CTRP User Call
Data Table 4

NIH NATIONAL CANCER INSTITUTE

August 25, 2020

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

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

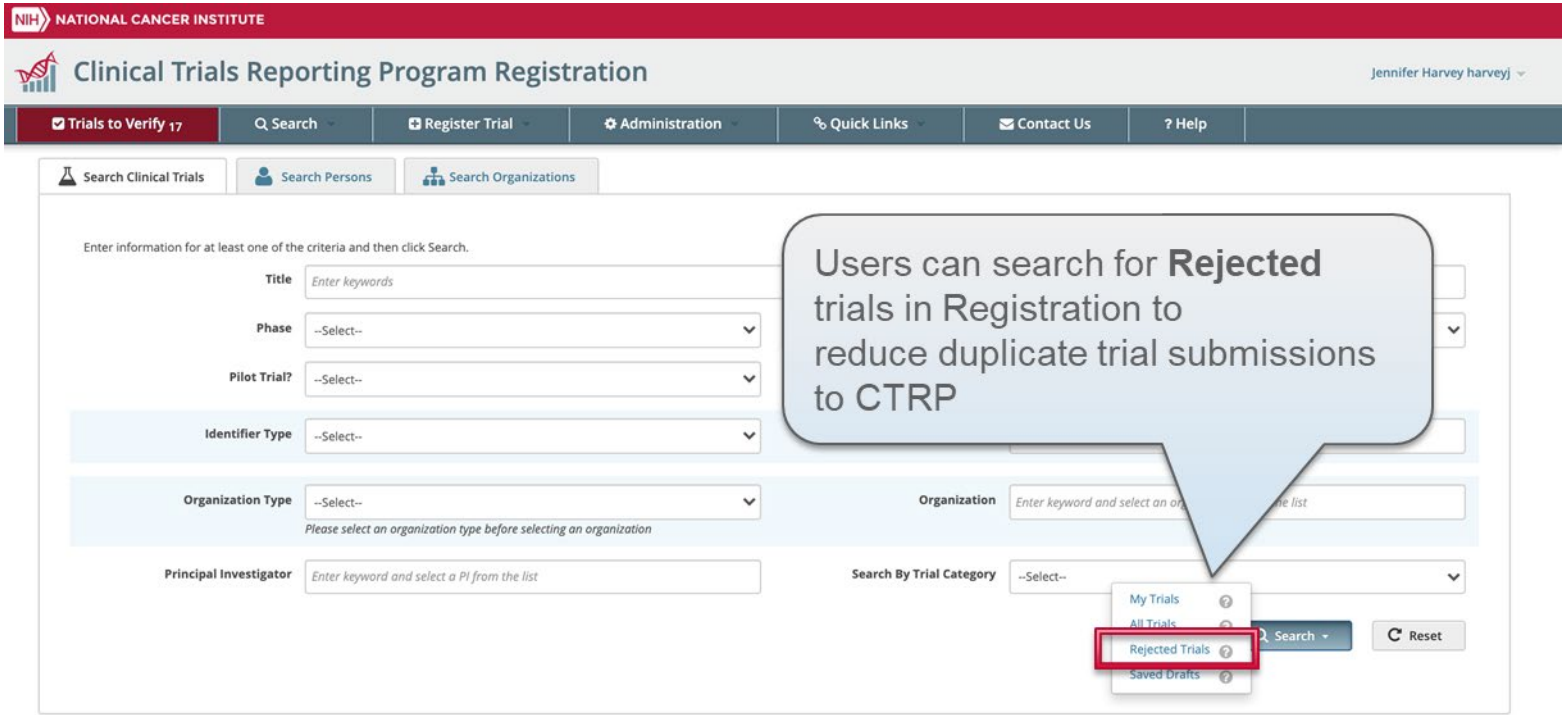
- CTRP requires Country Code for all Subject accrual submissions
  - Country code was previously required in all accrual submission methods, except for the *Batch Upload function* in CTRP Accrual
    - CTRP previously defaulted the Country Code to “US" if left blank
    - *Batch Upload function* now 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; z*ip 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



