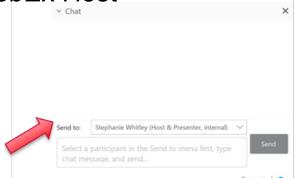
CTRP User Calls Submitting CTRP DT4 Questions to WebEx Host (Chat Box)

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



Agenda for Today's Call

- Recent CTRP Updates
- Schedule for CCSG CTRP-generated DT4 Reporting:
 - Interventional trials
 - Observational studies
 - Ancillary-Correlative studies
- CTRP Family (Organizations, Affiliates)
- CTRP Discrepancy Follow-up Process
- Batch Load Accrual Reporting for Abbreviated/Imported trials
- CTRP References / Training Links
- Next Steps



CTRP Data Table (DT4)

Recent CTRP Updates

CTRP ICD-O-3 Study Accrual Disease Codes/Descriptions Recent CTRP Updates

- CTRP enhanced the capture of ICD-O-3 study accrual disease data capabilities to support accurate reporting in CTRP on July 8, 2019
 - Enhancement includes updates to the current Morphology descriptions to ICD-O-3 Rev. 2
 (2020) and updates to capture Behavior as part of the Morphology
 - Both the Morphology and Topography codes will now display in the CTRP Accrual user interface
 - If your Center does not use ICD-O-3 disease coding, this update will not affect your submissions
 - Update does not change the format or mechanism of accrual reporting. CTRP now requires the complete ICD-O-3 code, Morphology and Topography, when reporting patient level accrual
 - For more information, please visit the following CTRP User Guides:
 - CTRP Diseases/Sites: https://wiki.nci.nih.gov/display/CTRPdoc/Searching+for+Diseases+and+Sites
 - Formats for submitting accrual: https://wiki.nci.nih.gov/display/CTRPdoc/Complete+Trial+Data+Record+Formats
 - CTRP RESTful services: https://wiki.nci.nih.gov/display/CTRP/NCI+CTRP+Accrual+REST+Service+Guide
 - Recommendation to download the current CTRP Accrual Batch File Tool (dated August 9, 2019) to remain compliant: https://wiki.nci.nih.gov/display/CTRP/CTRP+Accrual+Batch+File+Tool

CTRP Data Table (DT4)

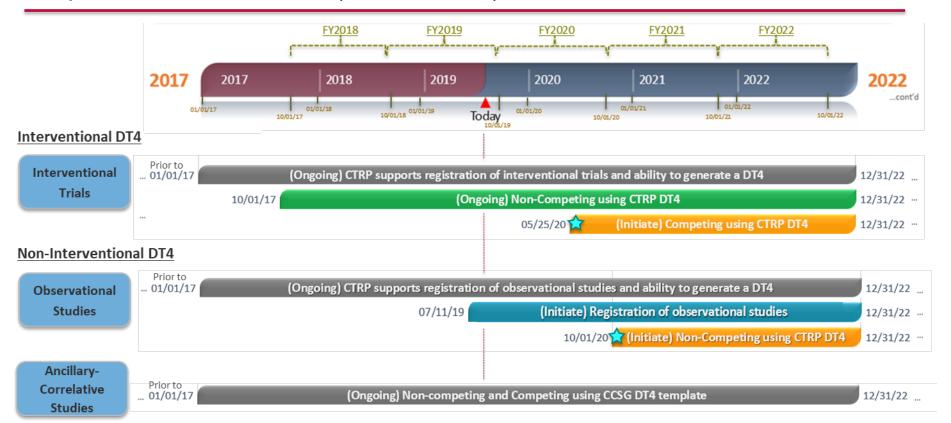
Schedule: CCSG Reporting for Interventional Trials, Observational Studies and Ancillary-Correlative Studies

CTRP-Generated Data Table 4 Schedule for CCSG CTRP-generated DT4 Reporting

- Presented at AACI CRI Meeting on July 11, 2019:
 - Interventional Trials
 - (Ongoing) Cancer Centers are currently submitting CTRP-generated DT4 for non-competing applications
 - FY 20: Submission with competing applications (beginning May 25, 2020)*
 - Observational Studies
 - CTRP currently supports reporting of non-interventional studies
 - FY 21: Submission of CTRP-generated DT4 with non-competing applications (beginning October 1, 2020)*
 - Ancillary-Correlative Studies
 - Continue to report using current CCSG DT4 format
 - i

* Office of Cancer Centers (OCC) to send revised Funding Opportunity Announcement (FOA) and related communications directly to Cancer Centers (e.g., Cancer Center Directors, Administrators)

