoring visit report.
3.3.16	CRA	**Investigational Medicinal Product (IMP) Management** Verify that IMP is managed in accordance with the approved protocol, applicable regulations, and Sponsor SOPs. The Monitoring Plan will specify the extent of monitoring required for central stock and Trial Location-held IMP. Confirm that: • IMP is supplied only to eligible participants and administered in accordance with the protocol and randomisation scheme (if applicable);

		• Storage conditions comply with protocol, Investigator's Brochure (IB), or SmPC requirements, and excursions are reported and managed appropriately; • Participants are appropriately instructed on IMP handling where self-administration occurs; • Receipt, dispensing, return, and accountability records are complete and accurate; • Disposal of unused IMP complies with regulatory requirements and Sponsor SOPs.
3.3.17	CRA	**Blinding (where applicable)** Verify that any unscheduled Unblinding is reported promptly in accordance with **KHP-CTOSOP 14.0: Emergency Code Break In Clinical Trials.** Escalate Blinding issues in line with **KHP-CTOSOP 6.0: Notification of Serious Breach** where applicable.
3.3.18	CRA	**Laboratories processing and/or analysing Human Biological Samples (where applicable)** Where specified in the Monitoring Plan, verify that Human Biological Samples (HBS) are collected, handled, stored, shipped, processed, and analysed in accordance with the protocol, **KHP-CTOSOP 19.0: Oversight of Central Laboratories Processing & Analysing Human Biological Samples Collected during a Clinical Trial** and **KHP-CTOSOP 20.0: Sample Management in Clinical Trials**, GCP, and applicable regulatory requirements.
3.3.19	CRA	**Trial Master File (TMF) Review** Verify that records held by the Chief Investigator and delegates in the TMF are accurate, complete, timely, and compliant with **KHP-CTOSOP 5.0: The Creation and Maintenance of Trial Master Files and Essential Documentation**, and sufficient to reconstruct Clinical Trial conduct.

3.4 Recording monitoring activities undertaken at a Trial Location

Task	Responsibility	Activity
3.4.1	CRA	**Pre-visit confirmation** Prior to a monitoring visit (on-site or remote), send a confirmation email to the Principal Investigator and relevant members of the Trial Location Team. Outline the planned monitoring activities to be undertaken during the visit.

		File confirmation email in the TMF. Ensure a copy is also in the ISF to ensure the site maintains a record of monitoring arrangements and planned oversight activities.
3.4.2	CRA	**Visit log (on-site monitoring only)** For on-site monitoring visits, complete an entry in the Trial Location visit log. • Where separate visit logs are maintained (e.g. Investigator Site File, Pharmacy, Laboratory), complete and sign each applicable log. • Where more than one member of KHP-CTO staff attends the visit (e.g. induction, shadowing, co-monitoring), each staff member must sign the visit log. • Each visit log entry must be reviewed by the Principal Investigator, or an appropriately delegated individual if the Principal Investigator is not present. The reviewer should initial the entry to confirm it is an accurate record of the visit.
3.4.3	CRA	**Recording remote monitoring activity** For remote monitoring activities, select the appropriate recording method based on the nature and extent of activity undertaken, using either: • A Monitoring Visit Report; or • A Remote Monitoring - Contact Comment Form.
3.4.4	CRA	**Recording on-site monitoring activity** For on-site monitoring visits, complete a Monitoring Visit Report using the approved template (see Related Templates section below). A single Monitoring Visit Report may cover multiple monitoring activities where: • All activities relate to the same Principal Investigator and clinical trial and occur within 10 working days from the date of the first included monitoring activity. • More than one Trial Location is visited (e.g. Principal Investigator office, Pharmacy, Laboratory), provided all locations fall under the responsibility of the same Principal Investigator; • Some monitoring activities are conducted remotely (e.g. remote access to medical records, telephone or video calls with the Principal Investigator); • More than one member of KHP-CTO staff undertakes monitoring activities (e.g. shadowing, induction, co-monitoring, handover). The CRA with primary responsibility for the Trial Location at the time of the visit is responsible for ensuring completion of the Monitoring Visit Report.

