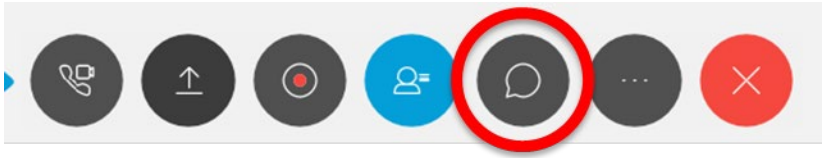
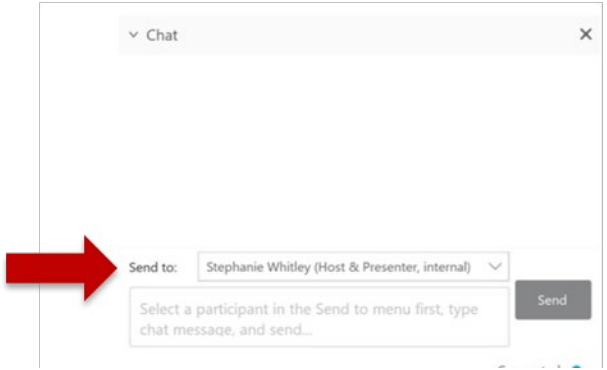
CTRP User Calls
Submitting CTRP Questions to WebEx Host (Chat Box)

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



- Select To recipient: WebEx Host



- Attendees' phones are muted upon meeting entry

Clinical Trials Reporting Program (CTRP)
User Community Call

NIH NATIONAL CANCER INSTITUTE

May 3, 2023

Today's Call

- Recent Updates
- Registration Submission Requirements
- Accrual Reporting for Participating Sites by Lead Organizations
- CTRP-Generated Data Table 4
- Other Topics

Recent CTRP Updates

Observational Studies
Ancillary-Correlative Studies
Pragmatic Trials
Clinical Trials Search API

CTRP Reporting:
Observational Studies

- As of October 2022:
  - **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
    - We request that you only send study status updates, e.g. updating the Primary Completion Date type from 'Anticipated' to 'Actual'

If you have any questions or issues regarding the reporting of Observational study registrations in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

CTRP Reporting:
Ancillary-Correlative Studies

- As of October 2022: (Cont'd)
  - **Registration of Ancillary-Correlative studies in CTRP is no longer in scope;** new submissions of Ancillary-Correlative studies will not be accepted
  - For all Ancillary-Correlative studies currently registered, CTRP will **only** accept study status updates
    - Amendments submitted for currently registered Ancillary-Correlative studies will be rejected

If you have any questions or issues regarding the reporting of Ancillary-Correlative study registrations in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

Pragmatic Trials

- Some trials submitted to CTRP and reported on a CTRP-generated Data Table 4 report do not fit traditional clinical trial design
  - Interventional trials require compliance with FDAAA and NIH Policy when indicated
  - Included in a CTRP-generated Data Table 4 report for interventional trials

Pragmatic Clinical Trials

- Definition: A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented
- CTRP classifies trials with the following characteristics as pragmatic[1,2]:
  - Unit of randomization may be other than an individual participant, e.g., the clinic, the healthcare system, or a neighborhood if a community setting
  - Intervention may be multi-level involving changes to:
    - Participant behavior, e.g., completing a symptom report measures online, and
    - Provider behavior, e.g., receiving the participant's symptom report and having to act on it
  - Data are often obtained directly from medical records and, are likely collected on a large number of participants
    - Data may be collected during a pre-intervention period and again during a post-intervention period in each clinic that is randomized
    - Participants for whom data are collected in the pre-intervention period may not be the same ones for whom data are collected in the post-intervention period

1 Pragmatic Trial Definition and Characteristics - CTMS - CTRP Documentation - NCI Wiki (nih.gov)

2 Data Guide - OCCWebApp 2.2 (cancer.gov), eData - OCCWebApp 2.2 (cancer.gov)

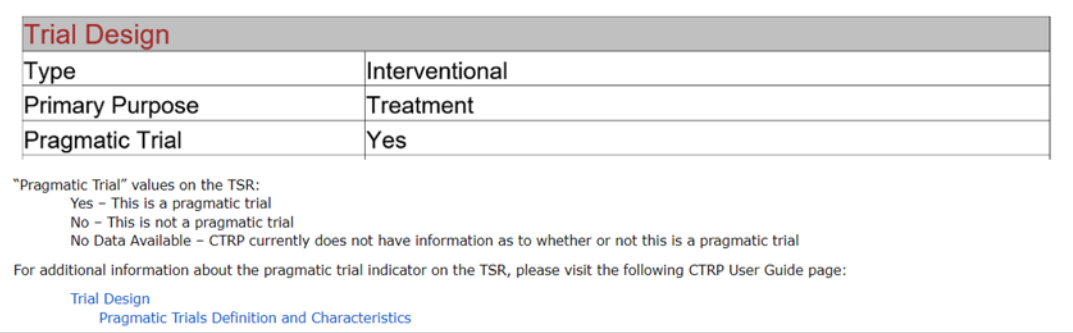
Pragmatic Trials: Registration/Classification in CTRP

