

## NCI CLINICAL TRIALS REPORT

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering the data, reviewing the collection of information, and reviewing the collection of information. **An agency may not conduct or sponsor a collection of information unless it displays a currently 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 Headquarters Office, Paperwork Project, NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-0794. Send all requests for further information to the Project Clearance Branch, NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-0794. Return the completed form to this address.

## ING PROGRAM (CTRP) SYSTEM

OMB No.: 0925-0600  
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MSEB, Bethesda, MD 20892-7974, ATTN: PRA (0925-0600). Do not

# **CTRP Trial Registration Participating Site Specification for**

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

## **About this Document**

This document provides you with everything you need to upload clinical trial participatin

### **Template Instructions**

The Template Instructions worksheet provides detailed instructions for preparin

### **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

## 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  
bmission of your data

data file.



# How to S1

## Main Step

- 1 Prep
- 2 Uplc

## Preparing

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- \*
- \*

2 Prep

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## Uploading

Upload your f

For detailed in

<https>

# Submit Complete Trial Participating Sites Data to the CTRP Trial Registration Application

## Steps for Uploading Your Data

1. Prepare the trial data file
2. Upload the file in the Trial-Related Documents section in the Registration application

## 3. Trial Data Files

Ensure 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 Institutional)
- Processing Statuses for trial updates: Accepted and beyond
- Processing Statuses for trial amendments: Abstraction Verified Response or Abstraction Verified No Response

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

### 4. You must adhere to the following requirements:

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

Conform to the valid values guidelines when entering trial data.

Identify each trial uniquely

Participating 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 primary study 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.

See the [Participating Site Data Spec](#) for more information and reference.

Participating site contact information is optional if the contact person is the investigator, or if the central contact information is provided for all participating 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 [ncictrp@ctro.nih.gov](mailto:ncictrp@ctro.nih.gov). Or, you can use the organization/person lookup features in the CTRP Trial Registration application to search for persons and organizations.

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

## **g Your File**

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

Instructions for registering trials, refer to the NCI CTRP Reporting Program Registration Site User's Guide at <https://wiki.nci.nih.gov/x/7ZF4B>

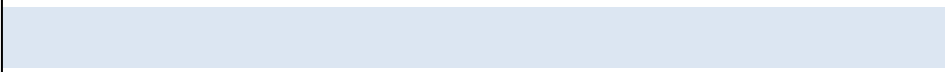
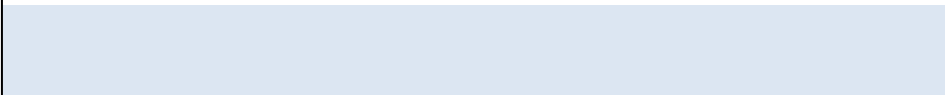
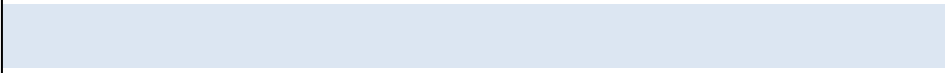
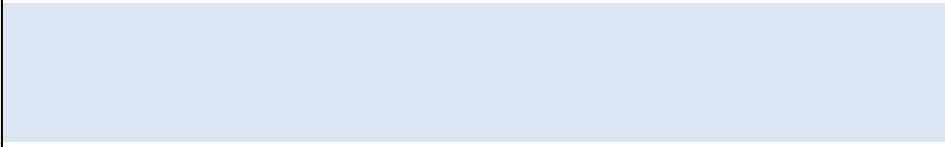
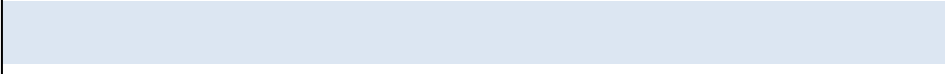
r Center. Optionally, provide a local trial identifier.

Element order	Element	Required?
	<b>Study participating site data</b>	
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	
	<b>Study site investigator's information</b>	
8	Investigator's Person PO-ID	
9	Investigator's Role in the study	Yes
10	Use investigator as site contact for the study	Yes
	<b>Study/Site Contact information</b>	
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
	<b>For participating sites only; lead organization must be included if it is also a participating site</b>
	Order in the list of participating sites
	Trial identifier at site
	<b>PO-ID for the organization must exist in the CTRP list of organizations</b>
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
	<b>Several records per one participating site are accepted</b>
	<b>PO-ID for the Person must exist in the CTRP list of Persons</b>
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
	<b>PO-ID for the Person must exist in the CTRP list of Persons</b>

	Email address specific to study
	Phone specific to study





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

<b>Note</b>	
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
<b>Study 1</b>								
	1	LI01	321	recruiting	10/20/2008	55	BM3	
	1							
	2	LI02	432	recruiting	11/2/2008	125		
<b>Study 2</b>								
	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
					<a href="mailto:info@mskc">info@mskc</a>	212-639-2000
<a href="mailto:clinicalstudydept@mskcc.org">clinicalstudydept@mskcc.org</a>	212-639-2000	123				

<b>Note</b>	
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
<b>Collaborator #</b>	<b>Collaborator Organization PO-ID</b>	<b>Collaborator role on the study</b>
1	123	Laboratory
2	234	Agent Source