3.4.5	CRA	**Monitoring visit follow-up communication** Prepare a monitoring visit follow-up email to inform the Principal Investigator and Trial Location Team of the outcome of the monitoring activities. The Monitoring Visit Report itself must not be sent to the site. Where appropriate, separate follow-up emails may be sent to distinct site teams (e.g. Pharmacy, Laboratory) to facilitate timely action. The follow-up email should include a summary of the visit, including as applicable: • Dates of the monitoring activities; • Scope of participant data verification completed; • Significant deviations identified (without duplicating the full deviation log); • Issues from previous visits that have been resolved; • Issues addressed during the visit; • Actions required by the Principal Investigator and Trial Location Team; • Actions required by the CRA or other Sponsor representatives; • Any other significant information discussed (e.g. upcoming Clinical Trial milestones). A copy of the follow-up email and the initial Monitoring Visit Report should be filed in the appropriate KHP-CTO Quality internal folder for the clinical trial. CRAs should track outstanding actions by reviewing the action items documented in the previous Monitoring Visit Report and/or follow-up emails prior to or at the subsequent monitoring visit.
3.4.6	CRA	**Submission for review** Submit the draft Monitoring Visit Report to the assigned sCRA for review and approval, within ten working days (or trial specific timeline if indicated in the monitoring plan) of the final monitoring activity covered by the report. Where the assigned sCRA is unavailable, the draft may be submitted to an alternative authorised reviewer, such as another sCRA or designated line manager, in accordance with delegated oversight arrangements.
3.4.7	sCRA	**Review** Review the draft report/form and follow-up email promptly. Provide feedback, clarifications, or required amendments to the CRA by email.
3.4.8	CRA	**Revisions, if applicable**

		Revise the report and follow-up email in line with reviewer feedback and resubmit to the reviewer for approval.
3.4.9	sCRA	**Approval** Approve the Monitoring Visit Report by wet-ink or electronic signature within ten working days (or trial specific timeline if indicated in the monitoring plan) of receipt of the draft report. Ensure the approved report is filed in the Trial Master File (TMF).
3.4.10	CRA	**Issue follow-up email** Send the approved follow-up email(s) to the Principal Investigator, copying delegated Trial Location Team members as appropriate. The email should be issued as soon as possible following report approval and, where feasible, within 5 working days from report finalisation. For urgent findings (e.g. significant deviations, participant safety issues, or time-critical actions), the CRA should not wait for formal report. These should be communicated to the site during the monitoring visit or immediately following identification, to ensure prompt action and resolution. Any such urgent discussions or communications should be documented in the Monitoring Visit Report (MVR) and filed in the appropriate internal KHP-CTO Quality folder. All follow-up emails should be filed in the TMF.
3.4.11	CRA	**Systems update** Ensure that relevant Clinical Trial management systems are updated, including (but not limited to): • Participant recruitment and status tracking; • Serious Adverse Event reporting and tracking; • Monitoring activity records, as applicable.

3.5 Transferring monitoring for a Trial Location from one CRA to another

Task	Responsibility	Activity
3.5.1	Non-Commercial Trials Manager or delegate	Assign a suitably experienced Clinical Research Associate (CRA) to assume responsibility for a Trial Location where the current CRA is unable to continue in the role for any reason.

