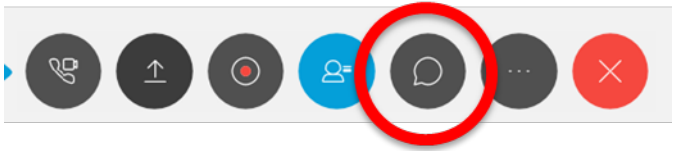
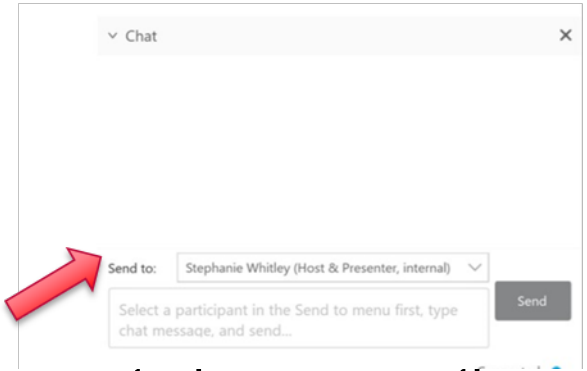
CTRP User Calls
Submitting CTRP DT4 Questions to WebEx Host (Chat Box)

- 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

NIH NATIONAL CANCER INSTITUTE

September 14, 2021

Agenda for Today's Call

- Recent & Planned Updates
  - Quarterly CTRP Accrual Outreach
- "Other" Trials, e.g., Pragmatic, Non-Consenting
- CTRP Generated Data Table 4
  - Interventional trials
  - Observational studies
  - Ancillary-Correlative studies
  - Data Correction Requests: Follow-up Process
- User Account Management
- Other Topics
- Next Steps

Recent CTRP Updates

Enhancements to Accrual Reporting

Quarterly CTRP Accrual Outreach: Rationale and Process

Augmenting Security

Improvements to Trial Verification

Support of CTRP-generated Data Table 4

IRB & NIH Grant Information (NCI Funded)

CTRP – What's New

- Enhancements to Accrual Reporting
  - Submission of a subset of demographic data when scientifically justifiable
    - New "Partial-Accrual" reporting functionality
  - Promoting timeliness of quarterly reporting
- Augmenting Security (User Account Management) - Transition to Okta
- Improvements to Trial Record Verification
- Support of CTRP-generated Data Table 4
  - Harmonizing CTRP-generated Data Table 4 Anatomic Sites with CCSG Data Table 3
  - Improved PDF version of the CTRP-generated Data Table 4 (for competing applications)
- Registration: IRB and NIH Grant Information (NCI Funded)

CTRP – Enhancements to Accrual Reporting

- CTRP previously required reporting each quarter of either:
  - Complete[1] accrual – required for all but Abbreviated/Imported trials
  - Cumulative accrual to date – accepted for Abbreviated/Imported trials only
- Complete demographic accrual is not required to achieve the scientific aims of some Interventional trials
- CTRP now can accept reporting of partial demographic data elements upon request and when justified based on the scientific nature of the trial
  - "Partial Accrual"[2] includes **Study Subject ID, Registration Date and Participating Site ID**
  - Reporting partial demographic data can be used to report participant registration date for industrial trials
    - Supports more accurate reports of accrual over time

[1] Protocol ID, Patient ID, Registering Institution Code, Patient Zip Code (if US); Country Code (if not US), Patient Birth (Month/Year), Gender, Ethnicity, Race, Date of Entry on Study, Disease Code

[2] https://wiki.nci.nih.gov/display/CTRPdoc/About+Accrual

CTRP – Facilitating Updates to Accrual Data

- Discrepancies identified by a participating site on multi-institutional trials may require communication with the Lead Organization (LO): (Institutional, Externally Peer-Reviewed trials) or the NCI operations office for National trials (i.e., CTEP, DCP)
- CTRP created the CTRP Data Correction Request email and form templates[1] for use when contacting:
  - Clinical Trials Reporting Office (CTRO) NCICTRO@mail.nih.gov
    and/or
  - Another NCI-Designated Cancer Center or NCI operations office representative for National trials' CTRP Data Correction

[1] https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Data+Correction+Requests

