CTRP Data Table 4 Report FAQ’s

The following table responds to some frequently-asked questions about the CTRP Data Table 4 report:

ID	Category	Question	Answer
1	CCSG Data Table 4 Specification	Where can I find the NCI Office of Cancer Centers (OCC) P30 Cancer Center Support Grant Data Table 4 specification?	Refer to https://cancercenters.cancer.gov/GrantsFunding/eData#dt4.
2	CTRP Data Table 4 Data Elements	Where can I find descriptions of the Data Table 4 data elements as generated in CTRP?	Refer to Data Elements Included in the CTRP Data Table 4 Report.
3	CTRP Data Refresh (DWH)	If I make data updates in CTRP Registration and/or Accrual, when can I expect to see this information on my CTRP DT4 report?	The data will show up on your CTRP DT4 report the next day.
4	CCSG Data Table 4 Specification	What is the definition of an interventional trial?	The definition used by the CTRP team for an interventional trial is: https://prsinfo.clinicaltrials.gov/definitions.html Interventional (clinical trial): Participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes. https://cancercenters.cancer.gov/Documents/CCSGDataGuide508.pdf Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
5	CTRP Data Table 4 Data Elements	Does CTRP support registration of non-interventional studies (observational and ancillary-correlative)?	• Continued support of interventional CTRP-generated Data Table 4 for both competing and non-competing applications • Observational CTRP-generated Data Table 4 for non-competing applications began in FY 22, e.g., Oct 1, 2021 • Ancillary-correlative trials continue to be submitted in a Center-generated Data Table 4 (current CCSG DT4 e-Template format)
6	CTRP Data Table 4 - Interventional Trials	When will CTRP-generated Data Table 4 (interventional trials) be used for Competing applications?	FY20/Ongoing: **Starting with May 25, 2020 competing centers**, Cancer Centers were required to generate their own CTRP DT4 report for interventional trials and submit to the NCI OCC. Refer to the following pages for submission-specific instructions: https://wiki.nci.nih.gov/display/CTRPdoc/About+the+CTRP+Data+Table+4+Report+-+Include+v4.4
7	Scope of Trials on the Report	What specific statuses does CTRP use to define open trials which should appear on our Data Table 4 for a specific reporting period?	Refer to the following pages: • Types of Trials Included in the CTRP Data Table 4 Report • Examples of Trials Included Based on Participating Site Status
8	Scope of Trials on the Report	If a trial/site has a status of Temporarily Closed for the entire reporting period, does CTRP include it on our Data Table 4 report?	Yes.
9	Scope of Trials on the Report	Does the CTRP Data Table 4 report include the date that a trial closed even if the date is after the reporting period?	Yes, the CTRP Data Table 4 report includes “Date Closed” even if the date is after the reporting period.
10	Scope of Trials on the Report	Our participating site is "Open" during the reporting period but does not appear on our Data Table 4 report. Why could this be the case?	If the Overall Trial Status reached a Closed to Accrual and/or Closed to Accrual and Intervention status prior to the reporting period, that Overall Trial Status takes precedence over what the participating site has as their status. The Data Table 4 report includes only those trials that meet *all* of the criteria listed in the Types of Trials Included in the CTRP Data Table 4 Report page.

11	Source of Data on multi-institutional trials	Who reports what data on multi-institutional trials, including Industrial and National trials?	If the Lead Organization is an NCI-designated Cancer Center, the Lead Organization reports all data, including trial and participating site status, and accrual data for all participating sites.
			
			Exceptions: NCTN and NCORP trials (National trials): CTEP and DCP PIOs report status and participating site information.
			
			• Industrial trials: Participating sites report participation, site recruiting status, and accrual data for their site(s) only.
			• Each Center is responsible for reporting their own Center-specific DT4 related information, e.g.:
			  ◦ Program Code.
			  ◦ Target Enrollment for their Center.
			  ◦ Center Principal Investigator (specify a PI for your Center to appear on the CTRP DT4)
			  ◦ Local Trial ID (optional).

