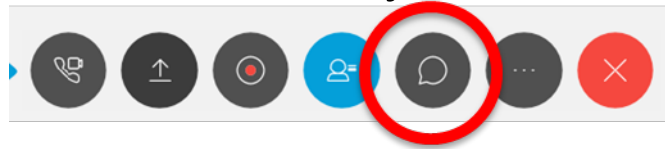


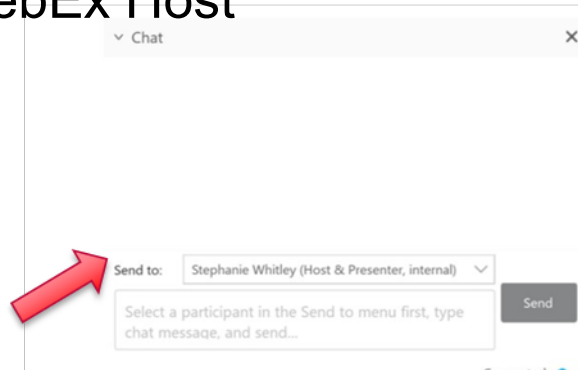
CTRP User Calls

Submitting CTRP DT4 Questions to WebEx Host (Chat Box)

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



- Select To recipient: WebEx Host



- Attendees phones are muted upon meeting entry

CTRP User Call Data Table 4

Agenda for Today's Call

- Recent CTRP Updates
 - Updated Accrual Batch File Tool Version
- CTRP Accrual Reporting Overview
- CTRP Accrual Reporting Batch File Submissions
 - Abbreviated/Imported trials
- Next Steps

CTRP: Accrual Reporting (Previous CTRP User Call References)

- Associated accrual topics covered during previous CTRP User Calls such as rules for submitting data (e.g., Lead Organization/Submitter) as well as accrual data elements and definitions:


- **July 18, 2018** (CTRP business rules and reporting responsibilities):

 <https://wiki.nci.nih.gov/display/CTRP/2018-07-18+User+Call+Meeting+Minutes>

- **September 26, 2018** (CTRP-generated DT4 data elements and related source information for data):

 <https://wiki.nci.nih.gov/display/CTRP/2018-09-26+User+Call+Meeting+Minutes>

Updated CTRP Accrual Batch File Tool (dated November 29, 2018)

- Recent updates made to the CTRP Accrual Batch File Tool version 1.9
 - **What's Changed?**
 - Modified race value “Native Hawaiian or other Pacific Islander” to “Native Hawaiian or Other Pacific Islander” (case sensitive – “O” in Other is now capitalized)
 - **Impact?**
 - Problematic if you use a previous version of the CTRP Accrual Batch File Tool and select the race data element/value, “Native Hawaiian or other Pacific Islander” (now “Native Hawaiian or Other Pacific Islander”) and upload
 - Recommendation to  the current CTRP Accrual Batch File Tool (dated November 29, 2018) to remain compliant