Planned CTRP Updates

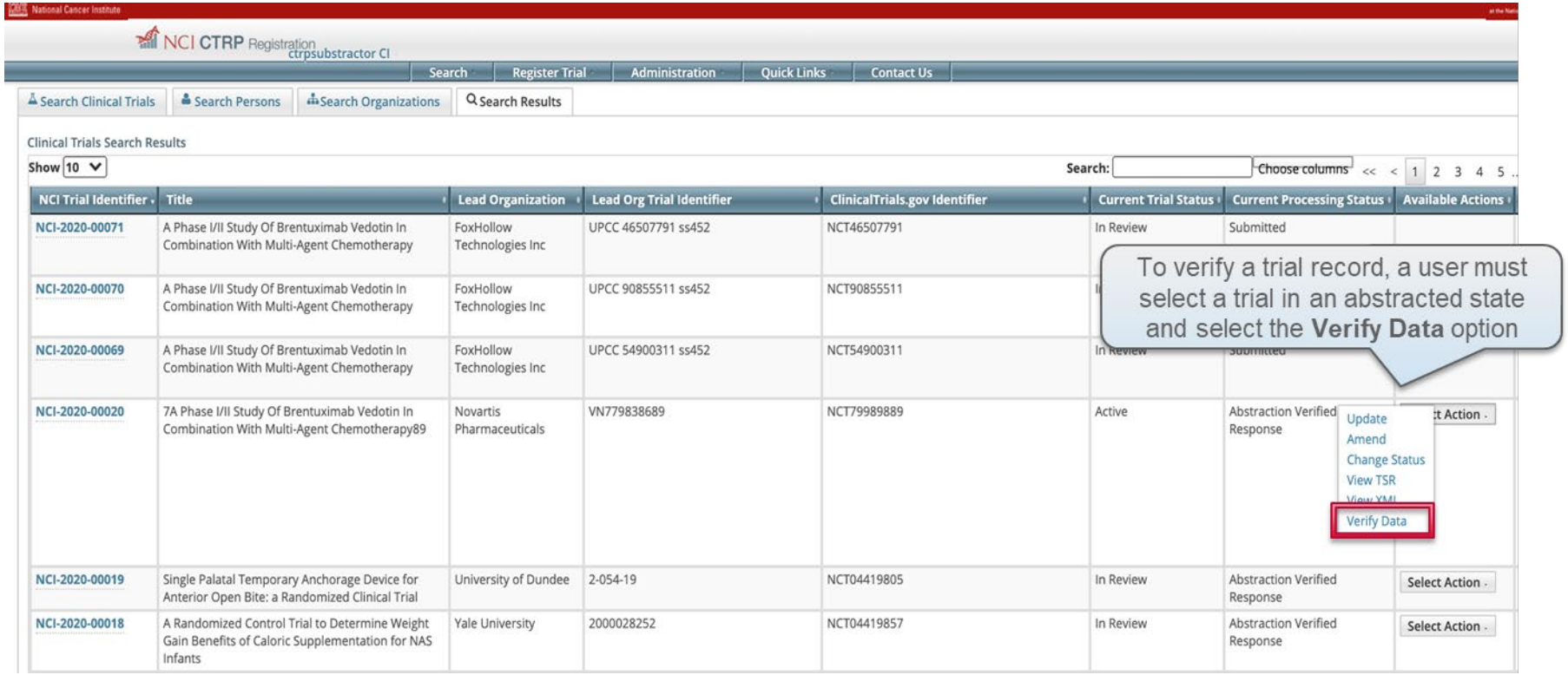
Trial Record Verification Date

Registration User Interface Updates

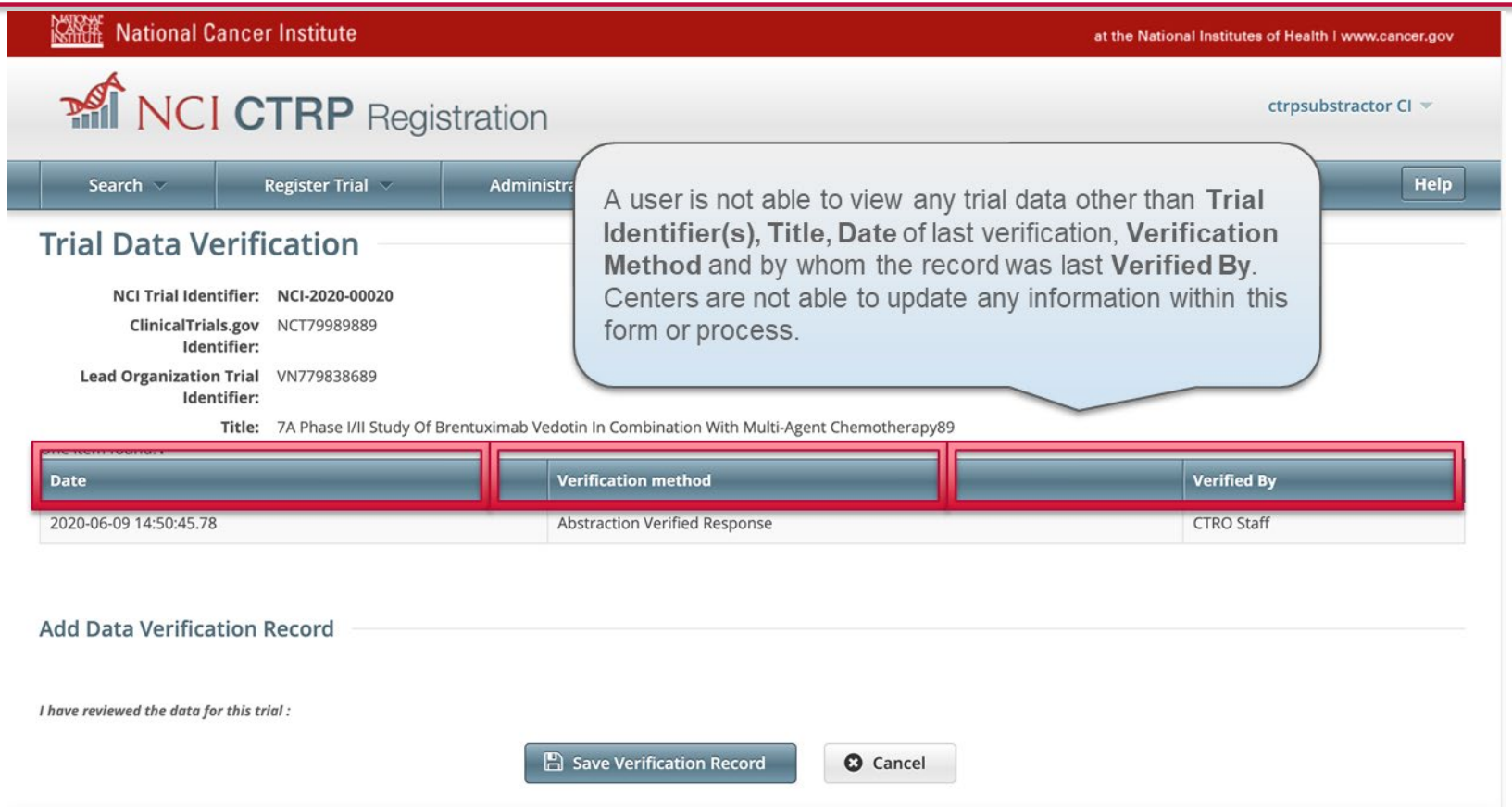
Registration: Trial Record Verification - Overview
Planned CTRP Updates

- 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**

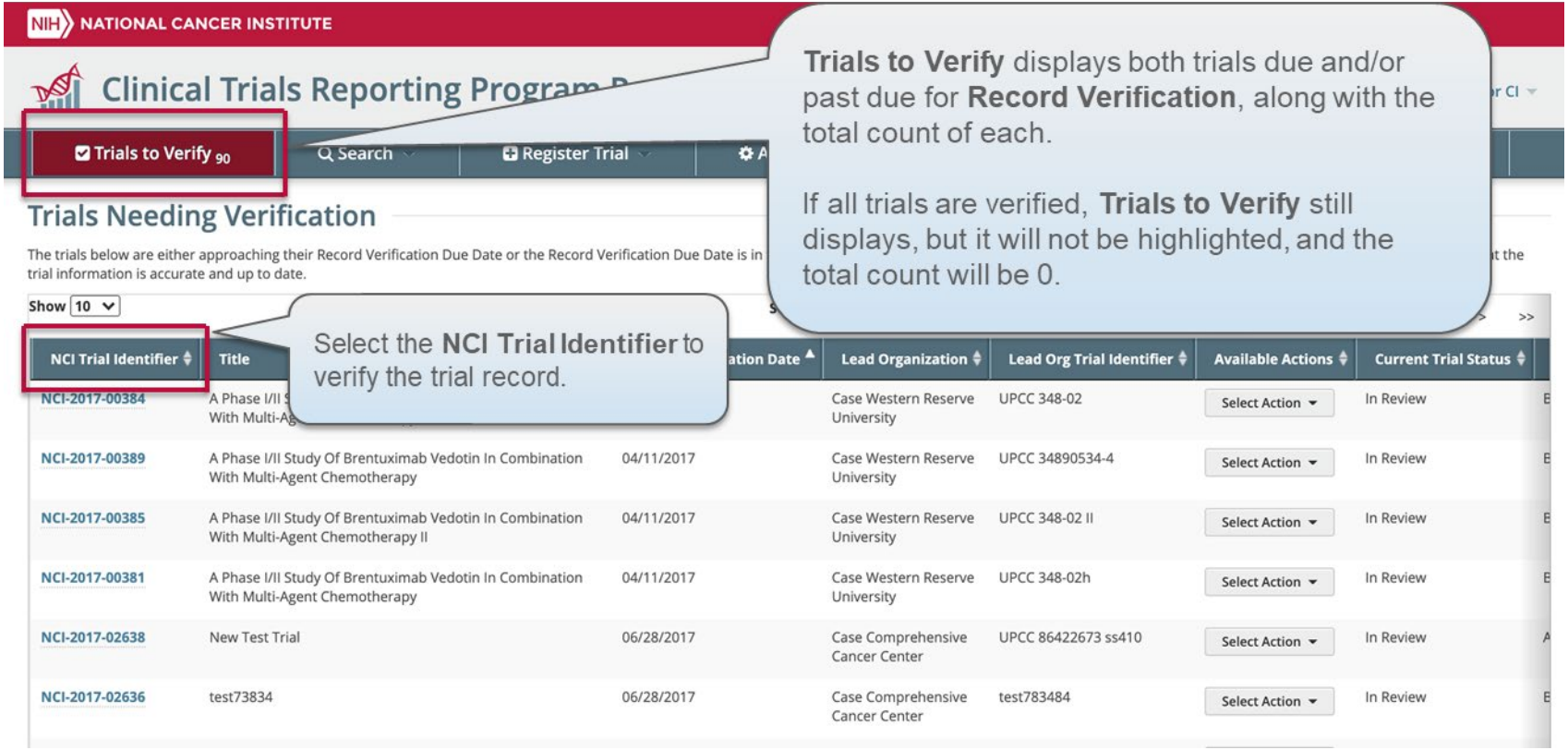
Registration: Trial Record Verification - Current Process
Planned CTRP Updates



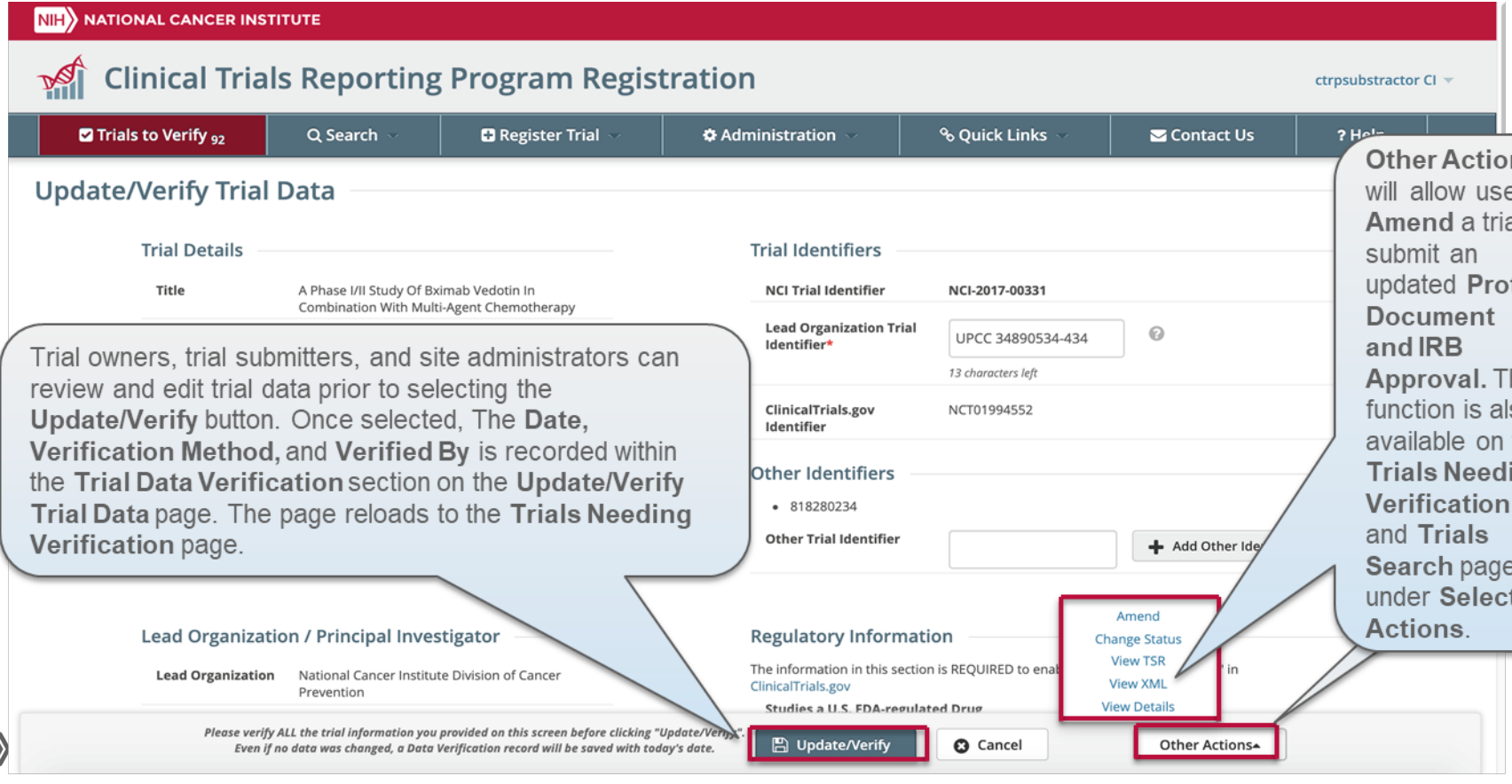
Registration: Trial Record Verification - Current Process (Cont'd)
Planned CTRP Updates



