

CTRP User Call Data Table 4

Agenda for Today's Call

CTRP Topics

- Recent & Planned Updates
- Expanded Access Trials
- CTRP Generated Data Table 4
 - Interventional trials
 - Observational studies
 - Ancillary-Correlative studies
 - Data Correction Requests: Follow-up Process
- User Account Management
- Other Topics
 - Supplemental Cancer Center Q&A
 - References / Training Links
- Next Steps

A large blue chevron graphic pointing to the right, composed of two overlapping shapes, occupies the left side of the slide.

Recent CTRP Updates

Flexible Accrual Reporting

ICD-O-3 Disease Codes

Display of Rejected/Submission Terminated Studies

Flexible Accrual Reporting - Overview

Recent CTRP Updates

- Implemented more flexible accrual reporting capabilities in July 2020
 1. Centers can now request to update the “**Default Accrual Reporting Type**” on a study registered in CTRP
 2. New Accrual Reporting Type, “**Partial Subject**” which requires the reporting of Study Subject ID, Registration Date and Participating Site data only

Note: Both of these scenarios require a ticket to be submitted to the CTRO (NCICTRO@mail.nih.gov) for review and approval, before any change is granted

Refer to Flexible Accrual User Guide pages for more information:



 <https://wiki.nci.nih.gov/display/CTRPdoc/About+Accrual>

 <https://wiki.nci.nih.gov/display/CTRPdoc/Searching+for+Trials+in+Accrual>

Flexible Accrual Reporting – Country Code

Recent CTRP Updates

- CTRP requires Country Code for all Subject accrual submissions
 - Country code was previously required in all accrual submission methods, except for the *Batch Upload function* in CTRP Accrual
 - CTRP previously defaulted the Country Code to “US” if left blank
 - *Batch Upload function* now requires the submission of a Country Code; will no longer default the Country Code value
- CTRP requires Zip Code for US, US territories and outlying islands
 - Zip code was previously required in all accrual submission methods for US *states*; zip code requirement now includes *US territories and outlying islands*
 - *Subject & Partial Subject Accrual: Zip Code not valid for countries that are not US, US territories and outlying islands*
 - *Zip Code must be a 5-digit or 9-digit (DDDDD-DDDD) value*

ICD-O-3 Disease Code Updates

Recent CTRP Updates

- ICD-O-3 disease codes:
 - CTRP is now using a hybrid model including codes from both the International Association of Cancer Registries (IACR) and NCI SEER
 - July 2019: CTRP switched from using NCI SEER codes to IACR, but it was recently noticed that there were 22 NCI SEER codes unsupported by CTRP
 - CTRP was modified to include the unsupported SEER Codes

Display of Rejected/Submission Terminated Studies

Recent CTRP Updates

- Implemented more robust display and search capabilities in July 2020

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Clinical Trials Reporting Program Registration Jennifer Harvey harveyj

Trials to Verify 17 Search Register Trial Administration Quick Links Contact Us Help

Search Clinical Trials Search Persons Search Organizations

Enter information for at least one of the criteria and then click Search.

Title

Phase

Pilot Trial?

Identifier Type

Organization Type
Please select an organization type before selecting an organization

Organization

Principal Investigator

Search By Trial Category

My Trials
All Trials
Rejected Trials
Saved Drafts

Search Reset

Users can search for **Rejected** trials in Registration to reduce duplicate trial submissions to CTRP

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Planned CTRP Updates

*Trial Record Verification Date
Registration User Interface Updates*

Registration: Trial Record Verification - Overview

Planned CTRP Updates

- Improve CTRP Registration user experience for trial owners, trial submitters, and site administrators to **Verify, Update** and **Amend** their trial records
 1. New page highlighting all **Trials Needing Verification**
 2. Ability to view all trial details on the **Verify** screen
 3. Simplified workflow allowing users to **Verify, Update** or **Amend** trials within same form
 4. New monthly email notification for alerting trial owners, trial submitters, and site administrators of **Trials Needing Verification**

Registration: Trial Record Verification - Current Process

Planned CTRP Updates

NCI National Cancer Institute

NCI CTRP Registration
ctrpsubstructor CI

Search Register Trial Administration Quick Links Contact Us

Search Clinical Trials Search Persons Search Organizations Search Results

Clinical Trials Search Results

Show 10 Search: Choose columns << < 1 2 3 4 5 ..

NCI Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	ClinicalTrials.gov Identifier	Current Trial Status	Current Processing Status	Available Actions
NCI-2020-00071	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	FoxHollow Technologies Inc	UPCC 46507791 ss452	NCT46507791	In Review	Submitted	
NCI-2020-00070	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	FoxHollow Technologies Inc	UPCC 90855511 ss452	NCT90855511	In Review	Submitted	
NCI-2020-00069	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	FoxHollow Technologies Inc	UPCC 54900311 ss452	NCT54900311	In Review	Submitted	
NCI-2020-00020	7A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy89	Novartis Pharmaceuticals	VN779838689	NCT79989889	Active	Abstraction Verified Response	Update Amend Change Status View TSR View YMA Verify Data Select Action
NCI-2020-00019	Single Palatal Temporary Anchorage Device for Anterior Open Bite: a Randomized Clinical Trial	University of Dundee	2-054-19	NCT04419805	In Review	Abstraction Verified Response	Select Action
NCI-2020-00018	A Randomized Control Trial to Determine Weight Gain Benefits of Caloric Supplementation for NAS Infants	Yale University	2000028252	NCT04419857	In Review	Abstraction Verified Response	Select Action

To verify a trial record, a user must select a trial in an abstracted state and select the **Verify Data** option

Registration: Trial Record Verification - Current Process (Cont'd)

Planned CTRP Updates

National Cancer Institute at the National Institutes of Health | www.cancer.gov

NCI CTRP Registration ctrpsubtractor CI

Search Register Trial Administration Help

Trial Data Verification

NCI Trial Identifier: NCI-2020-00020
ClinicalTrials.gov Identifier: NCT79989889
Lead Organization Trial Identifier: VN779838689
Title: 7A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy89

Date	Verification method	Verified By
2020-06-09 14:50:45.78	Abstraction Verified Response	CTRO Staff

Add Data Verification Record

I have reviewed the data for this trial :

Save Verification Record Cancel

A user is not able to view any trial data other than **Trial Identifier(s), Title, Date** of last verification, **Verification Method** and by whom the record was last **Verified By**. Centers are not able to update any information within this form or process.