CTRP – Confirmation of Quarterly Accrual Reporting

- Effective September 2012, CTRP required submission of quarterly accrual[1]
- Accrual submissions are due no later than 30 days after the last day of the quarter, i.e., the cut-off date of the previous quarter
  - Reminder, the LO on multi-institutional trials is required to report on behalf of all participating institutions
- Beginning 2021, CTRP contacts NCI-Designated Cancer Centers following each quarter to confirm submission of accrual
  - Facilitates accuracy and timeliness of accrual reporting for multi-institutional trials

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

NCI-Designated Cancer Center Monthly Accrual *2019 – 2021*
Institutional and Externally Peer-Reviewed Treatment Trials
(Excludes NCTN and Industrial Trials)

Data source: NCI's Clinical Trials Reporting Program (CTRP)
Presented at: NCI's Clinical Trials and Translational Research Advisory Meeting: July 14, 2021

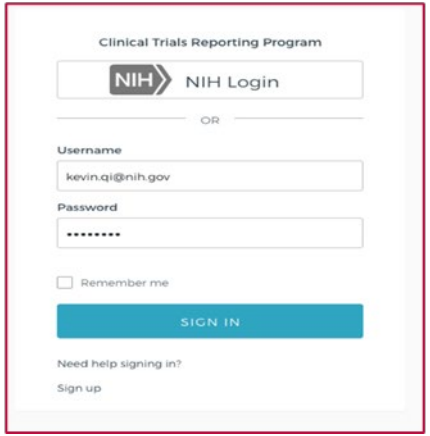
CTRP: Facilitating Record Verification and Augmenting Security

- Improvements to Record Verification[1]
  - Simplified Workflow
  - All trial details on Verify screen

[1] https://wiki.nci.nih.gov/display/CTRPdoc/Updating+Trial+Information

- Okta: NCI's multi-factor authentication system[2]

[2] https://wiki.nci.nih.gov/display/CTRPdoc/CTRP+Okta+Account+Setup



Harmonizing CTRP-Generated Data Table 4 Anatomic Sites with CCSG Data Table 3

- Anatomic Site Values[1] displayed on the CTRP-Generated DT4 report
  - Aligns to the CCSG Data Table 3 list

Previous DT4 Anatomic Site Value	Updated DT4 Anatomic Site Value
Leukemia, not otherwise specified	Leukemia, other
Breast – Female	Breast
Breast – Male	Breast
Hodgkin's Lymphoma	Hodgkin Lymphoma
Non-Hodgkin's Lymphoma	Non-Hodgkin Lymphoma
Soft Tissue / Sarcoma	Soft Tissue

Note: For trials with numerous "Primary Sites" (DT4 Anatomic Sites), the value "Multiple" for the DT4 Anatomic Site Code will be used and displayed on the CTRP-generated DT4 report. *All existing trials in CTRP have been updated to reflect this change as well.*

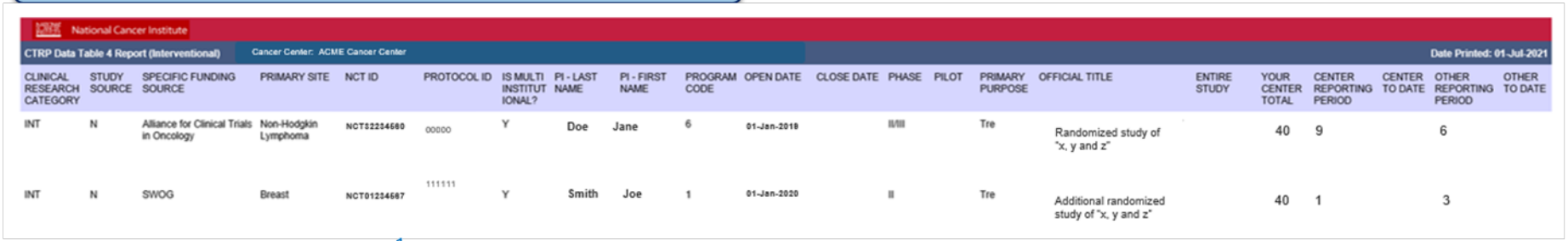
- [1] https://wiki.nci.nih.gov/display/CTRPdoc/Data+Table+4+Anatomic+Site+Values