 <https://wiki.nci.nih.gov/display/CTRP/CTRP+Accrual+Batch+File+Tool>

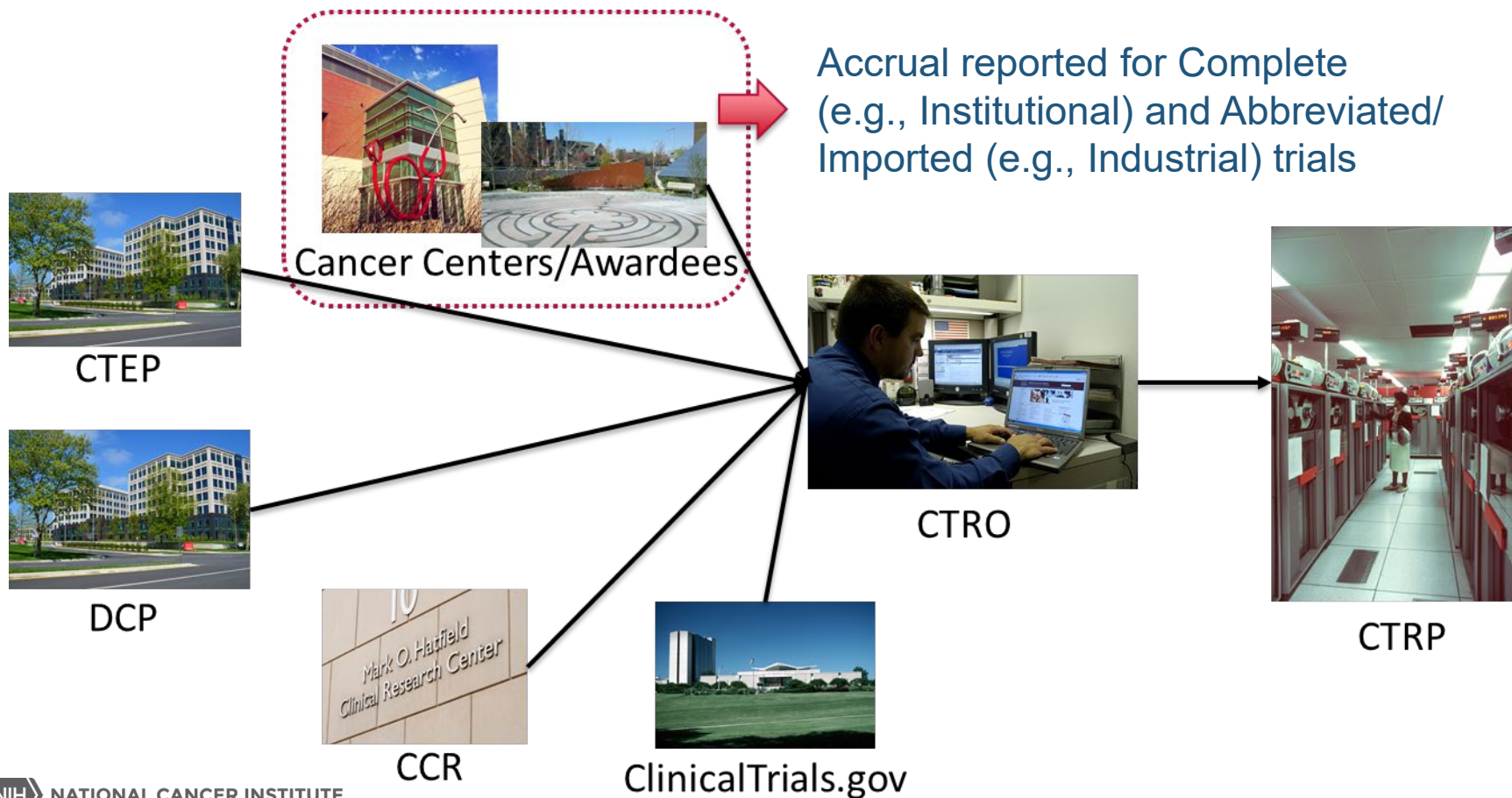
CTRP Data Table (DT4)

Accrual Overview

CTRP: Scope and Content (Trials and Accrual Reporting)

- Scope of trials for CTRP DT4
 - All *interventional* trials, regardless of funding source, conducted at one or more NCI-Designated Cancer Centers
 - Includes trials sponsored (per FDAAA) by NCI as well as trials sponsored by other entities (e.g. institutions, industry)
- Accrual reported regularly (e.g., at least quarterly or when accrual has changed) for all active trials
 - Patient level accrual data except for industrial trials
 - Cumulative accrual data for industrial trials
- CTRP currently accepts, but does not require, data on *observational* trials and *ancillary correlative studies*

CTRP: Data Sources (Trials and Accrual Reporting)



CTRP: Data Sources (Accrual Reporting)



Cancer Centers/Awardees

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

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



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

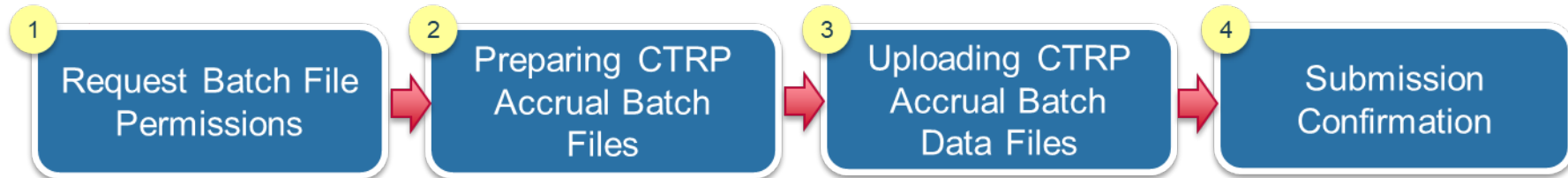
CTRP Data Table (DT4)