CTRP-Generated Data Table 4 (Interventional and Non-Interventional) Implementation Timeline (2017 – 2022)



CTRP-Generated Data Table 4 (Interventional) Implementation Timeline (2017 – 2022)

Interventional Trials

- Non-Competing As of FY19, Cancer Centers generate their own CTRP DT4 for interventional trials and submit directly to the NCI Office of Cancer Centers (OCC) CCSG mailbox (ccsgdata@mail.nih.gov)
- Cancer Centers to continue to submit CTRP DT4 for interventional trials for non-competing application submissions for ongoing submissions
- Competing FY20/Ongoing: Starting with May 25, 2020 competing centers,
 Cancer Centers will be required to generate their own CTRP DT4 report for interventional trials and submit to the NCI OCC
- Cancer Centers with a competing application due Jan 25, 2020 are <u>not</u> required to use CTRP-generated DT4 for their competing submission

CTRP-Generated Data Table 4 (Non-Interventional/Observational) Implementation Timeline (2017 – 2022)

Observational Studies

- Study Registration FY19/FY20/Ongoing: Continue (or initiate) reporting to CTRP of observational studies. Cancer Centers should register and report accrual for all observational studies open to accrual on or after January 1, 2018
 - Study Registration: Cancer Centers register studies with a limited number of data elements and with the protocol document (similar to Interventional trials)
 - Accrual Reporting: Cancer Center reports cumulative accrual no less than annually. CTRP can also support patient-level accrual reporting if more convenient for the submitting organization
- Non-Competing FY21/Ongoing: Starting with October 1, 2020 Cancer Centers will be required to generate their own CTRP DT4 report for observational studies* and submit directly to the NCI OCC CCSG mailbox (ccsgdata@mail.nih.gov)

CTRP Data Table (DT4)

CTRP Family (Organizations, Affiliates)

CTRP-Generated Data Table 4 CTRP Family - Organization Families

- Each Cancer Center defines its organizational structure or "organization family" in CTRP to support registration and accrual reporting
 - CTRP Cancer Center "Organization" includes your Cancer Center and your formal Consortium partners. Accrual at these sites is counted under "Center" on CTRP DT4
 - CTRP Cancer Center "Affiliates" are institutions (hospitals, treatment and/or research facilities) that are associated with but not a formal part of the Cancer Center. Accrual at these sites is counted under "Other" on CTRP DT4
 - Other NCI Designated Cancer Centers are NOT affiliates to Cancer Centers https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4
 - Information about CTRP Organization Families from October 11, 2017 CTRP User Call https://wiki.nci.nih.gov/display/CTRP/2017-10-11+User+Call+Meeting+Minutes
 - 1

Please contact the CTRO NCICTRO@mail.nih.gov if you would like to request a copy of your current CTRP Family and/or to request any updates

CTRP-Generated Data Table 4 CTRP Family - Organization Families (Cont'd)

• Accrual representation on a CTRP-generated DT4 report:

		Date Fillited	13-Aug-20	19				
			Center		Other		Entire Study	
ficial En	ntire	Your Center	Reporting	Center to	Reporting	Other to	Accrual to	
:le Stu	udy	Total	Period	Date	Period	Date	Date	Comments
ase III Comp	parison (5	2	4	0	0		
ase II Stu 30)	10	1	7	0	0	29	
)577 (CODEL)	_): Phase	6	0	0	0	0		
Randomized	d Phase I	7	0	1	0	0		
Single-Cer 35	5	42	0	41	0	0	41	



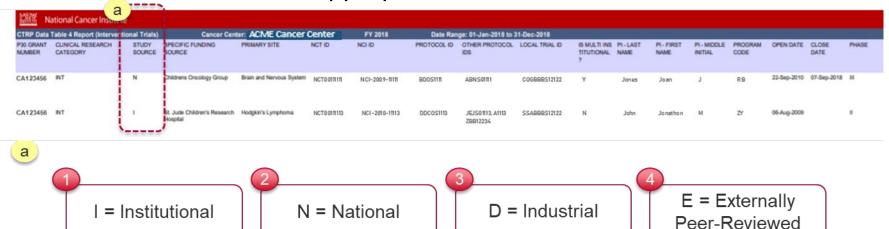
In this example, Cancer Center does not have any Affiliates as part of its CTRP Family

CTRP Data Table (DT4)