Registration: Trials Needing Verification Page New Process Planned CTRP Updates

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Clinical Trials Reporting Program

Trials to Verify 90

Trials Needing Verification

The trials below are either approaching their Record Verification Due Date or the Record Verification Due Date is in trial information is accurate and up to date.

Show 10

NCI Trial Identifier	Title	Registration Date	Lead Organization	Lead Org Trial Identifier	Available Actions	Current Trial Status
NCI-2017-00384	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02	Select Action	In Review
NCI-2017-00389	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 34890534-4	Select Action	In Review
NCI-2017-00385	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	Case Western Reserve University	UPCC 348-02 II	Select Action	In Review
NCI-2017-00381	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02h	Select Action	In Review
NCI-2017-02638	New Test Trial	06/28/2017	Case Comprehensive Cancer Center	UPCC 86422673 ss410	Select Action	In Review
NCI-2017-02636	test73834	06/28/2017	Case Comprehensive Cancer Center	test783484	Select Action	In Review

Trials to Verify displays both trials due and/or past due for **Record Verification**, along with the total count of each.

If all trials are verified, **Trials to Verify** still displays, but it will not be highlighted, and the total count will be 0.

Select the **NCI Trial Identifier** to verify the trial record.

Registration: Submit Update/Verify Record New Process Planned CTRP Updates

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Clinical Trials Reporting Program Registration

ctrpsubtractor CI

Trials to Verify 92 Search Register Trial Administration Quick Links Contact Us Help

Update/Verify Trial Data

Trial Details

Title A Phase I/II Study Of Bximab Vedotin In Combination With Multi-Agent Chemotherapy

Trial Identifiers

NCI Trial Identifier NCI-2017-00331

Lead Organization Trial Identifier* UPCC 34890534-434
13 characters left

ClinicalTrials.gov Identifier NCT01994552

Other Identifiers

- 818280234

Other Trial Identifier **+ Add Other Identifier**

Lead Organization / Principal Investigator

Lead Organization National Cancer Institute Division of Cancer Prevention

Regulatory Information

The information in this section is REQUIRED to enable studies in ClinicalTrials.gov

Studies a U.S. FDA-regulated Drug

Update/Verify **Cancel** **Other Actions**

Amend
Change Status
View TSR
View XML
View Details

Other Actions will allow users to **Amend** a trial and submit an updated **Protocol Document and IRB Approval**. This function is also available on the **Trials Needing Verification** page and **Trials Search** page under **Select Actions**.

Please verify ALL the trial information you provided on this screen before clicking "Update/Verify". Even if no data was changed, a Data Verification record will be saved with today's date.

Registration: Email Notifications (New Process)

Planned CTRP Updates

Date: 07/31/2020

Dear firstname lastname,

The following trial(s) are due for Data Verification in CTRP:

NCI ID	Lead Organization	Trial ID	Verification Due Date
NCI-2017-02629	test7382		08/20/2020

The following trial(s) are past due for Data Verification in CTRP:

NCI ID	Lead Organization	Trial ID	Verification Due Date
NCI-2017-02619	test945798		06/28/2018
NCI-2017-02623	test237823		06/28/2018
NCI-2017-02625	test648843		07/07/2018

NCI requests the verification of all trial data in CTRP at least every 6 months. The Data Verification due date is determined based on the following:

- Date the last data abstraction was verified (both new registration and amendment submissions) in CTRP
- Date the last Update was submitted in CTRP
- Date the last Data Verification was performed in CTRP

To perform the Data Verification, please follow these steps:

1. Log into the CTRP Registration Application via this direct link: <https://trials.nci.nih.gov/registry/protected/viewVerifyTrials.action>
2. Select the trial you wish to verify; review the TSR, if needed
3. If the data is accurate and up to date, click the Update/Verify button
4. If updates are needed, please address accordingly and then click the Update/Verify button


If you have questions on this process, please contact us at ncicro@mail.nih.gov

Thank you for your participation in the NCI Clinical Trials Reporting Program (CTRP).

- Users will now receive monthly email notifications regarding trials due and past due for Data Verification > *For example, trials due for Data Verification in May will start receiving the email notification in April*
- The notification will continue monthly until all trials due for Data Verification, both present and past, have been verified

Registration: General Forms (Updated User Interface)

Planned CTRP Updates



Clinical Trials Reporting Program Registration

ctrpsubstractor C

Trials to Verify 90 Search Register Trial Administration Quick Links Contact Us Help

Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (*).

Trial Details

Title* 4000 characters left ?

Phase* ?

Is this a Pilot?

Trial Type* **Interventional** **Non-interventional**

Primary Purpose* ?

Secondary Purpose

Trial Identifiers

Lead Organization Trial Identifier* ? 30 characters left

ClinicalTrials.gov Identifier ?

Other Identifiers

Other Trial Identifier

Registration and Search forms will have a new look

Expanded Access

Registration Best Practices

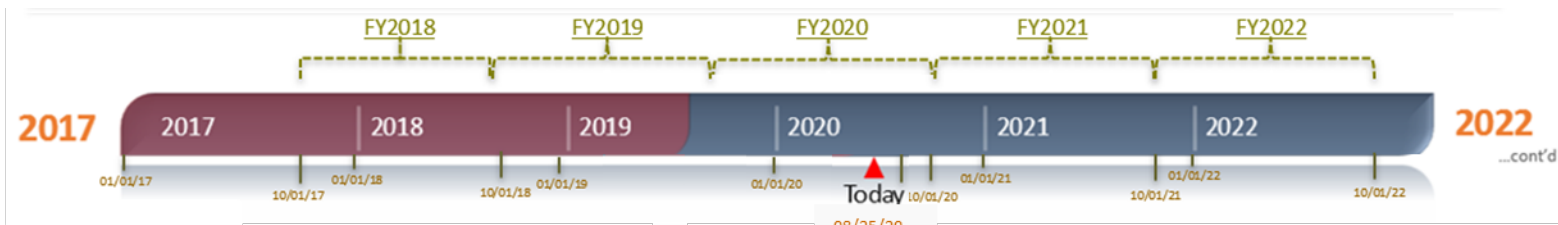
Expanded Access Registration Best Practices

