CTRP User Call

October 11, 2017

NIH NATIONAL CANCER INSTITUTE

CTRP DT4 Reporting – Scope of Trials on the Report

- Per the DT4 Data Guide: *DT 4 serves as a report of the cancer-related hypothesis-driven clinical research studies **open** at the Cancer Center during a center-defined 12-month reporting period.*
- **"Open" statuses in CTRP** = Active, Enrolling by Invitation, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention
- If a Center is not an "open" site on a trial during the reporting period, the trial is **excluded** from their CTRP DT4; even if the center is the Lead Organization.

CTRP DT4 Reporting – Scope of Trials on the Report (continued)

- If a Trial/Site is Temporarily Closed for the entire reporting period, it will be **included**.
- Currently, all Trials/Sites with a status of Withdrawn* are excluded, CTRP will be modified to **include** Trials/Sites which were “open” during the reporting period even if they subsequently Withdrawn.

*Withdrawn: Study halted prematurely, prior to enrollment of first participant.
https://wiki.nci.nih.gov/display/CTRPdoc/Trial+Status+Values+in+the+CTRP+and+ClinicalTrials.gov

CTRP DT4 Reporting – Observational and Ancillary-Correlative Studies

- CTRP DT4 in FY2018 is focused on Interventional trials.
- CTRP **supports** registration of non-interventional studies (observational and ancillary-correlative).
- Centers **can** generate a CTRP DT4 report for non-interventional studies.
  - Note: To be determined if CTRP DT4 will be <required> for non-interventional trials.

CTRP DT4 – Multi-Site Trials: Source of Data

- **Lead Organization** reports trial status and accrual data for all participating sites. Exceptions:
  - NCTN and NCORP trials: CTEP and DCP PIOs report status and participating site information
  - Industrial trials: Participating sites report participation, trial status, and accrual data for their site only.
- **Participating Centers** report:
  - Target Enrollment for their Center (Your Center Total), https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Targeted+Accrual
  - Program Code, https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Program+Codes
  - Local Trial ID (optional)
- NCI will batch load this data upon request. Please submit these requests to CTRP_Support@mail.nih.gov.

CTRP DT4 – Multi-Site Trials: Source of Data (continued)

- Some Centers note incomplete reporting by the Lead Org/Sponsor or disagree with the data for their Center reported by the Lead Organization (e.g., study type, study source, status dates and accruals)

➢ Centers can:

1) if you are a Participating Site on a multi-institutional trial, contact the Lead Org to update their information.

- If you are unsure of who to contact, please submit a request to Susan Nonemaker (susan.nonemaker@nih.gov) to request permission for contact details on your behalf.

2) if a National trial, contact the CTSU help desk (ctsucontact@westat.com) to triage and update their information.

3) provide comments on the CTRP DT4 report (Excel version prior to submission).

CTRP DT4 Reporting – Trial Status Transition Rules

- CTRP status transition rules do not allow certain status transition changes (e.g., closed back to open). This prevents trials that reached the terminal status of closed from appearing on a CTRP DT4 report.
  - Note: Centers have reported that their trial status transition rules may differ from that which is currently supported by CTRP (e.g., can go from closed back to open).

CTRP DT4 Reporting – Accrual Reporting

Patient accrual is only counted once.

- “Center12Mos” and “CenterToDate” count accruals for a Center and all organizations defined in CTRP as part of the Center “family”.
- “Other12Mos” and “OtherToDate” count accruals for all organizations defined in CTRP as “Affiliates” of a Center.
- A Center's Organization and Affiliation* relationships are the same for all trials and is defined at the discretion of the Cancer Center.

*Cancer Center “Affiliates” are institutions that have partnered with a Cancer Center to accrue patients on behalf of the center. Other NCI Designated Cancer Centers (e.g., multi-site trials) are NOT affiliates to Cancer Centers.