Registration: Trials Needing Verification Page New Process
Planned CTRP Updates



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



Trial owners, trial submitters, and site administrators can review and edit trial data prior to selecting the **Update/Verify** button. Once selected, The **Date, Verification Method,** and **Verified By** is recorded within the **Trial Data Verification** section on the **Update/Verify Trial Data** page. The page reloads to the **Trials Needing Verification** page.

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**.

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:

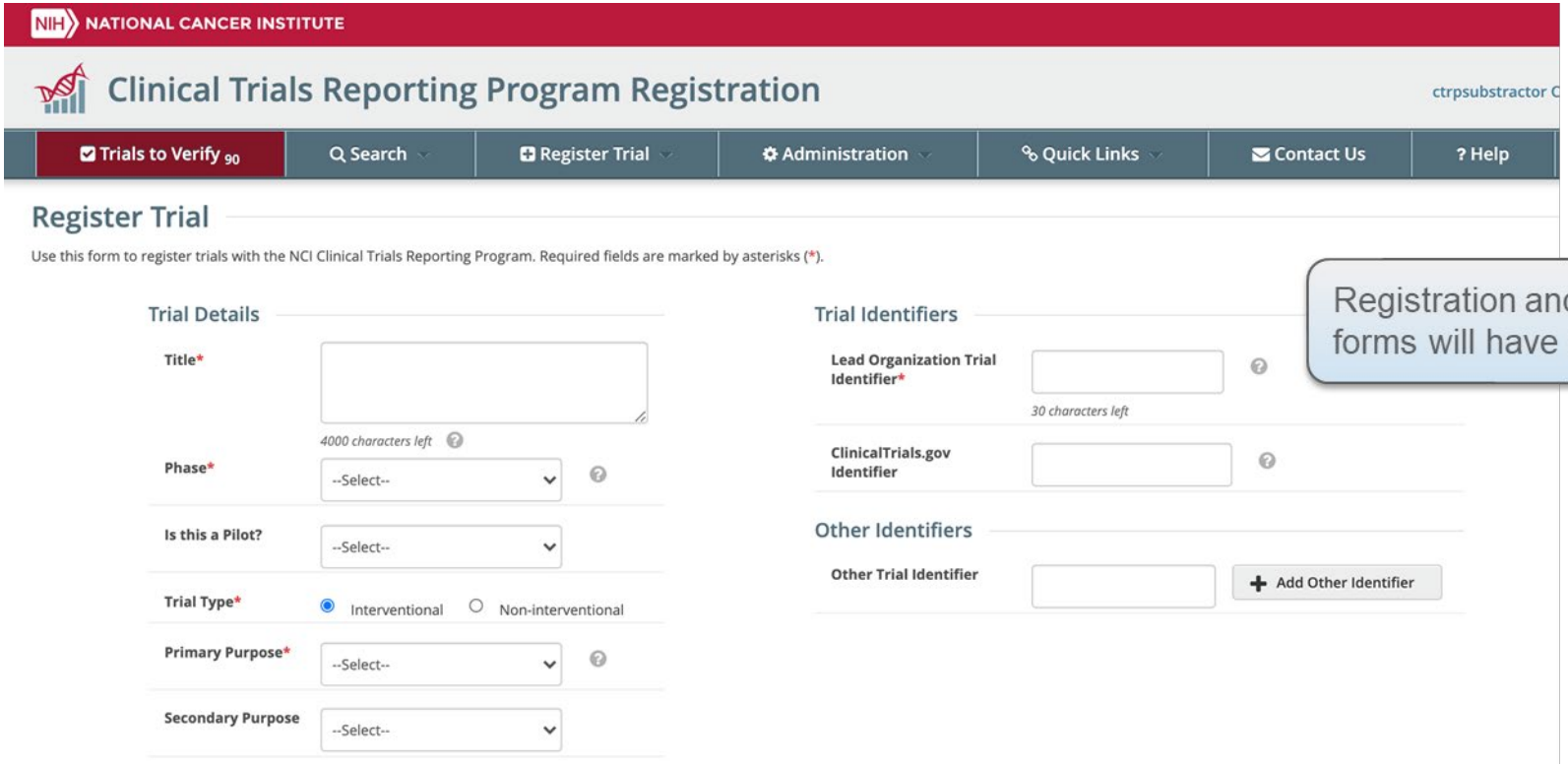
1. Log into the CTRP Registration Application via this direct link: https://trials.nci.nih.gov/registry/protected/viewVerifyTrials.action
2. Select the trial you wish to verify; review the TSR, if needed
3. If the data is accurate and up to date, click the Update/Verify button
4. If updates are needed,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

If you have questions on this process, please contact us at ncictro@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



Registration and Search forms will have a new look

Expanded Access

Registration Best Practices

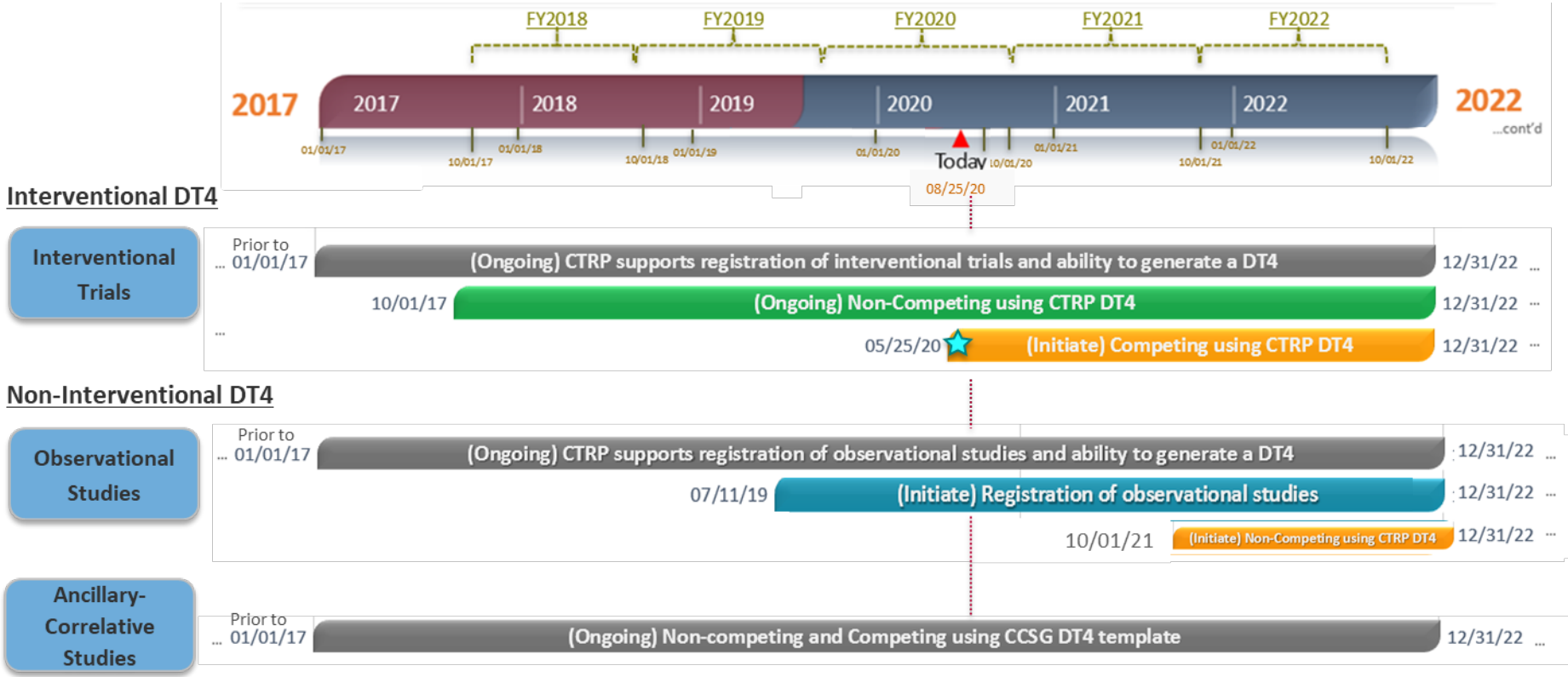
Expanded Access
Registration Best Practices