*Accrual Batch File Submissions
Overview / References*

CTRP: Accrual Reporting (Batch File Submissions)

Overview

- **Accrual Batch File Load Process**



- Request permission to submit CTRP accrual data from your center's CTRP Site Administrator
- Assignment of one of the roles; Trial Submitter, Site Accrual Submitter, Organization Family Accrual Submitter

- Trials must be fully abstracted by the CTRO (in CTRP Registration: Abstraction Verified Response, Abstraction Verified No Response) to successfully load accrual
- Participating Site must be on the trial in CTRP to successfully load accrual

- Upload via the CTRP Accrual web interface
- Single file as plain text file or in multiple text files that have been compressed into a Zip file

- Email from CTRP system highlighting submission receipt
- Resolve batch load file update errors

CTRP: Accrual Reporting (Batch File Submissions)

References

- Preparing CTRP Batch Load Files

 <https://wiki.nci.nih.gov/display/CTRPdoc/Preparing+CTRP+Accrual+Batch+Files+Introduction>

- Submitting Accrual Data Batch Load Files

 <https://wiki.nci.nih.gov/display/CTRPdoc/Submitting+Accrual+Data+Batch+Files>

- Resolving Batch File Load Errors

 <https://wiki.nci.nih.gov/display/CTRPdoc/Resolving+Accrual+Batch+File+Upload+Errors>

CTRP: Accrual Reporting (Batch File Submissions)

Communication – Abbreviated/Imported Trials

- For Summary Level Accrual (typically provided for Abbreviated/Imported - e.g., Industrial trials), subsequent accrual batch file uploads will replace previously submitted/uploaded accrual data. Batch uploads will not append data; cumulative accrual data must be uploaded with each accrual file submitted to CTRP.
- **Please ensure that your CTRP accrual batch file contains all cumulative accrual data for each participating site to date before uploading to CTRP. Failure to include cumulative accrual data will result in erasing previously submitted accrual information.**



<https://wiki.nci.nih.gov/display/CTRPdoc/Submitting+Accrual+Data+Batch+Files>

CTRP Data Table (DT4)

*Accrual Batch File Submissions
Example - Abbreviated/Imported Batch File*

CTRP: Accrual Reporting (Batch File Submissions)

Example: Abbreviated/Imported Trial Batch File

https://wiki.nci.nih.gov/display/CTRP/CTRP+Accrual+Batch+File+Tool

NIH NATIONAL CANCER INSTITUTE
NCI Wiki

New Account Helpful Tips

Confluence Spaces

Pages / ... / Resources for Reporting Accruals

CTRP Accrual Batch File Tool

Created by Unknown User (anthonel), last modified by Frost, Ruth (NIH/NCI) [C] on May 18, 2017

