

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 fifteen minutes per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the collection of information. An agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Washington, DC 20543-0142, Paperwork Project Director (0142-0001). Do not return the completed form to this address.

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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

	Added instructions to Input page. Adjusted 2.0 input page layout.	8/9/2019	Li Wang
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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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1 (15) minutes for this
gather and maintain the data
product or sponsor, and a person is
OMB control number.
information, including

974, ATTN: PRA (0925-0600).

Study Details	
*Study Id	Change Code

Subject Level Accrual

Partial Subject Level Accrual

Site Level Accrual

Complete Trial Details	Inst
*Study Subject ID	Subject Birth Date
*Study Subject Zip Code	The subject's age reported than 125 years.
*Study Subject Country	Subject Registrati
*Study Subject Birth Date	MM/DD/YYYY
*Study Subject Gender	Subject Disease C
*Study Subject Ethnicity	code system, please add b
Study Subject method of payment	site to this field. Delimite
*Registration Date	8543/3;C50.4
Registering Group Identifier	ZIP code is required fc
*Study Site Identifier	outlying islands that use th
*Subject Disease Code	Zip code must be a five
*Race	DDDD) value.
Race	
Race	
Race	
	Add Subject

~~Add Subject~~

Clear Data

Random Data

Summary Level Accrual

Instructions

Format: MM/YYYY
Month in CTRP cannot be greater

Month Date Format:

Code: For ICD-O-3 disease
both disease code and disease
described by a semicolon. For example:

For US, US territories and
the US Postal Codes.

Five-digit or a nine-digit (DDDD-

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
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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
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**Export
Subject Level
Accrual Data**

**Export
Partial Subject Level
Accrual Data**

Si

Clear All Data

**Export
Summary Level
Accrual Data**

Require

Data Element	Definition	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/YY)	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 payment	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