- 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)



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

1 2 3 4 5 6 7

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	Biodist	30	30	0	21	0	0	21	
CA086862	INT	D	Center fo	Multiple	NCT007	NCI-20	PBSC		1997053	Y	Doey	Joe	M	ET	02-Jul-1997	III		Oth	Filgrastim-Mobil	400	22	354	0	0			

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

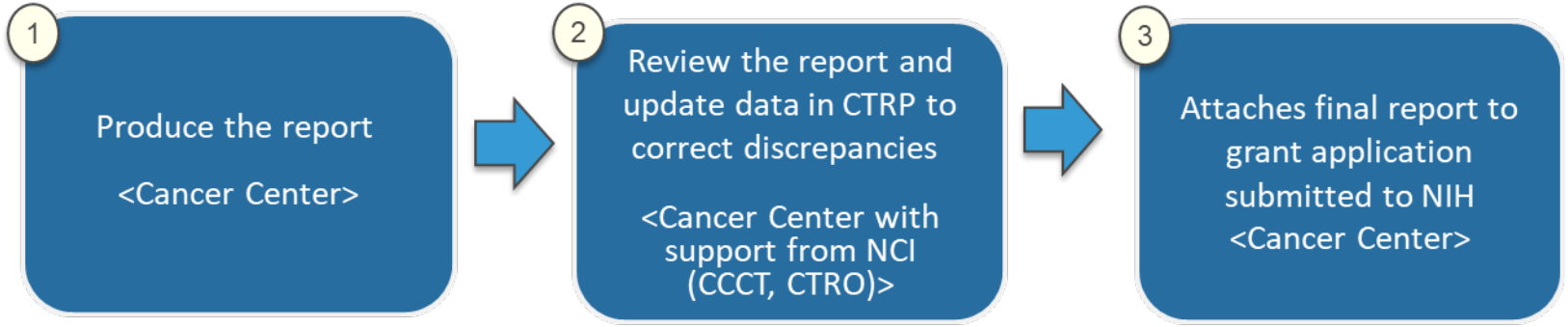
CTRP-Generated Data Table 4 for Competing Applications
Planned Enhancements

- 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)

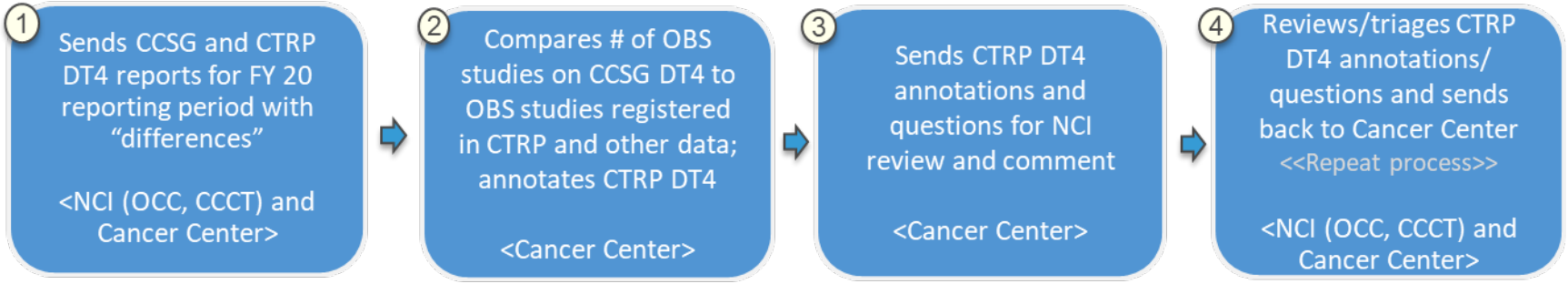
CTRP-Generated Data Table 4
Observational Studies – Scope and Reporting Requirements

- 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

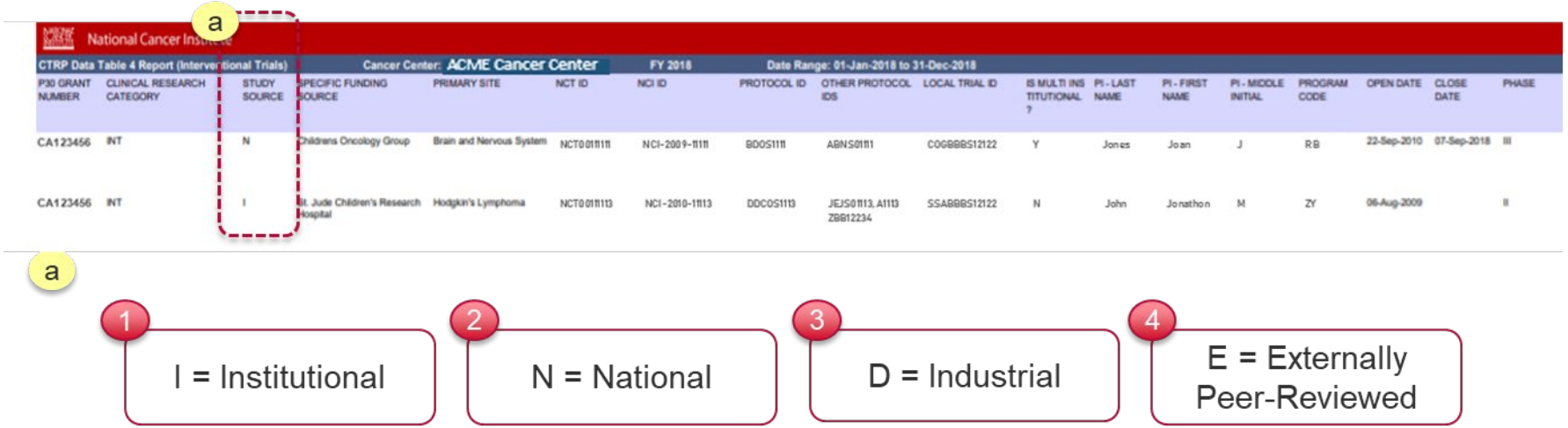
Discrepancy Follow-up Process

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*



* 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 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

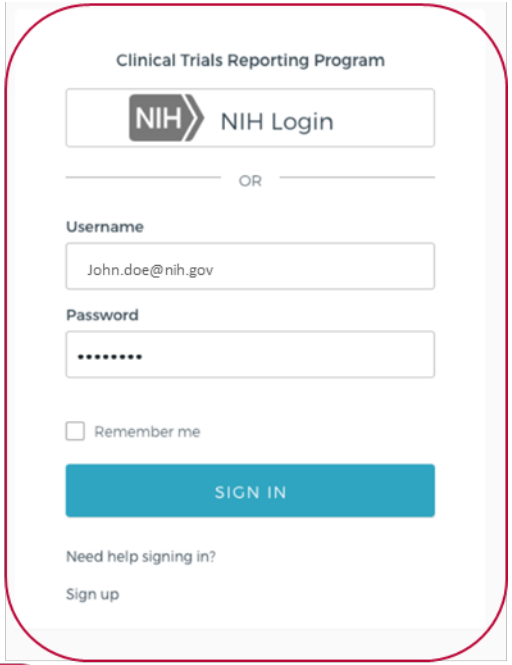
CTRP User Account Management

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)



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

www.cancer.gov

www.cancer.gov/espanol

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:

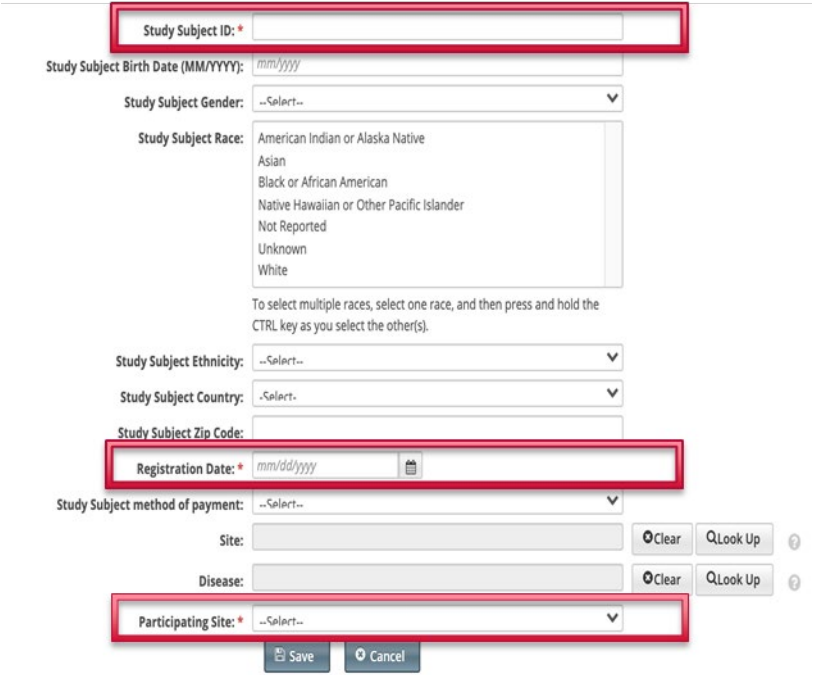
Trial Type	Default Accrual Reporting Type
Complete Interventional	Subject
Complete Non-Interventional	Subject
Abbreviated/Imported Interventional	Summary
Abbreviated/Imported Non-Interventional	Summary

  - 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

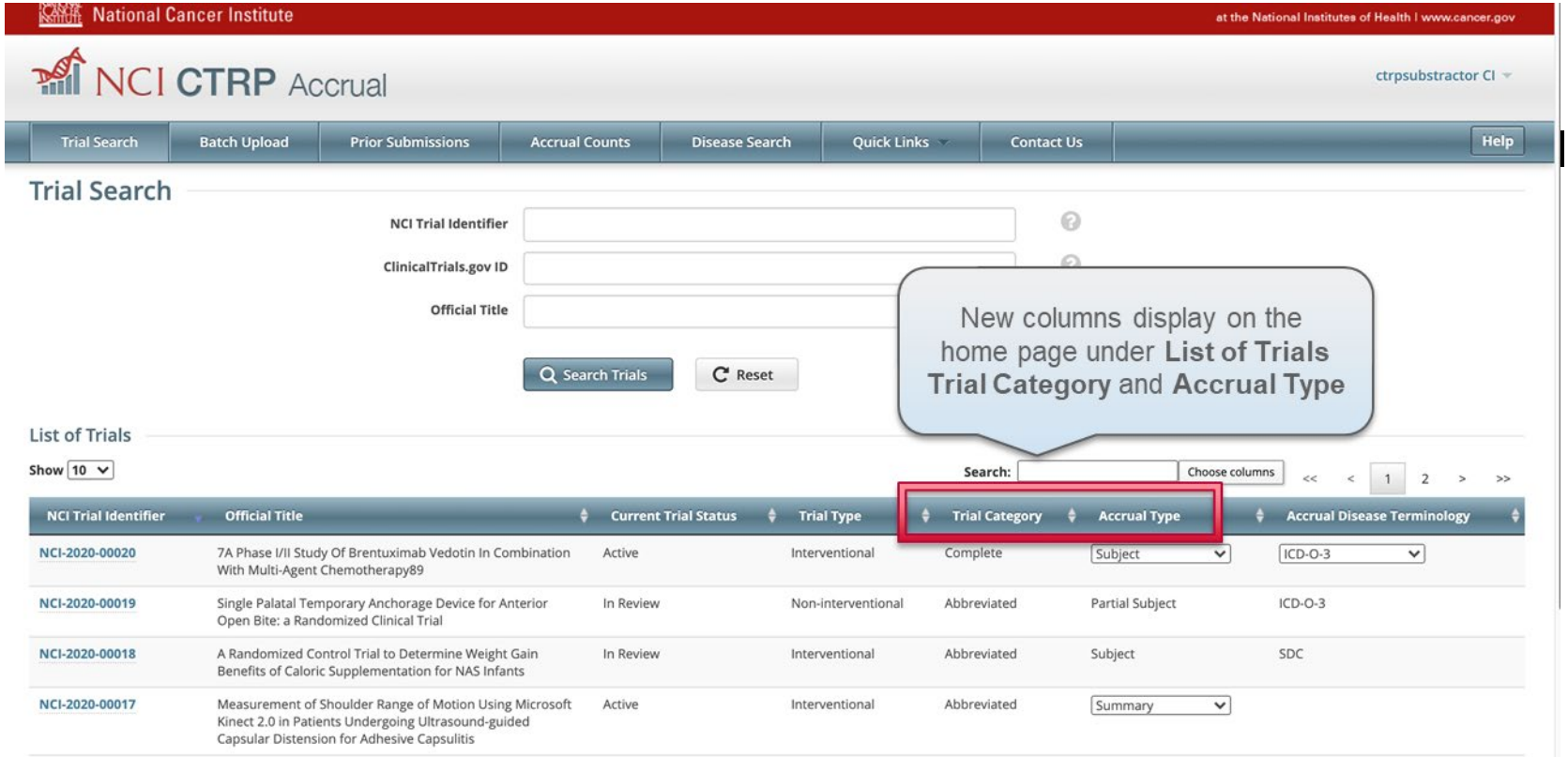
Flexible Accrual Reporting – Partial Subject Accrual
Recent CTRP Updates