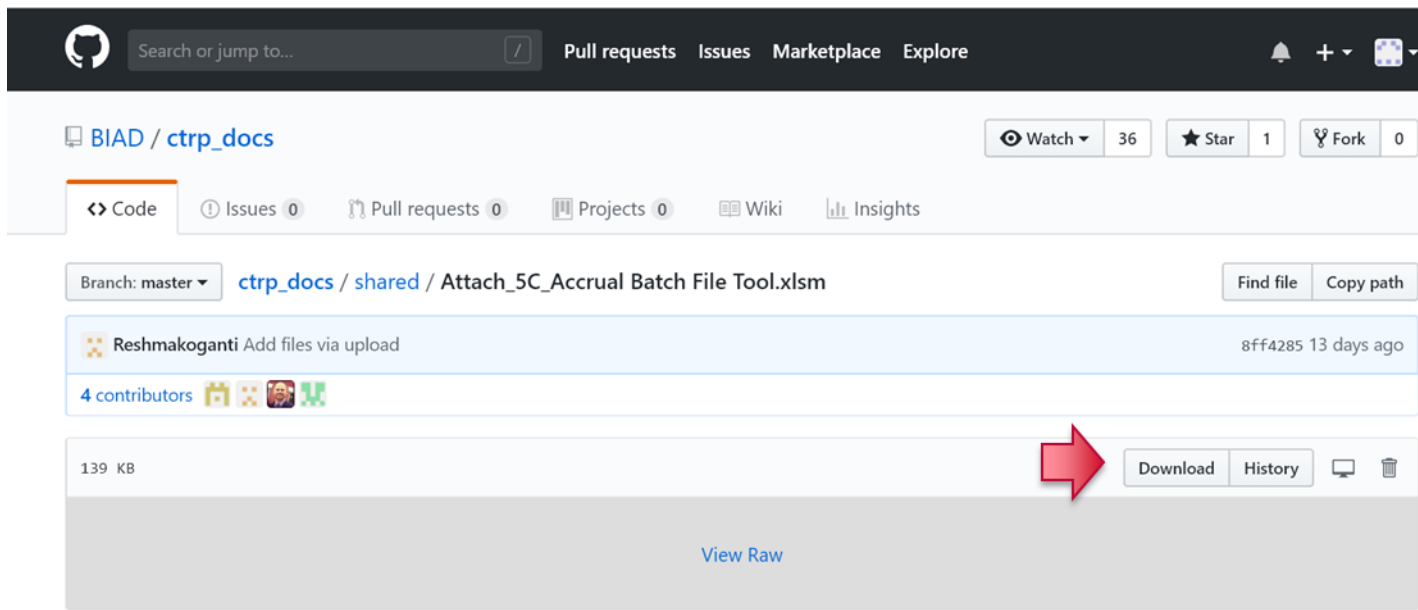
Click the link below to download the latest version of the Accrual Batch File Tool updated November 19, 2018. The CTRP Accrual Batch File Tool is not backwards compatible, usage of a previous version may result in file structure errors. Prior to using the tool, it is important to verify that the most recent version of the tool has been downloaded.

[Accrual Batch File Tool](#)

 <https://wiki.nci.nih.gov/display/CTRP/CTRP+Accrual+Batch+File+Tool>

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File



The screenshot shows the GitHub interface for the repository `BIAD / ctrp_docs`. The file path is `Branch: master > ctrp_docs / shared / Attach_5C_Accrual Batch File Tool.xlsm`. The file size is 139 KB. A red arrow points to the `Download` button in the file action bar. Other buttons include `History`, `Find file`, and `Copy path`. The repository has 36 watchers, 1 star, and 0 forks. The file was last updated 13 days ago by user `Reshmakoganti`.

DOWNLOAD

latest version
(dated November
29, 2018)



https://github.com/BIAD/ctrp_docs/blob/master/shared/Attach_5C_Accrual%20Batch%20File%20Tool.xlsm

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File

Attach_5C_Accrual Batch File Tool - Excel

File Home Insert Page Layout Formulas Data Review View Help ACROBAT Tell me what you want to do

Clipboard Font Alignment Number Styles Cells Editing Webex

N21

CTRP Accruals Spreadsheet

1

17 Purpose

The purpose of this Workbook is to provide a mechanism to capture accruals data to be imported into the CTRP accruals application using the Batch Import functionality. This is an alternative to entering data directly into the CTRP Accruals application using the website, generating a batch upload file directly, or using the CTRP accruals APIs. The ultimate goal of using this Workbook is to export data for import into CTRP Accruals using the Batch Import function on the CTRP Accruals website. Use of that website is outside the scope of these instructions

18

19

20 Entering Data

Data can be entered either through the Input Worksheet or directly into the Collections, Patients, Races, and Accrual Count Worksheets. The Input Worksheet requires that you first enter study details into the first section and then click either the Complete Trials button or Abbreviated Trials button to view the rest of the fields that are available. Then click the Add Subject or Add

Instructions Input Collections Patients Races Accrual Count Export Definitions

- Instructions tab highlights the tool version, purpose, entering data, exporting data

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File

Attach_SC_Accrual Batch File Tool - Excel

File Home Insert Page Layout Formulas Data Review View Help ACROBAT Tell me what you want to do