CTRP Discrepancy Follow-up Process

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 Lead Organization (LO)/Sponsor to confirm next steps regarding how to fix the data based on the appropriate CTRP workflow*



^{*} 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) 15

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

- Discrepancies identified on multi-institutional trials may require communication with the lead organization (LO) (institutional trials) or the NCI operations office for National trials (e.g., CTEP, DCP)
- We've created CTRP Data Correction Request email and form templates* for Cancer Centers to leverage when contacting the CTRO MCICTRO@mail.nih.gov (first pass review and triage) and/or follow-up with another NCI-designated Cancer Center or NCI operations office 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

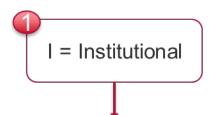
^{*} Cancer Centers can choose to send an email with the CTRP discrepancy data correction request in the body of the email or fill out a CTRP Data Correction Request Form and forward it to the CTRO or LO

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – Institutional Trials (Center is LO)



- If your Cancer Center is the Lead Organization*, update the trial directly:
- Make changes directly in CTRP for those fields that you can update including "Manage DT4 Information for Your Center" - Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI
- Confirm that all centers participating on the trial are recorded as PS(s) on the trial record in CTRP
- Contact the CTRO <a href="https://www.nctreen.com/nc
 - (e.g., trial has been abstracted and now read-only) to request updates

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – Institutional Trials (Center is PS)



If your Cancer Center is a Participating Site, do this:

- Make changes directly in CTRP for those fields that you can update (e.g., "Manage DT4 Information for Your Center" –
 Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI)
- For fields that the LO (e.g., another designated Cancer Center) is responsible for providing:
 - Contact the CTRO <u>NCICTRO@mail.nih.gov</u> asking them to 1). reach-out to the LO/Sponsor on your behalf requesting CTRP data updates <u>or</u> 2). you can request contact information for the LO CTRP Site Administrator (center, point of contact (POC) name, email) if you prefer to contact them directly

If you need to send the CTRO and/or LO (NCI-designated Cancer Center) an email, please include these key fields:



NCI ID, NCT ID, Reporting Period (if applicable to a CTRP DT4 report), Local Trial ID, Participating Site, PO ID, What the data currently is in CTRP (CTRP Field/Current Data)?

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:
 - CTRP lists the accrual submitted by CTEP for National trials
 - For National trials, CTRP may list the screening accrual instead of the intervention accrual, which may include screen failures
 - 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 is working to align these more closely to the PS-level dates for the center moving forward
 - Centers do <u>not</u> need to add a comment to their CTRP-generated DT4 for trials if the date difference is within six months
- i

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-Generated Data Table 4 Discrepancy Follow-up Process – National Trials (NCI Systems/Source Data)



CTRP receives data for National trials from upstream NCI systems.

As CTRP receives data for National trials from other NCI systems, it is important to <u>fix</u> any data discrepancies at the source.

 Data discrepancies (e.g., Open and Closed Dates, Accruals, Missing Participating Site) should be reviewed and triaged initially by the CTRO to confirm next steps (e.g., if accrual issue, CTRO will conduct an internal review of data between NCI systems and CTRP and communicate recommended next steps back to the Cancer Center).

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – National Trials (Center is PS)



N = National

For National trials where your Cancer Center is a Participating Site, do this:

- Make changes directly in CTRP for those fields that you can update (e.g., "Manage DT4 Information for Your Center" Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI)
- For fields that the LO is responsible for providing:
 - Contact the CTRO <u>NCICTRO@mail.nih.gov</u> with discrepancy-specific details so that they can review, triage and recommend a plan of action for follow-up (e.g., outreach to a specific NCI operations office)

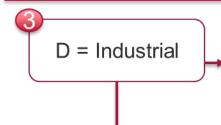
If you need to send the CTRO (for initial triage) a data correction request email, please include these key fields:



NCI ID, NCT ID*, Protocol ID, CTEP ID* (PS-level**), DCP ID*, Local Trial ID*, Participating Site Org, CTEP Org ID, What the data currently is in CTRP (CTRP Field/Current Data)?, What the data should be in CTRP (CTRP Field/Correct Data)?

*Optional IDs – Optional to include, however, the more trial identifiers which are provided will make it easier to identify the correct trial

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



CTRP relies on ClinicalTrials.gov https://www.clinicaltrials.gov/ for trial level record information

If the trial is not already registered in CTRP:

- Be the first Cancer Center to import the trial in from ClinicalTrials.gov using the import feature: https://wiki.nci.nih.gov/display/CTRPdoc/Registering+Abbreviated+%28Industrial+and+Other%29+Trials
- Add your PS information.