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

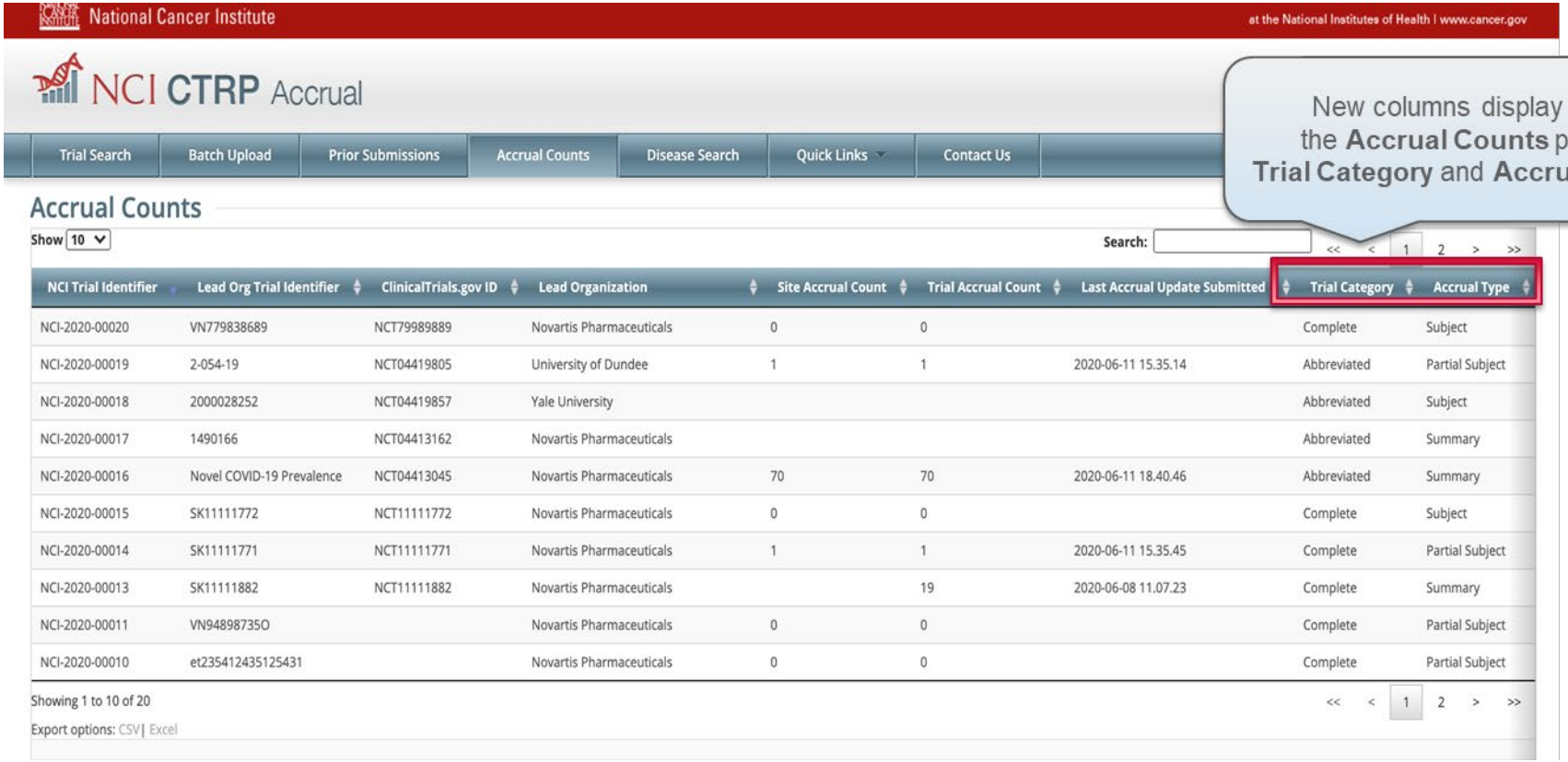


Accrual reporting remains the same, however, less information is required

Flexible Accrual – New fields for **Trial Category and Accrual Type**



Flexible Accrual – New fields for **Trial Category and Accrual Type**



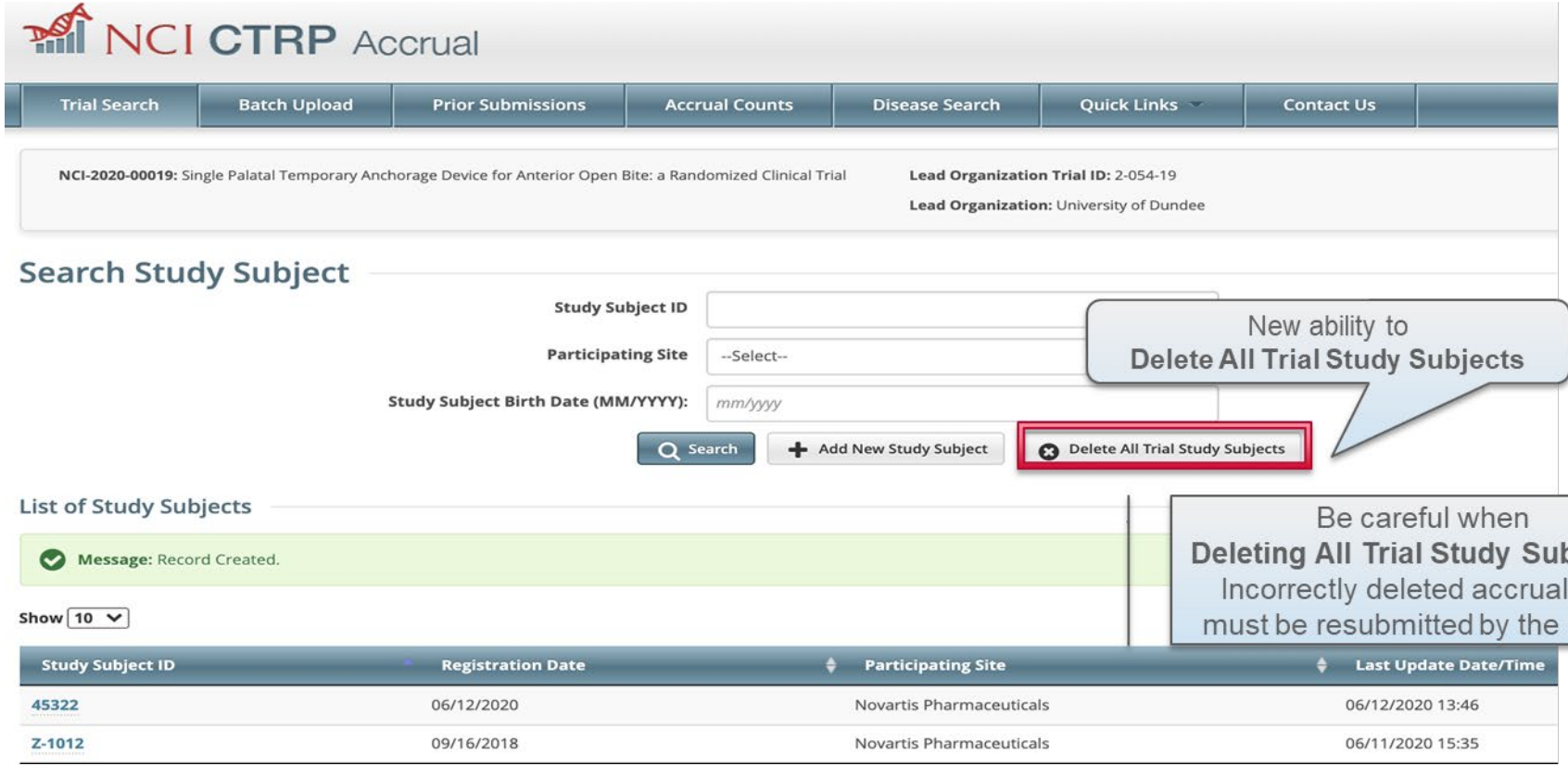
Flexible Accrual – Default Accrual Type

- 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



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)	Not required for Partial Accrual but if submitted, **Month and Year** are required. Birth Date must be < = **Registration Date** Birth Year must be < = 125 years
Study Subject Country	Required including batch upload tool
Study Subject Zip Code	Subject Accrual: **Zip Code** required for US, US territories and outlying islands Subject & Partial 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

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

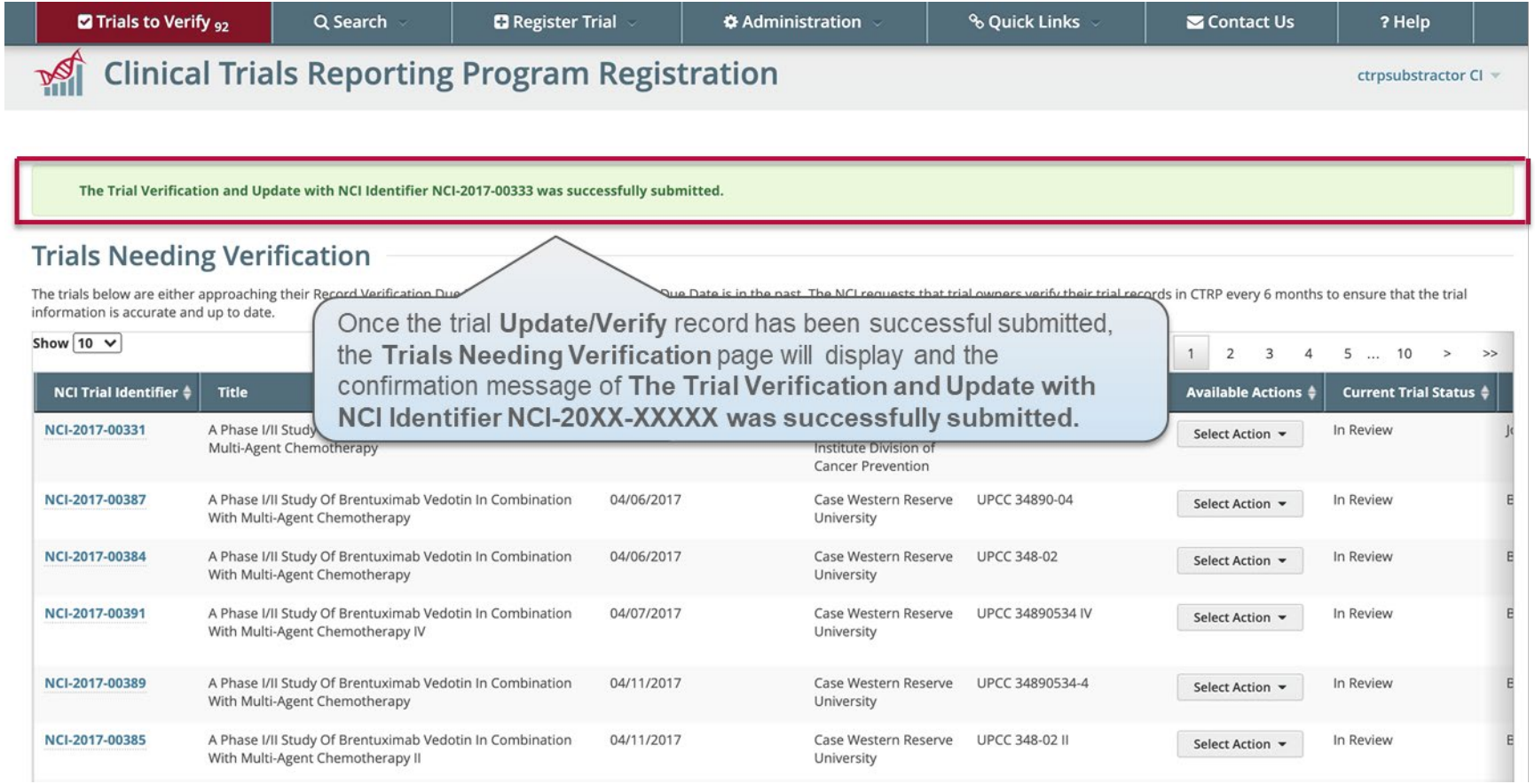
Accrual Data Element	Comments/Conditions
Registration Date	Month, Day and Year are required
Disease/Site Code	**Partial Subject:** **ICD-0-3: Disease** is not required. However, if **Disease** is reported, both **Site Name** and **Site Code** are required. **ICD-9 or ICD-10: Disease** is not required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

