Guideline number	**57.010G**	Version	**1.0**
Title	**Source data worksheets**		

A source data location plan (SDP) provided by the sponsor/CRO must be completed by the study team at the start of a study, this will determine the source and its location, and may include direct entry of source in EDC/eCRF. In the event a source data plan template is not provided Form 56.002M should be used.

Source worksheets may be developed by the site team prior to the study starting, in some cases the sponsor/CRO may provide these but the following steps must be followed prior to use, this includes with sponsor/CRO provided documents.

Procedure

1. Development

Source worksheets should be created using templates Form 57.010E/F. The data points from the protocol and EDC guidelines should be recorded on the forms for collection by the site team.

Transcription of source from electronic health records to paper worksheets can increase the risk of data errors, it must be agreed within the SDP which data will be recorded as source on worksheets.

When creating an eligibility worksheet each inclusion and exclusion criterion of the study protocol must be copied exactly to the worksheet.

Footers must be recorded on source worksheets detailing version of document, title, page numbers, protocol number and version.

2. Quality Control Check

Prior to implementation of a worksheet a quality control (QC) check must be performed by a staff member independent to the development of the worksheet. The data points within the protocol and EDC guidelines should be crosschecked, and the flow of information must work with the research activities requested. The QC checks must be documented in the template worksheet and submitted to the author. If changes are required, the author must update the worksheet and return to the staff member for a further QC check. This process must continue until the final version is ready to move to the approval stage. The final version including the QC check sign-off must be filed in the investigator site file.

The lead study nurse must QC check sponsor/CRO provided worksheets, returning any comments and request to update to the sponsor/CRO.

3. Approval

In some instances, the study sponsor/CRA may approve source worksheets, submit the final QC checked versions of the worksheets. Once approval received this must be filed in the investigator site file.

Once the QC checks and if applicable the sponsor/CRA approval has been obtained the study Principal Investigator must review all source worksheets alongside the protocol and EDC guidelines and confirm ready for use. PI sign off must be documented in the final version of the worksheet and filed in the investigator site file.

If changes are required during this process, the author must make the proposed changes and QC checks must be performed, repeating steps above.

The GCRF QA Team are available to support the teams through the development and review process of source worksheets.

4. Worksheet revision

If an amendment to the study protocol has been submitted by sponsor/CRO the source worksheets must be reviewed to the current version of the protocol. The steps above must be followed prior to implementation of new worksheet version. The worksheet footer must be updated to include the current approved version of the protocol.

Guideline signatories

Prepared by Signature	Eilidh Wright Date
Approved by Signature	Lynn Prentice Date

Document history

Version	Date	Description
1.0	18/10/2023	Creation and first release