CTRO abstracts: Non-imported fields e.g. Diseases, Interventions, Biomarkers, Anatomic Sites (supports DT4)

 Make changes directly in CTRP for those fields that you can update (e.g., DT4 Information for Your Center – Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI)

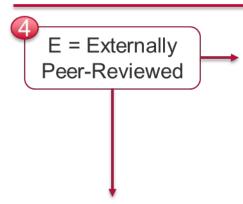
If the trial is already registered in CTRP:

 Please add your center as a PS using the "Add My Site" feature: https://wiki.nci.nih.gov/display/CTRPdoc/Using+the+Add+My+Site+Feature

Trial information that you can update after adding your site includes the following:

- Organization's local trial identifier
- Site principal investigator
- Organization family's program codes
- Site recruitment status and dates
- Make changes directly in CTRP for those fields that you can update (e.g., DT4 Information for Your Center Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI)

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – Externally Peer-Reviewed



If your Cancer Center is the Lead Organization, update the trial directly:

- Make changes directly in CTRP for those fields that you can update including "Manage DT4
 Information for Your Center" Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify
 a PI)
- Contact the CTRO <u>NCICTRO@mail.nih.gov</u> if you are unable to make the change in CTRP (e.g., trial has been abstracted and now read-only) to request updates

If your Cancer Center is a Participating Site, do this:

- Make changes directly in CTRP for those fields that you can update (e.g., "Manage DT4 Information for Your Center" Program Codes, Target Accrual for Your Center, Local Trial IDs, Specify a PI)
- Contact the CTRO <u>NCICTRO@mail.nih.gov</u> to request updates

CTRP Data Table (DT4)

Batch Load Process – Abbreviated/Imported Trials

CTRP: Data Sources (Accrual Reporting)



Cancer Centers/Awardees

Accrual for Complete and Abbreviated/Imported trials* can be submitted to CTRP via the following:

- 1. CTRP Accrual GUI/system: manual accrual entry
- 2. CTRP Batch File Load: accrual batch file loading
- 3. CTRP Web Services: automated accrual loading

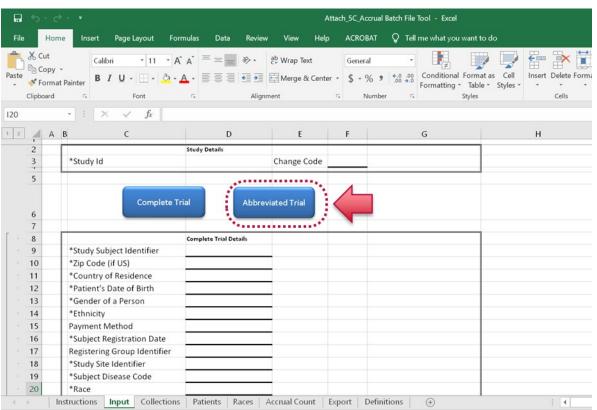
https://wiki.nci.nih.gov/display/CTRPdoc/NCI+CTRP+Accrual+User+Guide

CTRP: Accrual Reporting (Batch File Submissions)

- Complete initial accrual submission using batch load template and submit
- Subsequent Submissions
 - For Summary Level Accrual (typically provided for Abbreviated/Imported e.g., Industrial trials), subsequent accrual batch file uploads will replace previously submitted/uploaded accrual data
 - Batch uploads will not append data; cumulative accrual data must be uploaded with each accrual file submitted to CTRP
 - Please ensure that your CTRP accrual batch file contains <u>all</u> cumulative accrual data (from trial start) for each participating site to date before uploading to CTRP
 - Failure to include cumulative accrual data will result in erasing previously submitted accrual information
 - https://wiki.nci.nih.gov/display/CTRPdoc/Submitting+Accrual+Data+Batch+Files

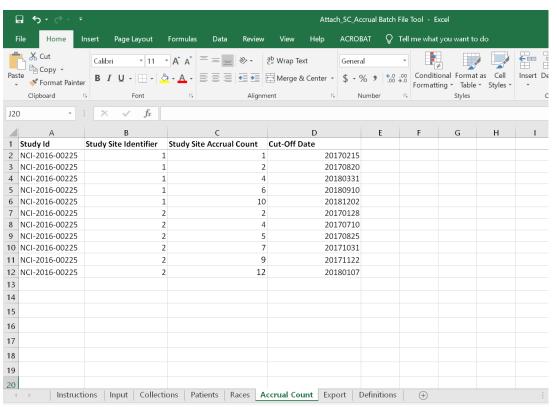


CTRP: Accrual Reporting (Batch File Submissions) – Cont'd Example: Abbreviated/Imported Trial Batch File



