NOTIFICATION TO RESPONDE

Public reporting burden for this collection of information is estimated t
time to review instructions, search existing data sources, gather and n
information. An agency may not conduct or sponsor, and a person is n
displays a current, valid OMB control number.
Send comments regarding this burden estimate or any other aspect o
the burden to
NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Be
Do not return the completed form to this address.

OMB#: 0925-0600 EXP. DATE: 3/31/13

NT OF ESTIMATED BURDEN

o average sixty (60) minutes for this questionnaire, including the
naintain the data needed, and complete and review the collection of
ot required to respond to, a collection of information unless it

f this collection of information, including suggestions for reducing

thesda, MD 20892-7974, ATTN: PRA (0925-0600).

CTRP Trial Registration Participating Site Specification f

The participating sites template is designed for recording participating site data for interv

About this Document

This document provides you with everything you need to upload clinical trial data to the

Template Instructions

The Template Instructions worksheet provides detailed instructions for preparin

Data Element Specifications

The specifications worksheet includes the following information:

1. Data elements
2. Order in which the data elements *must be* presented
3. Data element requirements
4. Valid values. The system accepts only those values listed in this doc
5. Comments. Additional information that helps you to ensure success

or Abbreviated Trials

ventional trials, especially if site-specific data is not included in the trial protocol.

CTRP Trial Registration system, including the following:

g your data and uploading them to the system.

cument
sful submission of your data

How to S

Main Step

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Preparing

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Uploadin

Upload your f

For detailed i
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ubmit Abbreviated Trial Participating Sites Data to the CTRP Trial R

s for Uploading Your Data

pare the trial data file
oad the file in the Trial-Related Documents section in the Registration application

g Trial Data Files

ure that your trial conforms to the supported criteria. This template supports the following:

Interventional trials
Abbreviated trials (Summary 4 Funding Sponsor Category is Industrial)
Updates to abbreviated CTRP trials with the processing status "Accepted" and beyond

pare an Excel spreadsheet (.xls) containing the mandatory and optional data for the trial(s) as specified in t

u must adhere to the following requirements:

st trial elements required for registration in the order specified in the Abbreviated Trial Data Spec tab in this
o not change the spelling of data elements or valid values.
onform to the valid values guidelines when entering trial data.
entify each trial uniquely
rticipating site information must include the following data elements:
* Study participating site data
* At least one study site investigator's information
* Participating site primary or central contact information. Generic contact information is accepted.
* Organization attribute
* Current recruitment status
* Status date
* Target accrual. This is mandatory if the target accrual is for a study at a participating site or if the lead or
udy site investigator's information must include the following data elements:
* Study site investigator data with person's attributes
* Investigator's role in the study at the site.
reference.

rticipating site contact information is optional if the contact person is the investigator, or if the central conta
st persons and organizations with PO-IDs.

Note: You can request a list of CTRP persons and organizations along with PO-IDs from the CTRO at nci

Or, you can use the organization/person lookup features in the CTRP Trial Registration application to sear

g Your File

file in the Trial-Related Documents section of the CTRP Registration Site's Register Trial page. Or, email y

Note: You can use the Abbreviated Batch Upload Template instead of this one. If you use the batch templ
to add your site information by its NCI Trial ID.

nstructions for registering trials, refer to the NCI CTRP Reporting Program Registration Site User's Guide a
ps://wiki.nci.nih.gov/x/7qViAw

r Center. Optionally, provide a local trial identifier.

ı.gov.

Trial elements Order	Trial data element	Required?
1	NCI Trial Identifier	Yes
2	Local trial identifier	Yes
3	[Submitting Organization] Organization PO-ID	
4	[Submitting Organization] Name	Yes if PO-ID is not provided
5	[Submitting Organization] Street Address	Yes if PO-ID is not provided
6	[Submitting Organization] City	Yes if PO-ID is not provided
7	[Submitting Organization] State/Province	Yes for US/Canada/Australia and if PO-ID is not provided
8	[Submitting Organization] Zip/Postal code	Yes if PO-ID is not provided
9	[Submitting Organization] Country	Yes if PO-ID is not provided
10	[Submitting Organization] Email Address	Yes if PO-ID is not provided
11	[Submitting Organization] Phone	
12	[Submitting Organization] TTY	
13	[Submitting Organization] FAX	
14	[Submitting Organization] URL	
15	[Submitting Organization] Organization Type	
16	[Site Principal Investigator] Person PO-ID	
17	[Site Principal Investigator] First Name	Yes if PO-ID is not provided
18	[Site Principal Investigator] Middle Name	
19	[Site Principal Investigator] Last Name	Yes if PO-ID is not provided
20	[Site Principal Investigator] Street Address	Yes if PO-ID is not provided

21	[Site Principal Investigator] City	Yes if PO-ID is not provided
22	[Site Principal Investigator] State/Province	Yes for US/Canada/Australia and if PO-ID is not provided
23	[Site Principal Investigator] Zip/Postal code	Yes if PO-ID is not provided
24	[Site Principal Investigator] Country	Yes if PO-ID is not provided
25	[Site Principal Investigator] Email Address	Yes if PO-ID is not provided
30	[Site Principal Investigator] Phone	Yes if PO-ID is not provided
31	[Site Principal Investigator] Phone Extension	
32	[Site specific] Program Code	
33	Site Recruitment Status	Yes
34	Site Recruitment Status Date	Yes
35	Date Opened for Accrual	Yes if study is opened for accrual
36	Date Closed for Accrual	Yes if study is closed for accrual
37	Site Target Accrual	

Valid Values	Comments	Definition			
	NCI trial identifier of the existing in CTRP trial to which this site is to be added				
	Trial identifier as assigned by the submitting organization				
	PO-ID or all mandatory organization attributes are required				
2-letter state/province code required for US/Canada, 2-3 letter code required for Australia					
	Include Phone Extension if any in the same field				
Institution, ordering group, repository, research based, cooperative group, cancer center, consortium, drug company, network					
	PO-ID or all mandatory person attributes are required				

2-letter state/province code required for US/Canada, 2-3 letter code required for Australia					
	Phone specific to study				
	Mandatory if exists and PO-ID is not provided				
	applicable for NCI-designated Cancer Center				
Not yet recruiting; Recruiting; Enrolling by invitation; Active, not recruiting; Completed; Suspended; Terminated; Withdrawn					
Format mm/dd/yyyy	Date when the recruitment status has come in effect				
Format mm/dd/yyyy					
Format mm/dd/yyyy					
	Necessary for NCI designated cancer centers				