3.5.2	Incoming CRA	Review key Clinical Trial documentation, key instruction manuals and trial-specific documentation, including but not limited to: • Laboratory manual • Pharmacy / IMP management manual (if applicable) • Data Management Plan (DMP) • eCRF completion guidelines • Protocol and all approved amendments • Investigator's Brochure (IB) or Reference Safety Information (RSI) • Monitoring Plan • Safety reporting procedures (SAE/SUSAR reporting process and timelines) • Source Data Location List (SDLL) • Delegation of Authority Log • Trial contact list / escalation pathways • Investigator Site File (ISF) index / Trial Master File (TMF) index • Training requirements and overview of site training records (including GCP and protocol-specific training) • Previous Monitoring Visit Reports (MVRs), including review of open actions and any emerging trends Record completion of this review as self-directed training in the personal training log.
3.5.3	Outgoing CRA	Complete the approved Study Handover Document template (see Related Templates section, below), providing sufficient detail to enable effective continuity of oversight. Send the completed Study Handover Document to the Incoming CRA.
3.5.4	Incoming CRA and the Outgoing CRA	Where possible, hold a handover meeting between the Incoming CRA and the Outgoing CRA. This may take place face-to-face or via Microsoft Teams. Record a brief summary of the meeting (including attendees, Trial Location(s) discussed, key issues, and the agreed date of formal transfer of responsibility) in the TMF.
3.5.5	Incoming CRA and the Outgoing CRA	Where the Incoming CRA and the Outgoing CRA attend a visit together, responsibility for compliance with the Monitoring Plan and for completion of the Monitoring Visit Report remains with the Outgoing CRA until the formal transfer of responsibility has taken place.
3.5.6	Outgoing CRA	Notify the Chief Investigator, Trial Manager (if applicable), Trial Location Principal Investigator, and Trial Location Team of the planned date for transfer of CRA responsibility.

		File the notification email in the TMF.
3.5.7	Incoming CRA	Sign the completed Study Handover Document to confirm acceptance of responsibility for the Trial Location. Where available, the Outgoing CRA should also sign the Study Handover Document to confirm completion of the handover. File the signed Study Handover Document in the TMF.
3.5.8	Incoming CRA	Update Clinical Trial management systems and other relevant records to ensure contact details for the Trial Location are current and accurate.

3.6 Transferring a Clinical Trial from one Lead CRA to another

Task	Responsibility	Activity
3.6.1	Non-Commercial Trials Manager or delegate	Assign a suitably experienced Clinical Research Associate to assume Lead CRA responsibility for the Clinical Trial where the current Lead CRA is unable to continue in the role for any reason.
3.6.2	Incoming Lead CRA	• Review key Clinical Trial documentation and oversight materials to ensure understanding of trial conduct, cross-site consistency, and risk management, including but not limited to: Protocol and study design documents, including approved protocol and all amendments • Monitoring framework, including Monitoring Plan (central and on-site approach), Risk Assessment, and Risk-Based Monitoring strategy and Source Data Location List (SDLL) guidance • Key manuals and guidance, including laboratory manual, pharmacy/IMP manual (if applicable), Data Management Plan (DMP), and eCRF completion guidelines • Participant and site-facing documentation, including informed consent forms, participant information sheets, questionnaires, and recruitment materials • Trial management structure and governance documents, including ISF/TMF index or structure, delegation log templates, training requirements, and trial-specific training materials across sites • Monitoring and site oversight outputs, including most recent Monitoring Visit Reports, outstanding actions and recurring issues across all sites

		• Site oversight tracking, including site activation/status tracker, recruitment status, and SAE trackers • Quality and compliance oversight, including CAPA log, serious breach log, audit/inspection findings, and any open monitoring or compliance issues (including deviations and CAPAs) Record completion of this review as self-directed training in the personal training log.
3.6.3	Outgoing Lead CRA	Complete the approved Study Handover Document template (see Related Templates section), providing sufficient detail to ensure continuity of Sponsor-level oversight, including: • Overall monitoring status and priorities; • Key risks and trends identified; • Outstanding actions, escalations, or follow-up required; and • Any Trial Location-specific or study-wide issues of concern. Send the completed Study Handover Document to the Incoming Lead CRA
3.6.4	Incoming Lead CRA and Outgoing Lead CRA	Where possible, hold a handover meeting between the Incoming Lead CRA and the Outgoing Lead CRA. This may take place face-to-face or via Microsoft Teams. Record a brief summary of the meeting (including attendees, Trial Location(s) discussed, key risks or issues, and the agreed date of formal transfer of Lead CRA responsibility) in the Trial Master File (TMF).
3.6.5	Incoming Lead CRA and Outgoing Lead CRA	Where both Lead CRAs jointly undertake Sponsor-level monitoring activities (e.g. co-monitoring, oversight visits, or shadowing), responsibility for compliance with the Monitoring Plan and for review and approval of monitoring outputs remains with the Outgoing Lead CRA until the formal transfer of responsibility has taken place.
3.6.6	Outgoing Lead CRA	Notify the Chief Investigator, Trial Manager (if applicable), and other relevant Sponsor or coordinating-centre stakeholders of the planned date for transfer of Lead CRA responsibility. File the notification email in the TMF.
3.6.7	Incoming Lead CRA	Sign the completed Study Handover Document to confirm acceptance of Lead CRA responsibility for the Clinical Trial. Where available, the Outgoing Lead CRA should also sign the document to confirm completion of the handover. File the signed Study Handover Document in the TMF.