CTRP-Generated Data Table 4: PDF Modifications

- Columns removed from the CTRP DT4 (PDF) used for competing[1]:
  - P30 Grant Number
  - NCI ID (CTRP identifier)
  - Other Protocol IDs
  - Local Trial ID
  - PI – Middle Name
  - Entire Study Accrual to Date
  - Comments

✓ Implementation of these changes as well as updated page width refinements improved legibility & facilitated loading CTRP-Generated DT4 PDF to eRA Commons/ASSIST

- Modified PDF (In Production) – Q2 2021



National Cancer Institute

CTRP Data Table 4 Report (Interventional) | Cancer Center: ACME Cancer Center | Date Printed: 01-Jul-2021

CLINICAL RESEARCH CATEGORY	STUDY SOURCE	SPECIFIC FUNDING SOURCE	PRIMARY SITE	NCT ID	PROTOCOL ID	IS MULTI INSTITUTIONAL?	PI - LAST NAME	PI - FIRST NAME	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
INT	N	Alliance for Clinical Trials in Oncology	Non-Hodgkin Lymphoma	NCT02234660	00000	Y	Doe	Jane	6	01-Jan-2019		II/III		Tre	Randomized study of "x, y and z"		40	9		6	
INT	N	SWOG	Breast	NCT01234567	111111	Y	Smith	Joe	1	01-Jan-2020		II		Tre	Additional randomized study of "x, y and z"		40	1		3	

[1] CCSG non-competing applications to continue to use the CTRP-Generated Data Table 4 "Download" - File Type "XLSX" (Excel) report export option

CTRP: IRB & NIH Grant Information (NCI Funded)
Registration Enhancements

- Exposed IRB information within Registration to allow users to record and modify as needed

  https://wiki.nci.nih.gov/display/CTRPdoc/Recording+Institutional+Review+Board+%28IRB%29+Information

  https://wiki.nci.nih.gov/display/CTRPdoc/Updating+Institutional+Review+Board+%28IRB%29+Information

- NCI Funded:
  - Updated the NIH Grant Information section in Registration:
    - Previous: **'Is this trial funded by an NCI grant?'** with values of Yes/No
    - Current: **'Is this Trial NCI funded?'** with values of Direct/Indirect/No

  https://wiki.nci.nih.gov/display/CTRPdoc/Recording+NIH+Grants

Planned CTRP Updates

ListServ to GovDelivery Communications
Upcoming CTRP Maintenance Notification

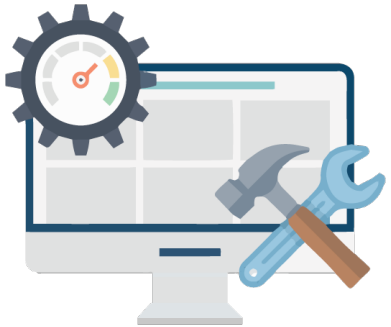
CTRP: Communications (Coming Soon)

- CTRP ListServ “CTRP Users” (e.g., announcements regarding upcoming enhancements, maintenance, user calls) to be transitioned over to a new communication mechanism “GovDelivery”
  - Migration of existing CTRP ListServ to GovDelivery behind the scenes
    - If you are on the existing CTRP ListServ user list, you will automatically be moved to the new CTRP GovDelivery distribution list

In the next few months, you will start to see CTRP ListServ announcements highlighting the timing, new CTRP GovDelivery email address and related look and feel for these communications

CTRP: System Downtime Notification

- CTRP will be unavailable this **Saturday, September 18, 2021** for system maintenance
  - CTRP Registration & Accrual, STRAP (CTRP-generated Data Table 4)
  - A notification(s) will also be sent out to the CTRP ListServ



CTRP Reporting

"Other" Trials", e.g., Pragmatic, Non-Consenting

“Other” Trials, e.g., Pragmatic, Non-Consenting

- Some trials submitted to CTRP and reported on CTRP-Generated Data Table 4 do not fit the traditional definitions of Interventional or Observational clinical trials
  - Require reporting to ClinicalTrials.gov per NIH policy if undertaken as part of a clinical trial required RFA/FOI, e.g.:
    - P50: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-029.html
    - UG1: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-015.html
    - R01: https://grants.nih.gov/grants/guide/pa-files/PAR-18-559.html
  - Trials are reported on CTRP-Generated Data Table 4

