2020-08-25 User Call Meeting Minutes

August 25, 2020

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Meeting Presentation

Welcome to the August 25 CTRP User Call! The topics covered in the 08-25-2020 Presentation are as follows:

- Recent & Planned Updates
    - Recent Updates:
        - Flexible Accrual Reporting
        - Country Code Requirements
        - Zip Code Requirements
        - ICD-O-3 Disease Code Requirements
        - Display of Rejected/Submission Terminated Studies (CTRP Registration)
    - Planned Updates:
        - Trial Record Verification Process (confirming, updating, identifying, emailing communication)
        - General User Interface updates
- Expanded Access Trials
- CTRP-Generated Data Table 4
    - Interventional Trials (Scope and Reporting Requirements)
        - PDF Format Change
    - Observational Studies (Scope and Reporting Requirements)
    - Ancillary-Correlative Studies
    - Data Correction Requests: Follow-up Process
    - CTRP Reporting Requirements by Centers
        - NIH/NCI Grant Funding Information
        - Reporting Sex vs. Gender with CTRP Accrual Reporting
- User Account Management
    - OKTA Migration > Centralized CTRP Login
    - CTRP User Account Process
- Center Q & A
- Next Steps
    - CTRP-Generated DT4 Reporting
        - **Interventional trials**: Cancer Centers to continue submitting CTRP-generated DT4 submissions for non-competing and competing applications
        - **Observational studies**: 1). Cancer Centers to initiate (or continue) to register Observational studies in CTRP open to accrual on or after
          January 1, 2018 and 2). participate in upcoming FY 21 reconciliation activities
    - Planned CTRP release details for Trial Record Verification and user interface updates *as well as the Okta migration for user accounts* to be communicated via CTRP ListServ communications
- Next user call is to be determined
    - Please submit any future CTRP user call agenda topics to the CTRO (NCICTRO@mail.nih.gov).
    - To join the CTRP Users Listserv (https://list.nih.gov/cgi-bin/wa.exe?SUBED1=ctrp-users-l&A=1). Please provide this link to any colleagues who would like to join the Listserv.

Discussion/Minutes

Pre-asked questions

- How should the Lead Organization (LO) report accrual in each of the following?
    - Patient transfers INTO the lead org site from a participating site (the patient becomes a LO site patient treated by a LO site investigator)
        - *The patient would not have enrolled to the study under LO site investigators*
    - Patient transfers FROM the LO site to a participating site (the patient is no longer being treated by a LO site investigator at the LO site)
        - *The patient would have enrolled to the study under a LO site investigator*
- How do I register a multi-site, non-NCI Designated Cancer Center or Industry led Observational study that doesn't have an NCT ID (not registered in ClinicalTrials.gov and Lead Org doesn't plan to register it in ClinicalTrials.gov)?
    - *Please contact the CTRO NCICTRO@mail.nih.gov to request assistance with registering Observational studies without an NCT ID*
- Is the inclusion of Expanded Access trials on the CTRP DT4 still optional?
    - *The reporting of an Expanded Access trial on a center-specific CTRP-generated DT4 is still at the discretion of the cancer center*
    - *If you have an Expanded Access trial registered in CTRP that you would like to exclude from your CTRP-generated Data Table 4 report, please send a message to the CTRO (NCICTRO@mail.nih.gov) to request exclusion*
- With Expanded Access protocols being in DT4, will single patient expanded access (compassionate use protocols) also be included?
    - *No, single patient compassionate use studies are out of scope for CTRP*

Open Discussion Questions (answered during meeting)

- What is the location on the Wiki to download ICD-O-3 code lists when there are updates?
    - *The ICD-O-3 code lists can be found at this link: https://wiki.nci.nih.gov/display/CTRPdoc/Accrual+Data+Elements+with+CTRP-Accepted+Values+for+Complete+Trials*

- How often, if ever, does CTRP run a comparison of center submitted CTRP data against data reported to ClinicalTrials.gov? We've had a recent issue where we are not the Lead Organization for an IIT, but our internal data matches that of ClinicalTrials.gov. However, it does not match CTRP and has created an inconsistency in our report.
    - *We do not formally compare all data between CTRP and ClinicalTrials.gov. For imported studies, we look at ClinicalTrials.gov to be the source of the trial level data. For non-imported studies (IIT and/or National studies), we look to the data submitter to provide any trial level data and updates. On an ad hoc basis, the CTRO may contact the Lead Organization if there is an obvious reporting issue.*

- How are centers to count accrual for a participant who withdrew consent prior to starting treatment? Should these accruals be reported on the CTRP-generated DT4 report?
    - *Generally, a participant is counted as an enrollment/accrual once they have signed the Informed Consent Form, even if the patient withdraws at a later time. However, this determination may vary across clinical trial protocols and each protocol should be reviewed for determining participant enrollment.*
- Will the Accrual API be affected by the switch to 2-part authentication?
    - *The authentication will change but 2-factor authentication will not be required, as the API user will have a token with their authentication.*

