CTRP Accruals Spreadsheet

NOTIFICATION TO RESPONDENT OF ESTIMATED

OMB#: 0925-0600 EXP. DATE: 10/31/22

Public reporting burden for this collection of information is estimated to average fifteer
questionnaire, including the time to review instructions, search existing data sources, g
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Revision	Purpose	Date	Author
1.0	Initial draft	9/23/2012	Patrick McConnell
1.1	Changed language	10/10/2012	Patrick McConnell
1.2	Changed language	10/17/2012	Patrick McConnell
1.3	Multi-study support	11/30/2012	Patrick McConnell
1.4	Fixed bugs reported by QA	12/26/2012	Patrick McConnell
1.5	Added country codes to fix PO-8965 reported by QA	10/19/2015	Reshma Koganti
1.6	Added Cut-Off Date	9/7/2017	Praneeth Polavarapu
1.7	Removed validation for the subject disease code	9/11/2017	Praneeth Polavarapu
1.8	Fix for export complete trials	2/8/2018	Praneeth Polavarapu
1.9	Changed race "Native Hawaiian or other Pacific Islander" to "Native Hawaiian or Other Pacific Islander"	11/29/2018	Reshma Koganti

2.0	Added instructions to Input page. Adjusted input page layout.	8/9/2019	Li Wang

Purpose

The purpose of this Workbook is to provide an 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

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, Add Partial Subject or Add Summary button respectively. If the data is valid and entered correctly, it will be moved into the correct worksheet. If you enter data into the Collections, Patients, Races, and Accrual Count Worksheets manually, you must insure that identifiers are correctly maintained across the spreadsheets and that the data is appropriately formatted. You can click the field names on the Input Worksheet to view the definition of the field.

Exporting Data

Data is exported to a CSV file by navigating to the Export Worksheet and clicking the Export button. You will be prompted for a file name, and any existing file will be overwritten. You can only export data for Complete Trials and Abbreviated trials separately by clicking the appropriate Export button. The study identifier is appended to the file name, and a different file is created for each study. Clicking the Clear All Data button will erase data from the Collections, Patients, Races, and Accrual Count worksheets.

Note

The Accrual Batch File Tool supports SDC, ICD-9, ICD-10, and ICD-O-3 patient disease codes. For ICD-O-3 code system, both disease code and disease site are required. Please add them into the **Subject Disease Code** field. Delimited by semicolon

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974, ATTN: PRA (0925-0600).

Study Details

*Study Id _____ Change Code _____

Subject Level Accrual | Partial Subject Level Accrual | Su

Complete Trial Details

*Study Subject ID _____

*Study Subject Zip Code _____

*Study Subject Country _____

*Study Subject Birth Date _____

*Study Subject Gender _____

*Study Subject Ethnicity _____

Study Subject method of payment _____

*Registration Date _____

Registering Group Identifier _____

*Study Site Identifier _____

*Subject Disease Code _____

*Race _____

Race _____

Race _____

Race _____

Inst

Subject Birth Date
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than 125 years.

Subject Registrati
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Subject Disease C
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ZIP code is required fo
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Zip code must be a five
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Add Subject

Add Adj Subject

Clear Data

Random Data

ummary Level Accrual

ructions

e Format: MM/YYYY
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on Date Format:

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or US, US territories and
ne US Postal Codes.