Pragmatic Clinical Trials[1]

Trials that aim to test interventions in settings to which the results are intended to apply and be used outside the context of a research study (pending supportive trial outcomes). Pragmatic trials are purposively designed to maximize external validity and applicability to real-world settings while maintaining internal validity. Trial design features that should be considered when planning for trial that is pragmatic in nature and overall intent include (but are not limited to) selection of primary outcome, primary analysis, setting, organization, eligibility (patients and/or providers), delivery, flexibility (delivery, adherence), follow-up, and recruitment approaches. For the purposes of this FOA, applicants must propose a pragmatic randomized controlled trial (’pragmatic trial’) with the main goal of producing rigorous, relevant and applicable evidence for the use of telehealth in cancer-related care delivery.

[1] https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-029.html

Pragmatic Trials: Characteristics

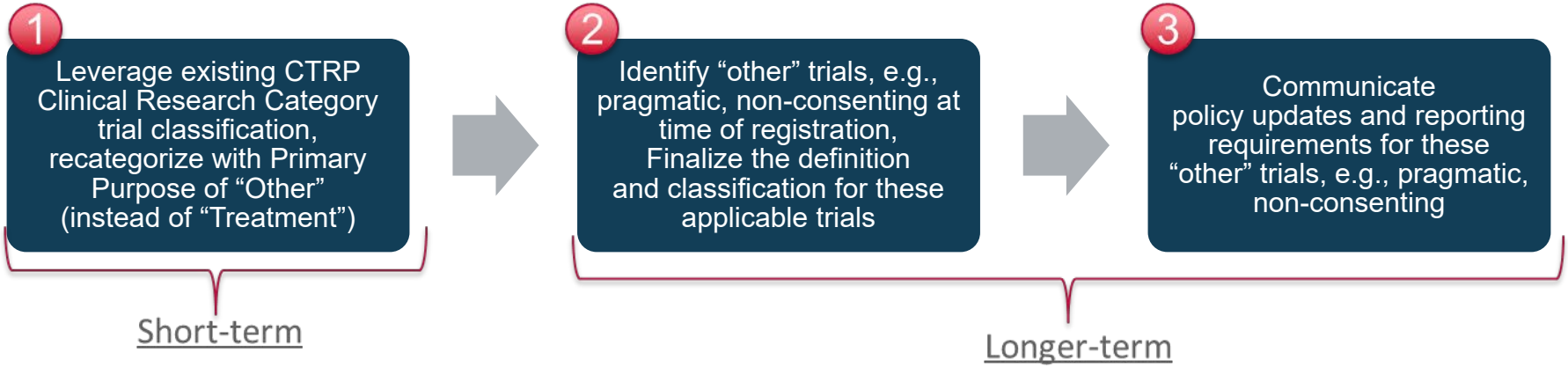
- Unit of randomization may be the clinic (or even the healthcare system)
- Intervention is likely multi-level involving changes to:
  - Patient behavior (e.g., completing a symptom report measures online), and
  - Provider behavior (e.g., receiving the patient's symptom report and having to act on it)
- Data (generally just from medical records) is likely collected during a pre-intervention period and again during a post-intervention period in each clinic that is randomized
  - Patients for whom data is collected in the pre-intervention period may not be the same ones for whom data is collected in the post-intervention period
  - In some of these studies investigators seek and obtain waivers of informed consent but in others they consent every patient
- There are also examples where the same type of design may be used to test an intervention in a community setting where the unit of randomization may be a neighborhood (e.g., promoting changes in exercise by modifying the built environment)

Pragmatic Trials: Examples (Interventional)