Clipboard Font Alignment Number Styles Cells

120

1	2	A	B	C	D	E	F	G	H
2				Study Details					
3				*Study Id	Change Code				
5									
6				Complete Trial	Abbreviated Trial				
7									
8				Complete Trial Details					
9				*Study Subject Identifier					
10				*Zip Code (if US)					
11				*Country of Residence					
12				*Patient's Date of Birth					
13				*Gender of a Person					
14				*Ethnicity					
15				Payment Method					
16				*Subject Registration Date					
17				Registering Group Identifier					
18				*Study Site Identifier					
19				*Subject Disease Code					
20				*Race					

Instructions Input Collections Patients Races Accrual Count Export Definitions

- Default view is “Complete Trial”(study subject level) accrual data entry
- Click on the “Abbreviated Trial” button to enter summary accrual

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File

The screenshot shows an Excel spreadsheet titled "Attach_5C_Accrual Batch File Tool - Excel". The spreadsheet is organized into several sections:

- Study Details:** Located in rows 2-5, this section includes a "Change Code" field and two buttons: "Complete Trial" and "Abbreviated Trial".
- Abbreviated Trial Details:** Located in rows 26-31, this section includes fields for "*Study Site Identifier", "*Study Site Accrual Count", and "Cut-Off Date". It also features an "Add Accrual" button, which is highlighted with a red arrow pointing to it from the right.
- Control Buttons:** At the bottom of the spreadsheet, there are two buttons: "Clear Data" and "Random Data".

The spreadsheet is displayed in a grid with columns A through H and rows 1 through 38. The "Input" tab is selected in the bottom navigation bar.

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

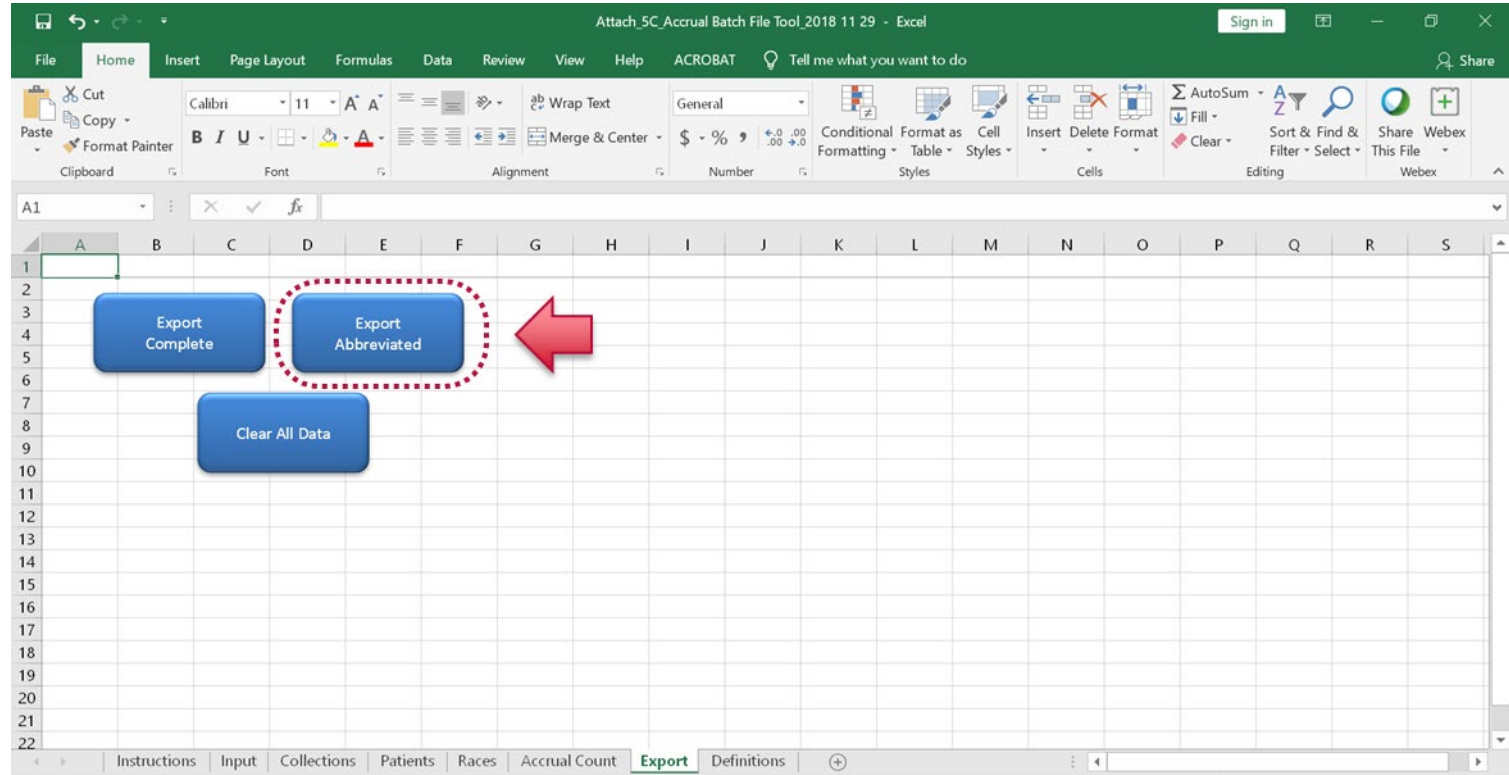
Example: Abbreviated/Imported Trial Batch File

