

# eCRFs Instructions Manual Version 2.3

## Summary of Changes since Version 2.2

References to CTCAE version were removed and Adverse Events and Baseline Symptoms eCRFs reflect changes to support version 4 of the CTCAE.

### General Instructions

- Using Pick Lists – Added instructions explaining how to search pick lists with over 1,000 items and listed them and in which CRFs they are used.
- Inserting Unplanned Visits – Added section explaining why and when and how to use unplanned visits.

### Appendices

- Appendix III – List of labs updated.
- Appendix IV – Added instructions on how to use LLI.

### Adverse Events

#### Purpose Section:

- Removed references to CTCAE version.
- Added instructions in case the patient dies while on study.
- Minor edits.

#### Field Descriptions Section:

- CTCAE Term – Removed references to CTCAE version and added instructions on how to search for item before displaying pick list.
- System Organ Class – Replaces the CTCAE Category field. Derived based on the CTCAE Term selection.
- Adverse Event Description – Removed references to CTCAE version and some example.
- Unexpected AE? – Added Unexpected AE (as defined by the NCI IRB). Replaces Listed in Consent.
- Attribution to Research – Added note about relationship with other Attributions.
- Expedited to Manufacturer – Added field and instructions.

### Baseline Symptoms

#### Field Descriptions Section:

- CTCAE Term – Removed references to CTCAE version and added instructions on how to search for item before displaying pick list.

- System Organ Class – Replaces the CTCAE Category field. Derived based on the CTCAE Term selection.
- Symptom Description – Example and field size updated.
- Grade – Removed references to CTCAE version.

## **Concomitant Measures and Medications**

### **Field Descriptions Section:**

- Agent Name – Added instructions on how to search for item before displaying pick list.
- Procedure / Measure – Field name changed from Procedure.
- Total Daily Dose – Size increased to 100 characters.
- Route – This field is now optional.

## **Course Assessment**

### **Field Descriptions Section:**

- Response Assessment – Added description of new acceptable responses including the RECIST ones. Added RECIST reference links.

## **Course Initiation**

### **Field Descriptions Section:**

- Treating Institution – Added instructions on how to search for item before displaying pick list.

## **Enrollment**

### **Field Descriptions Section:**

- Grade of Histology – Added note about the Gleason Score for Prostate patients.
- Treatment Assignment Code – Added instructions on how to search for item before displaying pick list.
- Date of Diagnosis – No longer accepts partial dates. Full date (DD-MMM-YYYY) is required.

## **Extent of Disease**

### **Field Descriptions Section:**

- Product – Instructions clarified.
- Total Tumor Volume – Instructions clarified.

## **Follow-up**

### **Purpose Section:**

- Clarified that the CRF does not need to be used if the patient died during the treatment portion of the study.

## **Labs**

### **Purpose Section:**

- Removed references to CTCAE version.
- Added instructions regarding the electronic load of lab results from the Clinical Center.
- Added reference to use of Unplanned Visits for entering outside (or non Clinical Center) labs.

### **Field Descriptions Section:**

- Grade – Removed references to CTCAE version.

## **Off Treatment**

### **Field Descriptions Section:**

- Best Response to Treatment – Added description of new acceptable responses including the RECIST ones.

## **Pharmacokinetics**

### **Field Descriptions Section:**

- Time Interval – Size increased to 6.

### **Validations Section:**

- PHM16 – Added note stating that Agents in the Study Medication CRF with routes of PO, Topical or CIV are ignored in this validation.

## **Prior Radiation Supplement**

### **Purpose Section:**

- Clarified instruction that prior radiation treatment collected should be only the ones related to the disease being studied by the protocol or clinically significant to the study.

## **Prior Surgery Supplement**

### **Purpose Section:**

- Clarified instruction that prior surgery treatment collected should be only the ones related to the disease being studied by the protocol or clinically significant to the study.

### **Field Descriptions Section:**

- Date of Surgery – No longer accepts YYYY dates. DD-MMM-YYYY or MMM-YYYY must be provided.

## **Prior Therapy Supplement**

### **Purpose Section:**

- Clarified instruction that prior therapy treatment collected should be only the ones related to the disease being studied by the protocol or clinically significant to the study.

## **Prior Treatment Summary**

### **Purpose Section:**

- Clarified instruction that prior treatment collected should be only the ones related to the disease being studied by the protocol or clinically significant to the study.

### **Field Descriptions Section:**

- Number of Prior Chemotherapy Regimens – Instructions clarified that this field should be used only for Chemotherapies.
- Date of Last Dose – No longer accepts YYYY dates. DD-MMM-YYYY or MMM-YYYY must be provided.