- Expanded access trials in CTRP should be registered by importing the record into CTRP from ClinicalTrials.gov
 - Advantages:
 - Consistent representation of primary purpose and trial status

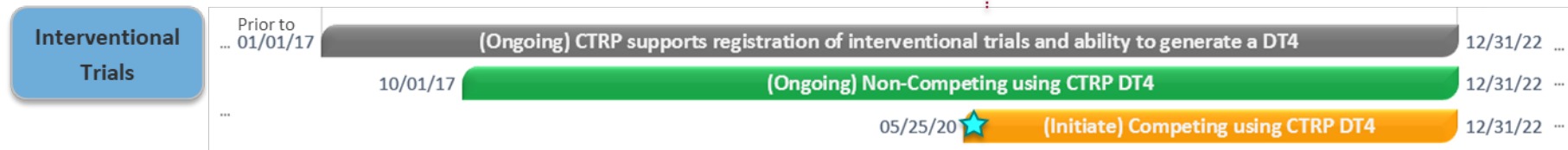
CTRP Generated DT4

Interventional trials
Observational studies
Ancillary-Correlative studies

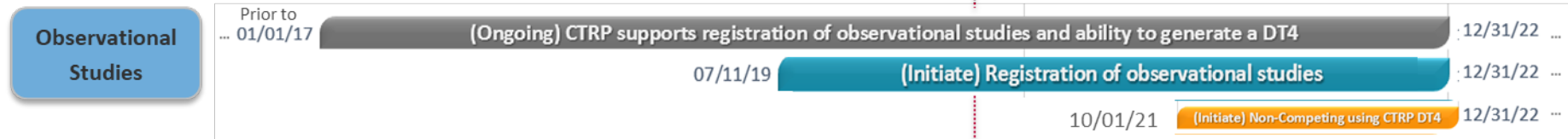
CTRP-Generated Data Table 4 (Interventional and Non-Interventional) Implementation Timeline (2017 – 2022)



Interventional DT4



Non-Interventional DT4



Ancillary-Correlative Studies



CTRP-Generated Data Table 4

Schedule for CCSG CTRP-generated DT4 Reporting

- Presented at AACI CRI Meeting on July 8, 2020:
 - Interventional Trials
 - (Ongoing) Cancer Centers are currently submitting CTRP-generated DT4 for non-competing applications
 - FY 20: Submission with competing applications (began May 25, 2020)*
 - Observational Studies
 - CTRP currently supports reporting of non-interventional studies
 - FY 21: Reconciliation activities with centers to be conducted
 - FY 22: Submission of CTRP-generated DT4 with non-competing applications (beginning October 1, 2021)
 - Ancillary-Correlative Studies
 - Continue to report using current CCSG DT4 format



* Office of Cancer Centers (OCC) released revised Funding Opportunity Announcement (FOA) on 11/04/2019:

<https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html>

CTRP-Generated DT4: Interventional Trials for Competing Applications Review and Submission Process: Lessons Learned to Date

- Formatting: Differences between CTRP-generated DT4 and the CCSG Competing Data Guide (August 27, 2019)*
 - Sort Order
 - Clinical Research Category (Interventional, Observational, Ancillary-Correlative)
 - Study Source (National, Externally Peer-Reviewed, Institutional, Industrial)
 - PI Last Name
 - Date Format
- Legibility: The font on the CTRP-generated DT4 PDF was too small for a reviewer to read
- Technical: Difficulty uploading CTRP-generated DT4 PDF to eRA Commons system due to column width restrictions



Refer to slide 24 for more details in support of the CTRP DT4 Competing submission process

*<https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4>

CTRP-Generated Data Table 4

Interventional Trials – Proposed PDF Modifications

- Columns targeted for removal from the CTRP DT4 PDF used for competing submissions:

1. P30 Grant Number
2. NCI ID (CTRP identifier)
3. Other Protocol IDs
4. Local Trial ID
5. PI - Middle Name
6. Entire Study Accrual to Date
7. Comments

CTRP Data Table 4 Report (Interventional)										Cancer Center: ACME Comprehensive Cancer Center										FY 2020		Date Range 01-Jan-2019 to 31-Dec-2019				Date Printed 22-Jun-2020			
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	Pilot	Primary Purpose	Official Title	Entire Study	Your Center Total	Center Reporting Period	Center to Date	Other Reporting Period	Other to Date	Entire Study Accrual to Date	Comments	
CA086862	INT	I	Universit	Prostate	NCT029	NCI-20	201605762		2016057	N	Doe	John		FRMI	27-Jul-2016		NA	YES	Dia	Bodist	30	30	0	21	0	0	21		
CA086862	INT	D	Center fd	Multiple	NCT007	NCI-20	PBSC		1997053	Y	Doev	Joe	M	ET	02-Jul-1997		III		Oth	Filgrastim-Mobili	400	22	354	0	0				

- Making these changes will:
 - Improve legibility
 - Facilitate loading CTRP-generated DT4 PDF to eRA Commons system

