2023-05-03 User Call Meeting Minutes

May 3, 2023

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Meeting Presentation

Welcome to the May 5 CTRP User Call! The topics covered in the 2023-05-03 Presentation are as follows:

- Recent CTRP Updates
    - Observational Studies *(Slide 5)*:
        - Scope for registration of Observational studies in CTRP has changed to those open to accrual as of or after 1/1/2020
        - For Observational studies currently registered in CTRP, which closed to accrual prior to 1/1/2020, study amendments are no longer required
    - Ancillary-Correlative Studies *(Slide 6)*:
        - Registration of Ancillary-Correlative studies in CTRP is no longer in scope
        - Amendments submitted for currently registered Ancillary-Correlative studies will be rejected
    - Pragmatic Trials (Slides 7 - 13)
        - CTRP TSR now displays the new pragmatic trial indicator
        - CTRP-generated DT4 now displays the new “Prag” column with pragmatic trials filtered at the end of the report
        - CTRO will continue to classify which trials are pragmatic in CTRP, working with Cancer Centers as-needed to further categorize
        - NCI will work with the community prospectively to update and refine the definition as needed
    - Clinical Trials Search API (Slide 14)
        - Recent updates
            - 2021 - CTS API Version 2 (v2) released
            - 2022 - Prior therapy structured eligibility criteria on a small subset of trials
- Registration
    - Submission Requirements (Slides 16 - 18)
    - Managing Multi-Institutional Trials (Slide 19)
    - Externally Peer-Reviewed Trials (Slide 20)
- Accrual
    - Accrual Reporting for Participating Sites by Lead Organizations (Slides 22 - 24)
        - Timely Reporting
        - Timely Responses to Data Requests
- CTRP Data Table 4 (Slides 26 - 29)
    - Interventional Trials
    - Observational Trials
    - Ancillary-Correlative Studies
    - Discrepancy Follow-up Process
- Data Correction Requests
    - Discrepancy Follow-up Process (Slides 31 - 35)
    - CTRP Reporting Requirements by Center (Slide 36)
- Other Topics
    - Resources (Slides 38 - 39)
    - CTRP User Account Manager (Slide 40)
    - CTRP Communications (Slides 41 - 42)
- 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 GovDelivery please click the link https://public.govdelivery.com/accounts/USNIHNCI/subscriber/new?cid=eb_govdel&topic_id=USNIHNCI_265 and register. Please provide this link to any colleagues who would like to join.

Discussion/Minutes

Overview/Training

- Would you be able to point me to the best place to find a "beginner's guide" to CTRP requirements? I'm new to uploading trial info and then am unsure what to do after that point?
    - Refer to slides 38-39 for information regarding general and introductory CTRP references/links. Please contact the CTRO NCICTRO@mail.nih.gov if you have any specific CTRP training needs.

Pragmatic Trials

- Please repeat the information regarding the Pragmatic trials on the Cancer Center DT4 report.
    - Refer to slides 11-12 for more details regarding Pragmatic trials displayed on a CTRP-generated DT4.
- What's the rationale for distinguishing pragmatic trials?

    - CTRP distinguishes pragmatic trials in support of the CCSG DT4 requirements https://cancercenters.cancer.gov/GrantsFunding/DataGuide.
- As we search our study portfolio for interventional Pragmatic Trials, is the cutoff for which Pragmatic trials should be registered 1/1/2017 (similar to observational trial registrations)?
    - Pragmatic trials are not a unique clinical research category per the CCSG DT4 requirements; pragmatic is an attribute of a trial. Please refer to the applicable CTRP registration requirements for your trials.
- How should accruals be handled for pragmatic trials for CTRP, such as only count those w/ prospective consent?
    - We are currently reviewing these on a case-by-case basis. Please contact the CTRO NCICTRO@mail.nih.gov to review specific trial details.
- For Pragmatic trials, if they do not consent participants,
  • Should they still be registered in CTRP and what should be counted as an accrual on a pragmatic trial that does not consent?
    - We are currently reviewing these on a case-by-case basis. Please contact the CTRO NCICTRO@mail.nih.gov to review specific trial details.
- Will the pragmatic trial field be included on the Ancillary DT4 templates?
    - Refer to slide 29 for more details regarding the CCSG DT4 template used for the submission of Ancillary-Correlative studies, which includes the pragmatic trial field.