- Previous Practice:
  - CTRO abstracted trials considered to be pragmatic with the *Primary Purpose* of *'Other'**
    - Comments were added to the CTRP record indicating why the trial was abstracted as pragmatic
- New Practice:
  - Pragmatic trials can be registered with any Primary Purpose
  - Once a trial is registered in CTRP, submitters may notify CTRO NCICTRO@mail.nih.gov stating that a trial is considered pragmatic
  - CTRO sets the 'Pragmatic Trial flag' during abstraction of newly registered submissions

* CTRO has since set the 'Pragmatic Trial Flag' for trials previously registered with Primary Purpose of 'Other', and submitters of these trials were notified

Pragmatic Trials: Display on a TSR

- CTRP Trial Summary Report (TSR) now includes a pragmatic trial indicator[1]
  - The field is in the 'Trial Design' table; labeled 'Pragmatic Trial'
  - Submitters of these trials are notified of the pragmatic indication upon receipt of the TSR



Trial Design	
Type	Interventional
Primary Purpose	Treatment
Pragmatic Trial	Yes

"Pragmatic Trial" values on the TSR:
Yes – This is a pragmatic trial
No – This is not a pragmatic trial
No Data Available – CTRP currently does not have information as to whether or not this is a pragmatic trial

For additional information about the pragmatic trial indicator on the TSR, please visit the following CTRP User Guide page:

Trial Design
Pragmatic Trials Definition and Characteristics

- Submit TSR feedback to CTRO for change requests to the Pragmatic Trial indicator
- Review of requests to add the Pragmatic flag are prioritized by CTRO based on the submission schedule for CCSG Data Table 4 for Competing & Non-Competing Applications

[1] Recent Changes to CTRP - CTMS - CTRP Documentation - NCI Wiki (nih.gov)

Pragmatic Trials: Display on a CTRP-Generated DT4

- CTRP-generated DT4 now displays pragmatic trials
  - Field is labeled ‘Prag’ with values of ‘Y’ or ‘N’ as abstracted by the CTRO
  - Value will be included in any format of the CTRP-generated DT4 report, e.g., PDF, Excel, CSV; does not have any impact on CTRP REST Services or CTRP REST Service users

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Prag	An indication as to whether the trial is a pragmatic (prag) trial.	**Prag**

Prag values:
Y – Yes, this is a pragmatic trial

N – No, this is not a pragmatic trial

[1] Recent Changes to CTRP - CTMS - CTRP Documentation - NCI Wiki (nih.gov)

[2] Data Elements Included in the CTRP Data Table 4 Report - CTMS - CTRP Documentation - NCI Wiki (nih.gov)

Pragmatic Trials: Display on a CTRP-Generated DT4 (Cont'd)

- New Implementation:

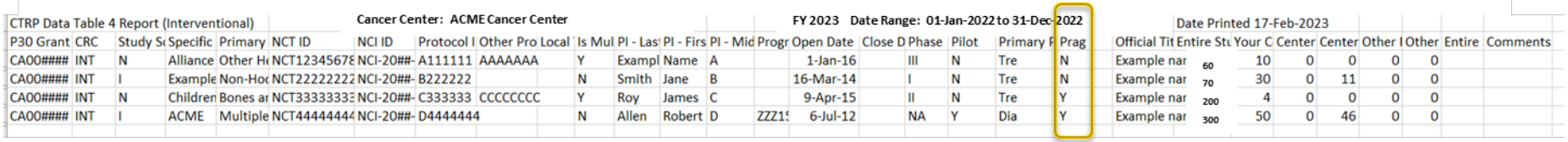
CTRP-generated DT4: Competing – PDF

National Cancer Institute

CTRP Data Table 4 Report (Interventional) | Cancer Center: ACME Cancer Center | FY 2023 | Date Range: 01 Jan 2022 to 31 Dec 2022 | Date Printed: 17-Feb-2023