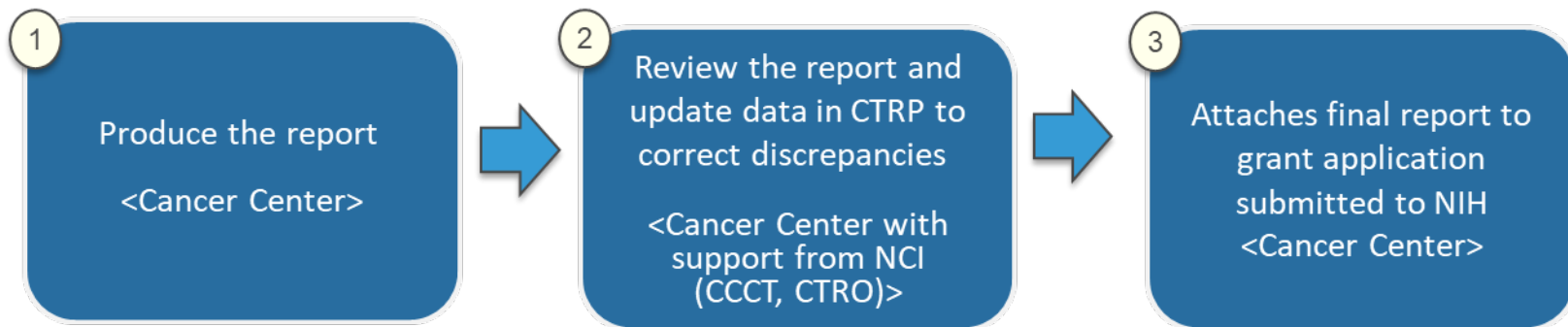
CTRP-Generated Data Table 4 for Competing Applications Planned Enhancements

- Remove columns from PDF version of CTRP DT4 report*
 - Excel report download option with all columns (*refer to previous slide*) will continue to be available <supporting non-competing submissions>
- Change sort order for Clinical Research Category and PI last name to harmonize CTRP DT4 and CCSG Competing Data Guide
- Until modifications to the CTRP-generated Data Table 4 are released, centers can download into Excel and make additional edits
 - Example: Sort, hide/remove columns, then save as a PDF version for submission to the eRA Commons system
- Date format in CTRP (DD-MMM-YYYY) will remain unchanged

*Aligns to mandatory Office of Cancer Centers Competing Data Guide requirements
<https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4>

CTRP-Generated DT4: Interventional Trials for Competing Applications Review and Submission Process

- (Type 2 / Renewal) Cancer Center initiates the CTRP-generated DT4 report generation and submission process



- 12-month period of their choice from last 5-years

- Only critical comments/discrepancies to be mentioned in the “Narrative”
- Upload to eRA Commons <https://era.nih.gov/> as an attachment to the renewal application (not emailed to the OCC CCSG mailbox)

CTRP-Generated Data Table 4

Observational Studies – Scope and Reporting Requirements

- All observational studies open to accrual on or after January 1, 2018
- Cancer Center enters ~15 data elements and submits the Protocol and IRB Approval documents
- CTRO abstracts additional data from the Protocol document, including participating sites
- Cancer Center reports cumulative accrual
 - CTRP can support patient level accrual reporting if more convenient for the submitting organization

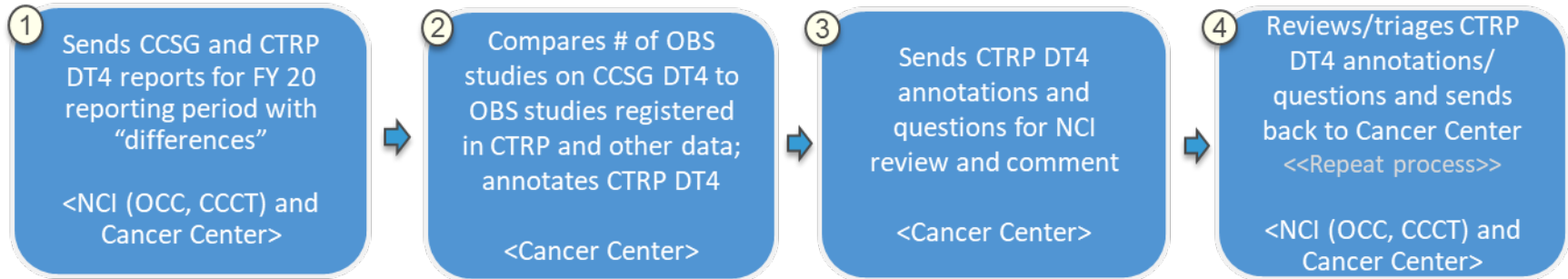


Refer to slide 26 for details in support of the CCSG DT4 to CTRP DT4 FY 21 reconciliation process

CTRP-Generated Data Table 4

Observational Studies Reconciliation

- FY 21 (starting Oct 1, 2020): initiate reconciliation of CTRP-generated DT4 for observational studies with Cancer Center CCSG DT4 reported data (similar to what was done for interventional trials)
 - NCI initiates review process; schedules a kick-off meeting with the Cancer Center, and aligns this process to the next scheduled non-competing submission timings





CTRP-Generated Data Table 4

Ancillary-Correlative Studies

- CTRP supports reporting of ancillary-correlative studies
- A timeline for development and implementation of CTRP-generated DT4 for ancillary-correlative studies has not been proposed
- Continue to report using current CCSG DT4 format

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



Data Correction Requests

Discrepancy Follow-up Process

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

- The Lead Organization (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 typically 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 questions regarding a specific trial and the identification of the LO and related reporting responsibilities in CTRP, please send a message to the CTRO (NCICTRO@mail.nih.gov) to review this with you in more detail

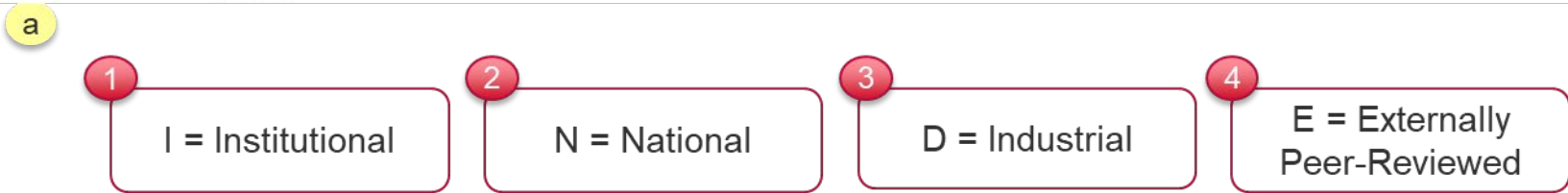
CTRP-Generated Data Table 4 Discrepancy Follow-up Process – Study Source

