NG PROGRAM (CTRP) SYSTEM

OMB No.: 0925-0600
Expiration Date: 08/31/2019

estimated to average 30 minutes per response,
sting data sources, gather and maintain the data
tion. **An agency may not conduct or sponsor, and a**
information unless it displays a currently valid
den estimate or any other aspect of this collection of
to: NIH, Project Clearance Branch, 6705 Rockledge
925-0600). Do not return the completed form to this

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 participating

Template Instructions

The Template Instructions worksheet provides detailed instructions for preparing

Participating Site Data Specification and Collaborator Data Specification

The specifications worksheets 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. Notes. Additional information that helps you to ensure successful su

Participating Site and Collaborator Examples

These worksheets provide examples of a typical participating sites/collaborator

or Complete Trials

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

g sites and collaborator data to the CTRP Trial Registration system, including the following:

g your data and uploading them to the system.

:ument
ıbmission of your data

data file.

How to S

Main Step

1 Prep
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Preparing

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Uploading

Upload your f

For detailed in
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ubmit Complete Trial Participating Sites Data to the CTRP Trial Regi

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
Complete trials (Data Table 4 Funding Sponsor Category is National, Externally Peer Reviewed, or Institut
Processing Statuses for trial updates: Accepted and beyond
Processing Statuses for trial amendments: Abstraction Verified Response or Abstraction Verified No Resp

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

must adhere to the following requirements:

t trial elements required for registration in the order specified in the Participating Site Data Spec tab in this
not change the spelling of data elements or valid values.
nform 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 org
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
t 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

Note: Although you can update Program Codes via the NCI CTRP Registration site, you can not update them via the

g Your File

ile in the Trial-Related Documents section of the CTRP Registration Site's Register Trial page.

nstructions for registering trials, refer to the NCI CTRP Reporting Program Registration Site User's Guide a
://wiki.nci.nih.gov/x/7ZF4B

· Center. Optionally, provide a local trial identifier.

Element order	Element	Required?
	Study participating site data	
1	Site #	Yes
2	Local Trial Identifier	
3	[Site] Organization PO-ID	Yes
4	Study Current Recruitment Status at site	Yes
5	Study Current Recruitment Status date	Yes
6	Site Target Accrual	Yes if either site or lead organization is cancer center
7	Program Code	
	Study site investigator's information	
8	Investigator's Person PO-ID	
9	Investigator's Role in the study	Yes
10	Use investigator as site contact for the study	Yes
	Study/Site Contact information	
11	Contact type	Yes
	Generic Contact	
12	Title for generic contact	Yes if generic contact is used
13	Contact Email	Yes if generic contact is used
14	Contact Phone	Yes if generic contact is used
15	Contact Phone Extension	
	Person Contact	

16	Contact Person's PO-ID	
17	Contact Email	Yes if personal contact is used and PO-ID is not provided
18	Contact Phone	Yes if personal contact is used and PO-ID is not provided

Allowed values	Note
	For participating sites only; lead organization must be included if it is also a participating site
	Order in the list of participating sites
	Trial identifier at site
	PO-ID for the organization must exist in the CTRP list of organizations
Not yet recruiting; Recruiting; Enrolling by invitation; Active, not recruiting; Completed; Suspended; Terminated; Withdrawn	
Date in the format mm/dd/yyyy	Date that corresponds to the current recruitment status change
Number	Mandatory if either site or lead organization is cancer center
	Site-specific Data Table 4 program code for NCI designated cancer center
	Several records per one participating site are accepted
	PO-ID for the Person must exist in the CTRP list of Persons
Principal Investigator, Sub-Investigator	
Yes/No	IF YES is selected, investigator will play participating site contact role for the study and no other participating site contact will be required
Site-Specific, Study-specific or central	Provide single contact for the study (study-specific) or site-specific contact for each participating site. This attribute is not required if site's investigator is assigned as site contact. There is no need to replicate central contact in each participating site record if central contact is selected and provided in the first record
	Generic contact or personal contact is required
	Several records per one participating site are accepted in case of site-specific contact type
	Email address specific to study
	Phone specific to study
	Mandatory if exists

	PO-ID for the Person must exist in the CTRP list of Persons
	Email address specific to study
	Phone specific to study

#	Element	Mandatory?	Value
	Collaborator information	**Optional**	
1	Collaborator #		
2	Collaborator Organization PO-ID		
3	Collaborator role on the study	Yes	Funding Source, Agent Source, Laboratory

Note	
Order in the list of collaborators	
PO-ID for the organization must exist in the CTRP list of organizations	

	1	2	3	4	5	6	7	
Site info	Site #	Local Trial Identifier	[Site] Organization PO-ID	Study Current Recruitment Status at site	Study Current Recruitment Status date	Site Target Accrual	Program Code	Site Investigator
Study 1								
	1	LI01	321	recruiting	10/20/2008	55	BM3	
	1							
	2	LI02	432	recruiting	11/2/2008	125		
Study 2								
	1	LI04	432	recruiting	11/2/2008	125		
	2	LI06	321	recruiting	10/20/2008	55	BM3	

8	9	10		11		12
Investigator's Person PO-ID	Investigator's Role in the study	Use investigator as site contact for the study	Site Contact Info	Contact type	Genetic Contact	Title
12345	Principal Investigator	YES		Site-Specific		
23456	Sub-investigator	NO				
34567	Principal Investigator	NO		Site-Specific		
34567	Principal Investigator	NO		Study_specific		Clinical Study Department
12345	Principal Investigator	NO				

13	14	15		16	17	18
Contact Email Address	Contact Phone	Contact Phone Extension	Personal Contact	Contact Person's PO-ID	Contact Email	Contact Phone
					info@mskc	212-639-2000
clinicalstudydept@mskcc.org	212-639-2000	123				

Note
Site is a NCI designated cancer center, includes 2 investigators. One of the investigators is selected as this site contact.
Site is a NCI designated cancer center, includes 1 investigator. Site-Specific contact is used (investigator is not used for site contact)
Generic study-specific contact is used; no need to provide contact for each site separately.

1	2	3
Collaborator #	**Collaborator Organization PO-ID**	**Collaborator role on the study**
1	123	Laboratory
2	234	Agent Source