CRC	STUDY SOURCE	SPECIFIC FUNDING SOURCE	PRIMARY SITE	NCT ID	PROTOCOL ID	IS MULTI INST?	PI - LAST NAME	PI - FIRST NAME	PROGRAM CODE	OPEN DATE	CLOSE DATE	PHASE	PILOT	PRIMARY PURPOSE	PRAG	OFFICIAL TITLE	ENTIRE STUDY	YOUR CENTER TOTAL	CENTER REPORTING PERIOD	CENTER TO DATE	OTHER REPORTING PERIOD	OTHER TO DATE
INT	N	Alliance for Clinical Trials in Oncology	Other Hematopoietic	NCT########	LMN123	Y	Smith	Joe		10-Jan-202#	10-Jan-202#	III	N	Tre	N	Sample trial for demonstrative purposes during meetings and for communications	60	10				
INT	I	ACME Cancer Center	Multiple	NCT########	PQR555	N	Doe	Jane	ZZZ151	26-Jul-202#		NA	Y	Dia	Y	Secondary example trial for demonstrative purposes during meetings and for communications	300	50		46		
INT	I	Pretend Center	Liver	NCT########	zzz1255	N	Example	Robert	ZZZ105	14-Jan-2013		II	N	Tre	Y	Third pretend official title example to include for illustration purposes		40		47		

CTRP-generated DT4: Non-Competing – Excel



CTRP Data Table 4 Report (Interventional) | Cancer Center: ACME Cancer Center | FY 2023 Date Range: 01-Jan-2022 to 31-Dec-2022 | Date Printed 17-Feb-2023

P30 Grant	CRC	Study So	Specific	Primary	NCT ID	NCI ID	Protocol I	Other Pro	Local	Is Mul	PI - Last	PI - Firs	PI - Mid	Progr	Open Date	Close D	Phase	Pilot	Primary P	Prag	Official Tit	Entire Stu	Your C	Center	Center	Other I	Other	Entire	Comments
CA00####	INT	N	Alliance	Other He	NCT12345678	NCI-20##-	A111111	AAAAAAA		Y	Exampl	Name	A		1-Jan-16		III	N	Tre	N	Example nar	60	10	0	0	0	0		
CA00####	INT	I	Example	Non-Hoc	NCT22222222	NCI-20##-	B222222			N	Smith	Jane	B		16-Mar-14		I	N	Tre	N	Example nar	70	30	0	11	0	0		
CA00####	INT	N	Children	Bones ar	NCT3333333	NCI-20##-	C333333	CCCCCCC		Y	Roy	James	C		9-Apr-15		II	N	Tre	Y	Example nar	200	4	0	0	0	0		
CA00####	INT	I	ACME	Multiple	NCT44444444	NCI-20##-	D4444444			N	Allen	Robert	D	ZZZ1	6-Jul-12		NA	Y	Dia	Y	Example nar	300	50	0	46	0	0		

Separates interventional pragmatic trials from other interventional trials

Screenshots of Competing & Non-Competing CTRP DT4 (INT) report mock-up

Pragmatic Trials: Summary

- 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 (CTS) API

- Scope
  - Registration data for trials open to accrual on or after 6/15/2015
  - Trials must have NCT ID
  - Expanded Access trials are not included
- Recent updates
  - 2021 – CTS API Version 2 (v2) released
    - Publicly available
    - An account is needed to receive an API key: https://clinicaltrialsapi.cancer.gov/signin
  - 2022 – Prior therapy structured eligibility criteria on a small subset of trials

Registration

Submission Requirements

Managing Multi-Institutional Trials

Externally Peer-Reviewed Trials

Registration: Submission Requirements

- When registering Externally Peer-Reviewed and Institutional trials[1], please submit:
  - 1) **Complete, clean protocol document** that is machine readable (able to copy/paste)
    2) IRB Approval (for the protocol being submitted) 3) ICF (if not part of the protocol)
    4) List of participating sites
  - Submission of these documents is required for accurate and timely CTRP abstraction
- When registering amendments, please also submit *at least* one of the following:
  - A **change memo** is a document that contains a summary of changes as compared to the original, or last amended, trial submission
  - A **protocol highlighted document** is a document that has been marked up, with or without using a 'Track Changes' feature

Missing or expired documentation leads to
submission rejection and/or substantial trial processing delays

[1] https://wiki.nci.nih.gov/display/CTRPdoc/Uploading+Trial-Related+Documents

Registration: Submission Requirements (Cont'd)

- Amendments versus Updates
  - If multiple amendments are available to submit, please upload all amendment documents together at the same time
  - Amendments include major changes to the protocol document, e.g. eligibility criteria, objectives, change in Principal Investigator (PI), target enrollment[1]
  - Minor protocol changes, e.g. staffing changes, new Informed Consent Form (ICF) language translations should be submitted as 'Updates'[2]

[1] https://wiki.nci.nih.gov/display/CTRPdoc/Examples+of+Amendments
[2] https://wiki.nci.nih.gov/display/CTRPdoc/Updating+Trials