e-digit or a nine-digit (DDDDD-

Add Accrual

Study Id **Change Code**

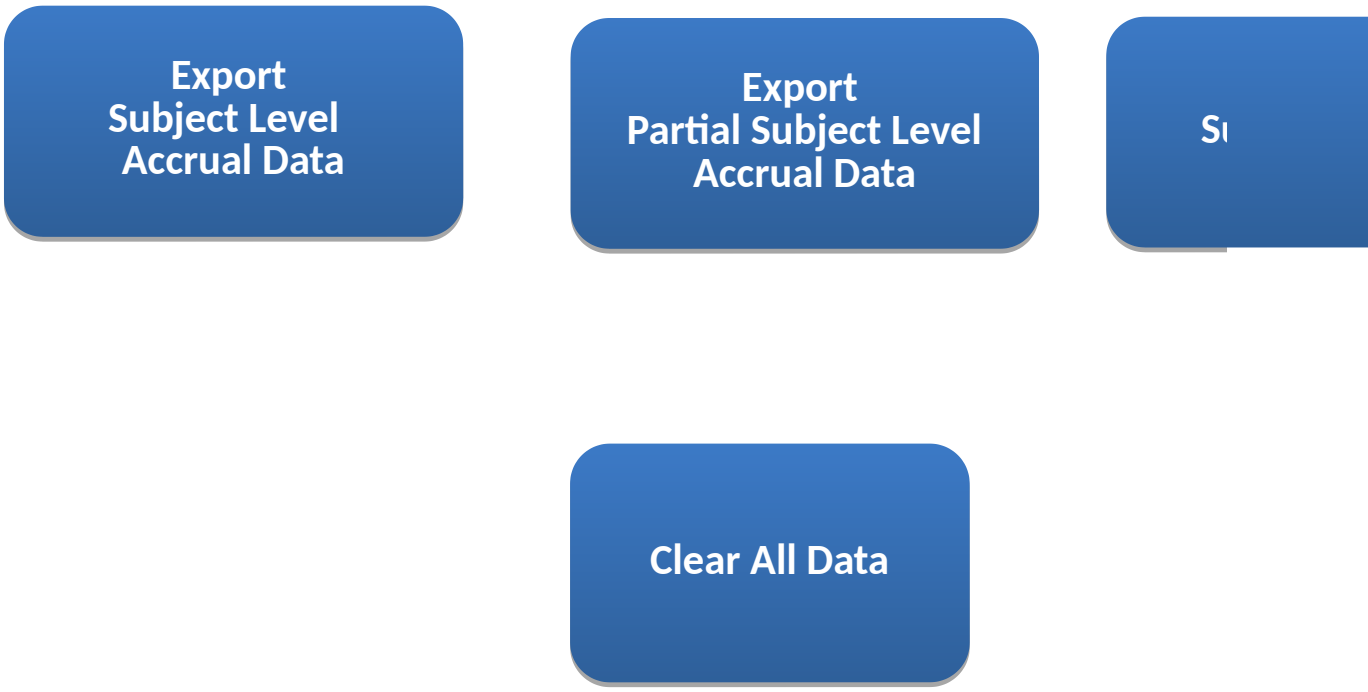
Study Id	Study Subject ID	Study Subject Zip Code	Study Subject Country	Study Subject Birth Date	Study Subject Gender

Study Subject Ethnicity	Study Subject method of payment	Registration Date

Registering Group Identifier	Study Site Identifier	Subject Disease Code

Study Id	Study Subject ID	Race

Study Id	Study Site Identifier	Study Site Accrual Count	Cut-Off Date


Export
Subject Level
Accrual Data
Export
Partial Subject Level
Accrual Data
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Clear All Data


Export
ummary Level
Accrual Data

Data Element	Definition	Require Subject
Study Id	This is the unique identifier assigned to the study.	R
Change Code	Whether the data has not changed since the last report	
Study Subject ID	Unique identifier (PO ID) assigned to the institution accruing the patient to the study.	R
Study Subject Zip Code	The string of characters used to identify the five-digit or 9-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIPcode, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery. Zip Code is mandatory if the patient's Country of Residence is the U.S, U.S. territories and outlying islands	C
Study Subject Country	CTRP is using the International Standards Organization country codes.	R
Study Subject Birth Date (MM/Y\	The month and year on which the person was born **Note: The subject's age reported in CTRP cannot be greater than 125 years.**	R
Study Subject Gender	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles.	R
Study Subject Ethnicity	The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories.	R
Study Subject method of paymer	Text term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service.	
Registration Date	Date the subject was registered for the study.	R
Registering Group Identifier	Unique identifier (PO ID) assigned to the group that originally registered the patient for the study	
Study Site Identifier	Unique identifier (numeric or alphanumeric) assigned to the study site	R
Subject Disease Code	Code that identifies a disease	R
Study Subject Race	The text for reporting information about race based on the Office of Management and Budget (OMB) categories.	R

Study Site Accrual Count	Numeric count of subjects accrued at a study site to date

ed/Conditional

Partial	Summary
R	R
R	
R	
R	R

R