Changes in CTRP for FDAAA Final Rule - Include 20170719

This page provides an overview of the new and updated data elements in CTRP for the FDAAA Final Rule. NCI has been implementing changes in the following areas of CTRP in support of the FDAAA Final Rule and ClinicalTrials.gov reporting:

1. Phase 1 - In May 2017, NCI updated CTRP to support capture and output of the FDAAA Final Rule data elements:
    a. The Protocol Abstraction (PA) web application, used by the CTRO, captures all new/modified FDAAA Final Rule data elements. These new/modified FDAAA Final Rule data elements are submitted to the CTRO during this phase to update the trial record during new trial /amendment abstractions.
    b. CTRP Abbreviated trial imports from ClinicalTrials.gov include the new/modified data elements if already provided on the ClinicalTrials. gov record.
    c. Nightly export of NCI-Sponsored trials from CTRP to the ClinicalTrials.gov Protocol Registration System (PRS) include the new/modified data elements.
    d. The CTRP-generated XML file that will be available after the processing of a new trial or amendment in CTRP includes all the new /modified FDAAA Final Rule data elements.
    e. The ClinicalTrials.gov PRS "Upload from NCI CTRP" feature imports the new/modified data elements, if submitted to the CTRO to update the trial record during new trial/amendment abstraction.
2. Phase 2 - In August 2017, NCI updated the CTRP trial registration website and services to support the capture of all FDAAA Final Rule data elements.
    a. CTRP Registration REST services support the submission of the new/modified FDAAA Final Rule data elements directly to CTRP via the REST services.
    b. Cancer Center CTRP users can enter the new/modified FDAAA Final Rule data elements directly in CTRP via the Registration web application.
    c. All FDAAA Final Rule/ClinicalTrials.gov fields are now optional. The "XML Required" field will no longer be available.
3. Phase 3 - In August 2017, NCI completed implementation including the following:
    a. The Trial Summary Report (TSR) includes the new/modified data elements as applicable.

For questions at any time, contact ncictro@mail.nih.gov.

The following tables briefly list the changes in CTRP to support the FDAAA Final Rule.

⚠ Some fields will be accessible only to the CTRO as these fields are captured during protocol abstraction.

Changes in **Sponsor/Responsible Party** data elements:

Field Label	Description of Change
Sponsor	Make this field optional.
Responsible Party	Make this field optional.

Changes in **Regulatory** data elements:

Field Label	Description of Change
Trial Oversight Authority Country and **Trial Oversight Authority Organization Name**	Remove the fields for these data elements.
Studies a U.S. FDA-regulated Drug Product	Add this data element.
Studies a U.S. FDA-regulated Device Product	Add this data element.
Delayed Posting Indicator	Rename the field for this data element to **Unapproved/Uncleared Device**. Make this field optional.
Post Prior to U.S. FDA Approval or Clearance	Add this data element.
Pediatric Post-market Surveillance	Add this data element.
Product Exported from the U.S.	Add this data element.
FDA Regulated Intervention Indicator	Make this field optional.
Section 801 Indicator	Make this field optional.

Changes in **IND/IDE** data elements:

Field Label	Description of Change
Expanded Access Indicator	Rename the field for this data element to **Availability of Expanded Access**. In this data element, add new value **Unknown**.
Exempt Indicator	Remove the field for this data element.
Expanded Access Record	Add this data element.

Changes in **Trial Status** data elements:

Field Label	Description of Change
Trial Start Date	In this data element, require the full date if the type is **Actual**. Update the current process to properly populate this date value when importing or exporting a ClinicalTrials.gov study.
Primary Completion Date	In this data element, require the full date if the type is **Actual**.
Completion Date	In this data element, require the full date if the type is **Actual**.

Changes in **Trial Design** data elements (abstracted by the CTRO):

Field Label	Description of Change
Primary Purpose	In this data element, add new value **Device Feasibility**.
Trial Phase	In this data element, rename the value **0** to **Early Phase 1 (or Phase 0)**.
Intervention Model	Rename the field for this data element to **Interventional Study Model**. In this data element, add new value **Sequential Assignment**.
Model Description	Add this data element.
Masking	Remove the field for this data element.
Masking Role (s)	Rename the field for this data element to **Masking**. Rename **Subject** check box to **Participant**. Rename **Caregiver** check box to **Care Provider**. Add check box **No Masking**.
Masking Description	Add this data element.
Study Classification	Remove the field for this data element.

Changes in **Outcome Measure** data elements (abstracted by the CTRO):

Field Label	Description of Change
Safety Issue	Remove the field for this data element.

Changes in **Eligibility Criteria** data elements (abstracted by the CTRO):

Field Label	Description of Change
Gender	Rename the field for this data element to **Sex**. In this data element, rename the value **Both** to **All**.
Gender	Add this data element.
Gender Eligibility Description	Add this data element.

Reference information:

- Final Rule Applicable Clinical Trial Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf
- Overview of the Final Rule changes: https://prsinfo.clinicaltrials.gov/webinars/finalrule/resources/Final_Rule_Webinar_One_Sept_27_2016.pdf
- Final Rule ClinicalTrials.gov trial registration changes: https://prsinfo.clinicaltrials.gov/webinars/finalrule/resources/Final_Rule_Webinar_Two_Oct_5_2016.pdf