- Default view is "Complete Trial"(patient level) accrual data entry
- Click on the "Abbreviated Trial" button to enter summary accrual

CTRP: Accrual Reporting (Batch File Submissions) Example: Abbreviated/Imported Trial Batch File



 Example represents summary accrual ("Cut-Off Date" represented for when accrual changed) for 2 Participating Sites

CTRP Data Table (DT4)

References / Training Links

CTRP DT4 References

- NCI CTRP Data Correction Request Email/Form Templates
 - https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Data+Correction+Requests
- NCI CTRP DT4 Report Data Elements:
 - https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report
- NCI CTRP DT4 Frequently Asked Questions (FAQs):
 - https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+DT4+Frequently+Asked+Questions
- CTRP DT4 User Calls:
 - Presentation/Q&A (CTRP DT4 Background/Business Rules) held July 18, 2018:
 - https://wiki.nci.nih.gov/display/CTRP/2018-07-18+User+Call+Meeting+Minutes
 - Presentation/Q&A (CTRP DT4>Source of Data) held September 26, 2018:
 - https://wiki.nci.nih.gov/display/CTRP/2018-09-26+User+Call+Meeting+Minutes
 - Presentation/Q&A (CTRP Accrual Reporting) December 4, 2018:
 - https://wiki.nci.nih.gov/display/CTRP/2018-12-04+User+Call+Meeting+Minutes
- Running CTRP DT4 Reports (General Information):
 - https://wiki.nci.nih.gov/display/CTRPdoc/Running+CTRP+Data+Table+4+Reports

CTRP DT4 References — Managing DT4 Information for Your Center (All Trials)

- CTRP Registration*: Managing Data Table 4 Information for Your Center**:
 - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Data+Table+4+Information+for+Your+Center
 - Targeted Accrual (Your Center Total on the CTRP DT4 report)
 - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Targeted+Accrual
 - Program Codes
 - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Program+Codes
 - Specifying a Principal Investigator (to appear on your CTRP DT4 Report). This doesn't change your PI listing on the overall trial record but does specify which PI name shows up on your CTRP DT4 report.
 - https://wiki.nci.nih.gov/display/CTRPdoc/Specifying+the+Center+Principal+Investigator
 - Local Trial IDs

 Optional Field
 - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Local+Trial+IDs



CTRP-Generated Data Table 4 Next Steps

- Continue submission for non-competing applications (interventional trials)
 - Cancer Centers to <u>proactively</u> generate and review their CTRP DT4 report from STRAP and add initial annotations ("Comments") regarding any discrepancies/differences from their local CTMS data
 - CTRP team to begin working with Cancer Centers with an FY 20 (October 1, 2019) non-competing due date by end-August 2019 to review any open discrepancies/lend support
- Cancer Centers to initiate (or continue) to register Observational Studies in CTRP open to accrual on or after January 1, 2018
- Next CTRP DT4 User Group Call to be scheduled in 1Q2020
 - Details to be communicated via the CTRP ListServ
 - For any requested agenda topics, please contact the CTRO <u>NCICTRO@mail.nih.gov</u>





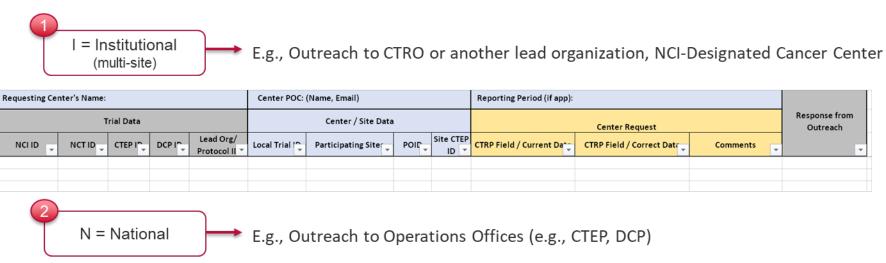
www.cancer.gov/espanol

Backup Slides - CTRP Data Table (DT4)

CTRP Data Correction Email and Form Templates

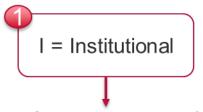
CTRP-Generated Data Table 4 Discrepancy Follow-up Process – CTRP Data Correction Request Forms