CTRP DT4 Reporting – Basket/Umbrella Trials

- CTRP DT4 will report basket/umbrella trials as registered in CTRP.
- NCI anticipates that future basket/umbrella trials, e.g. Pediatric MATCH, will register screening and component arms as separate Interventional trials.
  - Note: NCI MATCH is currently registered in CTRP as one trial, and, as a result, it is represented on CTRP DT4 only once.

CTRP DT4 Reporting – Trial Phase

- CTRP Trial Phases match those in ClinicalTrials.gov.
- Valid Trial Phases include: Early Phase I (previously Phase 0), I, II, III, IV, combinations of these phases, and N/A.
- Pilot is accepted in CTRP when associated with a valid Phase.
- Feasibility is not accepted as a Phase in CTRP.

Definitions: https://wiki.nci.nih.gov/display/CTRPdoc/Trial+Phase+Value+Definitions

CTRP DT4 Reporting

- **No Duplicate Trials**
  - CTRP DT4 does not allow reporting of two or more trials with the same ClinicalTrials.gov NCT ID; it can be represented only once.

- **Inclusion of Date that Trial Closed**
  - CTRP DT4 includes “Date Closed” even if the date is after the reporting period.

CTRP DT4 Report References – Data Elements

- **CTRP DT4:** https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report

- **CCSG DT4:** https://cancercenters.cancer.gov/GrantsFunding/eData#dt4

CTRP DT4 Report (Interventional Trials / Non-Competing)
Submission Process

- NCI initiates the DT4 report generation and review process.

- Send emails to Center ~4 weeks prior to DT4 submission due date with draft CTRP DT4 interventional trials report (Excel version).
- Update/fix data directly in CTRP and/or annotates CTRP DT4 report.
- Work with NCI to review any questions and/or discrepancies.
- Confirm final approved version of the CTRP DT4 report working with Center.
- Center to continue to reconcile data in CTRP on an ongoing basis.
- Create PDF version of final CTRP DT4 report interventional trials (Excel version with comments).
- Submit to the NCI OCC (cc'ing Center). Send final version of Excel to Center for reference purposes.
- Note: Non-interventional DT4 generated using CCSG DT4 template and sent to OCC separately.

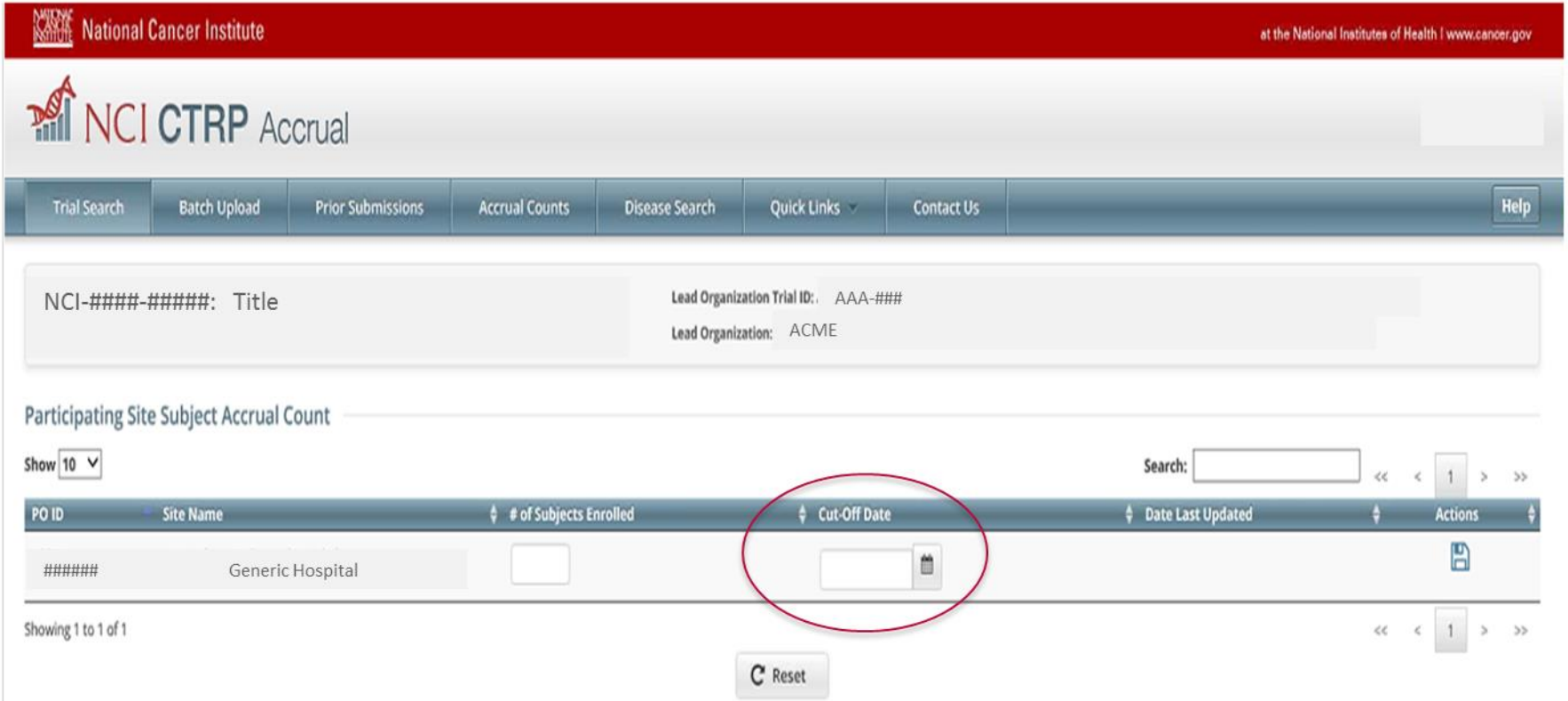
Updates to CTRP Data Table 4 Reporting System

