

2018-09-26 User Call Meeting Minutes

September 26, 2018



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Meeting Presentation

Welcome to the September 26th CTRP User Call! The topics covered in the [09-26-2018](#) Presentation are as follows:

- Review of each CTRP-generated DT4 Data Element
 - Column Name/Field Name
 - Description and Definition
 - Corresponding CCSG Column/Field Name
 - Source of Data
 - Editing/Updating Data
 - Notes/Comments
- Next user call will be scheduled for November.
- For any requested agenda topics, please contact the CTRO (NCICTRO@mail.nih.gov).

Discussion/Minutes

- Question about the use of multiple in the primary site field. The CTRP DT4 shows both "multiple" and "Multiple". I was told that "multiple" is system generated when multiple sites are added and "Multiple" is a value manually added during abstraction. What is the number of sites needed for a system generated "multiple" value? Thanks much, Diana
 - *CTRO practice is to abstract "Multiple" if there are more than three anatomic sites referenced on a trial. CTRP-generated DT4 from STRAP will display "multiple" (lower case) if there is more than one anatomic site on the trial to conform with the OCC CCSG DT4 requirement.*
- How are the closed and open dates reported for national (NCI cooperative group) trials? We do not report an open or closed date specific to our cancer center within CTRP for National trials. Does this require that we update site specific statuses of open or closed to CTSU?
 - *Centers do not report any information on National/Cooperative Group studies except for Center-specific Manage Your DT4 Information. Centers do not submit Participating Site (PS) data (open/closed statuses), accrual data, etc. for National/Cooperative Group studies. This information comes into CTRP from the NCI CTSU systems; so yes, if site status information needs to be updated please do so via CTSU and it will update CTRP.*
- Question about the "close date" field: The data elements table states that Withdrawn reflects a "closed" status in CTRP. However, the status transition rules will prevent any withdrawn trials from showing up in the DT4 (since they cannot have an Active date and therefore do not meet the criteria of an "open" trial). At our center, we have had instances of trials that are open to accrual but subsequently withdrawn. Per these parameters, this type of trial could show up in a DT4 one year and then drop off the following year. Can you validate that the intent of the DT4 is to exclude withdrawn trials?
 - *CTRP-generated DT4 logic looks to see if a study is active/open at a study and then site level. CTRP allows for a study to be active/open and then "Withdrawn". If the study is open and subsequently went Withdrawn it will show on the CTRP DT4 report if the open status was in the reporting period.*
- When you do the Add My Site activity on an industrial study in CTRP, the first few screens in CTRP that follow asks for your local ID and the local PI are you saying that even if we entered this info here it still will not show up on our DT4 unless we also entered this (again) in the Manage DT4 Information for your Center area in CTRP?
 - *We are looking to deprecate the local site ID from the "Add My Site" function and it will only be available at the Manage Your DT4 Information webpage. You are still required to fill out each PS Principal Investigator (PI) which is separate from the Center Principal Investigator field in the Manage Your DT4 Information.*
- Is there a way to get a list in the CTRP system of all of our affiliate/family members?
 - *Not currently as a system generated report that a cancer center can produce. We are working on that functionality. In meantime, contact the CTRO to obtain this information.*
- Does CTRP ever plan to allow the comments to be saved in CTRP so sites do not have to track them in a separate file?
 - *Yes, this is planned but we do not have a delivery date at this time.*
- Are the comments that are part of an official submission for a given report stored in CTRP and if so, can they be retrieved out of CTRP later?

- *No, they are not stored in CTRP. The Office of Cancer Centers (OCC) will have the comments on your submitted report.*
- We have some trials that are categorized as "basic science" and "interventional" isn't that disallowed?
 - *Basic Science is not a CTRP categorization. If there is a question on a specific trial's categorization, please contact the CTRO. NIH released recent guidelines on what is the definition an interventional study. <https://grants.nih.gov/policy/clinical-trials/definition.htm>*
- Are we supposed to submit the DT4 in a two part, one from your system and another from our system? Or is it only just from STRAP?
 - *With respect to interventional trials for non-competing; please submit only from STRAP. Non-interventional trials (observational/ancillary-correlative) should still be submitted via the traditional mechanism to the OCC.*
- In our Institution we have had changes in our program code, how do we make changes to previous protocols that some the program code has become obsolete?
 - *There are Instructions on how to edit program codes: <https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Program+Codes>. Site admins can edit this data and then assign new program codes to your trial. If you have any additional questions, please contact the CTRO for assistance.*
- There are industrial trials in CTRP coded as treatment, but they are not treating cancer. They are treating other diseases since clinicaltrials.gov is for all trials, not just cancer trials. For these trials, the sponsor is not willing to change the primary purposes since it is treating a disease just not treating cancer. Does CTRP ever plan to override the primary purposes pulled from clinicaltrials.gov to be cancer related?
 - *Such trials are reviewed with OCC and CTRP leadership. There are no immediate plans to override primary purpose on trials imported into CTRP from ClinicalTrials.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>)