Completion

The CRFs should collect all the information reflected in the trial, relating to patient eligibility, treatments, outcomes, and endpoints, accurately matching those detailed in the protocol.

All CRFs:

- Ensure that there are no blank spaces left. If the data at the time of completion cannot be entered, please use phrases that explain why, such as ‘unknown’, ‘missing’ and ‘test not done’. Please do not utilise ambiguous phrases as ‘not available’.
- Ensure that the data entered corresponds with what has been documented in the source data (e.g. Medical Records, ECG, and Lab Results), and that it is accurate and legible.
- If there are notable discrepancies with the source data, there should be an explanation given in the CRF and the significance noted.
- If there are Lab values outside the laboratory’s reference ranges or other range pre-identified within the study protocol, or if a value shows significant variation from one assessment to the next, the significance should be documented within the CRF along with the course of action taken.
- Each set of entries made on the CRF should be signed off and dated by the trained and authorised individual completing the CRF. The Principal Investigator should then review the data entered into the CRF, validating their review with a signature and date of review on each CRF page (or at the end of each visit, but page signature is suggested) for every trial subject in their care.
- In the case of multi centre studies, please ensure that ALL ORIGINAL data queries to be sent to the lead site, again to the relevant data management personnel for review, whilst copies are to be kept at the local sites that are participating within the study, whether it be a photocopy. Please see the diagram below to visually demonstrate the process with regards to data collection, as previously described

SOP 38b Associated Document 1 - CRF Design Guidance

The following has been taken from SOP 38b AD 1, for more information please click here

- If there is dose escalation, reduction or modification outlined in the protocol CRF must reflect this and enable this data to be documented