- New CTRP DT4 reporting system accounts will require 2-factor authentication.
- CTRP Engineering Support will email Cancer Center CTRP Data Table 4 Report users requesting that they contact them to set up a session to walk through the 2-part sign-on process.
  - To be conducted in waves from Oct 16 – 31, 2017.
- Transition to enhanced CTRP DT4 Reporting system to be completed by November 1, 2017.

Recent CTRP Updates

- Abbreviated/Industrial Trials accrual ***Cut Off Date*** field for cumulative reporting. *Refer to next slide for screen shot.*
  - CTRP User Guide Reference: https://wiki.nci.nih.gov/display/CTRPdoc/Working+with+Abbreviated+and+Other+Trial+Accruals
- "Pilot" may now be associated with any valid Trial Phase, e.g. Pilot Phase 2.
- CTRP DT4 report aligns to the effective dates of a Cancer Center Family (Organizations and Affiliations) to support a reporting period.
- Cancer Centers may now request that a trial be excluded from their CTRP DT4 report (e.g., non-cancer trials). Note – Please submit these requests to the CTRO (NCICTRO@mail.nih.gov).
- CTRP will batch load data upon request, e.g., Abbreviated/Industrial Trials Accrual (Cumulative), Program Codes, Your Center Total (Target Accruals), Local Trial IDs upon request.

Recent CTRP Updates (Cont'd) - Abbreviated/Industrial Trials accrual ***Cut Off Date***



CTRP Planned Updates

- Trials/Sites which were “Open” during a reporting period will be included on the DT4 report even if they are subsequently Withdrawn.
- “Local Trial ID” and “Pilot” will be added to CTRP DT4 report.
- Relax Trial Start Date and “Active” status date restrictions.
- DT4 Comments field to be added to CTRP Registration (and displayed optionally on CTRP DT4 report).
- Ability to add a Participating Site and Accrual on an Industrial trial upon registration.
- Ability to see summary accrual history in the Accrual module.
- Ability to add the Cancer Center Local Trial ID in the Registration module.
- Ability to add Participating Site Contact Information on Industrial trials.

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