Registration: Submission Requirements (Cont'd)

- When registering trials imported from ClinicalTrials.gov, e.g., Industrial
  - NCT ID is required
  - Site importing trial must be added at time of registration using 'Add My Site' feature
  - **Registration will be rejected without Participating Site (PS) details**

If lack of required documentation or NCT ID, please list trial(s) on the CTRP-generated Data Table 4 (DT4) report (Excel version), 'Supplemental – Not on Report' tab

Registration: Management of Multi-institutional Trials

- Institutional, Externally Peer-Reviewed registrations:
  - Registered by Lead Organization (LO), e.g., NCI-Designated Cancer Center
  - Changes requested by a PS should be directed to the LO
    - *CTRO* can facilitate discussion with LO who is responsible for any change*
- National registrations:
  - Registered by CTEP or DCP
  - Changes requested by a PS
    - *CTRO* can facilitate discussion with CTEP or DCP who is responsible for any change*
- Imported/Abbreviated registrations, e.g., Industrial
  - Changes to the ClinicalTrials.gov content, e.g., primary purpose, phase, etc. should be directed to the Sponsor/Responsible Party of the ClinicalTrials.gov record
  - Changes to CTRP-specific content, e.g., Study Source - contact CTRO*

* Email: NCICTRO@mail.nih.gov

Registration: Externally Peer-Reviewed Trials

- Externally Peer-Reviewed Trials: ROIs, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on this list:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Alex's Lemonade Stand Foundation (ALSF)
3. American Association of Cancer Research (AACR)
4. American Cancer Society (ACS), (national office only)
5. American Foundation for AIDS Research (amfAR)
6. American Institute for Cancer Research (AICR)
7. California Institute for Regenerative Medicine (CIRM)
8. Cancer Prevention Research Institute of Texas (CPRIT)
9. Center for Disease Control and Prevention (CDC)
10. Central Office of the Veterans Administration (VA), (excluding local/regional and "block" grants)
11. Environmental Protection Agency (EPA)
12. The Flight Attendant Medical Research Institute (FAMRI)
13. Florida Biomedical Research Program (FBRP)
14. Food and Drug Administration (FDA)
15. Howard Hughes Medical Institute (HHMI)
16. Leukemia and Lymphoma Society (LLS)
17. Melanoma Research Alliance (MRA)
18. Multiple Myeloma Research Foundation (MMRF)
19. National Institute for Occupational Safety and Health (NIOSH)
20. National Science Foundation (NSF)
21. New York State Department of Health Wadsworth Center/New York State Stem Cell Science Program (NYSTEM)
22. Patient-Centered Outcomes Research Institute (PCORI)
23. Prevent Cancer Foundation (PCF)
24. Prostate Cancer Foundation (PCF)
25. Stand Up to Cancer (SU2C)
26. Susan G. Komen for the Cure
27. The California Breast Cancer Research Program (CBCRP)
28. The California Tobacco Related Disease Research Program (TRDRP)
29. U.S. Army (DOD) special research programs*

* Note: Grants funded through the U.S. Army's, (DOD) special research programs in ovarian, breast and prostate cancer may also be listed in the category of peer reviewed funded grants

https://cancercenters.cancer.gov/documents/PRFundingOrgs508.pdf

Revised 07/19/2022

Accrual

Accrual Reporting for Participating Sites by Lead Organizations

CTRP Accrual: Timely Reporting by Lead Organizations

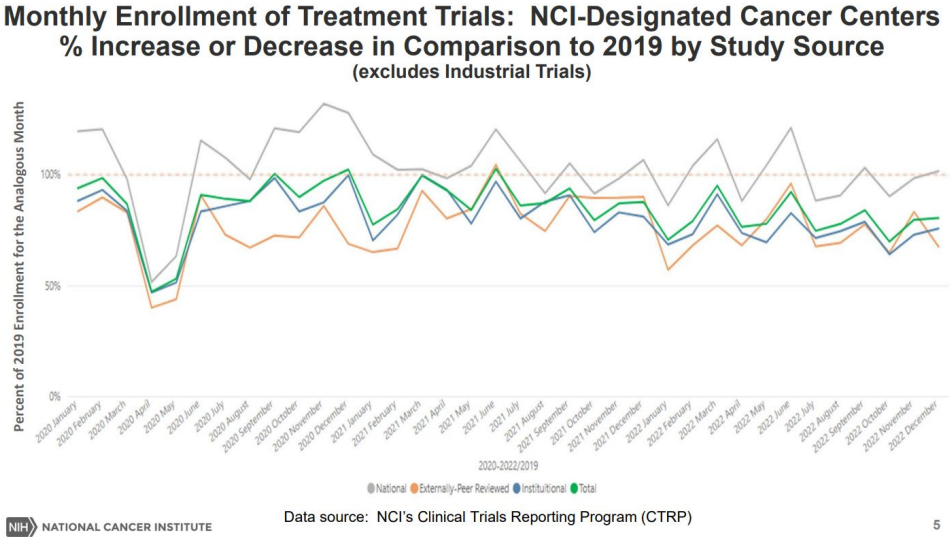
- Supports accurate accrual reporting for CTRP-generated DT4 reports
  - Date of submission of a Participating Site DT4 may differ from that of the LO
- Supports accurate NCI portfolio reporting
- Reports should be submitted as soon as possible after the cut-off date at the end of the quarter, but **no later than 30 days after the cut-off date**