3.6.8	Incoming Lead CRA	Update Clinical Trial management systems and other relevant Sponsor-level records to ensure that Lead CRA contact details, escalation pathways, and oversight responsibilities are current and accurate.

3.7 Remote monitoring

Remote monitoring is defined as monitoring conducted at central location away from the main Trial Location. It may replicate some on-site activities, including review essential records, remote Source Data Verification (SDV), which requires remote access to Electronic Medical Records (EMR). The extent and nature of remote monitoring that may be performed for a trial should be documented in the monitoring plan (refer to section 3.2). Remote monitoring can be conducted by different methods which can be combined depending on the Trial Locations available options which may include:

A) **Log in access:** Direct and full access to the site's EMR.
B) **Guided access:** source data shared via secure video conferencing platforms.
C) **Upload access:** Source data shared via a secure document repository
D) **Download access:** Pseudonymised source data shared via email or secure platforms where documents are downloaded.

Task	Responsibility	Activity
3.7.1	CRA	Confirm with Principal Investigator and/or Trial Location team what methods, if any, the trial location can accommodate for remote monitoring prior to conducting any remote monitoring visits. File details in the TMF and ensure filed in the ISF
3.7.2	CRA	Confirm with the Pharmacy contact and any other relevant support departments what methods, if any, the trial location can accommodate for remote monitoring prior to conducting any remote monitoring visits. File details in the TMF and ensure filed in the ISF

4. RELATED TEMPLATES

File Note Template
- Filename: File Note Template v2_1 (01-Nov-16).doc
- SharePoint Location: 05. Monitoring

Monitoring Plan template
- Filename: MP FINAL v3.2 13Oct23 FINAL.docx
- SharePoint Location: 05. Monitoring

Monitoring Visit Report template

- Filename: Monitoring Visit Report Template Final v13 CLEAN.docx
- SharePoint Location: 05. Monitoring

Remote Monitoring - Contact Comment Form template

- Filename: Remote Monitoring - Contact Comment Form_v1_27May2020.docx
- SharePoint Location: 05. Monitoring

Risk Assessment template

- Filename: Risk assessment -PART A.docx
- Filename: Risk assessment -PART B.docx
- SharePoint Location: 00 - Template

Study Handover Document template

- Filename: Study Handover Document template v1.0 02-Sep-16_template.doc
- SharePoint Location: 05. Monitoring

5. RELATED SOPS

- KHP-CTOSOP 5.0: The Creation and Maintenance of Trial Master Files and Essential Documentation
- KHP-CTOSOP 6.0: Notification of Serious Breach
- KHP-CTOSOP 7.0: Obtaining Informed Consent for Clinical Trials
- KHP-CTOSOP 13.0: Study Set-Up and Initiation of an Investigator Site
- KHP-CTOSOP 14.0: Emergency Code Break In Clinical Trials
- KHP-CTOSOP 16.0: Investigator Site Close-out Procedure
- KHP-CTOSOP 19.0: Oversight of Central Laboratories Processing and Analysing Human Biological Samples During a Clinical Trial
- KHP-CTOSOP 20.0: Sample Management in Clinical Trials

6. REFERENCES

1. The Medicines for Human Use (Clinical Trials) Regulations 2004 https://www.legislation.gov.uk/uksi/2004/1031/contents/made
2. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 https://www.legislation.gov.uk/uksi/2025/538/contents/made
3. ICH Topic (E6) guideline for Good Clinical Practice https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline
4. MHRA Guidance for Oversight and Monitoring Activities https://www.gov.uk/government/publications/oversight-and-monitoring-of-investigational-medical-product-trials/oversight-and-monitoring-activities