- 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-2016 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	SD051111	ABNS0111	C0GBBBS12122	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	DOC051113	JEJS01113, A1113, ZBB12234	SSABBS12122	N	John	Jonathon	M	ZY	06-Aug-2009		II



* 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) 31

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 the NCI operations office for National trials (e.g., CTEP, DCP)
- 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 *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 – 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 is working to align these more closely to the PS-level dates for the center 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



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 are submitted during the registration process (*e.g., SPORE/P50, R01, U01, etc*)
- 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
 - CTRP was updated to accommodate the new Sex value of Undifferentiated
 - Current accepted values: Male/Female/Unknown/Unspecified/Undifferentiated

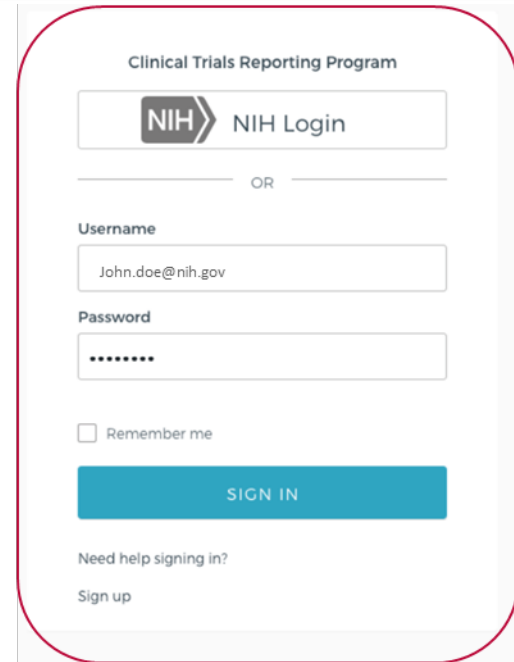
CTRP User Account Management

*Planned: Centralized CTRP Accounts/Login
New User Request, Deactivation*

CTRP User Account Management

Planned: OKTA Migration > Centralized CTRP Login

- New CTRP user account and login URL planned for 4Q2020:
 - CTRP user accounts will have multi-factor 2-part authentication capabilities for CTRP (Registration, Accrual, STRAP)
 - Centers will receive a new CTRP URL and User ID
 - When logging in for the first time, users will need to create a new password and set up their multi-factor 2-part authentication method (Okta Verify, SMS Authentication or Voice Call Authentication)



The screenshot shows the NIH Login interface for the Clinical Trials Reporting Program. At the top, it says "Clinical Trials Reporting Program". Below that is a button with the NIH logo and the text "NIH Login". Underneath is a horizontal line with "OR" in the center. Below the line are two input fields: "Username" with the example "John.doe@nih.gov" and "Password" with masked characters "*****". There is a checkbox labeled "Remember me" which is currently unchecked. Below the input fields is a blue "SIGN IN" button. At the bottom, there is a link for "Need help signing in?" and a "Sign up" link.



Initial CTRP ListServ message to be sent a month prior to this activity informing centers of the schedule and instructions

CTRP User Account Process

- It is important that CTRP user accounts reflect **active** CTRP users (Registration, Accruals, STRAP)
 - New User Account Requests
 - Deactivation Process
- Periodic reviews and outreach currently performed for CTRP users who have not logged in within the past 120 days



Please inform the CTRP Team CTRP_Support@mail.nih.gov (or CTRO NCICTRO@mail.nih.gov) if you have any staff changes so that we can properly deactivate accounts



Other Topics

Supplemental Cancer Center Q&A

Supplemental Cancer Center Q&A

- How should the LO report accrual in each of the following?
 - Patient transfers INTO the lead org site from a participating site (the patient becomes a LO site patient treated by a LO site investigator) <The patient would not have enrolled to the study under LO site investigators>
 - Patient transfers FROM the LO site to a participating site (the patient is no longer being treated by a LO site investigator at the LO site) <The patient would have enrolled to the study under a LO site investigator>
- How do I register a multi-site, non-NCI Designated Cancer Center or Industry led Observational study that doesn't have an NCT ID (not registered in ClinicalTrials.gov and Lead Org doesn't plan to register it in ClinicalTrials.gov)?
 - Please contact the CTRO NCICTRO@mail.nih.gov to request assistance with registering Observational studies without an NCT ID








Supplemental Cancer Center Q&A (Cont'd)

- Is the inclusion of expanded access trials on the CTRP DT4 still optional?
 - The reporting of an Expanded Access trial on a center-specific CTRP-generated DT4 is still at the discretion of the cancer center
 - If you have an Expanded Access trial registered in CTRP that you would like to exclude from your CTRP-generated Data Table 4 report, please send a message to the CTRO (NCICTRO@mail.nih.gov) to request exclusion
- With expanded access protocols being in DT4, will single patient expanded access (compassionate use protocols) also be included?
 - No, single patient compassionate use studies are out of scope for CTRP

Other Topics

CTRP 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>
 - Presentation/Q&A (**CTRP DT4 Reporting/Discrepancy Process**) August 14, 2019:
 <https://wiki.nci.nih.gov/display/CTRP/2019-08-14+User+Call+Meeting+Minutes>

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 Site Administrators can access these fields to update data for their Cancer Center

** Cancer Centers are responsible for adding/updating this information for all trials/studies (Institutional, National, Industrial and Externally Peer Reviewed) in CTRP Registration

Conclusion / Next Steps

- CTRP Generated DT4 Reporting
 - **Interventional trials:** Cancer Centers to continue supporting CTRP generated DT4 submissions for non-competing and competing applications
 - **Observational studies:** 1). Cancer Centers to initiate (or continue) to register Observational Studies in CTRP open to accrual on or after January 1, 2018 and 2). participate in upcoming FY 21 reconciliation activities
- Planned CTRP release details for Registration Trial Record Verification and user interface updates *as well as the Okta migration for user accounts* to be communicated via CTRP ListServ communications
- Please continue to send any future CTRP User Call agenda topics to the CTRO NCICTRO@mail.nih.gov



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Backup Slides - CTRP User Call (August 25, 2020)