	A	B	C	D	E	F	G	H	I
1	Study Id	Study Site Identifier	Study Site Accrual Count	Cut-Off Date					
2	NCI-2016-00225	1	1	20170215					
3	NCI-2016-00225	1	2	20170820					
4	NCI-2016-00225	1	4	20180331					
5	NCI-2016-00225	1	6	20180910					
6	NCI-2016-00225	1	10	20181202					
7	NCI-2016-00225	2	2	20170128					
8	NCI-2016-00225	2	4	20170710					
9	NCI-2016-00225	2	5	20170825					
10	NCI-2016-00225	2	7	20171031					
11	NCI-2016-00225	2	9	20171122					
12	NCI-2016-00225	2	12	20180107					
13									
14									
15									
16									
17									
18									
19									
20									

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

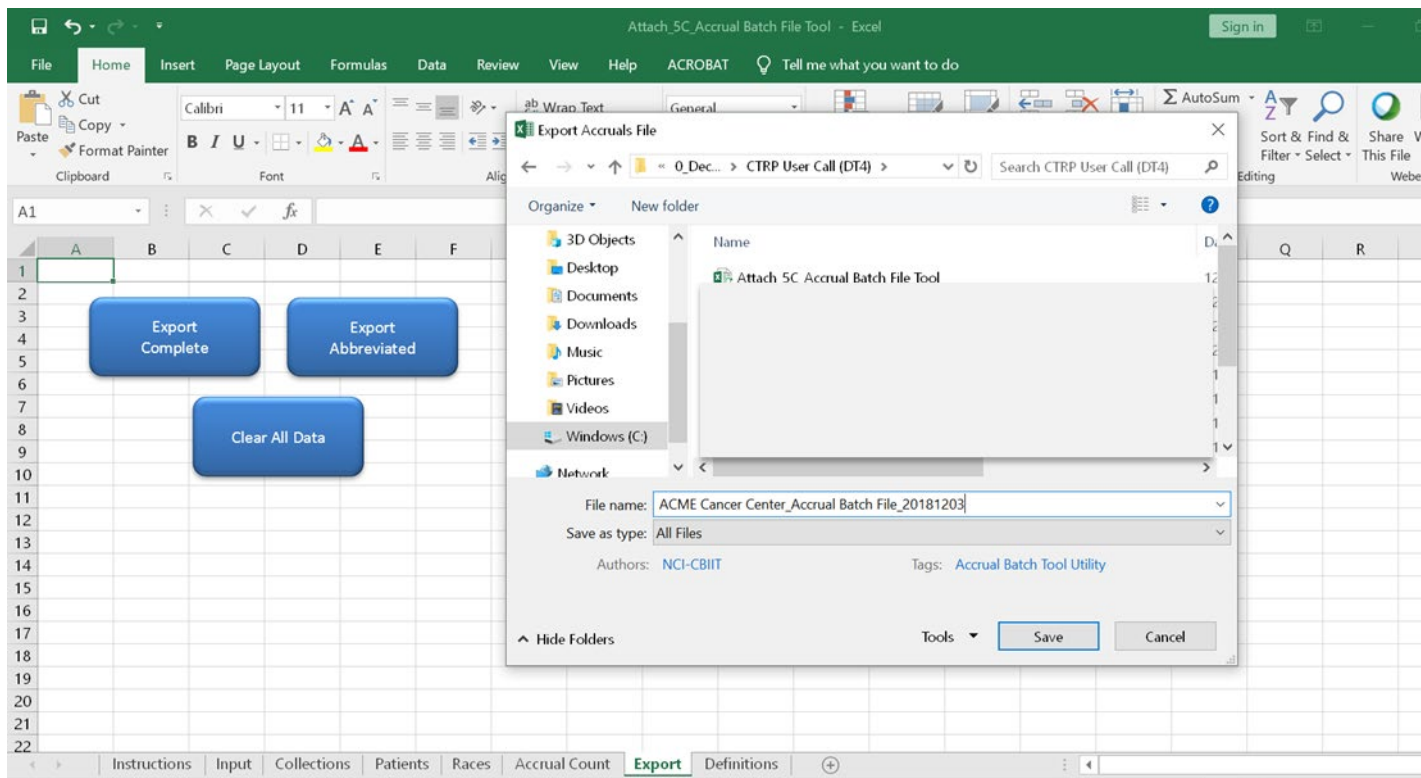
CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File



CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File



CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File

The screenshot displays the 'Attach_SC_Accrual Batch File Tool - Excel' application. The interface includes a standard Excel ribbon with tabs for File, Home, Insert, Page Layout, Formulas, Data, Review, View, Help, ACROBAT, and a search bar. The Home tab is active, showing options for Clipboard, Font, Alignment, Number, and Cells. The spreadsheet area is mostly empty, with a few blue buttons overlaid: 'Export Complete', 'Export Abbreviated', and 'Clear All Data'. A 'Success' dialog box is open, displaying the message 'Successfully exported 1 file' and an 'OK' button. The bottom status bar shows the current sheet is 'Export' out of several tabs: Instructions, Input, Collections, Patients, Races, Accrual Count, Export, and Definitions.

CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File

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

NCI CTRP Accrual Susan Nonemaker

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

Accrual Batch Upload

Click Browse and select the ZIP or TXT file that contains the accrual data. Then click Submit.

Batch File: No file chosen

- Choose recently updated CTRP Accrual Batch File and upload in the CTRP Accrual module

- Submit CTRP Accrual Batch File

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CTRP: Accrual Reporting (Batch File Submissions) – Cont'd

Example: Abbreviated/Imported Trial Batch File


NCI CTRP: Accrual SUBMISSION SUCCESSFUL fo_NCI-2016-00225 -

To Susan Nonemaker


Lead Organization: National Cancer Institute

CTRP-assigned Lead Organization ID: 1, 2


ClinicalTrials.gov ID: NCT12345678


Batch File Name:  ACME Cancer Center_Accrual Batch File_20181203._NCI-2016-00225 -


Submission Date 12/04/2018

 I

Date: 11/19/2018

 Susan Nonemaker

 Thank you for submitting your accrual counts to the NCI Clinical Trials Reporting Program (CTRP).

 Accrual counts for the following Study Site(s) were updated successfully as follows:

- 1, 2 - ACME Cancer Center

If you have questions about this or other CTRP topics, please contact us at ncictro@mail.nih.gov.

CTRP-Generated Data Table 4 for Interventional Trials: Next Steps

- Continue submission for non-competing applications
 - Enables all centers (including those who submitted competing applications in FY18) the opportunity to submit a non-competing CTRP-generated DT4 in FY19
 - Cancer Centers are now generating their own CTRP DT4 reports (interventional trials) and directly submitting their final CTRP DT4 (PDF “read only” and Excel version with comments) to the OCC CCSG mailbox (ccsgdata@mail.nih.gov)
- Next CTRP DT4 User Group Call to be scheduled for mid to late 1Q2019
 - Details to be communicated via the CTRP ListServ
- For any requested agenda topics, please contact the CTRO (NCICTRO@mail.nih.gov)



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