Registration

- How should we handle the registration type if a study changes funding mid-stream, i.e., from an IIT to an externally funded sponsor?
    - Please contact the CTRO NCICTRO@mail.nih.gov to review specific trial details. CTRO can work with you to appropriately assign the updated Study Source category if changes are applicable.
- Should long-term follow-up or extension studies be registered on CTRP or CT.gov? Should these be on or DT4 or register but not record as DT4 reportable?
    - Long-term follow-up or extension studies are in scope for CTRP and displayed on a CTRP-generated Data Table 4 as appropriate provided they meet registration requirements as outlined https://www.cancer.gov/about-nci/organization/ccct/ctrp/registration.

Observational Studies

- What if there was a observational that was open to accrual before 1/1/2020 and is still open to accrual. Is it exempt from the requirement?
    - Refer to slide 5 for more details. As per this example, this study would be considered in scope for CTRP, “Scope for registration of Observational studies in CTRP has changed to those open to accrual as of or after 1/1/2020”.

Accrual

- Is there a plan in the future to be able to flag those trials that count the screening accruals vs. interventional accruals?
    - There are currently no plans to implement a flag to indicate those trials that count the screening accruals vs. interventional accruals.

CTRP DT4

- Should cancer center's research program have a STRAP generated DT4 specific to their assigned interventional trials along with a separate non-STRAP generated DT4 document for non-interventional trials?
    - A Cancer Center can submit their CCSG Non-Competing CTRP-generated DT4 reports as separate Interventional trials and Observational studies DT4’s or as a combined CTRP-generated DT4 with both Interventional trials and Observational studies. It is up to the discretion of the Cancer Center regarding how they choose to submit.
    - Please contact your OCC Program Director and/or send an inquiry to the OCC mailbox ccsgdata@nih.mail.gov if you have any specific CCSG questions.
- Our STRAP generated DT4 for CY2022 interventional trials reports the closed date from the lead organization or for national studies, the closed to accrual date from the research base and not our local closed date. This makes it appear as though the study is still open at our center when we have already closed. How should we handle this?
    - For specific trial-related questions and/or data corrections including requests to update Participating Site-level “Closed Dates” for National trials, please contact the CTRO NCICTRO@mail.nih.gov to request that they follow-up and/or update the data in CTRP as appropriate. Please indicate if this is in support of an upcoming CCSG Competing submission.
    - The closed date value on the CTRP-generated DT4 is determined by the latest first “closed” date at any site associated with the Cancer Center on the trial. If the trial is still open at any participating site associated with the CTRP Family, this field will be blank/null on the CTRP-generated DT4 report.
    - CCSG Data Elements Included in the CTRP DT4 Report: Data Elements Included in the CTRP Data Table 4 Report.
    - Refer to slides 31-35 for more details regarding data discrepancies and National trials.
- The pdf version seems to be formatted differently than the guidelines, which format should be used for Observational, Correlative, etc
    - Refer to slides 26-27 for more details regarding using the CTRP-generated DT4 for Competing submissions. The CTRP-generated DT4 (PDF format) currently supports CCSG Competing submissions for Interventional trials. Please use the CTRP-generated DT4 (Excel format) for CCSG Non-Competing submissions for Interventional trials and Observational studies.
    - Please contact your OCC Program Director and/or send an inquiry to the OCC mailbox ccsgdata@nih.mail.gov if you have any CCSG questions.
- Can you clarify the Research Program DT4 reporting requirements for competing applications? Lastly, is there a way to generate a STRAP DT4 in a PDF format that is specific to a program code?
    - The CTRP-generated DT4 (PDF format) represents the requirements for the CCSG Competing submission for interventional trials.
    - Please contact your OCC Program Director and/or send an inquiry to the OCC mailbox ccsgdata@nih.mail.gov if you have any specific CCSG questions.
    - Note: A Cancer Center can generate a CTRP-generated DT4 (Excel format), format/tailor accordingly and ‘save as’ a PDF version

Search

- Is there a way to search for NCI number without being logged into CTRP. I know NCI numbers can be listed on ClinicalTrials.gov study records, but is there a way to search for NCI numbers?
    - You can search by NCI IDs on https://www.cancer.gov/about-cancer/treatment/clinical-trials/search. Trial records on Cancer.gov display the corresponding NCI ID.

References

- Will you post a recording of this webinar online?
    - Although we did not record the meeting, we post the final slides (PDF) and Q&A to the CTRP User Call Wiki page: 2023-05-03 User Call Meeting Minutes

Contact Links

- CTRO Mailbox (NCICTRO@mail.nih.gov)
- If you would like to receive future CTRP announcements, please subscribe to the Coordinating Center for Clinical Trials (CCCT) "Clinical Trials Reporting Program (CTRP) User Community" GovDelivery topic.