7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
09 Jun 2010	2.0	Transfer to Kings Health Partner Livery, Update to 2.0 GLOSSARY, 3.0 SCOPE and replacement of "monitor" to CRA throughout text	Jackie Powell
10 Nov 2010	3.0	Clarification that email is an accepted method of communication	Jackie Powell
22 Feb 2013	4.0	Update to glossary and procedures to reflect current practice and change of branding from JCTO to KHPCTO	Jackie Powell
03 Aug 2016	5.0	Update of Glossary and Procedures to reflect current practice	Jackie Pullen
04 Apr 2018	6.0	Update to include review of the Source Data Location List during routine monitoring visits	Jackie Pullen
01 Oct 2018	6.1	Minor amendment to include trials managed by KHP-CTO	Jackie Pullen
11 Aug 2021	6.2	Update to glossary terms and procedures to reflect current practice	Jackie Pullen
14 Apr 2025	6.3	Update to glossary terms and procedures to reflect current practice	Ann-Marie Murtagh
28 Apr 2026	7.0	SOP moved to new template. Update to terminology in respect of the amended Clinical Trials Regs in effect from the 28 Apr 2026.	Ann-Marie Murtagh

8. GLOSSARY

Adverse Event (AE) - Any untoward medical occurrence in a participant who has been administered an IMP, which does not necessarily have a causal relationship with that IMP.

Blinding - A procedure used in a Clinical Trial to withhold information about treatment allocation from one or more parties (e.g. participants, investigators, Sponsor staff) in order to minimise bias in Clinical Trial conduct, assessment, and reporting. 'Blind' and 'Blinded' to be construed accordingly.

Case Report Form (CRF) - A printed, optical or electronic document designed to record all of the protocol-required information for each trial participant, to be reported to the Sponsor.

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 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.

CTA Submission Package - The CTA submission form and all necessary supporting documents for the CTA submission.

Data Monitoring and Ethics Committee (DMEC) – An independent committee, convened prior to the commencement of a Clinical Trial, that periodically reviews accumulating safety and Clinical Trial data at predefined intervals, or when specified Clinical Trial milestones are met. The DMEC provides independent advice to the Chief Investigator and Sponsor on whether the Clinical Trial should continue, be modified, or be terminated, taking into account participant safety, ethical considerations, and the overall risk–benefit balance.

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 guidance on which records should be 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.

Human Biological Samples (HBS) – Materials of human origin collected for clinical care or research purposes, which contain biological information about an individual. They typically include tissues, cells, blood, blood components, bodily fluids, DNA, RNA, and other derivatives obtained directly or indirectly from a human body.

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.

Informed Consent Form (ICF) - A document by which a participant formally records their voluntary agreement to take part in a Clinical Trial, having been provided with and understood the information set out in the Participant Information Sheet.

Investigational Medicinal Product (IMP) – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Trial. This includes products with marketing authorisation when used in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

Investigator's Brochure (IB) - A Sponsor-prepared reference document that compiles the clinical and non-clinical data on an IMP that are relevant to its use in a Clinical Trial. It's intended to provide Clinical Trial staff with sufficient information to understand the rationale for the Clinical Trial, the known and potential risks and benefits of the IMP, including Adverse Reactions, and the appropriate management of participants. Where the IMP has a Marketing Authorisation, an SmPC will be available and it will supersede the IB as the RSI.

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 Clinical Trials Office (KHP-CTO) – The department established by 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 to 1) undertake the set up and financial Management of commercial research hosted by one or more of the KHP Partners, and 2) undertake the regulatory submissions and oversight, as well as monitoring activity for non-commercial research studies sponsored by one of the KHP Partners.