NCT ID	Title	Lead Org	Primary Purpose	Target Enrollment
NCT03988543	Implementation and Evaluation of an Expanded Bilingual Electronic Symptom Management Program across a Multi-Site, Fully-Integrated Comprehensive Cancer Center (NU IMPACT)	Northwestern	Supportive Care	12,671
NCT03850912	SIMPRO Research Center: Integration and Implementation of PROs for Symptom Management in Oncology Practice	Dana-Farber	Health Services Research	18,000
NCT03892967	Enhanced, EHR-Facilitated Cancer Symptom Control (E2C2) Trial	Mayo	Supportive Care	15,000

“Other” Trials, e.g., Pragmatic, Non-Consenting
CTRP Planning Considerations

- Discussed recently during AACI CRI July 15th Q&A session
  - Original plan communicated that a new Clinical Research Category will be created in support of “Pragmatic Trials”
  - Since then, a new proposed short-term plan* for how to handle in CTRP (and on a Cancer Center CTRP-generated DT4) has been confirmed



- E.g., Keep in CTRP as “interventional” (e.g., FDAAA policy/compliance), Primary Purpose “Other”, or keep as “Observational” based on the specific details of the trial/study

"Other" Trials, e.g., Pragmatic, Non-Consenting
Recategorize on CTRP Data Table 4

Current

Clinical Research Category	Study Source	Primary Site	NCT ID	NCI ID	Protocol ID	Is Multi Institutional?	Open Date	Close Date	Phase	Pilot	Primary Purpose	Official Title	Entire Study
INT	E	Lung	NCT44444444	NCI-2020-11111	ABCDEFG	Y	01-Jan-18	01-Jan-21	NA	NO	Dia	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	35200
INT	E	Multiple	NCT55555555	NCI-2020-22222	HIJKLMNOP	N	01-Jan-19		NA		Scr	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	30000
INT	I	Multiple	NCT66666666	NCI-2020-33333	QRSTUVWXYZ	N	01-Jan-20		II	NO	Tre	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	337

Changed to "Other"

Clinical Research Category	Study Source	Primary Site	NCT ID	NCI ID	Protocol ID	Is Multi Institutional?	Open Date	Close Date	Phase	Pilot	Primary Purpose	Official Title	Entire Study
INT	E	Lung	NCT44444444	NCI-2020-11111	ABCDEFG	Y	01-Jan-18	01-Jan-21	NA	NO	Oth	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	35200
INT	E	Multiple	NCT55555555	NCI-2020-22222	HIJKLMNOP	N	01-Jan-19		NA		Oth	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	30000
INT	I	Multiple	NCT66666666	NCI-2020-33333	QRSTUVWXYZ	N	01-Jan-20		II	NO	Oth	Pretend trial for "other", pragmatic/non-consenting as an example on a mock-up report for DT4 before recategorization of "Primary Purpose"	337

Screenshot of Non-Competing CTRP DT4 report mock-up. Excludes following columns for viewability: P30 Grant, Funding Source, Local Trial ID, PI Columns, Program Code, and Actual Accrual Columns

"Other" Trials, e.g., Pragmatic, Non-Consenting
Next Steps

- NCI will work with Cancer Centers to identify existing applicable trials
- CTRO will confirm re-categorization of Primary Purpose to “Other”
- Applicable trials to continue to appear on CTRP-generated Data Table 4
- NCI will implement an approach to identify applicable trials prospectively and work with Cancer Centers to categorize appropriately

CTRP Generated DT4

Interventional trials
Observational studies
Ancillary-Correlative studies

CTRP-Generated Data Table 4

- Continued support of interventional CTRP-generated Data Table 4 for both competing and non-competing applications
- Observational CTRP-generated Data Table 4 for non-competing applications is scheduled to begin in FY 22 (i.e., Oct 1, 2021)
- Ancillary-correlative trials continue to be submitted in a Center-generated Data Table 4

Trial Type	Competing	Non-competing
Interventional	Yes	Yes
Observational	No	Fall 2021
Ancillary-Correlative	Continue to submit in CCSG template; Center-generated Data Table 4	

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

- Presented at AACI CRI Meeting on July 15, 2021:
  - 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
    - FY 21: Reconciliation activities with centers initiated
    - FY 22: Submission of CTRP-generated DT4 with non-competing applications (Excel version) (beginning October 1, 2021); reconciliation activities with centers ongoing
  - Ancillary-Correlative Studies
    - Continue to report using current CCSG DT4 format

