

Title: Remote Monitoring and Source Data Verification

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Document History

Version	Description of update	Date Effective
1	New SOP	16-2-21
2	Scheduled update at three years with no changes.	1-5-24

1. Scope

- 1.1 This SOP applies to Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Clinical Investigations (MDCIs) which involve NHS Grampian staff, patients or resources. It also applies to NHSG R&D staff administering the process. This SOP applies in circumstances when onsite monitoring is not an option.
- 1.2  Although the requirements of ICH GCP only apply to CTIMPs it is best practice to apply the 'Principles of Good Clinical Practice' to **all** clinical trials. Compliance shall be monitored routinely.

2. Responsibilities

Sponsor/CI	Prepare a monitoring plan.
All Researchers	Comply with all Sponsor monitoring requests.
Monitor/CRA	Verify that source documents and other trial records are accurate, complete, kept up to date and maintained. Check accuracy and completeness of CRF entries, source documents and other trial-related records against each other.

3. Procedure

Source Data Verification

- 3.1 ICH GCP defines Source Data as - All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data is contained in source documents (original records or certified copies).
- 3.2 Source Documents- Original documents, data and records (eg hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm of magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
- 3.3 It is ethically essential that data collected during a clinical study can be verified as complete, accurate and reliable. As CRF data is a transcription of data recorded in source documents, eg

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Key to symbols  = Important point to note  = Warning

subject's hospital records, it must be ensured that no errors have occurred during transcription.

Monitoring

- 3.4 The monitoring process is designed to ensure that active CTIMPs and MDCIs conform to the principles of Good Clinical Practice (GCP) and relevant legislation.
- 3.5 Effective monitoring is necessary to ensure that:
- The rights, wellbeing and safety of the trial participants are protected.
 - Trial data is secure, high quality, accurate, complete and verifiable from source data.
 - The conduct of the trial is in compliance with the currently approved protocol / amendments and conducted by approved personnel.
 - Research misconduct and fraud is deterred and inadequate research practices are identified before they escalate to become research misconduct.
 - GCP is promoted, and compliance with the guidelines for research governance, including applicable regulatory requirements, is achieved.

Remote Monitoring Visit

- 3.6 It may be necessary, or desirable, to conduct routine monitoring visits remotely. These may be facilitated by telephone interview and/or completion of remote checklists. Alternatively the use of **Microsoft Teams** (NHS approved secure platform) may be used.
-  Other similar platforms not currently approved by NHS Grampian Information Governance /Information Security **must not** be used.
- 3.7  Monitors/CRA's activities are covered by the existing site agreement/OIDS between the Sponsor and NHS Grampian. All Parties are bound by legal obligations of confidentiality in respect of the participants. This applies to confidential patient information under common law, as well as Personal Data under UK GDPR and Data Protection Act 2018. Any breach of confidentiality will be treated as a breach of contract and, where the person responsible is a member of a regulated profession, the matter shall be reported to the appropriate body.
- 3.8  If Microsoft Teams is to be used **the recording facility must be turned off** and not used; as patient identifiable data will be shared across Microsoft Teams.
- 3.9  Where possible, redacted source data (including Trakcare) may be shared with the Monitors/CRA using a screen share on Microsoft Teams although this may not always be possible; due to the requirements of Source Data Verification and Sponsor SOPs. When necessary, unredacted source data and documents may be shared during remote monitoring using the secure nhs.scot email system, or by document sharing on Microsoft Teams.
- 3.10 The PI (or other member of the local research team, as appropriate) shall be contacted by the Monitor/CRA to arrange a convenient time for remote monitoring, at which the PI (or delegate) shall be available. A monitoring visit may, if required, be split over a number of days.
- 3.11  Trial specific documents may be requested by the Monitor/CRA prior to a monitoring visit and should be provided by the local team before the visit date. This may include arranging access to electronic records during the remote monitoring visit.
- 3.12  The ISF and, if appropriate, source documentation (including a proportion of the medical records), all Case Report Forms (CRFs) and any other trial documentation must be available on the day of the remote monitoring, when applicable.



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4. Abbreviations and definitions

CRA	Clinical Research Associate
CTIMP	Clinical Trial of an Investigational Medicinal Product
CRF	Case Report Form (or Clinical research Facility)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
MDCI	Medical device Clinical Investigation
OID	Organisation Information Document
PI	Principal Investigator
UK GDPR	UK General Data Protection Regulations

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