Backup Slides

Planned CTRP Updates

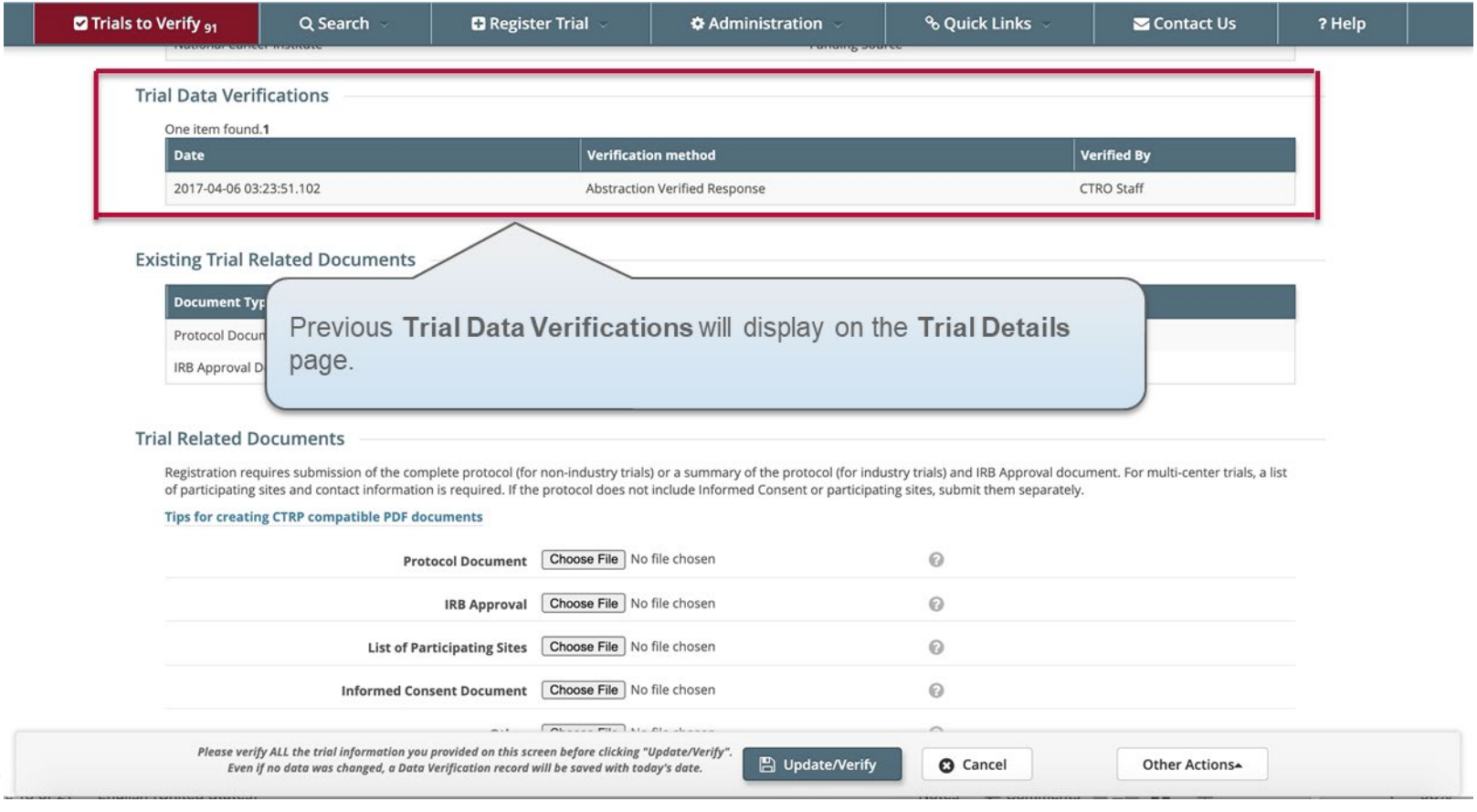
Trial Record Verification

Registration – Confirmation of Successful Update New Process

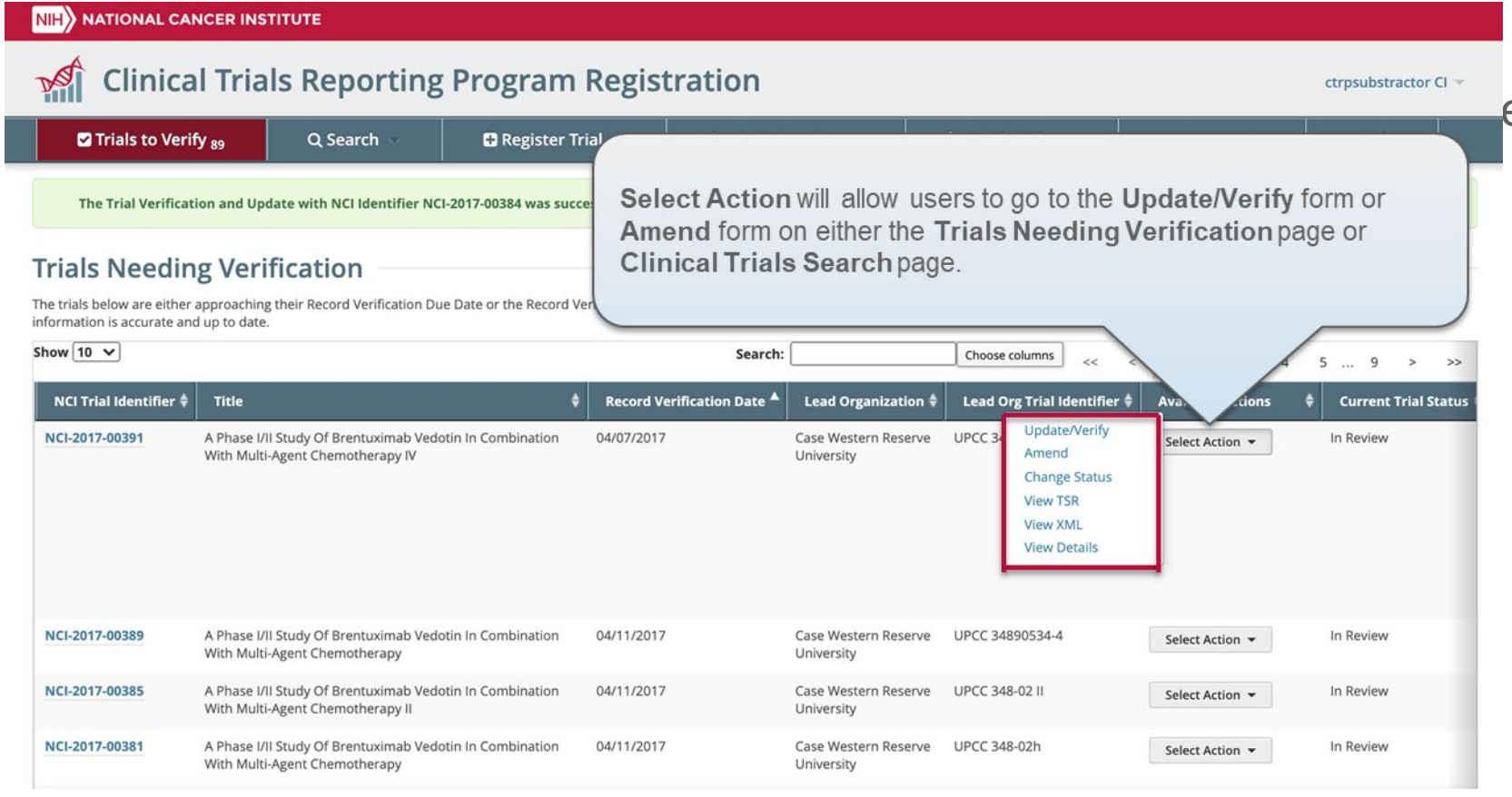


Once the trial **Update/Verify** record has been successful submitted, the **Trials Needing Verification** page will display and the confirmation message of **The Trial Verification and Update with NCI Identifier NCI-20XX-XXXXX was successfully submitted.**