* Office of Cancer Centers (OCC) released revised Funding Opportunity Announcement (FOA) on November 4, 2019: https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html

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

- All observational studies open to accrual as of 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
- LO reports cumulative accrual on *at least* an annual basis as determined by their CCSG submission schedule
  - Reminder, the LO on multi-institutional trials is required to report on behalf of all participating institutions
  - CTRP can support patient level accrual reporting if more convenient for the submitting organization

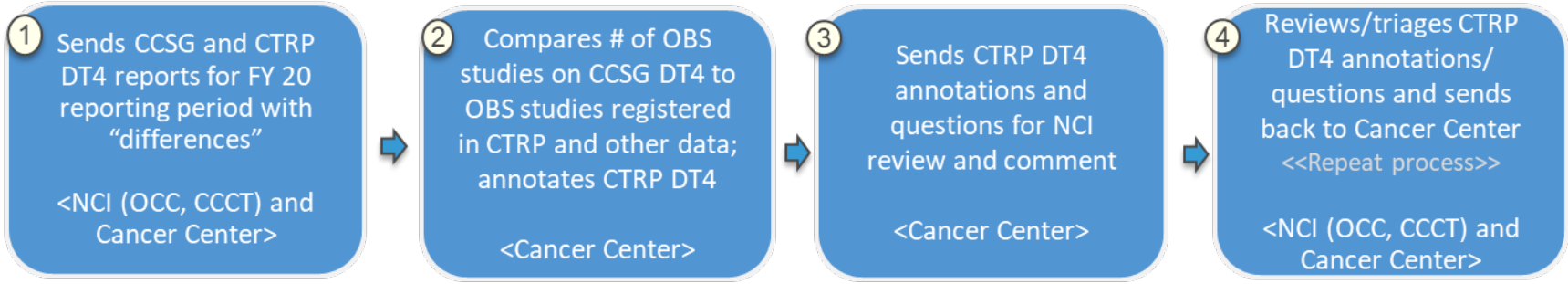
CTRP-Generated Data Table 4
Observational Studies – Scope and Reporting Requirements

- For my upcoming CCSG non-competing submission using the CTRP-Generated DT4 (Excel version), how do I address any data discrepancies at the time of submission?
  - Include annotations (column “Comments”) on your CTRP DT4 (Excel version) indicating the accurate data and/or in progress data correction activity
    - If your study is not listed on your CTRP DT4 (Excel), add a new tab to your report named “**Supplemental (Not on Report)**” and add these studies and details
    - Please contact the CTRO NCICTRO@mail.nih.gov to request assistance with supporting resolution of data discrepancies for specific Observational studies
- How do I register an Observational study that doesn't have an NCT ID (not registered in ClinicalTrials.gov)?
  - Please contact the CTRO NCICTRO@mail.nih.gov to request assistance with registering Observational studies without an NCT ID

CTRP-Generated Data Table 4
Observational Studies Reconciliation & Submission

- Reconciliation meetings to review CTRP-Generated DT4 for Observational studies with Cancer Center CCSG DT4 reported data
  - Cancer Centers to own/initiate the registration of Observational studies in CTRP
  - NCI initiates supporting review process; schedules a kick-off meeting with the Cancer Center; *aligns this process to the next scheduled non-competing submission timings*

Cancer Centers will be contacted at least 4-6 weeks prior to their next non-competing application



- Cancer Centers are responsible for directly submitting their CTRP DT4 report (Observational studies) to the OCC CCSG mailbox ccsgdata@mail.nih.gov

