

# CTRP Accruals Spreadsheet

## NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 02/28/2026

Public reporting burden for this collection of information is estimated to average thirty (30) minutes for this questionnaire, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing 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 aspect of this collection of information, including suggestions for reducing the burden to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7972, Bethesda, MD 20892-0797. Send all comments to this address. Do not return the completed form to this address.

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 input page layout.	8/9/2019	Li Wang
2.0			
2.1	Added the column Disease Code System in Patient. Changes to Random data and Export functionality for the new field Disease	8/24/2023	Sreeja Harshan
2.2	Change reference to "gender" to "sex"	8/31/2023	Matt Fischer
2.3	Deprecate Study Subject Method of Payment	8/31/2023	Sreeja Harshan
2.4	Deprecate Registering Group Identifier	9/5/2023	Sreeja Harshan
2.5	Change Max Age to 120	12/16/2024	Sreeja Harshan
2.6	Gender-Sex change CTRP-8537	2/18/2025	Sreeja Harshan
2.7	Update Disclaimer screenshot	2/24/2025	Sreeja Harshan

## 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, ICD9, ICD10, 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.

The following fields have been deprecated and is no longer used in the system:

1. Study Subject Method of Payment

## **STATEMENT OF ESTIMATED BURDEN**

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<b>Study Details</b>	
*Study Id _____	Change Code _____

Subject Level Accrual

Partial Subject Level

Site

	Complete Trial Details	Inst
*Study Subject ID	_____	<b>Subject Birth Date For</b>
*Study Subject Zip Code	_____	The subject's age reported
*Study Subject Country	_____	than 120 years.
*Study Subject Birth Date	_____	
*Study Subject Sex	_____	<b>Subject Registration</b>
*Study Subject Ethnicity	_____	
*Registration Date	_____	<b>Subject Disease Code</b>
*Study Site Identifier	_____	system, please add both d
*Subject Disease Code	_____	this field. Delimited by a s
Disease System Code	_____	8543/3;C50.4
*Race	_____	
Race	_____	<b>ZIP code</b> is required for
Race	_____	
Race	_____	



Clear Data

Random Data

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## Summary Level Accrual

<b>Instructions</b>
<b>Format:</b> MM/YYYY MM in CTRP cannot be greater than 12
<b>Date Format:</b> MM/DD/YYYY
<b>Example:</b> For ICD-O-3 disease code 158201 and disease site to 40. For example: 158201;40
US, US territories and outlying possessions





**Study Id**

**Change Code**

<b>Study Id</b>	<b>Study Subject ID</b>	<b>Study Subject Zip Code</b>	<b>Study Subject Country</b>	<b>Study Subject Birth Date</b>	<b>Study Subject Sex</b>
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Study Subject Ethnicity	<del>Study Subject method of payment</del>	Registration Date	<del>Registering Group Identifier</del>
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**Study Site  
Identifier**

**Subject Disease Code    Disease System 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**

**Si**

**Clear All Data**

**Export  
Summary Level  
Accrual Data**

## Requirements

Data Element	Definition	Requirement
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/YYYY)	The month and year on which the person was born <b>Note: The subject's age reported in CTRP cannot be greater than 120 years.</b>	R
Study Subject Sex	Text designations that identify sex. Sex means a person's classification as male or female based on biological distinctions.	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	This is deprecated and is no longer used.	
Registration Date	Date the subject was registered for the study.	R
Registering Group Identifier	This is deprecated and is no longer used.	
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	
Disease System Code	Can be specified for Patient, if different from the Disease Code System of the Study.	

**ed/Conditional**

<b>Partial</b>	<b>Summary</b>
R	R

R

R

R	R
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R