Backup Slides

Recent CTRP Updates
Flexible Accrual Reporting

Flexible Accrual Reporting – Default Accrual Reporting Type

Recent CTRP Updates

- Centers can now request to update the default accrual reporting type on a study registered in CTRP
- Current default accrual reporting types are as follows:

Trial Type	Default Accrual Reporting Type
Complete Interventional	Subject
Complete Non-Interventional	Subject
Abbreviated/Imported Interventional	Summary
Abbreviated/Imported Non-Interventional	Summary

- E.g., Allow centers with protocol submissions on Interventional trials, who may not have collected subject/patient level demographic data, the ability to register the protocol in the Complete workflow but submit either Partial or Summary level accrual

Note: Only one type of accrual reporting is allowed per trial and only the CTRO can update the accrual type on an Active trial once accrual has been reported

Flexible Accrual Reporting – Partial Subject Accrual

Recent CTRP Updates

- New “Partial Subject” only requires the reporting of Study Subject ID, Registration Date and Participating Site data (other fields are optional)

Study Subject ID: *

Study Subject Birth Date (MM/YYYY): mm/yyyy

Study Subject Gender: --Select--

Study Subject Race: American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
Not Reported
Unknown
White

To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).

Study Subject Ethnicity: --Select--

Study Subject Country: --Select--

Study Subject Zip Code:

Registration Date: * mm/dd/yyyy

Study Subject method of payment: --Select--

Site: Clear QLook Up ?

Disease: Clear QLook Up ?

Participating Site: * --Select--

Save Cancel

Accrual reporting remains the same, however, less information is required

Flexible Accrual – New fields for Trial Category and Accrual Type

National Cancer Institute at the National Institutes of Health | www.cancer.gov

NCI CTRP Accrual ctrpsubtractor CI ▾

Trial Search Batch Upload Prior Submissions Accrual Counts Disease Search Quick Links ▾ Contact Us Help

Trial Search

NCI Trial Identifier

ClinicalTrials.gov ID

Official Title

New columns display on the home page under List of Trials Trial Category and Accrual Type

List of Trials

Show 10 ▾

Search: Choose columns << < 1 2 > >>

NCI Trial Identifier	Official Title	Current Trial Status	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology
NCI-2020-00020	7A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy89	Active	Interventional	Complete	Subject ▾	ICD-O-3 ▾
NCI-2020-00019	Single Palatal Temporary Anchorage Device for Anterior Open Bite: a Randomized Clinical Trial	In Review	Non-interventional	Abbreviated	Partial Subject	ICD-O-3
NCI-2020-00018	A Randomized Control Trial to Determine Weight Gain Benefits of Caloric Supplementation for NAS Infants	In Review	Interventional	Abbreviated	Subject	SDC
NCI-2020-00017	Measurement of Shoulder Range of Motion Using Microsoft Kinect 2.0 in Patients Undergoing Ultrasound-guided Capsular Distension for Adhesive Capsulitis	Active	Interventional	Abbreviated	Summary ▾	

Flexible Accrual – New fields for Trial Category and Accrual Type



- Trial Search
- Batch Upload
- Prior Submissions
- Accrual Counts
- Disease Search
- Quick Links ▾
- Contact Us

New columns display on the **Accrual Counts** page
Trial Category and **Accrual Type**

Accrual Counts

Show 10 Search: << < 1 2 > >>

NCI Trial Identifier	Lead Org Trial Identifier	ClinicalTrials.gov ID	Lead Organization	Site Accrual Count	Trial Accrual Count	Last Accrual Update Submitted	Trial Category	Accrual Type
NCI-2020-00020	VN779838689	NCT79989889	Novartis Pharmaceuticals	0	0		Complete	Subject
NCI-2020-00019	2-054-19	NCT04419805	University of Dundee	1	1	2020-06-11 15.35.14	Abbreviated	Partial Subject
NCI-2020-00018	2000028252	NCT04419857	Yale University				Abbreviated	Subject
NCI-2020-00017	1490166	NCT04413162	Novartis Pharmaceuticals				Abbreviated	Summary
NCI-2020-00016	Novel COVID-19 Prevalence	NCT04413045	Novartis Pharmaceuticals	70	70	2020-06-11 18.40.46	Abbreviated	Summary
NCI-2020-00015	SK11111772	NCT11111772	Novartis Pharmaceuticals	0	0		Complete	Subject
NCI-2020-00014	SK11111771	NCT11111771	Novartis Pharmaceuticals	1	1	2020-06-11 15.35.45	Complete	Partial Subject
NCI-2020-00013	SK11111882	NCT11111882	Novartis Pharmaceuticals		19	2020-06-08 11.07.23	Complete	Summary
NCI-2020-00011	VN948987350		Novartis Pharmaceuticals	0	0		Complete	Partial Subject
NCI-2020-00010	et235412435125431		Novartis Pharmaceuticals	0	0		Complete	Partial Subject

Showing 1 to 10 of 20 << < 1 2 > >>
Export options: CSV | Excel

Flexible Accrual – Default Accrual Type

- Once a new trial has been registered in CTRP, **Accrual Type** will be set based on the following default accrual type settings.

Study Type	Accrual Reporting Type
Complete Interventional	Subject Level
Imported Interventional	Summary Level
Complete Non-Interventional	Subject Level
Imported Non-Interventional	Summary Level

- Accrual Type** can only be changed by users for Complete, non-interventional studies without existing accrual data.
- Accrual Type** can be changed or switched for other types of studies by contacting the CTRO at NCICTRO@mail.nih.gov.

Flexible Accrual – Delete All Trial Study Subjects

NCI CTRP Accrual

Trial Search | Batch Upload | Prior Submissions | **Accrual Counts** | Disease Search | Quick Links | Contact Us

NCI-2020-00019: Single Palatal Temporary Anchorage Device for Anterior Open Bite: a Randomized Clinical Trial | Lead Organization Trial ID: 2-054-19
Lead Organization: University of Dundee

Search Study Subject

Study Subject ID:
Participating Site: --Select--
Study Subject Birth Date (MM/YYYY):

New ability to Delete All Trial Study Subjects

List of Study Subjects

Message: Record Created.