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

Data Correction Requests

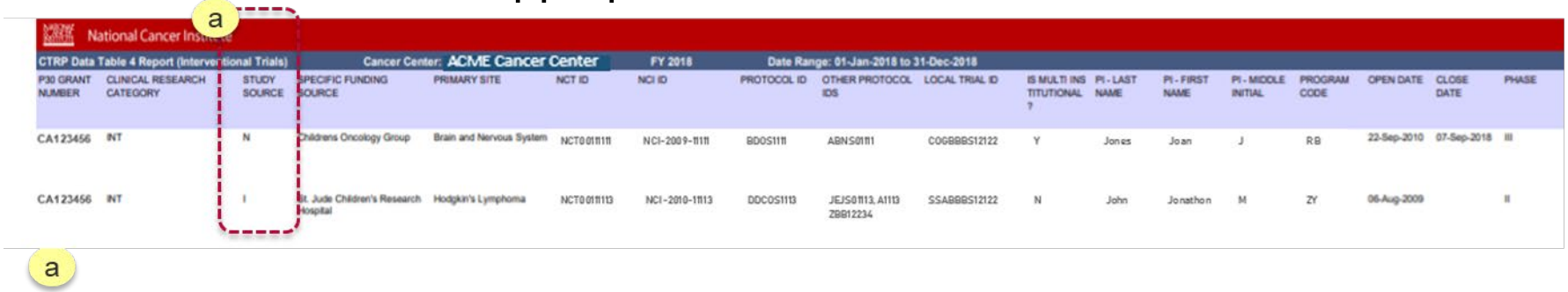
Discrepancy Follow-up Process

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

- The LO is the coordinating/lead center of the trial, responsible for the trial-specific research protocol > The organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial
  - If the trial is already registered in CTRP, your center should be listed as the LO, as your center registered the trial and provided a protocol document as the submitting organization
  - LO is 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-2018 to 31-Dec-2018

P30 GRANT NUMBER	CLINICAL RESEARCH CATEGORY	STUDY SOURCE	SPECIFIC FUNDING SOURCE	PRIMARY SITE	NCT ID	NCI ID	PROTOCOL ID	OTHER PROTOCOL IDS	LOCAL TRIAL ID	IS MULTI INSTITUTIONAL ?	PI - LAST NAME	PI - FIRST NAME	PI - MIDDLE INITIAL	PROGRAM CODE	OPEN DATE	CLOSE DATE	PHASE
CA123456	INT	N	Childrens Oncology Group	Brain and Nervous System	NCT0011111	NCI-2009-1111	BDOS1111	ABNS0111	COGBBBS12122	Y	Jones	Joan	J	RB	22-Sep-2010	07-Sep-2018	III
CA123456	INT	I	St. Jude Children's Research Hospital	Hodgkin's Lymphoma	NCT0011113	NCI-2010-1113	DDCOS1113	JEJS0113, A1113 ZBB12234	SSABBBS12122	N	John	Jonathon	M	ZY	06-Aug-2009		II

a

a

1 I = Institutional

2 N = National

3 D = Industrial

4 E = Externally Peer-Reviewed

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

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

- Discrepancies identified on multi-institutional trials may require communication with the LO (Institutional, Externally Peer Reviewed trials) or 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 and does not affect inclusion

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
    - Currently accepted values: Male/Female/Unknown/Unspecified/Undifferentiated

CTRP User Account Management

New User Request, Deactivation

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

CTRP DT4
References/Training Links

CTRP References – CTRP User Calls

- CTRP 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**) held 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**) held August 14, 2019:
    https://wiki.nci.nih.gov/display/CTRP/2019-08-14+User+Call+Meeting+Minutes
  - Presentation/Q&A (**CTRP DT4 Reporting/Expanded Access**) held August 25, 2020
    https://wiki.nci.nih.gov/display/CTRP/2020-08-25+User+Call+Meeting+Minutes

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 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

- "Other" Trials, e.g., Pragmatic, Non-Consenting
  - NCI will work with Cancer Centers to identify existing applicable trials
  - CTRO will confirm re-categorization of Primary Purpose to “Other”
- CTRP Generated DT4 Reporting
  - **Interventional trials**: Cancer Centers to continue supporting CTRP-Generated DT4 submissions for non-competing and competing applications
  - **Observational studies**: Cancer Centers to initiate (or continue) to register Observational Studies in CTRP open to accrual as of or after January 1, 2018
    - Participate in upcoming FY 22 reconciliation activities
    - Leverage CTRP-Generated DT4 (Excel version) for next non-competing; annotate with comments/data discrepancies as appropriate and continue to resolve
- Please continue to send any future CTRP User Call agenda topics to the CTRO NCICTRO@mail.nih.gov

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