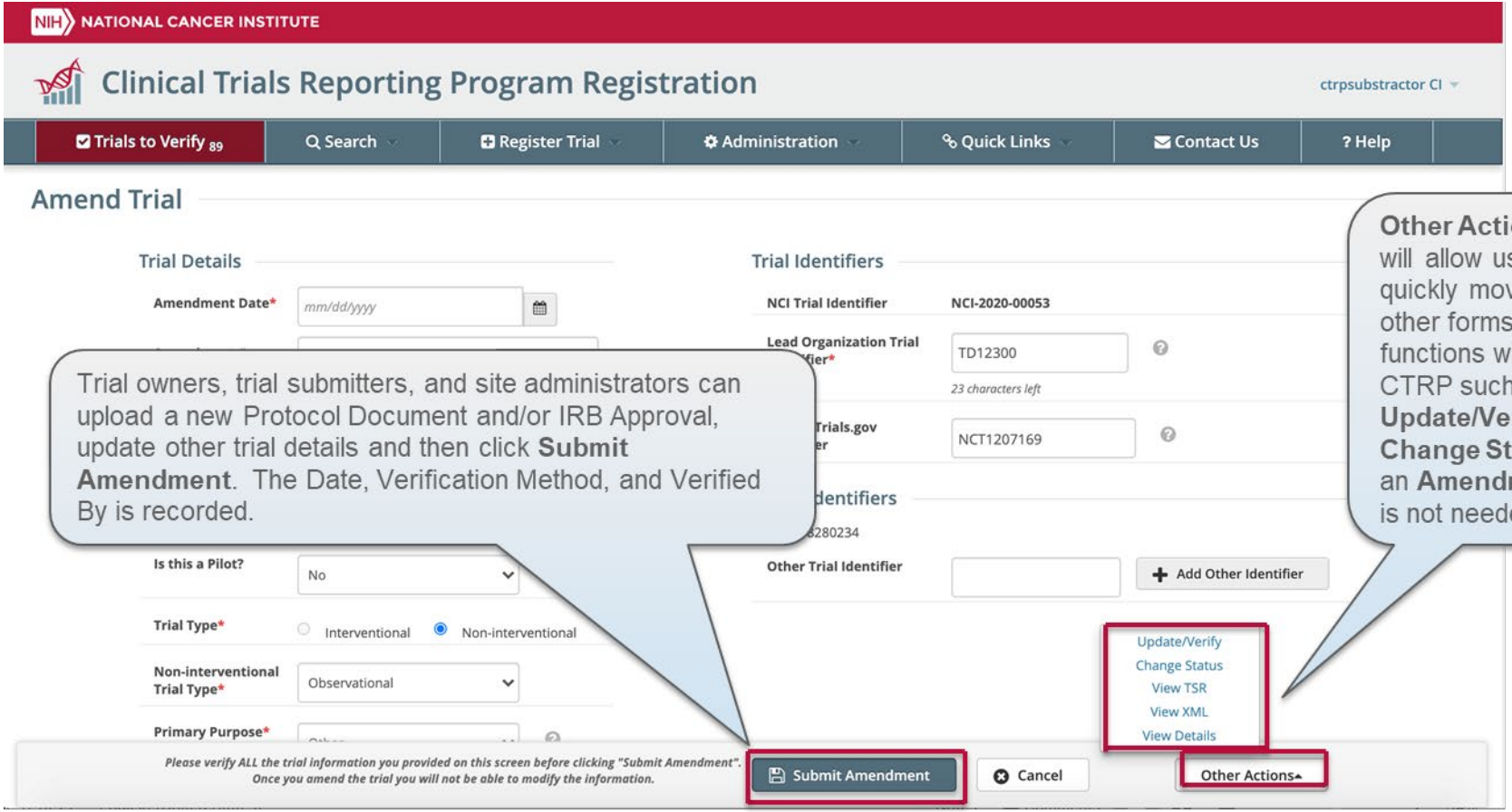
Registration – Trial Record Verification History New Process



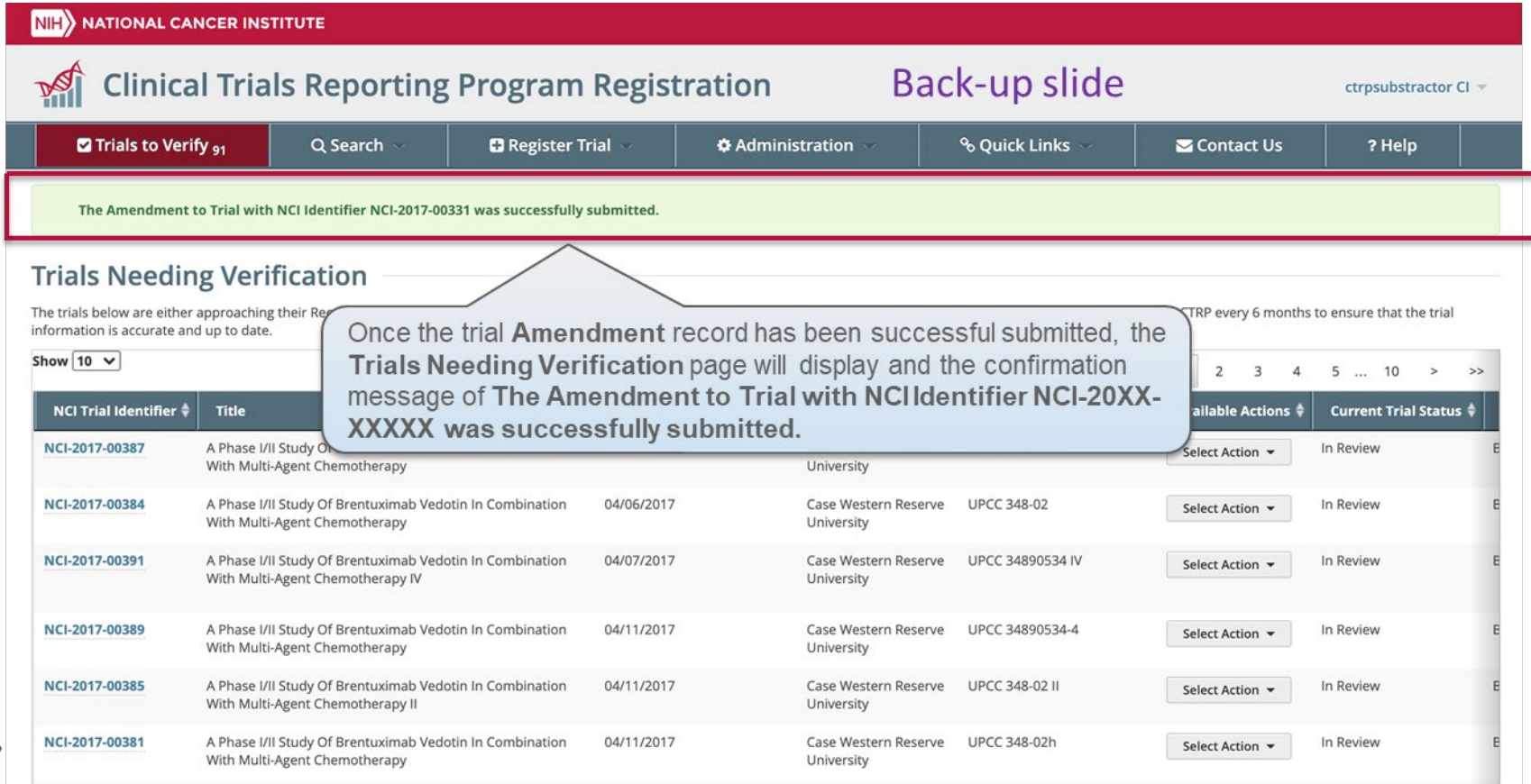
Registration – Select Action Features New Process



Registration – Amend Trial New Process



Registration – Confirmation of Successful Amendment New Process



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.**

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 ID	Participating Sites	POID	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")

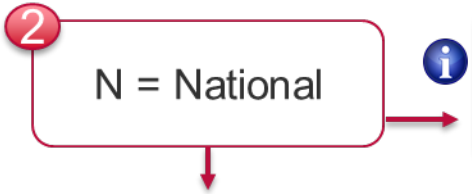
Dear CTRO (or LO CTRP Site Administrator):

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

NCI ID	
NCT ID	
Reporting Period (if app)	
Local Trial ID	
Participating Sites	
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

- Brief Example -

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

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)

2

N = National

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")

- Detailed Example -

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 *	
CTRP Field/Correct Data *	
Comments *	

Please let me know if you have any questions.

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