Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

STH Researcher

Responding to Data Queries

SOP History	*01/024*
SOP Number	*A125*
Created	*STH Research Department (AL)*
Reviewed by	*STH Research Department (AL) 28 January 2009*
Superseded	*1.3, 01 April 2005*
Version	*1.4*
Date	*15 November 2006, reviewed 04 August 2009*
Related SOPs	*A124 Maintaining the CRF*
	A122 AE recording
	A126 Monitor Visit
	A101 Study Set up
Approved by	*Research Manager*

Standard Operating Procedure: STH Researcher

Responding to Data Queries

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, Research Governance Framework 2005 and ICH Good Clinical Practice guidelines. This SOP will outline procedures for responding to data queries.

Background

After the Case Report Form (CRF) is completed by the Investigator or delegated person, the data is submitted to the analysing group (usually sponsor or a Contract Research Organisation - CRO- on the sponsor's behalf) by the agreed method of submission.
Data can be submitted electronically (eCRF), by post, by fax or can be collected.
It is the investigator's responsibility to ensure the accuracy, completeness, legibility and timeliness of the data. The analysing group will enter the data onto their database tool and perform computer program checks which question any discrepancies of the data. From these checks, data queries forms (DQF) are raised and returned to the investigator for their response. A DQF is usually issued in triplicate: one to be kept at site, one for the monitor and one for the analysing group.

Definition

A data query can be:
- a discrepancy between the source document and the CRF data
- an unclear entry in the CRF
- missing data.

Data Queries forms (DQF) are generated throughout the study or at the end of the study before the analysis of the data has taken place. A prompt response is expected by the investigator in order to confirm or correct the data.
DQFs will continue to be issued until the data is complete.

Procedure

1. The sponsor or delegate decides on the most relevant method of data capture and discrepancy checks.
2. The sponsor and STH Investigator agree who can respond to the DQF and make the required data changes to the CRF.
3. The STH Investigator completes a Delegation of Duties Form to document who is able to respond to DQFs.
4. The STH Investigator or delegate completes the Case Report Form (CRF) and submits this to the analysing group by the agreed method.
5. The sponsor or delegate performs the data checks and issues DQFs either directly to the STH Investigator or to the monitor on the Sponsor's behalf (as determined by study monitoring arrangements).
6. The STH Investigator or delegate reviews the query and provides a response in the space provided on the DQF.
7. The STH Investigator or delegate makes required changes to the CRF in black ball point pen.
8. The STH Investigator or delegate dates and initials each change.
9. The STH Investigator or delegate retains a copy of the DQF at site and files it with the patient CRF.
10. The STH Investigator or delegate does not correct the CRF if the original ('top copy') of the CRF has been submitted to the analysing group. Changes to the data are documented on the DQF and filed with the patient CRF.
11. The STH Investigator signs and dates the completed DQF.
12. The STH Investigator or delegate returns the completed DQF to the analysing group by the agreed method (fax, post, email etc).