12	Non-Cancer Trials	How should we represent non-cancer trials (such as a bone marrow transplant trial) in CTRP and for Data Table 4 reporting?	You can register non-Cancer trials in CTRP but exclude them from the CTRP Data Table 4 report. If you have a non-cancer trial registered in CTRP, send a message to the CTRO (NCICTRO@mail.nih.gov) and request that this trial be excluded from your Data Table 4 report.
13	Expanded Access Trials	Should we include Expanded Access studies on the Data Table 4 report?	It is up to the discretion of each Cancer Center in regards to whether or not you would like to include Expanded Access studies on your CTRP DT4 report. If you have an Expanded Access trial registered in CTRP that you would like to exclude from your CTRP Data Table 4 report, send a message to the CTRO (NCICTRO@mail.nih.gov) and request that this trial be excluded from your Data Table 4 report.
14	Healthy Volunteers	Should we count healthy volunteers aligned to an interventional trial for Data Table 4 reporting accrual?	Yes, but exclude donors.
15	Veterans Administration (VA) Trials	Should we register VA trials in CTRP and count them for Data Table 4 reporting?	It is up to the discretion of the center. You could count VA accrual in the “Center” column, in the “Other” column, or not at all for a given Center’s CTRP generated Data Table 4 for both interventional and non-interventional trials. A majority of Centers are including these trials as Affiliations in their CTRP Family so that accrual data shows up in the “Other” columns.
16	Managing Data Table 4 Information for Your Center	How do we add site /center-specific information associated with Data Table 4 fields to CTRP?	You can add this information at the following “Managing Data Table 4 Information for your Center section in Registration. Managing Data Table 4 Information for Your Center. This includes data entry and updates to the following data (refer to below link): • Program Codes • Target Accrual (Your Center Total) • Specifying a Principal Investigator (PI) to appear on your CTRP DT4 report • Local Trial IDs (optional)
17	Managing Data Table 4 Information for Your Center: Program Codes	How do we add program code data in CTRP?	You can update program codes at the participating site level in CTRP Registration. For instructions, refer to Managing Program Codes. Note: Program Code data was initially migrated into CTRP from the NCI Office of Cancer Centers database based on your center-specific data. Please review this information to confirm that your Program Codes are current and haven't changed. If they have, you can update them under the Managing Program Codes section and reflect the active period for a specific set of codes.
18	Managing Data Table 4 Information for Your Center: Your Center Total (Target Accrual)	How do we add target accrual data for our center in CTRP?	You can update targeted accrual ("Your Center Total" on the Data Table 4 report) at the participating site level in CTRP Registration. For instructions, refer to Managing Targeted Accrual. Note: This targeted accrual is different than the Entire Study targeted accrual number for the overall trial that is abstracted from the protocol document.
19	National Trials: Source of Data	How can I update the data in CTRP for National trials?	National trials are NCI-managed and data is sent directly from NCI systems to CTRP on a regular basis (e.g., weekly) from various source systems. If you have specific questions related to data on your CTRP-generated Data Table 4 report for National trials (Study Source=N), the CTRP team will take a first pass review in regards to reviewing your questions/discrepancies. Please send an email to the CTRO (NCICTRO@mail.nih.gov) if you have any questions regarding data for National trials on your CTRP Data Table 4 report and the CTRP team will investigate initially on your behalf and identify next steps.

