



Great Western Hospitals **NHS**

NHS Foundation Trust

Standard Operating Procedure:

MONITORING VISIT

SOP NUMBER: 003

Version Number & Date:- 2 dated 15.03.2017

Superseded Version Number & Date(if applicable): Vs1
31.01.2017


Effective Date: 15.03.2017

Review Date: 01/04/2018

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BACKGROUND

According to ICH GCP (5.18.1, 1996) the purposes of study monitoring are to verify that:

- the rights and well-being of human subjects are protected
- the reported trial data are accurate, complete and verifiable from source documents
- the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP and with the applicable regulatory requirement(s)

An important part of a monitoring visit is comparing the entries in the case report forms with the original source documents (e.g. laboratory results, patient hospital notes). This procedure is known as Source Data Verification.

PURPOSE

To describe the preparation and procedure to follow during and following monitoring visits.

PROCEDURE

1. WHO?

The Sponsor will appoint Monitors and specify when monitoring visits are to take place. Monitoring visits will be arranged in advance by the Monitor with the site Research Team (who are responsible for ensuring that the R&I Department are aware immediately of the impending visit). The Principal Investigator and the Research staff working upon the study should be available during the visit. The Monitor will be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.

2. WHEN?

The Sponsor will specify the frequency and nature of monitoring visits. ICH GCP (5.18.3) specifies that in general there is a need for on-site monitoring, before, during and after the trial; however, in exceptional circumstances the Sponsor may determine that central monitoring in conjunction with procedures such as Investigator's meetings and training and extensive written guidance can assure appropriate conduct of the trial in accordance with ICH GCP.

3. HOW?

Preparing for the Monitoring Visit

PI/Research Nurse to notify R&I Department of the visit. A member of the R&I Team will arrange for appendix 2 & 3 to be printed off and available for signature by the monitor prior to any required electronic system access being given. (appendix 1 is the overarching agreement signed by the R&I Manager for external access to the Trusts PAS-EPS System) An appropriate member of the Research team will be available to assist with the following:

- The Site File, all Case Report Forms and source documents should be available in readiness for the monitoring visit. If large numbers of patients have been recruited to a specific trial, the Research staff should agree with the Monitor prior to the visit, which patient notes will be required for Source Data Verification. (Some notes may be presented electronically as the Trust moves towards an electronic only patient notes system).
- All Research staff working on the study and the Principal Investigator should be informed that the monitoring visit is scheduled
- A room or desk should be booked for the use of the Monitor during the visit
- The Monitor should inform Research staff if they plan to visit other departments (e.g. Pharmacy) during the monitoring visit

During the Monitoring Visit

- A member of the Research Team/R&I Department should be available to meet the Monitor and ensure that all Case Report Forms and required source data are available
- If Medway is required for participant information the Confidentiality form and Medway monitor access form must be signed (appendix 2&3) by the Monitor prior to any access to this system being given
- If required, the Principal Investigator should be available for at least part of the monitoring visit
- The Monitor will normally require time to review the Case Report Forms and source data alone and then arrange to meet a member of the Research team and/or the Principal Investigator afterwards to discuss any problems or outstanding issues
- The specific activities of a Monitor are listed in ICH GCP (1996) section 5.18.4

Following the Monitoring Visit

- All source documents should be returned to the respective departments
- The Monitor will submit a written report to the Principal Investigator summarising what has been reviewed and stating significant facts/findings, deviations and deficiencies, actions to be taken and/or actions recommended ensuring compliance. **A copy of this must be provided to the R&I Manager.**
- The written report should be filed in the Study File
- A member of the Research Team should seek to address all outstanding actions promptly
- R&I will conduct a review to ensure compliance and submit an email to Information Governance to confirm that only the relevant participant notes have been viewed or inform of any breach of DPA

4. APPENDICES

(Appendix 1) Request for External Access to the Trust's PAS/EPS System (overarching sign off by R&I Manager)

(Appendix 2) Declaration of Confidentiality

(Appendix 3) Monitor Access to patient records on Medway v1