2023	Cut Off Date	Due Date
Q1	March 31	April 30
Q2	June 30	July 31
Q3	September 30	October 31
Q4	December 31	January 31

https://www.cancer.gov/about-nci/organization/ccct/ctrp/accrual

CTRP Accrual: Timely Reporting by Lead Organizations (Cont'd)

- If accrual is not submitted on time:
  - Delays CTRP-generated DT4 reporting for other participating Cancer Centers
  - Limits ability to run accrual analyses using CTRP data, e.g., recent NCI National Cancer Advisory Board (NCAB) presentation*



* https://deainfo.nci.nih.gov/advisory/ncab/0223/Doroshow.pdf

CTRP Accrual: Timely Responses to Data Requests

- Subject diseases with invalid ICD-O-3 Morphology/Topography codes
- Duplicate subject ID's (within a trial)
- Occurs outside of the Trial and Site ‘Open to Accrual’ dates
- Future registration dates

Please respond to accrual outreach requests in a timely manner. If you have any questions or issues regarding accrual reporting in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

CTRP Data Table 4

Interventional Trials
Observational Studies
Ancillary-Correlative Studies
Discrepancy Follow-up Process

CTRP-Generated Data Table 4 Submissions

- Continued support of CTRP-generated Data Table 4 for Interventional & Observational[1]
- Ancillary-Correlative continues to be submitted in a CCSG Center-generated Data Table 4[2]

Trial Type	Competing	Non-competing
Interventional	Yes	Yes
Observational	No	Yes
Ancillary-Correlative	Continue to submit in CCSG template; Center-generated Data Table 4	

Cancer Centers are expected to, 1). review and update their CTRP data throughout the year,
2). Facilitate their own CTRP-generated DT4 reviews and submission process to the Office of Cancer Centers (OCC)

[1] Data Elements Included in the CTRP Data Table 4 Report - Include DT4

[2] Data Guide - OCCWebApp 2.2 (cancer.gov), eData - OCCWebApp 2.2 (cancer.gov)

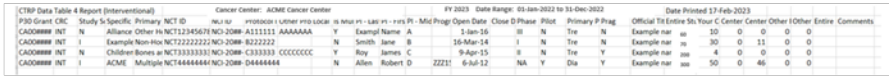
CTRP-Generated Data Table 4 Submissions
Interventional

- Continue to submit in CTRP-generated Data Table 4

CTRP-generated DT4 (PDF) version:

- Competing Type 2/Renewal applications[1]
  - Read only; Comments are NOT acceptable
  - Submission Process[2]: Center uploads CTRP-generated DT4 (PDF) to the eRA Commons/ASSIST system

CTRP-generated DT4 (Excel) version:



- Non-Competing Research Performance Progress Reports (RPPR) applications[1]
  - Comments (Column AD in the report) are acceptable
  - Submission Process[2]: Center emails CTRP-generated DT4 (Excel) to OCC CCSG ccsgdata@mailnih.gov

If you have any questions and/or data correction requests regarding Interventional study data in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

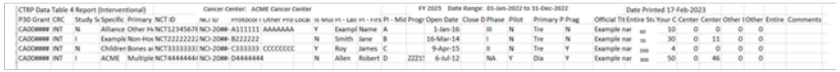
[1] Data Guide - OCCWebApp 2.2 (cancer.gov), eData - OCCWebApp 2.2 (cancer.gov)

[2] https://wiki.nci.nih.gov/display/CTRPdoc/About+the+CTRP+Data+Table+4+Report

CTRP-Generated Data Table 4 Submissions
Observational

- Continue to submit in CTRP-generated Data Table 4

CTRP-generated DT4 (Excel) version:



