Swansea University Prifysgol Abertawe | Swansea Trials Unit Uned Dreialon Abertawe

Case Report Form Design Guidelines

1 Guideline of Contents

- The CRF must collect sufficient data to support analysis of the protocol's outcome measures
- All Inclusion/Exclusion criterion questions must be as listed in the protocol. Each CRF visit should require confirmation of Informed Consent.
- Patient identifiable data (other than pseudo anonymised data) must not be collected in the CRF.
  - Where required, identifiable data will be kept in a separate database
- According to the complexity of the research project, CRF completion guidelines (STU-AD-TMP-024) may be required:
  - A copy of the CRF completion guidelines (version controlled) should be maintained in the appropriate section of the TMF
  - Details of how and when a paper CRF should be returned should also be included (where required)

2 CRF Design

All CRF pages must follow the format of the CRF Template (see Appendix 1) unless there is agreement from STU on another template.

2.1 Main Page Content

- The CRF layout should have a logical ordering
- The format of questions must provide standardised answers that aid completion
- Design format should:
  - Avoid collecting free text (where possible)
  - Ask explicit questions
  - Avoid double negatives in the questions
  - Provide pre-coded answer options to ease the analysis e.g. "yes"/"no"/ "Not applicable"/ "Not known" "Please specify"
  - Indicate if a question can have one answer or multiple answers
  - Use absolute, rather than comparative, questions, e.g.: None, Mild, Moderate, Severe; rather than Better, Same, Worse
  - Collect raw data rather than calculated data, e.g. for age, collect birth date
  - Collect dates and time in a uniform fashion as required by the DMS
  - Pre-specify the choice of units wherever possible e.g. mg, ml, cm etc.
  - Ensure consistency across the CRF booklet (units, terminology etc.)
  - Avoid duplication of data e.g. date of birth only needs to be collected at screening as this is unlikely to change during the course of the research project
  - Give the option to report 'not done' or 'unknown' to avoid ambiguity in questions left blank

  - If missing data is anticipated for key questions then provide questions that record the reason why the data is missing
  - Include fields for “time” if time of assessment/intervention or sampling is essential
  - Ensure data is collected to satisfy CONSORT requirements

- Depending on the data required by the research project protocol, a standard CRF document might include, but is not limited to, the following:
  - Front Cover Sheet (Basic Instructions)
  - Eligibility form
  - Baseline/screening form (including demographic data and medical history)
  - Randomisation/registration form
  - Demographic data
  - Concomitant Medication Log
  - Treatment form (treatment, doses, administration routes, reductions)
  - Patient Completion (documenting the date, reason and circumstances for the cessation of visits or data collection due to withdrawal, death, progression or other)
  - Follow-up forms
  - Patient Withdrawal
  - Adverse Event Log (STU-AD-TMP-008)

The STU CRF library (STU-AD-TMP-023) contains templates for the above CRFs and should be amended and utilised as necessary.

<<Short Title/Number of Trial>>

Site Number: | | | |

Participant Number: | | | | Participant Initials: | | | Participant DOB: | D | D | M | M | Y | Y | Y | Y |

<<Form Name>>

Initials of person completing form: | | | | Date: | DD | MM | YYYY |