The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspections

DLV-GEN-SOP-001

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Contents

1. Background/Introduction

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) sponsors a wide range of studies conducted within the UK (including CTIMPs, ATIMPs and clinical investigations of non-CE marked device trials). The Trust also "hosts" studies, acting as a research site where the Sponsor is external to the organisation.

As a result of acting both as a Sponsor and host, studies are subject to audit, monitoring and regulatory inspection.

ICH GCP E6 (R2) defines Monitoring as "The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the Protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement.

ICH GCP E6 (R2) defines Inspection as "The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authorities"

ICH GCP E6 (R2) defines Audit as "A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed, and accurately reported according to the Protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Participant information is held within paper medical notes, as part of eRecord the named Electronic Health Record (EHR) at NuTH, BadgerNet Maternity, BadgerNet Neonatal and a Trust built Document Store. Access to the notes/eRecord, Maternity and Neonates and Document Store is allocated to healthcare professionals based on their activities in providing participant care. This is to maintain participant confidentiality and the principles of the General Data Protection Regulations 2018.

2. Purpose

The purpose of the SOP is to describe the process to allow Monitors, Auditors and Regulatory Inspectors to view the participant records within eRecord and Document Store, whilst conducting on site and/or remote monitoring, audits and inspections.

3. Scope of Document

The SOP is applicable to all Chief Investigators (CIs), Principal Investigators (PIs) and delivery staff who support monitoring activities at The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH).

This SOP is also applicable to staff within the Newcastle Joint Research Office (NJRO) who provide guidance to delivery teams regarding monitoring in hosted studies, and NJRO staff who act as sponsor representatives for NuTH sponsored studies.

4. Definitions

ATIMP – Advanced Therapy Investigational Medicinal Product
CI – Chief Investigator
CTIMP – Clinical Trial Investigational Medicinal Product
eCRF – Electronic Case Report Form
EHR – Electronic Health Record known as eRecord
HRA – Health Research Authority
ISF – Investigator Site File
MHRA - Medicines and Healthcare products Regulatory Agency
NJRO – Newcastle Joint Research Office
NuTH – The Newcastle upon Tyne Hospitals NHS Foundation Trust
PI – Principal Investigator
PIS – Patient Information Sheet
QC – Quality Control
R&D – Research and Development
SDV – Source Data Verification

5. Roles & Responsibilities

It is the role of the study teams to apply for and authorise access for the Monitors, Auditors and Regulatory Inspectors.

It is the role of IT services to grant access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for a specified period.

It is the responsibility of Monitors, Auditors and Regulatory Inspectors to complete access applications and adhere to the rules of access. *Regulatory Inspectors may not provide all data requests on access forms due to confidentiality limitations*.

It is the responsibility of the study teams to provide basic training to the Monitors, Auditors and Regulatory Inspectors to facilitate their navigation of the systems.

It is the role of the study teams to review the full audit report received from IT listing all patients' records accessed by Monitors/Auditor/Regulatory Inspector's to confirm all eRecord activities

It is the responsibility of IT services to ensure that access to the systems is withdrawn at the end of the agreed period.

It is the role of the study teams to make sure that all documentation pertaining to Monitor access is retained in the study Investigator Site File

6. Procedures

Monitors, Auditors or Regulatory Inspectors will be granted time limited, read only access to participant information held within eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store.

Access cannot be limited to study specific participants. Monitors, Auditors or Regulatory Inspectors will be able to see all participant records. Monitors, Auditors or Regulatory Inspectors (as applicable) will be expected to adhere to the Trusts Acceptable Use Declaration and Confidentiality Agreement.

All activity within eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store is monitored via the audit trail. Activity by Monitors, Auditors and Regulatory Inspectors will be subject to review to ensure that the terms of use of the systems have not been violated.

There are two different types of monitoring, and their considerations are explained below.

To note: It is the Trust preference that Pre-Site Selection Visits (PSSVs) and Site Initiation Visits (SIVs) are conducted remotely where possible and practical to do so. If necessary SIV on-site requests can be honored following space/capacity review by the relevant delivery team. If support/advice is required contact the Industry Team.

6.1 On Site Monitoring

On site monitoring is still possible and the procedure is described in the working instruction below:

DLV-GEN-WI-003 Gaining Physical On-site Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors

If input from the NJRO is required, teams should use the following contact details:

- Commercial monitoring requests: nuth.trustindustry@nhs.net
- Non-commercial monitoring requests: nuth.genericqueries@nhs.net

6.2 Remote Monitoring

There are risks in relation to participant confidentiality that must be mitigated when supporting remote monitoring methods. Remote monitoring and SDV must not result in confidential participant information being sent to the sponsor/monitor or stored by the sponsor/monitor if this has not already been addressed in the Participant Information Sheet (PIS)/consent form. For instance, non-redacted copies of medical notes, from which individuals may be identified, must not be emailed, posted or transferred to the monitor/sponsor.

Sponsors should consider what monitoring needs to be done in real time, and what checks can be undertaken later, taking a risk-based approach. Where a change to access to confidential participant information will arise because of changes to remote monitoring (or where the proposed remote monitoring conflicts with information in the PIS and/or consent form), sponsors must ensure that the revised PIS and consent form, along with the risk assessment justifying the changes to access confidential participant information, are submitted via the amendment process. Teams must also ensure that participants are re-consented where necessary.

Monitoring should follow the details included in the monitoring plan. Although remote access for monitoring is the preferred choice at NuTH, where the monitoring plan dictates on-site visits (for example: for cause or for patient safety), this must be accommodated. Monitors should continue to gain access to SDV via the appropriate processes.