CTRP Data Correction Request Form examples:



Requesting Center's Name:				Center POC: (
Trial Data Center / Site Data			Accru	aal Correction	Participating Site Correction	Response from Outreach		
CTEP ID _ DCP ID _	Local Trial	Participating Sites		Current Accrual Count	Correct Accrual Cou	Comments	Comments	

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – Institutional Trials (Email Template)



Example email/form to send to the CTRO NCICTRO@mail.nih.gov for review and triage. Post review, the Cancer Center will be instructed by the CTRO regarding who to contact (e.g., designated Cancer Center CTRP Site Administrator contact information) or can reach-out directly on behalf of the Cancer Center in support of further outreach related to CTRP data correction requests

If your Cancer Center is a Participating Site, follow this email template example:

To: ·NCICTRO@mail.nih.gov (CTRO) or jane.doe@genericcancercenter.com (LO CTRP Site Administrator)						
Subject: CTRP Discrepancy / Data Correction Request ("ACME Cancer Center")						
Dear CTRO (or LO CTRP Site Administrator):						
We would like to request the following CTRP data corrections for our center:						
NCI ID NCT ID NCT ID Reporting Period (if app) Local Trial ID Participating Site PO ID CTRP Field/Current Data CTRP Field/Correct Data Comments						
John Clean-up / ACME Cancer Center / john.cleanup@needhelpcancercenter.com / Phone: (111) 555-5555						

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – National Trials (Email Template - Brief)



Example email/form to send to the CTRO NCICTRO@mail.nih.gov for review and triage. Post review, the Cancer Center will be instructed by the CTRO regarding who to contact (e.g., CTEP or CTSU) and related next steps

 For National trials, try to avoid referring to a discrepancy on the CTRP DT4 report, instead please focus on the specific data to be corrected in CTRP

If your Cancer Center is a Participating Site, follow this email template example:

To: NCICTRO@mail.nih.gov (CTRO) or e.g., ncictephelp@ctep.nci.nih.gov, ctsucontact@westat.com

<u>Subject</u>: CTRP Discrepancy / Data Correction Request ("ACME Cancer Center")

<u>- Brief Example -</u>

Dear CTRO (or responsible reporting party/operations):

We would like to request the following updates to be made in CTRP for the following for our center:

Accrual

- "For Trial CTEP ID and Site/Center CTEP ID, there is only ## accrual when there should be ##."
- "For Trial CTEP ID and Site/Center CTEP ID, there is ## accrual missing on mm/dd/yyyy"

Please let me know if you have any questions.

Regards,

John Clean-up / ACME Cancer Center / john.cleanup@needhelpcancercenter.com / Phone: (111) 555-5555

CTRP-Generated Data Table 4 Discrepancy Follow-up Process – National Trials (Email Template - Detailed)



Example email/form to send to the CTRO NCICTRO@mail.nih.gov for review and triage. Post review, the Cancer Center will be instructed by the CTRO regarding who to contact (e.g., CTEP or CTSU) and related next steps

 For National trials, try to avoid referring to a discrepancy on the CTRP DT4 report, instead please focus on the specific data to be corrected in CTRP

If your Cancer Center is a Participating Site, follow this email template example:

To: NCICTRO@mail.nih.gov (CTRO) or e.g., ncictephelp@ctep.nci.nih.gov , ctsucontact@westat.com Subject : CTRP Discrepancy / Data Correction Request ("ACME Cancer Center")	5
	<u>- Detailed Example -</u>
Dear CTRO (or CTEP, CTSU, DCP):	
We would like to request the following CTRP data corrections for our center:	
NCI ID *	
NCT ID •	
Protocol ID ,	
CTEP ID .	
DCP ID .	
Local Trial ID ,	
Participating Site Org •	
CTEP Org ID ,	
CTRP Field/Current Data • I	
CTRP Field/Correct Data *	
Comments *	
Please let me know if you have any questions.	
Ficase ict ille kilow ii you have ally questions.	
Regards,	
John Clean-up / ACME Cancer Center / john.cleanup@needhelpcancercenter.com / Phone: (111) 555-5555	

CCSG DT4 References

- NCI Office of Cancer Centers (OCC) CCSG DT4 Report Data Elements:
 - https://cancercenters.cancer.gov/GrantsFunding/eData#dt4
- NCI OCC CCSG DT4 Report Template:
 - https://cancercenters.cancer.gov/GrantsFunding/GrantsFunding
 - Download eData Templates > DT4