Copy of Data Elements Included in the CTRP Data Table 4 Report - Include DT4PragRelease

The data elements in the Data Table 4 report generated from CTRP closely align with that of the P30 Cancer Center Support Grant (CCSG). For information on the CCSG Data Table 4 report, refer to https://cancercenters.cancer.gov/GrantsFunding/eData#dt4. The following tables describe the data elements displayed in the CTRP Data Table 4 report, and demonstrate this alignment of data elements with the CCSG report.

For instructions on configuring the report, refer to Generating the CTRP Data Table 4 Report.

CTRP Data Table 4 reporting for interventional trials (non-competing CCSG applications) started in FY18 (after October 1, 2017). NCI transitioned to CTRP DT4 for interventional trials for competing CCSG applications in FY20 (started May 25, 2020 submissions).

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Cancer Center Organizational Family (Cancer Center Family already setup in CTRP which appears in CTRP Data Table report drop-down for your center)	The name of the CTRP organization family as defined by the Cancer Center. The CTRP Data Table 4 report uses the CTRP Family-Organization relationships to select trials for a report. Reports are based on a Cancer Center Family. All trials for which the Family organizations or affiliates are participating sites are included in the report. Organizations and Affiliates can only be assigned formally to one designated Cancer Center at a time.	(No column) (CTRP Data Table 4 report title)
Cancer Center Organizational Family (Organizations) (Cancer Center Family already setup in CTRP)	Trials associated with a Cancer Center's Organization(s) (e.g., your Cancer Center and its formal Consortium Partners) are reported in the "Center Reporting Period" and "Center To Date" accrual columns.	(No column) (CTRP Data Table 4 report title)
Cancer Center Organizational Family (Affiliations) (Cancer Center Family already setup in CTRP)	Trials associated with a Cancer Center's Affiliation(s), i.e. trials at hospitals, treatment facilities, and /or research facilities that are associated with but not a formal part of the Cancer Center (e.g., nearby community hospitals) are reported in the "Other Reporting Period" and "Other To Date" accrual columns.	(No column) (CTRP Data Table 4 report title)
Reporting Period Start Date (CTRP Data Table 4 selection criteria)	The date you have specified as the start date for the reporting period.	**Reporting StartDate** (CTRP Data Table 4 report title)
Reporting Period End Date (CTRP Data Table 4 selection criteria)	The date you have specified as the end date for the reporting period.	**Reporting EndDate** (CTRP Data Table 4 report title)
Trial Type Indicator (CTRP Data Table 4 selection criteria)	An indication whether the report includes data from a specific trial type or all trial types. For information, refer to Trial Types and Subtypes. • All • Interventional • Non-interventional	(No column) (CTRP Data Table 4 report title)

Fiscal Year (CTRP Data Table 4 selection criteria)	The annual period you have specified for the report (e.g., FY 2018 January 1, 2017-December 31, 2017).	**FY** (CTRP Data Table 4 report title)

Scope of Trials on the Report

For a trial to be included on a Cancer Center's CTRP Data Table 4 report, the trial must be "Open" at both the Overall Trial-level and at the Participating Site-level for the selected reporting period. CTRP DT4 logic looks at the first Open and first Closed recruitment statuses for the Overall Trial and the Site when deciding which trials to include on a report.

Open statuses include the following:

- **Active**
- **Available**
- **Enrolling by Invitation**
- **Temporarily Closed to Accrual**
- **Temporarily Closed to Accrual and Intervention**
- **Temporarily Not Available**

The following table describes the elements that appear in the CTRP report as columns.

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
P30 Grant Number	The Cancer Center Support Grant number. This is the P30 Grant Serial number (such as CAxxxxxx). This is NOT the grant associated with the lead organization of the trial.	**GrantNumber**
Clinical Research Category	The trial type. The primary investigative techniques used in the protocol (interventional or non-interventional). The non-interventional category includes observational and ancillary/correlative studies. For information, refer to Trial Types and Subtypes. The report uses the following abbreviations: • **INT** = Interventional trial **Note: Expanded Access studies are currently listed in CTRP under the Interventional trial category.** • **OBS** = Observational, non-interventional trial • **ANC/COR** = Ancillary/Correlative non-interventional trial	**ClinicalResearchCat**
Study Source	The type of Data Table 4 funding sponsorship (National, Externally Peer-Reviewed, Institutional, or Industrial). For information, refer to CTRP Trial Categories, Study Sources. The report uses the following abbreviations: • **N** = National • **E** = Externally Peer-Reviewed • **I** = Institutional • **D** = Industrial Trials that are imported as Industrial/Other such as Consortia trials are included in the source category as N, E, I. The Study Source column indicates only the content of the trial, not how the trial is entered.	**StudySource**
Specific Funding Source	The CTRP organizations listed as Data Table 4 Funding Sponsor for the trial. Sponsor or source of the funding mechanism.	**FundingSource**
Primary Site	The Data Table 4 Anatomic Sites for the trial. The anatomic site(s) on which the trial or study is focused. If a Clinical Research Study covers more than one Anatomic Site, the Site column should be coded "multiple." For a list of values, refer to Data Table 4 Anatomic Site Values.	**PrimarySite**
NCT ID	The unique ID assigned to the trial by the National Clinical Trial program (ClinicalTrials.gov) for trials that have been submitted to ClinicalTrials.gov Protocol Registration System (PRS) previously. This ClinicalTrials.gov ID appears as "NCT" followed by 8 numeric characters (such as NCT12345678).	**NCTID**
NCI ID	The unique ID assigned to the trial by the CTRP.	**NCIID**

Protocol ID	The lead organization trial ID. The unique ID assigned to the trial by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.	**ProtocolID**
Other Protocol IDs	Additional IDs assigned to the trial, including the following: • CTEP or DCP • Unique IDs from other registries • NIH grant numbers • Protocol numbers assigned by the review board • Other IDs	**OthProtocolID**
Local Trial ID	The unique ID assigned at the Cancer Center level and used at the sites level to identify a trial. For instructions on specifying this information in CTRP, refer to Managing Local Trial IDs. Note: Identifier that the Cancer Center has provided which helps them to map the trial from their local CTMS to CTRP.	**LocalTrial ID**
Is Multi Institutional?	An indication whether there is more than one Cancer Center participating in the trial, derived as follows: • **Y** (Yes) = There is more than one site (organization) participating in the trial, and these participating sites are not *all* members of the same Cancer Center (organization family). • **N** (No) = One or more sites are participating in the trial, but all participating sites are members of the same Cancer Center. Note: Based on CTRP (rather than ClinicalTrials.gov relationships).	**IsMultiInst**
PI (Principal Investigator) - Last Name, First Name, Middle Initial	The PI fields on the CTRP-generated DT4 report include the Last Name, First Name and Middle Initial of the PI from the Center who is responsible for the Clinical Research Study. • If a Site Administrator has specified a Center Principal Investigator in CTRP, the CTRP-generated DT4 report displays that name. For instructions on specifying this information in CTRP, refer to Specifying the Center Principal Investigator. • If no Center Principal Investigator is specified in CTRP, this field is blank/null on the CTRP-generated DT4 report.	**LastName**, **FirstName**, **MiddleName**
Program Code	The alphanumeric code that identifies the clinical research program. A code assigned by the Cancer Center to each participating site on a trial to classify the type of cancer research being conducted by the trial at that site. Multiple program codes are separated with semicolons. For instructions on specifying this information in CTRP, refer to Managing Program Codes.	**ProgCode**
Open Date	The official start date of a trial at your Center determined by 1) the date of activation noted in an official clinical trial activation announcement or 2) date of first patient accrual if the trial in question did not have a formal activation announcement. This value on CTRP DT4 is determined by the earliest “open” status date at any site associated with the center on the trial. The following trial statuses reflect an “open” status in CTRP: Active, Enrolling by Invitation, Available, Temporarily Closed to Accrual or Temporarily Closed to Accrual and Intervention, Temporarily Not Available.	**OpenDate**
Close Date	The date the clinical research study closed to accrual. This does not include patient follow-up. If the study is still open at any site associated with the family, this field will be blank/null on the CTRP-generated DT4 report. This 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. The following statuses reflect a “closed” status in CTRP: Closed to Accrual, Closed to Accrual and Intervention, Complete, Administratively Complete or Withdrawn, No longer Available, Approved for Marketing.	**CloseDate**
Phase	The phase of investigation, as defined by the US FDA for trials involving investigational new drugs. For details, refer to Trial Phase Value Definitions.	**Phase**
Pilot	An indication whether the trial is a pilot trial.	**IsPilot**
Primary Purpose	The main reason for conducting the trial. The report uses the following abbreviations: • **Tre** = Treatment • **Pre** = Prevention • **Sup** = Supportive Care • **Scr** = Screening • **Dia** = Diagnostic • **Hsr** = Health Services Research • **Bas** = Basic Science • **Dev** = Device Feasibility • **Oth** = Other For more information about these values, refer to Primary Purpose Value Definitions. For instructions on specifying the primary purpose for a trial, refer to Recording Trial Details.	**PrimaryPurpose**
Prag	An indication as to whether the trial is a pragmatic (prag) trial.	**Prag**
Official Title	The official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document).	**OfficialTitle**

Entire Study	The anticipated (target) number of subjects (accrual) for the entire trial if the specified Cancer Center is the lead organization. A blank field indicates that the specified Cancer Center is not the lead organization.	**EntireStudy**
Your Center Total	The participating site (Cancer Center) target accrual. The system displays this value if available in CTRP for the trial. For instructions on specifying this information in CTRP, refer to Managing Targeted Accrual. However, the value should be reported in this column if it is at all available, whether in CTRP or otherwise.	**YourCenterTotal**

Center Reporting Period	The total number of subjects accrued for the trial for all organizations in the Cancer Center Family with the relationship "Organization" for the time period you selected.
	• If detailed accrual information was reported for the trial, the system calculates accrual within the specified time period (such as 12 months) based on the Subject Registration Date.
	• If summary accrual was reported (such as for Industrial trials), the system calculates accrual for a selected time period as follows:
	  ○ If a cut-off date is available, the system calculates accrual based on the cut-off date.
	  ○ If a cut-off date is not available, the system uses the accrual registration date as the cut-off date.
	The system calculates accrual for a selected time period based on the difference between the last summary accrual reported before the time period and the last summary accrual reported within the time period. If no summary accrual was reported before the time period selected, the system displays the last summary accrual reported within the time period as the accrual count for the time period.
	For an example, refer to CTRP Data Table 4 Report Accrual Calculation.
		Center12Mos

Center to Date	The total number of subjects accrued to date (as of the selected time period end date) for the trial for all organizations in the Cancer Center Family with the relationship "Organization". For an example, refer to CTRP Data Table 4 Report Accrual Calculation.	**CenterToDate**

Other Reporting Period	The total number of subjects accrued for the trial for all organizations in the Cancer Center Family with the relationship "Affiliation" for the time period you selected.
	• If detailed accrual information was reported for the trial, the system calculates accrual within the specified time period (such as 12 months) based on the Subject Registration Date.
	• If summary accrual was reported (such as for Industrial trials), the system calculates accrual for a selected time period as follows:
	  ○ If a cut-off date is available, the system calculates accrual based on the cut-off date.
	  ○ If a cut-off date is not available, the system uses the accrual registration date as the cut-off date.
	The system calculates accrual for a selected time period based on the difference between the last summary accrual reported before the time period and the last summary accrual reported within the time period. If no summary accrual was reported before the time period selected, the system displays the last summary accrual reported within the time period as the accrual count for the time period.
		Other12Mos

Other to Date	The total number of subjects accrued to date (as of the selected time period end date) for the trial for all organizations in the Cancer Center Family with the relationship "Affiliation".	**OtherToDate**
Entire Study Accrual To Date	• If the Lead Organization, column is populated with a summary of accrual for all participating sites on the trial through the last day of the reporting period (directly and not directly connected to the Lead Organization CTRP Family). • If a Participating Site, column is blank.	**Entire Study Accrual To Date**
Comments	To use this column: 1. Export the report to Microsoft Excel. For instructions, refer to Working with CTRP Automated Reports. 2. In the spreadsheet, add comments to this column. (NCI recommends up to 50 characters.) 3. Print the spreadsheet to PDF.	**Comments**