

Considerations for Layout

The following guidance should be taken into consideration with regards to the appearance of the document.

- CRFs should be well aligned, and the arrangement of data fields should be clear, logical and user friendly. Consistency with regards to formatting should also be adhered to with regards alignment, margins, spacing and fonts.
- Particular attention to the header and footer of these documents should be taken, with the study code as well as the patient number pertaining to the study to be highly visible and be considered to be a standard.
- All CRF pages should be paginated, with headers and footers with the study code and participant code (on every page) to be highly visible to ensure if any pages get misplaced, they can be easily reunited and all the data is recovered.
- There should be space for the person making the clinical assessment as to the patient's viability to participate within the study or/and the person who is completing the CRF to sign and date the page. This acts as verification and confirmation that the data collected is accurate.
- CRF pages should be sequentially arranged in order of patient visits.
- The data fields should be arranged to ensure that they are easy to use, clear and logical.
- If in paper format consideration should be given to how the pages are to be stored within a file or are to be bound into a booklet, ensure that the margins should allow enough room for this reason.
- The separation of sections using section dividers can be used to ensure clarity and be user friendly. (For example, Visit 1 section, Visit 2 section, IMP record, concomitant medications, adverse events).
- It may be advisable in the case of multi-centre studies to incorporate other site specific identifiers to ensure it is known where the CRF pages have originated from.

SOP 38b Associated Document 1 - CRF Design Guidance

The following has been taken from SOP 38b AD 1, for more information please click [here](#)