2021-09-14 User Call Meeting Minutes

September 14, 2021

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Meeting Presentation

Welcome to the September 14 CTRP User Call! The topics covered in the 09-14-2021 Presentation are as follows:

- Recent & Planned Updates
    - Recent Updates *(Slides 5 – 13)*:
        - Enhancements to Accrual Reporting
        - Augmenting Security (User Account Management) – Transition to Okta
        - Improvements to Trial Record Verification
        - Support of CTRP-generated Data Table 4
        - Registration: IRB and NIH Grant Information (NCI Funded)
    - Planned Updates *(Slides 15 – 16)*:
        - CTRP ListServ "CTRP Users" to be transitioned to a new communication mechanism "GovDelivery"
        - CTRP System Downtime Notification (9/18/2021)
- "Other" Trials, e.g., Pragmatic, Non-Consenting *(Slides 18 – 24)*
- CTRP-Generated Data Table 4 *(Slides 26 – 37)*
    - Interventional Trials
    - Observational Studies
    - Ancillary-Correlative Studies
    - Data Correction Requests: Follow-up Process
- User Account Management *(Slide 39)*
- Other Topics/Center Q & A *(Slides 41 – 43)*
- Next Steps *(Slide 44)*
    - 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://go.usa.gov/xM386). Please provide this link to any colleagues who would like to join the Listserv.

Discussion/Minutes

NCI Funded Designation

- For the NCI Funded change for indirect and direct funding, are these changes only going forward or will they be retroactive?
    - *CTRP has retroactively added the indirect/direct funding for trials already in the system.*
- Can you reiterate the reason for registering studies that have no direct or indirect NCI funding?
    - *NCI's expectation is that all studies at a Cancer Center will have at least indirect funding. The option to support No NCI Funding is for other trials that may be added into CTRP in support of expanded cancer clinical trial search requirements, e.g., Veterans Affairs (VA) cancer clinical trials.*
- Will NCI funded be added to DT4 or is this just CTRP data being collected for other purposes?
    - *There is no current expectation to include a data element for NCI Funded on the DT4 report.*

"Other" Trials, e.g., Pragmatic Studies, Non-Consenting

- What level of accrual reporting would these "Other" trials (aka Pragmatic) require? Full or Partial?
    - *From a technical perspective, CTRP can collect Summary, Partial Subject, or Subject level accrual for these studies. Defining the type of accrual would be on a case-by-case basis, please reach out to CTRO (NCICTRO@mail.nih.gov) for assistance with specific trials.*

Observational Studies in CTRP

- Is there a reason we would submit studies which closed to accrual prior to 2020?
    - *Yes, the expectation is to include any trial(s) open to accrual as of or after 01/01/2018. Other cancer centers may have these trials open on an NCI FY2022 (and/or future) DT4 report.*
- For Observational industry studies where the sponsor is not planning to register in ClinicalTrials.gov, there is a concern about sharing the protocol which is not technically "owned" by the institution. Do you have any work around for this?
    - *Yes, please reach out to CTRO (NCICTRO@mail.nih.gov) for assistance with these trials.*
- Just to confirm, Observational accruals can be submitted annually and will not require to be reported on quarterly?

    - *Correct, the Lead Organization reports cumulative accrual on at least an annual basis as determined by their CCSG submission schedule.*
- Can accrual for Observational studies be updated in bulk (with a minimal data set)? Particularly for those which are closed to accrual.
    - *Batch accrual loading is available, please contact the CTRO (NCICTRO@mail.nih.gov) to confirm any direct parameters.*
- Just to confirm, cumulative accrual can be submitted for Observational studies instead of Subject-level accrual?
    - *Correct, however, only one type of accrual can be reported. If the Lead Organization is reporting Summary, Partial Subject, or Subject level accrual, that accrual will be continued throughout all accrual reported.*
- Is CTRP still in the process of reaching out to Cancer Centers regarding reconciliation observational studies?
    - *Yes, Cancer Centers will be contacted at least 4-6 weeks prior to their next non-competing application. If any additional questions arise, please reach out to the CTRO (NCICTRO@mail.nih.gov) proactively to request a meeting/ask questions.*

National Accrual

- Are there plans to indicate which National trials report screening accruals vs. intervention accruals?
    - *If the "Primary Purpose" is "Screening", all patients counted on the DT4 report are screened patients. If the "Primary Purpose" is "Treatment", all patients counted on the DT4 report should be patients registered on the "Interventional" step of the trial.*

Manage DT4 Elements

- Is there a plan to align the data elements that we have to manually update in the "Manage DT4 Information" with data we are already entering when we register a trial? A lot of duplicate entry is necessary. It is very time consuming.
    - *The CTRP team has been reviewing this alignment and considering various options for how to further streamline potentially in the future. Please note that there are different levels of data elements represented and managed when a trial is registered (e.g., Overall-trial level) versus "Manage DT4 Information" (e.g., Cancer Center-level) which need to be managed as separate data.*

Contact Links

- CTRO Mailbox (NCICTRO@mail.nih.gov)
- To join the CTRP Users Listserv (https://go.usa.gov/xM386)