Show

Study Subject ID	Registration Date	Participating Site	Last Update Date/Time
45322	06/12/2020	Novartis Pharmaceuticals	06/12/2020 13:46
Z-1012	09/16/2018	Novartis Pharmaceuticals	06/11/2020 15:35

**Be careful when Deleting All Trial Study Subjects!!
Incorrectly deleted accrual data must be resubmitted by the center**

Flexible Accrual – Batch Upload and REST Services

- Few changes have been made to the process for submitting accrual data via **Batch Upload** and **REST Services**.
 - **Country Code** is required for for all submission methods including **Batch Upload**
 - **Zip code** is required for US, US territories and outlying islands for all submission methods
- When submitting accrual via **Batch Upload** and **REST Services**, ensure your accrual type is properly set on your trial within the Accrual UI before submitting accrual data.
 - For Non-Interventional Complete trials without existing accrual, the **Accrual Type** can be changed within the UI.
 - For all other type of trials contact CTRO at NCICTRO@mail.nih.gov, to change the **Accrual Type**.
- Accrual records submitted with a different accrual type than what is on the trial record will be rejected.

Flexible Accrual – Special Conditions and Validation Rules

Accrual Data Element	Comments/Conditions
Study Subject Birth Date (MM/YYYY)	<p>Not required for Partial Accrual but if submitted, Month and Year are required.</p> <p>Birth Date must be \leq Registration Date</p> <p>Birth Year must be \leq 125 years</p>
Study Subject Country	<p>Required including batch upload tool</p>
Study Subject Zip Code	<p>Subject Accrual: Zip Code required for US, US territories and outlying islands</p> <p>Subject & Partial Accrual: Zip Code not valid for countries that are not US, US territories and outlying islands</p> <p>Zip Code must be a 5 digit or 9 digit (DDDDD-DDDD) value</p>

Flexible Accrual – Special Conditions and Validation Rules (Cont'd)

Accrual Data Element	Comments/Conditions
Registration Date	Month, Day and Year are required
Disease/Site Code	<p><u>Partial Subject:</u></p> <p>ICD-0-3: Disease is <u>not required</u>. However, if Disease is reported, both Site Name and Site Code are required.</p> <p>ICD-9 or ICD-10: Disease is not required</p> <p><u>Study Subject:</u></p> <p>Disease Code is required for all studies, even Prevention studies</p> <p>ICD-0-3: Site Name and Site Code are required.</p>




Backup Slides

Planned CTRP Updates
Trial Record Verification

Registration – Confirmation of Successful Update New Process

Trials to Verify 92 Q Search + Register Trial Administration Quick Links Contact Us ? Help

 Clinical Trials Reporting Program Registration ctrpsubtractor CI

The Trial Verification and Update with NCI Identifier NCI-2017-00333 was successfully submitted.

Trials Needing Verification

The trials below are either approaching their Record Verification Due Date or their Record Verification Due Date is in the past. The NCI requests that trial owners verify their trial records in CTRP every 6 months to ensure that the trial information is accurate and up to date.

Show 10

Once the trial Update/Verify record has been successful submitted, the Trials Needing Verification page will display and the confirmation message of The Trial Verification and Update with NCI Identifier NCI-20XX-XXXXX was successfully submitted.

NCI Trial Identifier	Title	Record Verification Due Date	Record Verification Status	Available Actions	Current Trial Status
NCI-2017-00331	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy		In Review	Select Action	In Review
NCI-2017-00387	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/06/2017	In Review	Select Action	In Review
NCI-2017-00384	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/06/2017	In Review	Select Action	In Review
NCI-2017-00391	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy IV	04/07/2017	In Review	Select Action	In Review
NCI-2017-00389	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	In Review	Select Action	In Review
NCI-2017-00385	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	In Review	Select Action	In Review

Registration – Trial Record Verification History New Process

☑ Trials to Verify 91 🔍 Search ➕ Register Trial ⚙ Administration 🔗 Quick Links ✉ Contact Us ? Help

Trial Data Verifications

One item found.1

Date	Verification method	Verified By
2017-04-06 03:23:51.102	Abstraction Verified Response	CTRO Staff

Existing Trial Related Documents

Document Type
Protocol Document
IRB Approval Document

Previous Trial Data Verifications will display on the Trial Details page.

Trial Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, submit them separately.

[Tips for creating CTRP compatible PDF documents](#)

Protocol Document	<input type="button" value="Choose File"/>	No file chosen	?
IRB Approval	<input type="button" value="Choose File"/>	No file chosen	?
List of Participating Sites	<input type="button" value="Choose File"/>	No file chosen	?
Informed Consent Document	<input type="button" value="Choose File"/>	No file chosen	?

Please verify ALL the trial information you provided on this screen before clicking "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.

Registration – Select Action Features New Process

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Clinical Trials Reporting Program Registration

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Trials to Verify ⁸⁹ Q Search + Register Trial

The Trial Verification and Update with NCI Identifier NCI-2017-00384 was successful.

Trials Needing Verification

The trials below are either approaching their Record Verification Due Date or the Record Verification information is accurate and up to date.

Show Search: Choose columns << < > >> 5 ... 9

NCI Trial Identifier	Title	Record Verification Date	Lead Organization	Lead Org Trial Identifier	Available Actions	Current Trial Status
NCI-2017-00391	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy IV	04/07/2017	Case Western Reserve University	UPCC 348-02h	<ul style="list-style-type: none">Update/VerifyAmendChange StatusView TSRView XMLView Details Select Action	In Review
NCI-2017-00389	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 34890534-4	Select Action	In Review
NCI-2017-00385	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	Case Western Reserve University	UPCC 348-02 II	Select Action	In Review
NCI-2017-00381	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02h	Select Action	In Review

Registration – Amend Trial New Process

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Trials to Verify ⁸⁹ Search Register Trial Administration Quick Links Contact Us Help

Amend Trial

Trial Details

Amendment Date*

Is this a Pilot?