Additional Questions Asked During Meeting

- **CTRP Trial Registration and Scope**
    - Can you please clarify the registration of expanded access studies, should they be registered in CTRP?
        - *CTRP requests centers to register Expanded Access trials in CTRP by importing the record into CTRP from ClinicalTrials.gov. (slide 17)*
    - What if an NCT ID is missing for expanded access?
        - *For any trials requested to be imported (including Expanded Access) to CTRP without an NCT ID, please contact the CTRO (NCICTRO@mail.nih.gov). CTRO can confirm if the trial is in scope for CTRP and if so, will facilitate registration (slide 40)*
    - Should Ancillary/Correlative studies be registered in CTRP?
        - *CTRP supports registration of Ancillary/Correlative studies. There is no current requirement to register these studies in CTRP. (slide 27)*
    - When should a cancer center that is planning to submit for an initial CCSG award begin registering protocols in CTRP?
        - *The center can start to register any NIH grant funded trials as soon as possible, but they should hold off an any additional trials until the grant is awarded. The center should contact their Office of Cancer Centers (OCC) Program Director for specific questions.*
    - *If a study is imported from Clinicaltrials.gov, how soon can we see it displayed in our CTRP-generated DT4? Also is there any additional information required to complete registration of study once imported from clinicaltrials.gov?*
        - *Once the trial has been Imported, a site must add themselves as a Participating Site (PS) before the abstraction process begins. After the trial is abstracted, it will be available on a CTRP-generated DT4 report if the status dates are in scope for the reporting period. The abstraction process is completed by the CTRO within 10-business days after registration (both new trial and amendment registrations).*
- **Record Verification Process**
    - How can we access the list of studies for our center which have not been verified in CTRP within the last 6 months?
        - *This can be found in CTRP Registration (slides 12 & 13)*
    - Who will the emails indicating which trials are due for Record Verification in CTRP be sent to?
        - *The email notifications will be sent to Site Admins, Trial Owners and Trial Submitters.*
    - Will we be able to download the list of trials that are due for record verification into a CSV or Excel report?
        - *Yes, there will be a download option for the trials requiring record verification.*
- **Accrual Questions**
    - Regarding the recent Flex Accrual release changes, a center must request (and get approval for) the ability to report Summary accrual on Complete Interventional trials. Why must we gain approval to report Summary accrual data for a non-treatment healthcare delivery research type of protocol?
        - *CTRP policy is to collect Subject accrual on all Interventional trials (even non-treatment trials). The exception to allow the reporting of Partial Subject or Summary accrual requires a case-by-case review of the protocol for Interventional trials before approval is granted.*
    - Has there been any additional thought about multi-step studies, trials that include a screening and treatment component? These trials are becoming more frequent and the sponsors count both types of accrual steps. How are Observational multi-step accruals to be counted?
        - *For Interventional multi-step trials, the Interventional step (not the screening step) would be counted for accrual (with the exception of MATCH, Alchemist, and Lung Map trials).*
        - *For Observational multi-step trials, the Observation step (not the screening step) would be counted for accrual.*
- **Other Topics**
    - The "Entire Study" column on the CTRP-generated DT4 report is the only way for an Investigator Initiated Trial Lead Org receive "credit" for all accrual reported on the trial (other than accrual within the Center's family). How final is the decision to remove it for the CTRP-generated DT4 PDF?
        - *This change was made in order to allow the CTRP-generated DT4 report to match the eRA Commons size requirements for Competing CTRP-generated DT4 submissions. The center also has the option to download the Excel version and create a PDF version to include this column.*
    - Would it be possible with the planned updates to add the correction templates on the registration page?
        - *CTRP follows NCI guidelines for the CTRP log-in pages. The CTRP Data Correction templates will remain in the CTRP User Guide wiki: https://wiki.nci.nih.gov/x/iQgXG.*
    - We need to be able to have Open and Closed dates on National trials within a more narrow time frame than six months from either the Open or Closed dates. The NCI may think it's fine to have this type of discrepancy, but reviewers during competing review will be reviewing our CTRP-generated DT4 for low accruing studies. If a study Open or Close date is 5 months inaccurate, this can negatively impact our review.
        - *The NCI is aware of these date differences and is working to align these more closely to the PS level dates for their center, moving forward. In the interim, for any trials that require a PS status update, please contact the CTRO (NCICTRO@mail.nih.gov) for assistance.*

- If the Lead Org requests to remove an observational trial from a CTRP-generated DT4, how will the participating site report it?
  - *Trials can be removed from all sites on a CTRP-generated DT4 report at the Lead Orgs request/approval (e.g., non-cancer trial) or removed only from a certain participating site(s) (e.g., Expanded Access trial) at the sites request. If there is a concern with a trial that was removed from your CTRP-generated DT4 report, please contact the CTRO (NCICTRO@mail.nih.gov).*

Contact Links

- CTRO Mailbox (NCICTRO@mail.nih.gov)
- To join the CTRP Users Listserv (https://list.nih.gov/cgi-bin/wa.exe?SUBED1=ctrp-users-l&A=1)