

CTRP Accruals Spreadsheet

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 8/31/19

Public reporting burden for this collection of information is estimated to average fifteen (15) minutes per respondent, including the time to review instructions, search existing data sources, gather and maintain 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, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: Paperwork Project Manager. 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

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. 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.

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Study Details

***Study Id** _____ **Change Code** _____

Complete Trial

Abbreviated Trial

Complete Trial Details

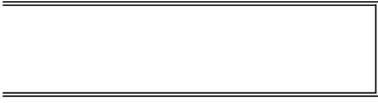
*Study Subject Identifier	_____
*Zip Code (if US)	_____
*Country of Residence	_____
*Patient's Date of Birth	_____
*Gender of a Person	_____
*Ethnicity	_____
Payment Method	_____
*Subject Registration Date	_____
Registering Group Identifier	_____
*Study Site Identifier	_____
*Subject Disease Code	_____
*Race	_____
Race	_____
Race	_____
Race	_____

Add Subject

Add Accrual

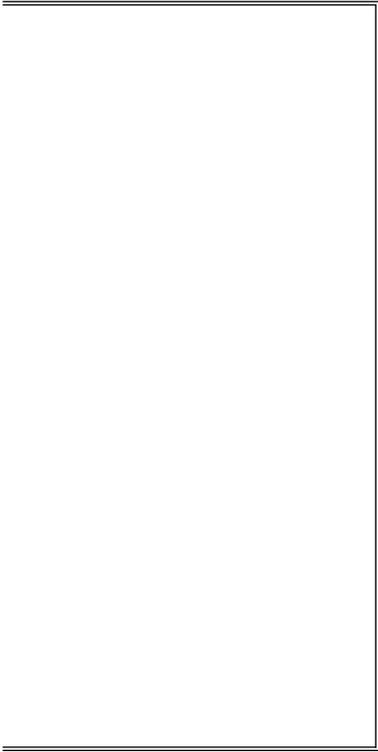
Clear Data

Random Data



Change Code

- 1
- 2



***Country of Residence**

AF

AL

DZ

AS

AD

AO

AI

AQ

AG

AR

AM

AW

AU

AT

AZ

BS

BH

BD

BB

BM

BT

BO

BA

BW

BV

BR

IO

BN

BG

BF

BI

KH

CM

CA

CV

KY

***Gender of a Person**

Female

Male

Unknown

Unspecified

***Ethnicity**

Hispanic or Latino

Not Hispanic or Latino

Not Reported

Unknown

CF
TD
CL
CN
CX
CC
CO
KM
CG
CD
CK
CR
CI
HR
CU
CY
CZ
DK
DJ
DM
DO
TP
EC
EG
SV
GQ
ER
EE
ET
FK
FO
FJ
FI
FR
FX
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MX
FM
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MN
MS
MA
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NA
NR
NP
NL
AN
NC
NZ
NI
NE
NG
NU
NF
MP
NO
OM
PK
PW
PA
PG
PY
PE
PH
PN
PL
PT
PR
QA

RE
RO
RU
RW
KN
LC
VC
WS
SM
ST
SA
SN
SC
SL
SG
SK
SI
SB
SO
ZA
GS
ES
LK
SH
PM
SD
SR
SJ
SZ
SE
CH
SY
TW
TJ
TZ
TH
TG
TK
TO
TT
TN
TR
TM
TC
TV

UG
UA
AE
GB
US
UM
UY
UZ
VU
VE
VN
VG
VI
AX
BL
GG
IM
JE
ME
MF
PS
RS
TL
WF
EH
YE
ZM
ZW

Payment Method	*Race	*Subject Disease Code
Managed Care	American Indian or Alaska Na	SDC
Medicare	Asian	ICD-9
Medicaid	White	ICD-10
Medicaid and Medicare	Black or African American	ICD-O-3
Medicare and Private Insuran	Not Reported	
Military or Veterans Sponsore	Unknown	
Military Sponsored (Includin	Native Hawaiian or Other Pacific Islander	
No Means of Payment (No Insurance)		
Other		
Private Insurance		
Self-Pay (No Insurance)		
State Supplemental Health Insurance		
Unknown		
Veterans Sponsored		

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
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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 Identifier	Study Site Accrual Count	Cut-Off Date
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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. Zip Code is mandatory if the patient's Country of Residence is the U.S.
* Country of Residence	For non-U.S. residents only. This should be used when patient participation from foreign countries is involved. For patients from outside the U.S., enter the foreign country code. Leave blank if the patient is a U.S. resident. CTRP is using the International Standards Organization country codes. Note: Either Zip code (if U.S resident) or country code (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