  - Non-Competing RPPR applications[1]
    - Comments (Column AD in the report) are acceptable
    - "Supplemental (Not on Report)" tab - Center to create this tab in their Excel file and list any missing studies from CTRP which are still in progress/*to be registered in CTRP* and/or do not have an NCT ID
    - Submission Process[2]: Center emails CTRP-generated DT4 (Excel) to OCC CCSG ccsgdata@mail.nih.gov
      - CTRP/CTRO does not get copied on your CTRP-generated DT4 Non-Competing submissions

If you have any questions and/or data correction requests regarding Observational study data in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

[1] https://cancercenters.cancer.gov/GrantsFunding/eData
[2] https://wiki.nci.nih.gov/display/CTRPdoc/About+the+CTRP+Data+Table+4+Report

Data Table 4 Submissions
Ancillary-Correlative

- Continue to submit in CCSG template; Center-generated Data Table 4[1]
  - At this time, CTRP no longer accepts registration of Ancillary-Correlative studies
    - For all Ancillary-Correlative studies currently registered, it is no longer necessary to submit amendments; CTRP will **only** accept study status updates
      - LO's can request to have currently registered Ancillary-Correlative in CTRP rejected
  - Submission Process: Center emails CCSG DT4 (Excel) to OCC CCSG ccsgdata@mail.nih.gov

If you have any questions and/or data correction requests regarding Ancillary-Correlative study data in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

[1] Data Guide - OCCWebApp 2.2 (cancer.gov), eData - OCCWebApp 2.2 (cancer.gov)

Data Correction Requests

Discrepancy Follow-up Process

CTRP-Generated Data Table 4
Discrepancy Follow-up Process

- Please submit any CTRP-generated DT4 requests/data corrections to the CTRO at least 1-3 months in advance of your upcoming submission
  - Reviewed as aligned to other data correction requests already in the queue across 64 NCI-Designated Cancer Centers taking into account other submission details

If CTRP overall trial-level (and PS-level) data isn't accurate in CTRP:

- It delays CTRP-generated DT4 reporting for other participating Cancer Centers
- It limits the ability to run analyses using CTRP data for broader portfolio reporting

- If you have any questions and/or data correction requests regarding study data in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov
- If CCSG policy-specific questions, please reach-out to the OCC/Program Director for your Center

CTRP-Generated Data Table 4
Discrepancy Follow-up Process – Lead Organization

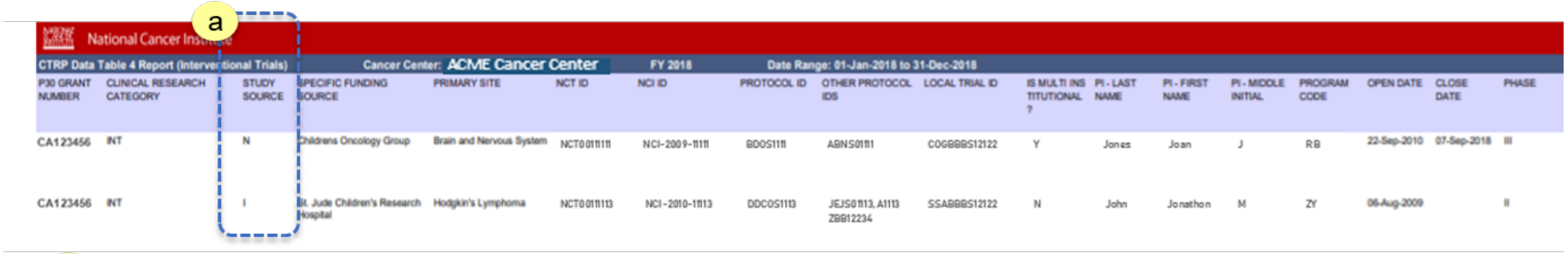
- The LO is the coordinating/lead center of the trial, responsible for the trial-specific research protocol > The organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial
  - If the trial is already registered in CTRP, your center should be listed as the LO, as your center registered the trial and provided a protocol document as the submitting organization
  - LO is often indicated in the CTRP Registration record (“Data Table 4 Funding Sponsor”) as well as on your CTRP-Generated DT4 report, e.g., “Specific Funding Source” column

If you have any questions regarding a specific trial and the identification of the LO and related reporting responsibilities in CTRP, study data in CTRP, please contact the CTRO, NCICTRO@mail.nih.gov

[1] https://strap.trials.nci.nih.gov/documentation/docs/glossary/#lead-organization:trial-leaders-and-collaborators_none

CTRP-Generated Data Table 4
Discrepancy Follow-up Process – Study Source

- If your Cancer Center identifies a discrepancy on your CTRP-Generated DT4 report, it is helpful to review the trial-specific **Study Source** and LO/Sponsor to confirm next steps regarding how to fix the data based on the appropriate CTRP workflow*