6.2.1 Centralised & Off-site monitoring

- Centralised monitoring of data acquired by electronic data capture systems (e.g., eCRFs, imaging data, ePROs etc.) may be put in place by sponsors to provide additional monitoring capabilities that can supplement and temporarily replace on-site monitoring through a remote evaluation of ongoing and/or cumulative data collected from trial sites, in a timely manner.

- Additional off-site monitoring activities may include the use of phone calls, video calls/visits, e-mails, or other online tools to discuss the trial with the investigator and site staff. These activities may be used to get information on the clinical trial progress, to exchange information on the resolution of problems, review of procedures, trial participant status as well as to facilitate remote site selection and investigator training for critical trials.

- Off-site monitoring may also involve remote SDV which is covered below.

6.2.2 Remote Source Data Verification (SDV)

- The trust may receive various requests to support sponsors with remote SDV. These might include:
  (1) direct, read-only remote access to specific systems holding participant's documentation using two factor authentication.
  (2) the sharing of pseudo anonymised redacted copies of trial related source documents with the monitor; or
  (3) video review of participant's documentation with site team support (i.e., monitors requesting the site team to access systems whilst sharing their screen via video call) or the review of participant's documentations via phone call (i.e., monitors requesting the site team to verbally confirm data in specific systems).

  Whereby all three options may be used, option one (1) is the preferred and most secure access method.

- There are risks associated with each of these SDV methods therefore it is important that control measures can be implemented when considering whether the trust can support such requests.

- Guidance from the MHRA and HRA also advises that SDV may be done remotely by electronic means only if the necessary security arrangements can be put in place and if the arrangements are in line with the PIS/consent form. Remote SDV must not result in confidential participant information being sent to the sponsor/monitor or stored by the sponsor/monitor if this has not already been addressed in the PIS and consent form.

- Some general stipulations around remote SDV are detailed below, along with mitigations to protect participant confidentiality.

  ○ In all cases, site staff and monitors must be trained on the SDV process. As part of this, site teams must acknowledge this SOP prior to any remote SDV taking place Monitors should be made aware of this SOP.
  .
  ○ Remote SDV of medical records may only take place from a remote monitoring location within the UK, EU/EEA, without any links to third countries. On-Site monitoring may use the same principles and application process to access SDV.

  ○ Monitors must sign a 'Non trust IT Research Monitor Request Form' before remote SDV can occur, where they must commit to securely destroy any copies of redacted documents (If applicable), whether paper or electronic, as soon as they have been used for SDV. They must also commit not to make any copy, screenshot or recording in the case of video system access (via screen sharing)

of any non-pseudo anonymised document. Monitors and auditors agree to only review SDV of patient's entered onto the specific trial, they are contracted to. Review on non-research patients or patients enrolled in other trials is strictly forbidden.

○ Performance of remote SDV by the monitor may only occur in locations that prevent viewing/access by any unauthorised person, through a secure internet connection and on a computer appropriately protected against unauthorised access to the data.

○ The local site team should establish whether access to SDV is feasible and manageable, and what the practicalities are aspects to consider may include local capacity based upon the amount of data requested for SDV. On-site monitors should be provided with an appropriate space to conduct their duties confidentially.

○ The monitor should be provided with the appropriate patient identification numbers, specific to the trial, to prevent access to non-applicable records.

Further stipulations for each of the SDV methods are detailed below.

(1) SDV via direct, read only access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store

- Direct access by monitors to systems holding participant documentation away from the site creates issues around participant confidentiality. However, it is possible utilising a One Time Code. This is a secure multi-factor authentication platform for Remote Access to monitor/inspect study information stored within BadgerNet Maternity, BadgerNet Neonatal, Document Store and eRecord at The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH)

- Concerns around this method remain because there is:

  - Inability to limit read only system access to participants consented to the study, coupled with a lack of oversight to observe which participant records are being accesses by monitors.

  - Unknown security of the device where the records are being accessed (e.g., difficult to ensure adequate firewalls, secure log in and passwords of devices used by monitors etc.); and

- Inability for the trust to oversee where remote access takes place (e.g., there is potential for monitors to access records in an open plan office, public space or other location where others who are not authorised could view sensitive participant information).

(2) SDV via the sharing of pseudo anonymised (redacted) copies of trial related source documents:

- Site teams may also receive requests to support remote SDV by scanning and transferring redacted source documents to monitors.

- Facilitation of this method causes increased pressure on clinical staff, so it is important that sponsors ensure extra burdens are not placed on investigators/NuTH teams around scanning and uploading excessive amounts of redacted source documents.

- NuTH teams are permitted to support this method of remote SDV involving the redaction by site staff (pseudo anonymised) of source records, subject to the following:

    - There is clear urgency and reasoning for remote SDV (e.g., final data cleaning steps before database lock in pivotal trials investigating serious or life-threatening conditions with no satisfactory treatment option); and

    - Confirmed capacity and capability of delivery staff.

The method of remote monitoring and the procedures are described in the working instruction below:

DLV-GEN-WI-012 Gaining Secure Remote Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors

7. References

Data Protection Act 2018

ICH GCP E6 (R2) November 2016

Access to Electronic Health Records by Sponsor representatives in clinical trials

8. Appendices

DLV-GEN-T-001 Non-Trust IT Research Monitor Request Form

DLV-GEN-WI-003 Gaining Physical On- site Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors

DLV-GEN-WI-012 Gaining Secure Remote Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors