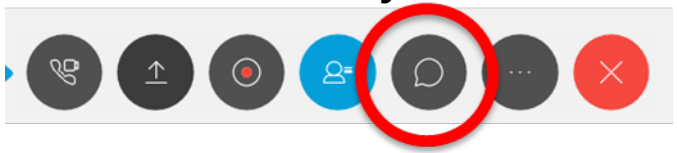
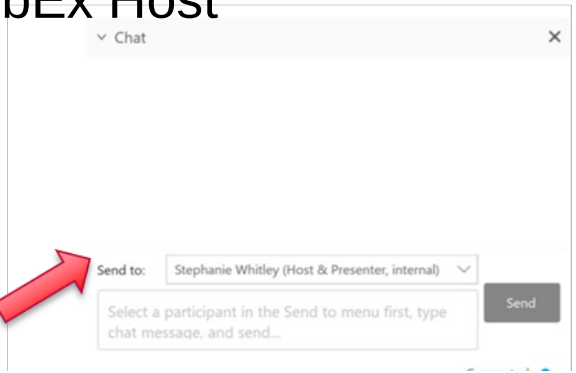
CTRP User Calls
Submitting CTRP DT4 Questions to WebEx Host (Chat Box)

- Click on the chat icon at the bottom of your screen



- Select To recipient: WebEx Host



- Attendees phones are muted upon meeting entry

CTRP User Call
Data Table 4

NIH NATIONAL CANCER INSTITUTE

September 26, 2018

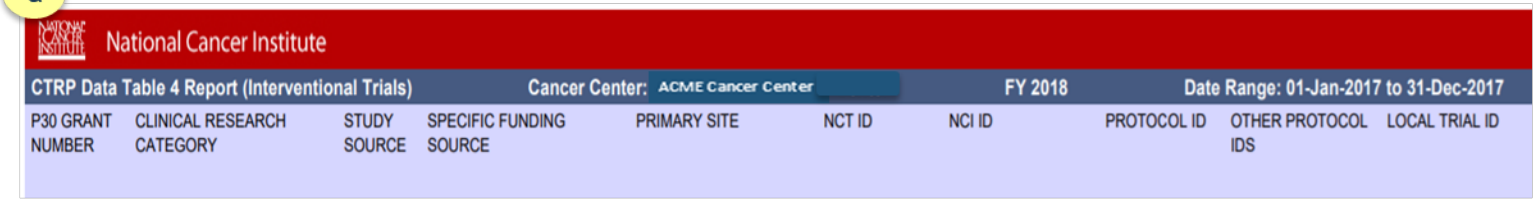
Agenda for Today's Call

- 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 Steps

CTRP-Generated Data Table 4 for Interventional Trials
CTRP-generated DT4 Column Headers

- CTRP-generated DT4 Column Headers

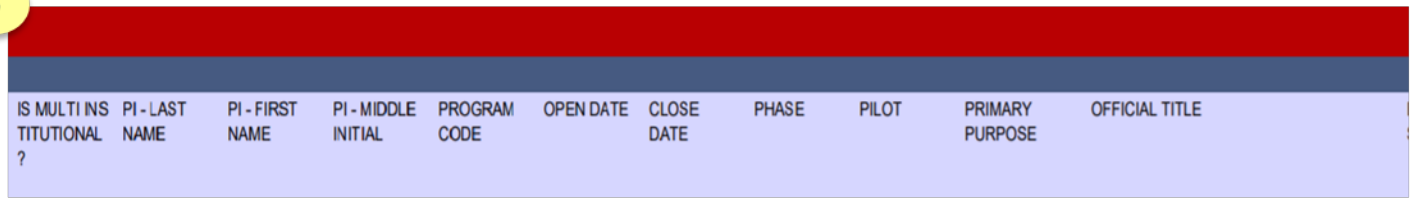
a


National Cancer Institute

CTRP Data Table 4 Report (Interventional Trials) Cancer Center: ACME Cancer Center FY 2018 Date Range: 01-Jan-2017 to 31-Dec-2017

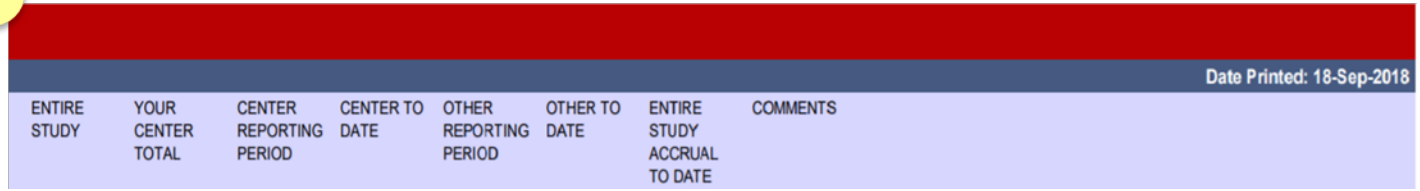
P30 GRANT NUMBER	CLINICAL RESEARCH CATEGORY	STUDY SOURCE	SPECIFIC FUNDING SOURCE	PRIMARY SITE	NCT ID	NCI ID	PROTOCOL ID	OTHER PROTOCOL IDS	LOCAL TRIAL ID

b



IS MULTI INSTITUTIONAL?	PI - LAST NAME	PI - FIRST NAME	PI - MIDDLE INITIAL	PROGRAM CODE	OPEN DATE	CLOSE DATE	PHASE	PILOT	PRIMARY PURPOSE	OFFICIAL TITLE

c


Date Printed: 18-Sep-2018

ENTIRE STUDY	YOUR CENTER TOTAL	CENTER REPORTING PERIOD	CENTER TO DATE	OTHER REPORTING PERIOD	OTHER TO DATE	ENTIRE STUDY ACCRUAL TO DATE	COMMENTS

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements)

- CTRP DT4 Data Elements (definitions aligned to each DT4 column header)
  - https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+R

NIH NATIONAL CANCER INSTITUTE
NCI Wiki

Confluence Spaces

Pages / ... / About the CTRP Data Table 4 Report

Data Elements Included

Created by Frost, Ruth (NIH/NCI) [C], last modified on Se

The data elements in the Data Table 4 report genera
Data Table 4 report, refer to https://cancercenters.ca
Table 4 report, and demonstrate this alignment of da

For instructions on configuring the report, refer to Ge

CTRP Data Table 4 reporting for interventional trials
for interventional trials for competing CCSG applicati

CTRP Data Element	De
Cancer Center Organizational Family (Cancer Center Family already setup in CTRP which appears in CTRP Data Table report drop-down for your center)	The Dat rep org Org Cer
Cancer Center Organizational Family	Tri

Confluence Spaces

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 Terminal (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**

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - P30 Grant Number

a

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**

CCSG eData: The P30 grant application identification number (e.g., 123456)

- New Registration:
  - Assigned for all trials automatically by the CTRP system for each center based on the Office of Cancer Centers (OCC) Grant Number for the P30 application.
- Edits/Updates: Cancer Centers cannot update existing P30 grant number information and must contact the CTRO for assistance.

P30 Grant Number which appears on your CTRP-generated DT4 is not the same as the trial-specific NIH Grant Number / P30 Grant information https://wiki.nci.nih.gov/display/CTRPdoc/Recording+NIH+Grants that a center adds in CTRP Registration associated with the Lead Organization (Org).

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Clinical Research Category

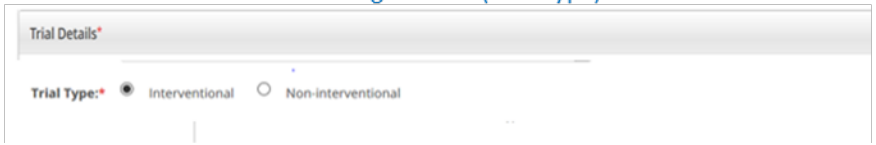
a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

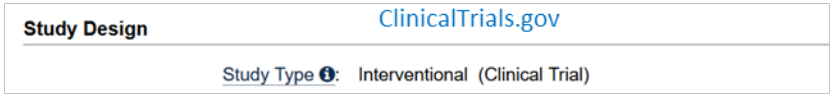
CCSG eData: The Clinical Research Category in which the clinical research or protocol is listed Valid entry: INT, OBS, or ANC/COR)

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated/Imported Trials (e.g., Industrial): Assigned by the Sponsor/Responsible Party on ClinicalTrials.gov.
- Edits/Updates: Cancer Centers cannot update existing Trial Type information and must contact the CTRO for assistance.

CTRP Registration (Trial Type)



ClinicalTrials.gov



CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Study Source

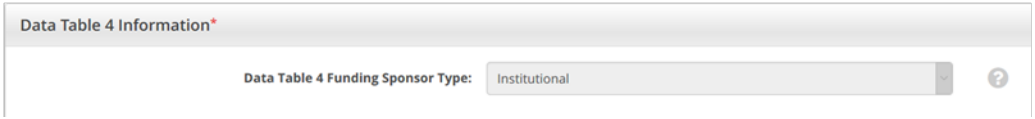
a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: The category of the trial sponsor or Study Source. Valid entry: N, E, I, or D. N - National Cooperative group, E - Externally Peer-Reviewed, I – Institutional, D – Industry

- New Registration:
  - Complete Trials: Assigned by Lead Org/Submitter during trial registration and viewable under "Data Table 4 Funding Sponsor Type".
    - NCI has logic for what trials are assigned at the "National" category that are submitted by NCI CTEP and/or DCP.
  - Abbreviated/Imported Trials: Default is Industrial. Contact the CTRO to change the Study Source if required.
- Edits/Updates: Cancer Centers cannot update existing Data Table 4 Funding Sponsor Type/Study Source information and must contact the CTRO for assistance.

CTRP Registration (Data Table 4 Funding Sponsor Type)



CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Specific Funding Source

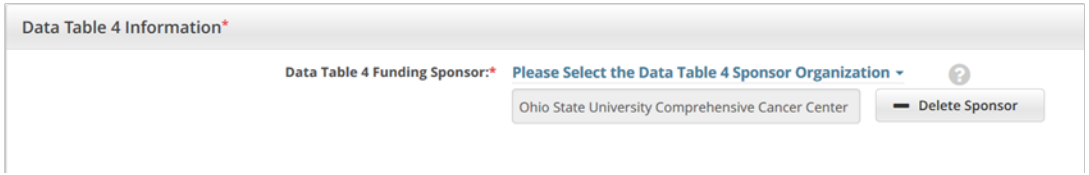
a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Specific Funding Source	The CTRP organizations listed as Data Table 4 Funding Sponsor for the trial. Sponsor or source of the funding mechanism.	**FundingSource**

CCSG eData: The specific name of the financial sponsor for the clinical research study. For institutionally sponsored trials or studies, list the name of the applicable funding agencies, (e.g., NCI, NYU) Note: this column is previously known as Sponsor.

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated/Imported (e.g., Industrial Trials:): Derived from the Sponsor value on ClinicalTrials.gov. Sponsor becomes Lead Org, and Lead Org becomes the Funding Source.
- Edits/Updates: Cancer Centers cannot update existing Data Table 4 Funding Sponsor/Specific Funding Source information and must contact the CTRO for assistance.

CTRP Registration (Data Table 4 Funding Sponsor)



CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Primary Site

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Primary Site	The Data Table 4 Anatomic Sites for the trial. The anatomic site(s) on which the trial or study is focused. For a list of values, refer to Data Table 4 Anatomic Site Values.	**PrimarySite**

https://wiki.nci.nih.gov/display/CTRPdoc/Data+Table+4+Anatomic+Site+Values

CCSG eData: The primary anatomic cancer site(s) (i.e., breast, ovary) the clinical research study focuses on. If the clinical research study is broadly applicable to a number of potential anatomic sites, enter the term "multiple" in this column

- New Registration:
  - Abstracted by CTRO for all trials.
- Edits/Updates: Cancer Centers cannot update existing Primary Site "Data Table 4 Anatomic Site" information and must contact the CTRO for assistance.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) NCI ID, NCT ID, Protocol ID, Other Protocol IDs

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
NCI ID	The unique ID assigned to the trial by the CTRP.	**NCIID**

CCSG eData: The unique ID assigned to the trial by the NCI's Clinical Trials Reporting Program (CTRP)

• New Registration: System assigns during the registration process. Edits/Updates: Contact CTRO for changes.

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: 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). (i.e., NCT00009876)

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: The unique identifier for the study. List the common protocol number that the trial is known under nationally, if one exists. For other trials that do not have an NCT number or a common protocol number that the trial is known under nationally, use an internal protocol identification or IRB number

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Additional IDs assigned to the trial, including the following: NCI, Cancer Therapy Evaluation Program (CTEP) or Division of Cancer Prevention (DCP), unique IDs from other registries, Protocol numbers assigned by the review board, other IDs

• New Registration: Lead Org/Submitter submits during the registration process. Edits/Updates: Contact CTRO for changes.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Local Trial ID

a

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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.	**LocalTrialID**

CCSG eData: The unique ID assigned at the Cancer Center level and used at the sites level to identify a trial

- New Registration and Edits/Updates: Cancer Centers (CTRP Site Administrators) can add and update center-specific Local Trial ID information under "**Managing DT4 Information for Your Center**".

Serves as a helpful field to map trial identifiers from a Cancer Center-specific local CTMS to CTRP.
Optional field in CTRP Registration and on the CTRP-generated DT4.
If this field is left blank in CTRP Registration, it will be blank on your CTRP DT4.

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Is Multi Institutional?

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Indicate whether the study is a multiple institutions; use "Y" for yes and "N" for no

- New Registration:
  - Automatically derived by the CTRP system for all trials.

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements)
PI (Principal Investigator) – Last Name, First Name, Middle Initial

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData:
- Last Name: The last name of the Principal Investigator from your Center who is responsible for this Clinical Research Study,
- First Name: The first name or initial of the Principal Investigator from your Center who is responsible for this Clinical Research Study Do not include a period (.)
- Middle Name: The middle name or initial of the Principal Investigator from your Center who is responsible for this Clinical Research Study Do not include a period (.)

- New Registration and Edits/Updates: Cancer Centers (CTRP Site Administrators) can add and update PI information for all trials to specify a PI to appear on your CTRP DT4 under "**Managing DT4 Information for Your Center**".

If this field is left blank in CTRP Registration, it will be blank on your CTRP DT4

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Program Code

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: An alphanumeric Program Code that identifies the Research Program affiliated with the clinical research study as defined by the Center in Data Tables 1B and 2A. For clinical research studies that span more than one. Research Program, include both Program Codes in this column. Refer to the Falls, R. example in the CCSG Data Guide

- New Registration and Edits/Updates: Cancer Centers (CTRP Site Administrators) can add and update center-specific Program Code information under "**Managing DT4 Information for Your Center**".

If this field is left blank in CTRP Registration, it will be blank on your CTRP DT4

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Open Date

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: The official start date (activation) of a trial determined as follows 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

- New Registration:
  - Complete Trials: Added by the Lead Org/Submitter for all Participating Sites. System-derived status/date value for "Open".
  - Abbreviated/Industrial Trials: Once trial is registered in CTRP and abstracted by CTRO, Cancer Centers are responsible for adding their own PS status/date information. System-derived status value for "Open".
- Edits/Updates:
  - Complete Trials: If Lead Org/Submitter, update status/date information. If PS, contact the CTRO for assistance to update this information.
  - Abbreviated/Industrial Trials: Cancer Centers can directly edit this information.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Close Date

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Close Date	The date the clinical research study closed to accrual. This does not include patient follow-up. If the study is still open, this field will be blank/null on the CTRP-generated DT4 report. This value on the CTRP-generated DT4 is determined by the latest "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**

CCSG eData: The date the clinical research study closed to accrual. If the study is still open, leave this field blank

- New Registration:
  - Complete Trials: Added by the Lead Org/Submitter for all Participating Sites. System-derived status/date value for "Close".
  - Abbreviated/Industrial Trials: Once trial is registered in CTRP and abstracted by CTRO, Cancer Centers are responsible for adding their own PS status/date information. System-derived status value for "Close".
- Edits/Updates:
  - Complete Trials: If Lead Org/Submitter, update status/date information. If PS, contact the CTRO for assistance to update this information.
  - Abbreviated/Industrial Trials: Cancer Centers can directly edit this information.

CTRP Data Table 4 report includes "Close Date" even if the date is after the reporting period.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Phase

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Acceptable phases include Early Phase I, I, I/II, II, II/III, III, IV, N/A. Note: do not include blank spaces

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated/Imported (e.g., Industrial Trials): Assigned by the Sponsor/Responsible Party on ClinicalTrials.gov.
- Edits/Updates: Cancer Centers cannot update existing Phase information and must contact CTRO for assistance.

CTRP Registration (Phase)

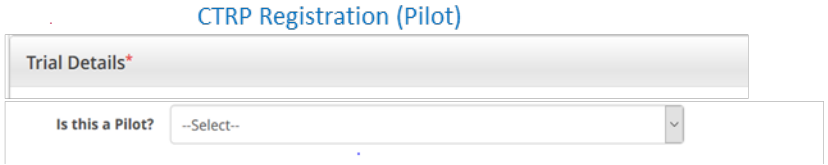
CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Pilot

b

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Pilot	An indication whether the trial is a pilot trial.	**IsPilot**

CCSG eData: Pilot attribute can be assigned to any phase. Indicate whether the study is a pilot phase; use "Y" for yes and "N" for no

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated Trials/Imported Trials: Not applicable.
- Edits/Updates: Cancer Centers cannot update existing Pilot information and must contact the CTRO for assistance.



CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Primary Purpose

b

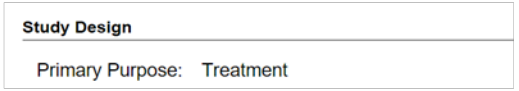
CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Primary Purpose	The main reason for conducting the trial. The report uses the following abbreviations: • **Tre** = Treatment • **Pre** = Prevention • **Sup** = Supportive Care • **Scr** = Screening • **Dia** = Diagnostic • **Hsr** = 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**

CCSG eData: The type or primary purpose of clinical trial. Valid entry: Tre, Pre, Sup, Scr, Dev, Dia, Hsr, Bas, or Oth

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated Trials: Assigned by the Sponsor/Responsible Party on ClinicalTrials.gov.
- Edits/Updates: Cancer Centers cannot update existing Primary Purpose information and must contact CTRO for assistance.

CTRP Registration (Primary Purpose)

ClinicalTrials.gov



CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Official Title

b

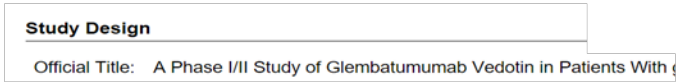
CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Official Title	The official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document).	**OfficialTitle**

CCSG eData: Official name of the protocol provided by the study principal investigator or sponsor (Limit: 600 characters or fewer)

- New Registration:
  - Complete Trials: Assigned by the Lead Org/Submitter during the trial registration process.
  - Abbreviated Trials: Assigned by the Sponsor/Responsible Party on ClinicalTrials.gov.
- Edits/Updates: Cancer Centers cannot update existing Official Title information and must contact CTRO for assistance.

CTRP Registration (Title)

ClinicalTrials.gov



CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Entire Study

c

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: The total targeted accrual for the entire study. For both single-site and multi-site trials initiated at your Center, indicate the total number of participants needed for the entire study. For multi-site trials that your Center participates in but did not initiate, leave this column empty. *Do not submit a targeted range, such as "10 – 100."*

- New Registration:
  - Complete Trials: CTRO abstracts from the protocol submitted by Lead Org.
  - Abbreviated/Industrial Trials: Not applicable, for abbreviated trials, this field will be blank.
- Edits/Updates: Cancer Centers cannot update existing Entire Study information and must submit an amendment to the CTRO.

CTRP-Generated Data Table 4 for Interventional Trials
References (CTRP-generated DT4 Data Elements) - Your Center Total

c

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: The targeted accrual for your Center. For single-site and multi-site trials initiated at your Center, indicate the total number of participants your Center is expected to accrue for the study. *Do not submit a targeted range, such as "10 – 100."*

- New Registration and Edits/Updates: Cancer Centers (CTRP Site Administrators) can add and update "Your Center Total" (Target Accrual) information for all trials under "**Managing DT4 Information for Your Center**".

If this field is left blank in CTRP Registration, it will be blank on your CTRP DT4.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) Center Reporting Period, Center to Date

C

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name

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

CCSG eData: Provide the number of participants accrued to this clinical research study during the identified 12-month reporting period study your Cancer Center and its formal Consortium Partners

C

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Provide the number of participants accrued to this clinical research study to date at your Cancer Center and its formal Consortium Partners. This number is a cumulative figure, not an annual total.

- New Registration:
  - Complete Trials: System-calculated field. Accrual added by Lead Org/Submitter for all PS's.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers add their own accrual.
- Edits/Updates:
  - Complete Trials: System-calculated field. Accrual is updated by Lead Org/Submitter for all PS's. CTRO can follow-up with Lead Org/Submitter on behalf on a PS to request updates.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers update their own accrual.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) Other Reporting Period, Other to Date

C

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name

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

CCSG eData: Provide the number of participants accrued to this clinical research study during the identified 12-month reporting period at all hospitals, treatment facilities, and/or research facilities that are a formal part of the Cancer Center (e.g., nearby community hospitals).

C

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Provide the number of participants accrued in the clinical research study to date at all hospitals, treatment facilities, and/or research facilities that are a formal part of the Cancer Center (e.g., nearby community hospitals). This number is a cumulative figure, not an annual total.

- New Registration:
  - Complete Trials: System-calculated field. Accrual added by Lead Org/Submitter for all PS's.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers add their own accrual.
- Edits/Updates:
  - Complete Trials: System-calculated field. Accrual is updated by Lead Org/Submitter for all PS's. CTRO can follow-up with Lead Org/Submitter on behalf on a PS to request updates.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers update their own accrual.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) Entire Study Accrual To Date

c

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Pending OCC website updates.

- New Registration:
  - Complete Trials: System-calculated field. Accrual added by Lead Org/Submitter for all PS's.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers add their own accrual.
- Edits/Updates:
  - Complete Trials: System-calculated field. Accrual is updated by Lead Org/Submitter for all PS's. CTRO can follow-up with Lead Org/Submitter on behalf on a PS to request updates on their behalf.
  - Abbreviated/Industrial Trials: System-calculated field. Cancer Centers update their own accrual.

CTRP-Generated Data Table 4 for Interventional Trials References (CTRP-generated DT4 Data Elements) - Comments

c

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
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**

CCSG eData: Optional free text field that allows user to enter notes or remarks on the current record

- Cancer Centers add/edit "Comments" on their CTRP-generated DT4 (Excel version; column AC) of the report.
  - Not a stored value in CTRP. Cancer Centers *copy and paste* comments from one version of their CTRP-generated DT4 (Excel version) to the next to preserve information.

Optional field on the CTRP-generated DT4.

"Factual" comments are added at the discretion of each Cancer Center.

CTRP-Generated Data Table 4 for Interventional Trials:
Next Steps

- Continue submission for non-competing applications
  - Enables all centers (including those who submitted competing applications in FY18) the opportunity to submit a non-competing CTRP-generated DT4 in FY19
  - Cancer Centers will now be generating their own CTRP DT4 reports (interventional trials) and directly submitting their final CTRP DT4 (PDF “read only” and Excel version with comments) to the OCC CCSG mailbox (ccsgdata@mail.nih.gov)
- New CTRP DT4 Frequently Asked Questions (FAQs) available
  - https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+DT4+Frequently+Asked+Questions
- Next CTRP DT4 User Group Call to be scheduled for November 14, 2018 from 3:00pm-4:00pm ET
  - Details to be communicated via the CTRP ListServ

www.cancer.gov **www.cancer.gov/espanol**

CTRP-Generated Data Table 4 for Interventional Trials
Recent CTRP Updates – Local/Site Open and Close Dates

- CTRP DT4 Report “Open Date” and “Close Date” previously at the overall trial level
  replaced with the local/site center-specific “Open Date” and “Close Date”.

Study Source	Specific Funding Source	Primary Site	NCT ID	NCI ID	Protocol ID	Other Protocol IDs	Local Trial ID	Is Multi Institutional?	PI - Last Name	PI - First Name	PI - Middle Initial	Program Code	Open Date	Close Date	Phase
N	Alliance fo	Breast - Fe	NCT02750	NCI-2015-	A011401	A011401,	16-716	Y	Ligibel	Jennifer	A	1	8/29/2016		III
N	ECOG-ACR	Melanom	NCT01274	NCI-2011-	E1609	E1609, CD	11-275	Y	Hodi	Frank	S	35	5/25/2011	7/26/2016	III
N	Childrens	Myeloid a	NCT01371	NCI-2011-	AAML103	AAML103	13-120	Y	Weinstein	Howard	J		6/20/2011	7/31/2017	III

Please see the CTRP User Guide for additional information:
https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report

CTRP-Generated Data Table 4 for Interventional Trials
Recent CTRP Updates – New Entire Study Accrual to Date

- New CTRP DT4 total accrual “Entire Study Accrual to Date”) report implementation example (comparable to “Entire Study” implementation):

Data Table 4 Report (Interventional)						Cancer Center:								
ber	Clinical Research Category	Study Source	Specific Funding Source	Primary Site	NCT ID	NCI ID	Entire Study	Your Center Total	Center Reporting Period	Center to Date	Other Reporting Period	Other to Date	Entire Study Accrual To Date	Comments
356	INT	I	Center	Multiple	NCT#####	NCI###_#	60	50	0	46	0	0	56	
356	INT	N	Childrens	multiple	NCT#####	CI-2016-		90	13	76	0	0		

56 is shown as Entire Study Accrual to Date as there was 46 accrual from Example Center and 10 from a different center that was not connected to example Center.

Blank as this is a National study. This field would only be populated if the Example Center is the Lead Organization (same rule as Entire Study indicating Overall Trial target accrual.

Please see the CTRP User Guide for additional information:
https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report

CTRP Data Table (DT4)

Review of Overall Business Rules, Data Elements and Fields

CTRP-Generated Data Table 4 for Interventional Trials
Overview – Trial Representation

- A trial must be registered in CTRP to appear on the CTRP-generated DT4
- A unique trial is registered only once in CTRP
  - CTRP DT4 does not support reporting of two or more trials with the same NCT ID; it can be reported only once
- A Cancer Center's Organizational components are the same for all trials and are defined by ***the Cancer Center, not by NCI or CTEP***
- Each accrued patient is counted only once
- A trial must be "open" at both the overall trial level and participating site level to appear on the CTRP-generated DT4

CTRP-Generated Data Table 4 for Interventional Trials Overview – Trial Representation (Open Statuses)

- **“Open” statuses in CTRP include:** Active, Available, Enrolling by Invitation, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Temporarily Not Available
  - If the status of a trial at a site is Temporarily Closed for the entire reporting period, it will be **included**
- If a Center is not “open” during the reporting period, the trial does not appear on CTRP-generated DT4, even if the Center is the Lead Organization

CTRP-Generated Data Table 4 for Interventional Trials Overview – Trial Representation (Study Source)

- Trials in CTRP are categorized by type of Data Table 4 Funding Sponsorship or Trial Submission Category (Study Source*).
  - **Complete Trials**:
    - **Institutional:** In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results
    - **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks
    - **Externally Peer-Reviewed:** R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations**.
  - **Abbreviated Trials:**
    - **Industrial/Other:** A pharmaceutical company controls the design and implementation of these clinical research studies.

* https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Trial+Categories,+Study+Sources
**http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf

CTRP-Generated Data Table 4 for Interventional Trials
Overview – Data Source for Multi-Institutional Trials (Workflow)

- **Lead Organization** registers trial, including primary purpose**,** reports trial status and accrual data for all participating sites. *Exceptions*:
  - NCTN and NCORP trials: CTEP and DCP PIOs report status and participating site information
  - Industrial trials:
    - Trial level information is imported from ClinicalTrials.gov
    - Participating sites report the status of the trial in their site and accrual data for their site only. ***Pharmaceutical companies do not report to CTRP***.
- **Participating Centers** report:
  - Target Enrollment for their Center
  - Program Code
  - Local Trial ID (optional)
  - Specifying the Principal Investigator (PI) for their center

CTRP-Generated DT4 Feedback: Change in Work Flow
Overview – Discrepancies in Multi-institutional Trials (Workflow)

- Participating sites disagree with the data reported by the Lead Organization
  - Incomplete accrual
  - Study type
  - Study source
  - Status dates
- Resolving data discrepancy requires contact with:
  - Lead Organization (Institutional trials)
  - CTEP (National trials)
- CTRP Generated DT4 enables submitter to annotate each trial record

CTRP-Generated Data Table 4 for Interventional Trials Overview – Use of Data from ClinicalTrials.gov

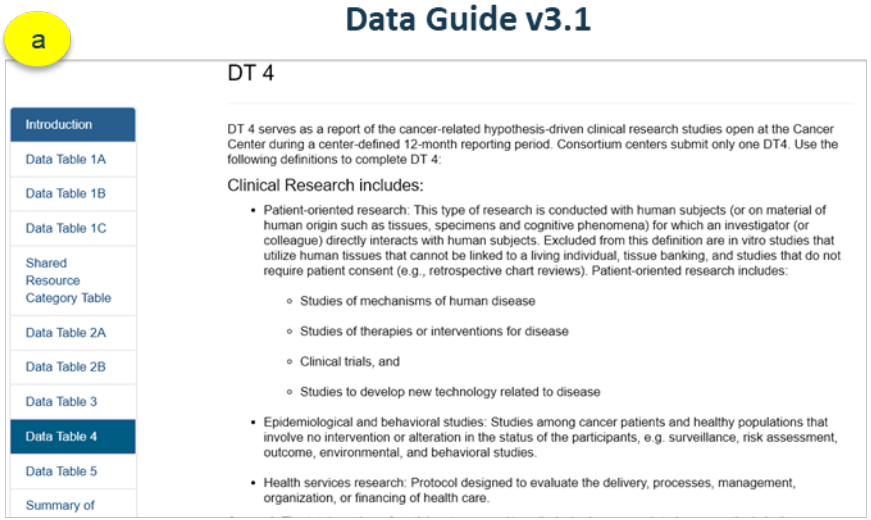
- ClinicalTrials.gov (and not the protocol record) is the source of content for Industrial trials and most trials registered in the abbreviated workflow
- Cancer Centers provide center-specific content, e.g. participating site information and center-specific Data Table 4 information such as target enrollment

CTRP-Generated Data Table 4 for Interventional Trials
References (Cancer Center Support Grant DT4)

- P30 Cancer Center Support Grant (CCSG) DT4 Guidelines

https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4

a



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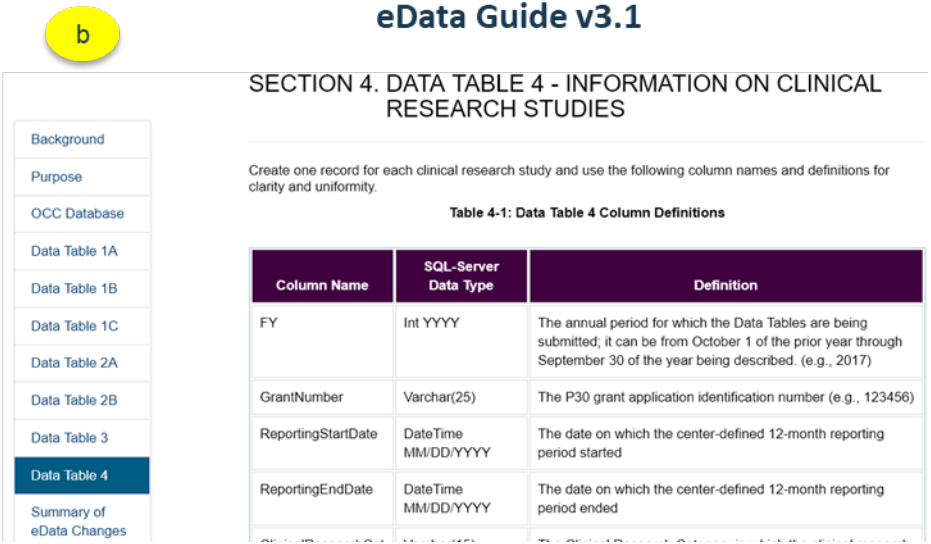


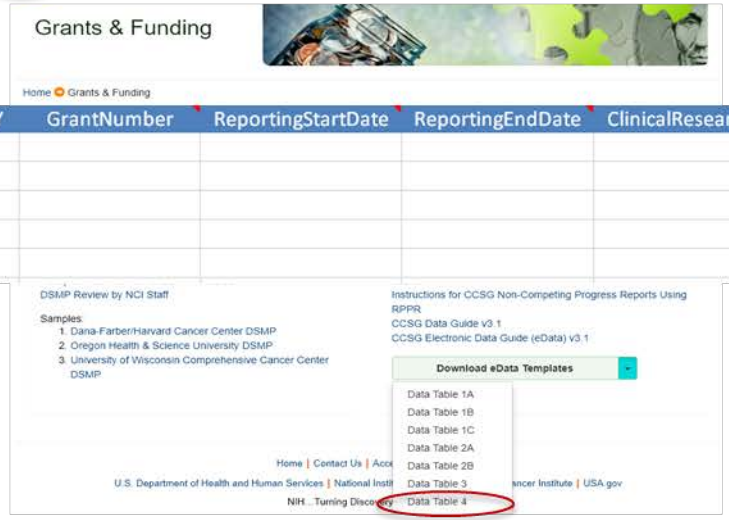
https://cancercenters.cancer.gov/GrantsFunding/eData#dt4

CTRP-Generated Data Table 4 for Interventional Trials
References (Cancer Center Support Grant DT4)

- P30 Cancer Center Support Grant (CCSG) DT4 Guidelines (Cont'd)

b1

eData Templates



FY	GrantNumber	ReportingStartDate	ReportingEndDate	ClinicalResearchCat	StudySource	FundingSource	PrimarySite	NCTID	ProtocolID	OthProtocolID	NCIID

Note: CTRP-generated DT4 has a few more columns than the current eData Data Table 4 Template used for non-interventional trials.

https://cancercenters.cancer.gov/GrantsFunding/GrantsFunding