National Cancer Institute

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

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	IS MULTI INSTITUTIONAL ?	PI - LAST NAME	PI - FIRST NAME	PI - MIDDLE INITIAL	PROGRAM CODE	OPEN DATE	CLOSE DATE	PHASE
CA123456	INT	N	Childrens Oncology Group	Brain and Nervous System	NCT0011111	NCI-2009-1111	BDOS1111	ABNS01111	COGBBBS12122	Y	Jones	Joan	J	RB	22-Sep-2010	07-Sep-2018	III
CA123456	INT	I	St. Jude Children's Research Hospital	Hodgkin's Lymphoma	NCT0011113	NCI-2010-1113	DDCOS1113	JEJS01113, A1113 ZBB12234	SSABBBS12122	N	John	Jonathon	M	ZY	06-Aug-2009		II

a Study Sources:

1. I = Institutional
2. N = National
3. D = Industrial
4. E = Externally Peer-Reviewed

* Note: Some minor instances when the Study Source does not align to the standard workflow; e.g., trials that are Imported/Other can be shown as Institutional, Externally-Peer Reviewed or National (even though it is Imported)

CTRP-Generated Data Table 4
Discrepancy Follow-up Process – CTRP Data Correction Requests

- Discrepancies identified on multi-institutional trials may require communication with the LO (Institutional, Externally Peer Reviewed trials) or CTEP and/or DCP PIO for National trials
- CTRP created **CTRP Data Correction Request email and form templates*** for Cancer Centers to leverage when contacting the CTRO NCICTRO@mail.nih.gov (first pass review and triage) and/or follow-up with another NCI-designated Cancer Center *or the NCI Operations Office, e.g., CTEP, DCP PIO representative for National trials* in support of a specific discrepancy "CTRP data correction request"

CTRP Data Correction Request email/form templates can be viewed/downloaded:
https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Data+Correction+Requests

* Cancer Centers can choose to send an email with the CTRP discrepancy data correction request in the body of the email or fill out a CTRP Data Correction Request Form and forward it to the CTRO or LO

CTRP-Generated Data Table 4
Discrepancy Follow-up Process – National Trials

- CTRP captures only one accrual number. For multi-step trials, e.g., trials with a Screening and Intervention accrual step:
  - National trials: CTEP reports Intervention accrual to CTRP for Interventional, treatment studies
- Open and Closed Dates
  - CTRP DT4 reports may display different 'Open' and 'Closed' dates for some National trials. NCI is aware of these date differences and continues to work to align these more closely to the PS-level dates for the centers moving forward
  - Centers do not need to add a comment to their CTRP-generated DT4 for trials if the date difference is within six months and does not affect inclusion of the trial on the DT4 report

If a National trial appears as incorrectly 'Open' on your CTRP-generated DT4, please send an email to the CTRO NCICTRO@mail.nih.gov for their review and disposition

CTRP Reporting Requirements by Centers
Registration: Complete/Accurate Registration and Accrual Reporting

- NIH/NCI grant funding information required during CTRP study registration
  - Ensure that all study related NIH/NCI grants in addition to the Cancer Center P30 are submitted during the registration process, *e.g., SPORE/P50, R01, U01*
- Reporting Sex vs. Gender with CTRP Accrual Reporting
  - "Sex" means a person's classification as male or female based on biological distinctions; "Gender" means a person's self-representation of gender identity.
    - CTRP requests the submission of participant's Sex with accrual reporting
    - Currently accepted values: Male/Female/Unknown/Unspecified/Undifferentiated

Other Topics

Resources

User Account Management

Communications

Resources

- *About CTRP*
  https://www.cancer.gov/about-nci/organization/ccct/ctrp
- *CTRP User Calls**
  https://wiki.nci.nih.gov/display/CTRP/CTRP+User+Call+Meeting+Minutes
- *CTRP Recent Changes*
  https://wiki.nci.nih.gov/display/CTRPdoc/Recent+Changes+to+CTRP
- *CTRP Registration User Guide*
  https://wiki.nci.nih.gov/display/CTRPdoc/NCI+CTRP+Registration+User+Guide
- *CTRP Accrual User Guide*
  https://wiki.nci.nih.gov/display/CTRPdoc/NCI+CTRP+Accrual+User+Guide
- *CTRP STRAP User Guide*
  https://wiki.nci.nih.gov/display/CTRPdoc/NCI+CTRP+Reports+Reference+Guides
- *CTRP Data Correction Request Email/Form Templates*
  https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Data+Correction+Requests