20	Accrual Reporting	How does CTRP count accrual data on the Data Table 4 report?	CTRP counts patient accrual only once. • “Center12Mos” and “CenterToDate” count accruals for a Center and all organizations assigned in CTRP as an "Organizational" part of the Center. • “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 (such as multi-site trials) are NOT affiliates to Cancer Centers.
21	Accrual Reporting (Organizational, Affiliations)	Can you describe the difference between an Organization and Affiliation and how these are assigned in CTRP?	The organizational structure and related family in CTRP is defined at the discretion of the Cancer Center. • An organization is defined as a Lead Organization, Responsible Party/Sponsor, Participating Site or a Collaborator on a trial in CTRP. • 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 (such as multi-site trials) are NOT affiliates to Cancer Centers. Note: The Cancer Center is responsible for collecting and submitting the data for these affiliates to the NCI. The Cancer Center responsibilities for reporting Affiliate data are not different than Cancer Center reporting (that is, National trials are reported by CTEP, DCP, CCR, multi-center Institutional trials are reported by the lead organization, Industrial trial participation is reported by the Cancer Center).
22	Accrual Reporting (Trial by Trial Basis)	Can a Cancer Center's Organizational and Affiliation relationships vary on a trial by trial basis?	No, a Cancer Center's Organizational and Affiliation relationships are the same for all trials in CTRP. CTRP does not have the ability to assign Organizational and Affiliation on a trial by trial basis at this time.
23	Accrual Reporting (Definition)	What is the definition of accrual?	Accrual is the total number of participants enrolled in the clinical trial. Enrolled means a participant’s, or their legally authorized representative’s, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol. For more information, refer to https://prsinfo.clinicaltrials.gov/definitions.html#IntEnrollment.
24	Basket /Umbrella Trials	How will CTRP report basket/umbrella trials for Data Table 4 reporting?	The CTRP Data Table 4 report will report basket/umbrella trials as registered in CTRP. • NCI MATCH is registered in CTRP as one trial, and, as a result, it is represented on CTRP DT4 only once. • Each sub-trial of Pediatric MATCH is registered as a separate interventional trial. CTRP will show each sub-trial separately.
25	MATCH	How is accrual represented for a MATCH trial on the CTRP DT4 report?	In terms of CTRP representation, MATCH is registered once and it is the screening accrual data that is displayed on a center-specific CTRP DT4 report.
26	Pediatric MATCH	What information do we need to enter for Pediatric MATCH trials as a participating site?	NCI reports Pediatric MATCH trials to CTRP. Cancer Centers will need to add their center’s CTRP Data Table 4 specific info, such as program code and target enrollment (Your Center Total), by treatment trial.
27	Trial Phase	What are the CTRP trial phases as compared to ClinicalTrials.gov?	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. • CTRP does not accept Feasibility and Pilot as a Phase. • CTRP supports use of Pilot YES or Null for trials of all Phases. For definitions, refer to Trial Phase Value Definitions.
28	Multiple NCT IDs	Does CTRP allow us to enter duplicate trials with the same NCT ID in CTRP?	No, the CTRP Data Table 4 report does not allow reporting of two or more trials with the same ClinicalTrials.gov NCT ID; it can be represented only once.
29	Removed as a Participating Site from a Trial	I noticed a trial on my Data Table 4 report with my organization as a participating site but we never have and do not intend to participate on that trial and would like to be removed.	The Lead Organization/Submitter will need to be contacted and approved removing your center as a Participating Site on a trial. To request to be removed from the trial, you can send a request to the CTRO (NCICTRO@mail.nih.gov) who will contact the Lead Organization on your behalf and/or send you their contact information. Alternatively, indicate proposed updates in a comment (column AC) on your Excel CTRP-generated Data Table 4 and send to the CTRO (NCICTRO@mail.nih.gov) who will contact the Lead Organization on your behalf.
30	Lead Organization Contact Information	How can I obtain contact information for a lead organization's Study Coordinator if I need to update data in CTRP where my organization is a participating site?	You can send a request to the CTRO (NCICTRO@mail.nih.gov) who will then provide you with the contact information for the Lead Organization CTRP Site Administrator (name and email).

31	Abbreviated /Industrial Trials Accrual	Industrial trial accrual (summary/cumulative) does not reflect the correct dates in CTRP for Data Table 4 reporting.	CTRP has been updated to address requested enhancements to CTRP Summary Accrual editing and viewing for Abbreviated and Other Trials. The CTRP Accrual application's Participating Site Subject Accrual Count page now provides Cancer Centers with the ability to Add, View, and Edit summary accrual information; # of Subjects Enrolled and Cut-Off Date. Please see the User Guide for additional instructions: Recording and Updating Participating Site Accrual Counts: https://wiki.nci.nih.gov/display/CTRPdoc/Recording+and+Updating+Participating+Site+Accrual+Counts Please refer to the CTRP DT4 User Call Presentation/Q&A (CTRP Accrual Reporting) December 4, 2018: https://wiki.nci.nih.gov/display/CTRP/2018-12-04+User+Call+Meeting+Minutes

32	Complete /Multi-Institutional Trials: Discrepancy Follow-up Process	How do I make and/or request updates to data in CTRP for Complete /Multi-Institutional /Institutional trials?	If your Center is the Lead Organization/Sponsor:
			
			• Make changes directly in CTRP for those fields that you can update.
			• Please confirm that organizational entities (Organizations, Affiliations) for your Center are
			• added to the trial as a Participating Site(s).
			• Contact the CTRO (NCICTRO@mail.nih.gov) if you are unsure and/or can't edit data.
			
