

Standard Operating Procedure

Title: MONITORING VISITS		
REF: SOP 012	Version: 04	Issue No: 1
Template Source: Merseyside & Cheshire Cancer Research Network		Date: 18/02/05
Reviewed by: Professor Rod Owen		Date: 05/11/2009
Approved by: Dr M J Maxwell		Date: 21/05/07
Due for Revision		Date: 05/11/2012
This SOP is effective from:		Replaces: Version 03 (21/05/07)

1. BACKGROUND

For every clinical trial performed to ICH Good Clinical Practice standards, a Monitor appointed by the Sponsor must visit the trial site to ensure that: 'the trial is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice Guidelines and the applicable regulatory requirements'. The purpose of this is to ensure the rights and well-being of trial subjects are protected.

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 record card patient's hospital notes, ECG printouts). This procedure is known as Source Document Verification (SDV). The ICH GCP Guidelines encourage direct access to original source documents by Monitors in order to perform SDV. The Guidelines state that: 'written information provided to subjects should include an explanation that the Monitor will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject.'

2. PURPOSE

This procedure describes the preparation for, and the procedure to follow during, monitoring visits.

3. OTHER RELATED PROCEDURES

SOP 006 Study Files & Filing
 SOP 009 Case Report Form (CRF) Completion.

MONITORING VISITS	
REF: SOP 012	VERSION: 03

4. WHEN

Depending on requirements of the sponsor, the first visit usually takes place soon after the first patient is enrolled. Depending on the study requirements, visits may take place as frequently as approximately every four to six weeks, to less frequently, such as every quarter during the study. Depending on the length of the study and its progress, this interval may be prolonged or shortened. Non-commercial and academic studies tend not to be monitored as frequently as commercially sponsored trials.

All relevant documents should generally be gathered together before the planned visit.

5. WHO

Monitoring visits are arranged by the Monitor (also known as Clinical Research Associate). These visits will be arranged with the Principal Investigator and/or other research staff, such as co-investigator and research practitioner as appropriate. The research practitioner will usually be responsible for gathering the required documentation in preparation of the monitoring visit.

6. HOW

6.1. Preparation:

All case report forms and the site study file should be up to date, including any outstanding corrections from the last visit.

Where possible, all source documents should also be available, including those from other departments, e.g. Radiology, which may be relevant to the study.

A room or quiet desk should be set aside for the use of the Monitor during the visit.

Prepare details of numbers of patients screened and enrolled in the study and of any other outstanding business requiring discussion.

6.2. During the visit:

Where required by the Monitor, the Principal Investigator, and if possible the co-investigator, should be available on the day of the visit. If there is a research practitioner he or she should also be available.

It is preferable that the Principal Investigator always be available for at least a period of each monitoring visit.

MONITORING VISIT	
REF: SOP 012	VERSION: 03

The Monitor will normally require time to go through the CRFs and associated source documents alone, with a meeting with the appropriate site staff afterwards to discuss any problems or outstanding business. Appropriate staff should make themselves available for such discussion.

The Monitor may also wish to examine facilities at the study site and check storage of the study medication and drug accountability. If so, appropriate arrangements should be made in advance and the Monitor should be accompanied by a member of the research staff on visits to other departments.

If the visit is because of a serious adverse event, or some other specific purpose, the Monitor should inform you of any special requirements beforehand.

6.3. After the visit:

Source documents should be returned to the respective departments.

Missing data should be obtained and corrections made promptly.

If the Monitor supplies a report of the monitoring visit this should be filed in the study file. The study file should be updated with a log of all visits made by the Monitor.