** CTRP User Calls listed from 2018 – current; includes agenda, slides and Q&A from each webinar*

Resources
Cont'd

- *About CTRP-Generated DT4*
  https://wiki.nci.nih.gov/display/CTRPdoc/Running+CTRP+Data+Table+4+Reports
- *CTRP DT4 Report Data Elements*
  https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report
- *CTRP DT4 Frequently Asked Questions (FAQs)*
  https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+DT4+Frequently+Asked+Questions
- *CTRP Managing DT4 Information for Your Center**
  https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Data+Table+4+Information+for+Your+Center
- *CTRP DT4 Submission Instructions*
  https://wiki.nci.nih.gov/display/CTRPdoc/About+the+CTRP+Data+Table+4+Report
- *OCC CCSG DT4 Data Guide & eData Guide*
  Data Guide - OCCWebApp 2.2 (cancer.gov), eData - OCCWebApp 2.2 (cancer.gov)

** Includes links to associated Targeted Accrual, Program Codes, Specifying a PI for Your Center, Local Trial ID's*
Reminder: Cancer Centers are responsible for adding/updating this information for all trials/studies (Institutional, National, Industrial and Externally Peer Reviewed) in CTRP Registration

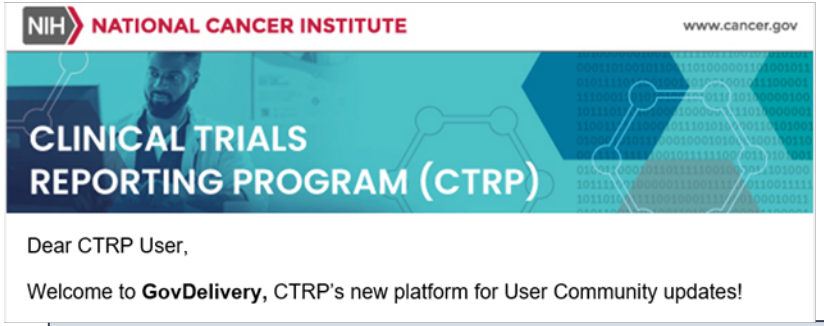
CTRP User Account Management

- It is important that CTRP user accounts reflect **active** CTRP users
  - **New User Account Requests** - Please see the following user guide with instructions on how to request a new CTRP user account: https://wiki.nci.nih.gov/display/CTRPdoc/Creating+a+CTRP+Account
  - **Account Deactivation Requests** – Please inform the CTRP Engineering Team (CTRP_Support@mail.nih.gov) regarding any user-related staff changes so these CTRP accounts can be properly deactivated

Please inform CTRP CTRP_Support@mail.nih.gov if you have any new CTRP user requests and/or existing user-related staff changes so that we can properly update accounts

CTRP Communications

- Recently transitioned CTRP ListServ "**CTRP Users**", *e.g., announcements regarding upcoming enhancements, maintenance, user calls* **to new email platform, GovDelivery**

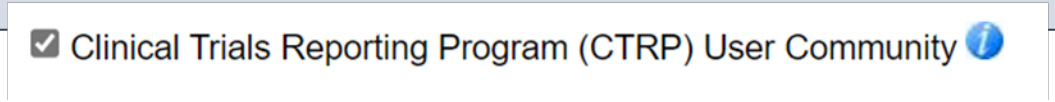


Announcements are now sent from the new email address NCI Clinical Trials Reporting Program (CTRP) *CTRP-USERS@updates.cancer.gov*

If you would like to receive future CTRP User Community announcements*, please sign up for email updates on the NCI's subscription page > found under the "Coordinating Center for Clinical Trials (CCCT)" topic:

https://public.govdelivery.com/accounts/USNIHNCI/subscriber/topics

Found under "Coordinating Center for Clinical Trials (CCCT)" subscription topic



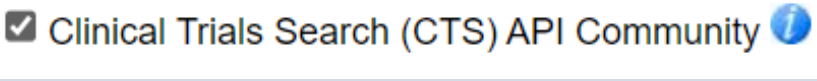
* Direct link: https://public.govdelivery.com/accounts/USNIHNCI/subscriber/new?cid=eb_govdel&topic_id=USNIHNCI_265

CTRP Communications (Cont'd)

- CTS API User Community
  - Inaugural CTS API User Community call held December 6, 2022
  - Next call to be scheduled in May/June 2023 – focusing on ontology/crosswalks

If you would like to join the CTS API User Group, please sign up for email updates on the NCI's subscription page > found under the "Cancer Health Information" topic:

https://public.govdelivery.com/accounts/USNIHNCI/subscriber/topics



Questions and/or feedback please contact the CTRO, NCICTRO@mail.nih.gov

Thank you for joining us today!

www.cancer.gov

www.cancer.gov/espanol