**General Completion Guidelines**

**General Principles for CRF Completion**

* Use black ball point pen only, never use pencil. (pCRF Only)
* The correct version of the CRF form must be completed. (pCRF Only)
* Where selection boxes indicate a selection of Y or N or numerical options (i.e. 1, 2, 3), only ONE entry should be recorded per box (pCRF Only)
* The CRFs must be completed, dated and signed by an Investigator or designee as soon as the requested information is available (eCRF and pCRF)
* Where free text is required, handwriting should be legible for anybody to read. (pCRF Only)
* If a correction needs to be made, simply cross out the incorrect entry. Do this with a single line so that the original entry is still readable. Enter the correct data and initial and date the correction. Never use correction fluid or obliterate the entries made on the paper CRF, it is important that someone is able to trace back. (pCRF Only)
* The investigator site should always retain a copy of each completed form (pCRF Only)
* Changes must not be made to copied CRF pages once the original has been returned to the Trial Coordinator (pCRF Only)
* CRFs must only be completed by authorised personnel who have received trial-specific training and are competent in CRF completion. They should also have completed and signed the site’s trial Delegation Log (eCRF and pCRF)
* The PI should retain regular oversight and timely sign off of the CRFs, particularly those relating to a patient’s eligibility (eCRF and pCRF)
* Avoid writing patient’s personal information, such as name, surname, address, phone, email (eCRF and pCRF)

**Header Boxes (eCRF and pCRF)**

The following data must be completed in the header of every completed CRF:

* Patient Initials: First and last initials only if specified in the protocol
* Site Code: The site number allocated at site initiation
* Participant ID number: Each participant will receive a unique study ID number

**Completion of Dates (eCRF and pCRF)**

* The date format should be specified and be consistent throught. To avoid confusion dates should be captured as “dd/mm/yyyy” for example 01/01/2012.

**Completion of Time (eCRF and pCRF)**

* Time should be completed in a uniform/consistent manner (HH:MM)

**Unavailable Data (eCRF and pCRF)**

* **All** applicable questions must be answered
* Where data are not available **please do not leave the answer blank** as this will create unnecessary data queries
* Leave the missing data pending if later on the data will be known, and filled out.
* Please include one of the following abbreviations instead:
* NK = Not known (if the information is unretrievable and will never be known)
* NA = Not applicable (if the information is not relevant for the field)
* ND = Not done (if a test or a procedure is not done)
* For missing dates use the following rules: NK/NK/NKNK or NK/NK/2020 or NK/01/2020
* For missing hours use the following rules: NK :15 or NK :NK

**Correcting Errors (pCRF Only)**

* Errors should be crossed out with a single line (i.e. mistake), the correction inserted and the change initialled and dated by the investigator or designee
* Typing correction fluid should **NOT** be used
* If it is not clear why a change has been made, an explanation should be written next to the change

**Sending CRFs to the Trial Coordinator (pCRF only)**

* Completed **SAE/AESI/PREGNANCY** forms should be sent to the trial coordinator **within 24 hours** of becoming aware of the event
* Other CRF pages should be sent in a timely manner, ideally within two weeks of the end of a treatment/period/visit