Lead CRA – The CRA providing Sponsor-level oversight of monitoring activities for a Clinical Trial, with responsibility for coordinating and supervising CRA activities across Trial Locations, ensuring consistent implementation of the Monitoring Plan, identifying and escalating emerging risks or trends, and supporting the Sponsor in maintaining oversight of participant safety, data integrity, and compliance with GCP and applicable regulations.

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.

Modification - Any change to a Clinical Trial after initial approval that affects the information or conditions on which the Clinical Trial was authorised. Includes minor modifications, Modifications of an Important Detail (MOIDs), Route A and Route B substantial modifications.

Monitoring Plan - A Sponsor-approved document that sets out how Clinical Trial monitoring will be conducted, managed, and documented, using a risk-based approach to ensure participant safety, data integrity, and compliance with the approved protocol and applicable regulations.

Monitoring Visit Report (MVR) – A Sponsor document completed by the CRA following a monitoring visit, which records the activities performed, observations made, findings identified, and actions required, and provides evidence of ongoing Sponsor oversight of Clinical Trial conduct, participant safety, data integrity, and compliance with the approved protocol, GCP, and applicable regulations.

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

Participant Information Sheet (PIS) - A document provided to potential Clinical Trial participants that clearly explains the purpose, procedures, risks, benefits, and practical implications of taking part in a Clinical Trial, enabling them to make an informed decision about participation.

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

Reference Safety Information (RSI) – The authoritative document used to determine the expectedness of SARs occurring during a Clinical Trial. It defines which SARs are considered expected for the IMP, based on the safety information available at the time, and is used by the Sponsor to assess whether a SAR qualifies as a SUSAR. If the IMP has a Marketing Authorisation, the SmPC will be used as the RSI. If the IMP does not have a Marketing Authorisation, the IB will be used as the RSI.

Regulations – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended including the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025).

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

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.

Risk Assessment - A structured, documented evaluation performed by the sCRA to identify and assess risks to participant safety, data integrity, and regulatory compliance in a Clinical Trial, and to define proportionate risk-mitigation and monitoring measures in accordance with the Regulations and ICH GCP E6 (R3) by extension.

Senior Clinical Research Associate (sCRA) – A staff member employed by the KHP-CTO to undertake advanced CRA duties, including the line management of CRAs.

Serious Adverse Event (SAE) - An Adverse Event that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect.

Serious Breach - Under Part 4, paragraph 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), a serious breach is defined as a breach of the conditions and principles of good clinical practice, or of the approved clinical trial protocol (as amended in accordance with regulations 22 to 25), which is likely to affect to a significant degree either the safety or the physical or mental integrity of trial participants, or the scientific value of the clinical trial. Where such a breach occurs, the sponsor is required to notify the licensing authority in writing within seven days of becoming aware of the breach.

Source Data Location List - A document that identifies how Source Records are originally recorded, categorised and stored for a Clinical Trial.

Source Data Verification (SDV) - The process by which Clinical Trial data recorded in the Clinical Trial database or CRF are checked against the original Source Records to confirm that the data are accurate, complete, consistent, and verifiable.

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 Clinical Trial; 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 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.

Summary of Product Characteristics (SmPC) - A regulatory document approved by the MHRA that provides authoritative information for healthcare professionals on the safe and effective use of a medicinal product. It includes details on the product's composition, indications, dosing, contraindications, warnings and precautions, interactions, pharmacological properties, and known Adverse Reactions, and forms part of the product's Marketing Authorisation. Where a medicinal product does not have a Marketing Authorisation (i.e. an unlicensed IMP), an SmPC will not be available, and the equivalent safety information is provided through the IB, which serves as the RSI for pharmacovigilance and safety reporting.

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 Clinical Trial.

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.

Unblinding - A procedure used in a Clinical Trial in which treatment allocation is revealed for an individual participant or, in rare cases, for the Clinical Trial as a whole. Unblinding may occur in accordance with the protocol (e.g. at EoT), or prematurely, where necessary to protect participant safety or to meet regulatory reporting requirements. 'Unblind' and 'Unblinded' to be construed accordingly.

Urgent Safety Measure (USM) - An urgent safety measure that must be taken to protect Clinical Trial participants against an immediate hazard to their health or safety.