			If your Center is not the Lead Organization/Sponsor, and is only a Participating Site:
			
			• You can send an email to the CTRO (NCICTRO@mail.nih.gov) and they can:
			  ◦ Follow-up directly with the Lead Organization CTRP Site Administrator on your behalf to request CTRP updates.
			  ◦ Provide you with the Lead Organization CTRP Site Administrator contact information (name and email).
			  ◦ You can also include a comment on your CTRP DT4 Excel report (column AC) with details and the CTRO can follow-up directly with the Lead Organization.
			• Typical requests for follow-up with a Lead Organization include:
			  ◦ Add your Center as a Participating Site to the trial.
			  ◦ Update statuses/dates and/or accruals on your behalf which are missing or incorrect.

33	Abbreviated /Industrial Trials: Discrepancy Follow-up Process	How do I make and/or request updates to data in CTRP for Abbreviated /Industrial trials?	If the trial is already registered in CTRP:
			Please add your Center as a Participating Site using the "Add My Site" feature:
			
			• Trial information that you can update after adding your site includes the following:
			  ◦ Organization's local trial identifier
			  ◦ Site principal investigator
			  ◦ Organization family's program codes
			  ◦ Site recruitment status and dates
			
			If the trial is not already registered in CTRP.
			
			• Please import the trial in from ClinicalTrials.gov using the "Import Feature".
			
			CTRP Data Correction Requests

34	National Trials: Discrepancy Follow-up Process	How do I make and/or request updates to data in CTRP for National trials?	Please send an email to the CTRO (NCICTRO@mail.nih.gov) if you have any questions regarding data for National trials on your CTRP Data Table 4 report and the CTRP team will investigate initially on your behalf and identify next steps. CTRP Data Correction Requests
35	National Trials Out of Scope	There are trials shown as Observational in ClinicalTrials.gov but are not in CTRP, why is this the case?	In discussions with CTEP leadership, we were informed the below studies are ancillary-correlative and out of scope for CTRP reporting. At the request of CTEP these submissions were rejected. COG was informed and continues to update the clinicalTrials.gov records. Noting, These are listed as Observational in ClinicalTrials.gov as there is not a category for ancillary/correlative. If additional clarification regarding the trial type is required, please contact CTEP PIO Protocol&InformationOffice@mail.nih.gov • NCI-2009-00383 - NCT00772200 - ALTE07C1 • NCI-2009-00382 - NCT00736749 - ALTE05N1 • NCI-2011-03822 - NCT00082745 - ALTE03N1
36	National Trials Out of Scope	Study Noted as Out of Scope for CTRP	DCP-001 was confirmed out of scope for CTRP by DCP because it is considered a one-time data collection study. If there is any additional clarification required, please contact DCP PIO.

37	Comments Scope	What type of comments should be made in the Comments field?	Comments in this element should be restricted to scientific comments for the participating site (Incorrect Manage DT4 elements, accrual, or inclusion differences). The Office of Cancer Centers looks to the Lead Org to provide data on Trial-Level data elements, so a comment is not required for inconsistencies between the participating site and the lead org. If a participating site strongly disagrees with the categorization of any of the Trial-Level data elements, please send an email to the CTRO (NCICTRO@mail.nih.gov) to confirm if the data element is correctly abstracted. If the participating site is also the lead org, please send an email to the CTRO (NCICTRO@mail.nih.gov) to take steps to correct any incorrectly categorized data elements for the trial. Trial-Level Data Elements (provided by the Lead Org or System Generated): • Clinical Research Category • Study Source • Specific Funding Source • Primary Site • NCT ID • NCI ID • Protocol ID • Is Multi-Institutional • Phase • Pilot • Primary Purpose • Official Title • Entire Study • Entire Study Accrual to Date
38	CTRP Data Table 4 Submission Process	Can you please specify the CTRP Data Table 4 submission process?	Please see submission requirements and supportive guidelines here: CTRP Data Table 4 Report Submission Process.
39	Support	What are the approved browser types and versions for CTRP Data Table 4 report generation?	Refer to Browser Support in STRAP.