Trial Type* Interventional Non-interventional

Non-interventional Trial Type*

Primary Purpose*

Trial Identifiers

NCI Trial Identifier

Lead Organization Trial Identifier*
23 characters left

Trials.gov Identifier*

Other Trial Identifier


- Update/Verify
- Change Status
- View TSR
- View XML
- View Details


Please verify ALL the trial information you provided on this screen before clicking "Submit Amendment". Once you amend the trial you will not be able to modify the information.

Trial owners, trial submitters, and site administrators can upload a new Protocol Document and/or IRB Approval, update other trial details and then click **Submit Amendment**. The Date, Verification Method, and Verified By is recorded.

Other Actions will allow users to quickly move to other forms or functions within CTRP such as **Update/Verify** or **Change Status** if an **Amendment** is not needed.

Registration – Confirmation of Successful Amendment New Process

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 Clinical Trials Reporting Program Registration Back-up slide ctrpsubtractor CI ▾

Trials to Verify ₉₁ Q Search ▾ Register Trial ▾ Administration ▾ Quick Links ▾ Contact Us ? Help

The Amendment to Trial with NCI Identifier NCI-2017-00331 was successfully submitted.


Trials Needing Verification

The trials below are either approaching their Reporting Period or have not been reported to the TRP every 6 months to ensure that the trial information is accurate and up to date.

Show ▾

NCI Trial Identifier ▾	Title	Available Actions ▾	Current Trial Status ▾
NCI-2017-00387	A Phase I/II Study Of ... With Multi-Agent Chemotherapy	Select Action ▾	In Review
NCI-2017-00384	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/06/2017	Case Western Reserve University UPCC 348-02 Select Action ▾ In Review
NCI-2017-00391	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy IV	04/07/2017	Case Western Reserve University UPCC 34890534 IV Select Action ▾ In Review
NCI-2017-00389	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University UPCC 34890534-4 Select Action ▾ In Review
NCI-2017-00385	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	Case Western Reserve University UPCC 348-02 II Select Action ▾ In Review
NCI-2017-00381	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University UPCC 348-02h Select Action ▾ In Review

Once the trial **Amendment** record has been successful submitted, the **Trials Needing Verification** page will display and the confirmation message of **The Amendment to Trial with NCI Identifier NCI-20XX-XXXXX was successfully submitted.**



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Backup Slides

*CTRP Data Correction/
Discrepancy Follow-up Process*

CTRP-Generated Data Table 4

Discrepancy Follow-up Process – CTRP Data Correction Request Forms

- CTRP Data Correction Request Form examples:

1 I = Institutional (multi-site) → E.g., Outreach to CTRO or another lead organization, NCI-Designated Cancer Center

Requesting Center's Name:					Center POC: (Name, Email)				Reporting Period (if app):			Response from Outreach
Trial Data					Center / Site Data				Center Request			
NCI ID	NCT ID	CTEP ID	DCP ID	Lead Org/ Protocol ID	Local Trial	Participating Site	POIC	Site CTEP ID	CTRP Field / Current Data	CTRP Field / Correct Data	Comments	

2 N = National → E.g., Outreach to CTRO or CTSU, CTEP

Requesting Center's Name:				Center POC: (Name, Email)					Response from Outreach
Trial Data		Center / Site Data			Accrual Correction			Participating Site Correction	
CTEP ID	DCP ID	Local Trial ID	Participating Sites	Site CTEP ID	Current Accrual Count	Correct Accrual Count	Comments	Comments	

CTRP-Generated Data Table 4

Discrepancy Follow-up Process – Institutional Trials (Email Template)

1

I = Institutional



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):

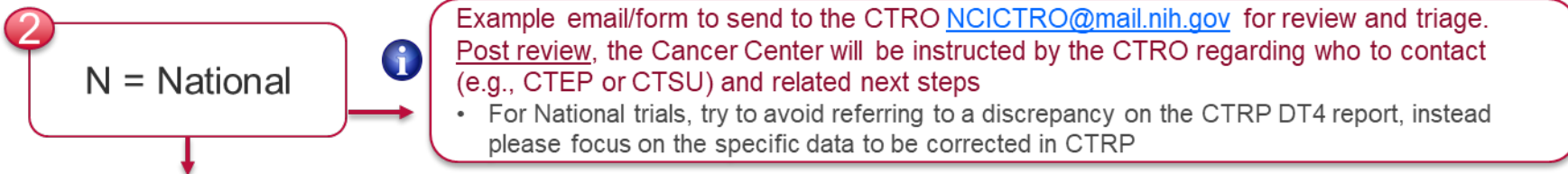
We would like to request the following CTRP data corrections for our center:

NCI ID	<input type="text"/>
NCT ID	<input type="text"/>
Reporting Period (if app)	<input type="text"/>
Local Trial ID	<input type="text"/>
Participating Sites	<input type="text"/>
PO ID	<input type="text"/>
CTRP Field/Current Data	<input type="text"/>
CTRP Field/Correct Data	<input type="text"/>
Comments	<input type="text"/>

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)



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”)

- Brief Example -

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*”

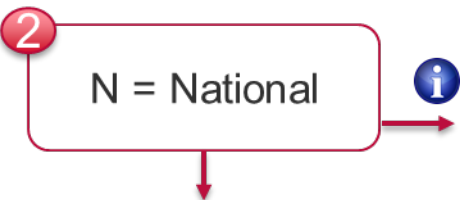
Please let me know if you have any questions.

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., ncictephhelp@ctep.nci.nih.gov, ctsucontact@westat.com

Subject: CTRP Discrepancy / Data Correction Request (“ACME Cancer Center”)

Dear CTRO (or CTEP, CTSU, DCP):

We would like to request the following CTRP data corrections for our center:

NCI ID	<input type="text"/>
NCT ID	<input type="text"/>
Protocol ID	<input type="text"/>
CTEP ID	<input type="text"/>
DCP ID	<input type="text"/>
Local Trial ID	<input type="text"/>
Participating Site Org	<input type="text"/>
CTEP Org ID	<input type="text"/>
CTRP Field/Current Data	<input type="text"/>
CTRP Field/Correct Data	<input type="text"/>
Comments	<input type="text"/>

Please let me know if you have any questions.

Regards,

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

- Detailed Example -