NOTIFICATION TO RESPONDENT OF ESTIM

Public reporting burden for this collection of information is estimated to av
questionnaire, including the time to review instructions, search existing da
needed, and complete and review the collection of information. An agenc
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number.
Send comments regarding this burden estimate or any other aspect of thi
suggestions for reducing the burden to
NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethe
(0925-0600).
Do not return the completed form to this address.

OMB#: 0925-0600 EXP. DATE: 3/31/2013

ONDENT OF ESTIMATED BURDEN

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s, search existing data sources, gather and maintain the data
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CTRP Accruals Spreadsheet

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

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

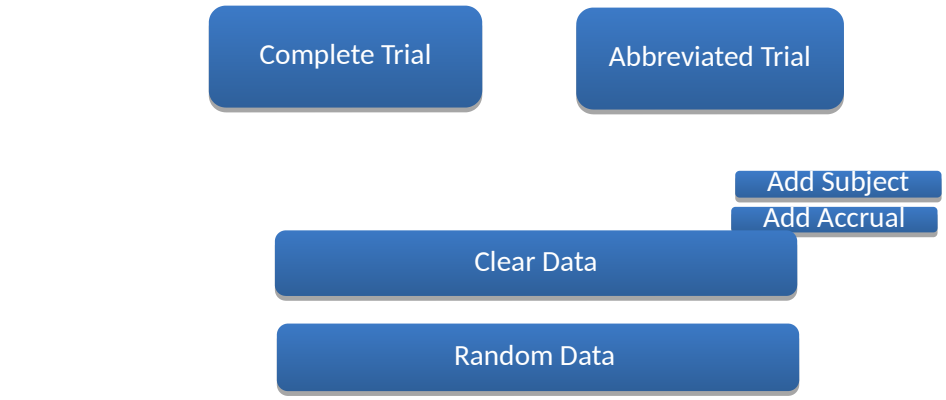
Data can be entered either through the Input Worksheet or directly into the Collections, Patients, Races, and Accrual Count Worksheets. The Input Worksheet requires that you first enter study details into the first section and then click either the Complete Trials button or Abbreviated Trials button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

Study Details

***Study Id** _____ Change Code _____



Study Id **Change Code**

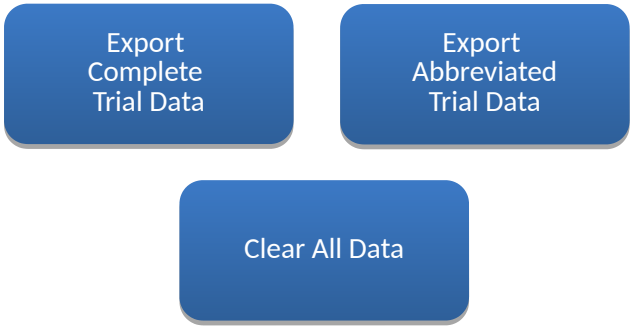
Study Id	Study Subject Identifier	Zip Code (if US)	Country of Residence	Patient's Date of Birth	Gender of a Person

Ethnicity	Payment Method	Subject Registration Date

Registering Group Identifier	Study Site Identifier	Subject Disease Code

Study Id	Study Subject Identifier	Race

Study Id	Study Site Accrual Count	Study Site Identifier


Export
Complete
Trial Data
Export
Abbreviated
Trial Data
Clear All Data

Data Element	Definition
*Study Id	This is the unique identifier assigned to the study.
Change Code	Whether the data has not changed since the last report
*Study Subject Identifier	Unique identifier (PO ID) assigned to the institution accruing the patient to the study.
*Zip Code (if US)	The string of characters used to identify the five-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.
*Country of Residence	The name of a country from which a person or their biological family had previous residence or past ancestors. Condition: either Zip code (if U.S resident) or country (if not U.S resident) is mandatory.
*Patient's Date of Birth	The month and year on which the person was born
*Gender of a Person	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles.
*Ethnicity	The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories.
Payment Method	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.<y.
*Subject Registration Date	Date the subject was registered for the study.<y.
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
*Subject Disease Code	Code that identifies a disease.< study.<y.
*Race	The text for reporting information about race based on the Office of Management and Budget (OMB) categories.<y.
*Study Site Accrual Count	Numeric count of subjects accrued at a study site to date