NOTIFICATION TO RESP

Public reporting burden for this collection of information is estim
time to review instructions, search existing data sources, gathe
information. An agency may not conduct or sponsor, and a pers
displays a current, valid OMB control number.
Send comments regarding this burden estimate or any other as
the burden to
NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 79
Do not return the completed form to this address.

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

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nated to average sixty (60) minutes for this questionnaire, including the
r and maintain the data needed, and complete and review the collection of
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spect of this collection of information, including suggestions for reducing

74, Bethesda, 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 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

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.

cument
ubmission of your data

data file.

How to S

Main Step

1 Prep
2 Uplo

Preparing

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2 Prep

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Uploadin

Upload your f

For detailed i
http

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 (Summary 4 Funding Sponsor Category is National, Externally Peer Reviewed, or Institutio
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

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.

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

r 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	
4	[Site] Name	Yes if PO-ID is not provided
5	[Site] Street Address	Yes if PO-ID is not provided
6	[Site] City	Yes if PO-ID is not provided
7	[Site] State/Province (US/Canada/Australia)	Yes for US, Canada, Australia and if PO-ID is not provided
8	[Site] Zip/Postal code	Yes if PO-ID is not provided
9	[Site] Country	Yes if PO-ID is not provided
10	[Site] Email	Yes if PO-ID is not provided
11	[Site] Phone	
12	[Site] Phone extension	
13	[Site] TTY	
14	[Site] FAX	
15	[Site] URL	
16	Is it NCI designated cancer center?	Yes
17	Study Current Recruitment Status at site	Yes
18	Study Current Recruitment Status date	Yes
19	Site Target Accrual	Yes if either site or lead organization is cancer center
20	Program Code	
	Study site investigator's information	
21	Investigator's Person PO-ID	
22	Investigator's First Name	Yes if PO-ID is not provided
23	Investigator's Middle name	
24	Investigator's Last Name	Yes if PO-ID is not provided
25	Investigator's Email	Yes if PO-ID is not provided
26	Investigator's Phone	Yes if PO-ID is not provided

27	Investigator's Phone Extension	
28	Investigator's Street Address	Yes if PO-ID is not provided
29	Investigator's Zip/Postal Code	Yes if PO-ID is not provided
30	Investigator's City	Yes if PO-ID is not provided
31	Investigator's State/Province (US/Canada, Australia)	Yes if country is US, Canada, Australia and PO-ID is not provided
32	Investigator's Country	Yes if PO-ID is not provided
33	Investigator's TTY	
34	Investigator's FAX	
35	Investigator's URL	
36	Investigator's Role in the study	Yes
37	Use investigator as site contact for the study	Yes
	Study/Site Contact information	
38	Contact type	Yes
	Generic Contact	
39	Title for generic contact	Yes if generic contact is used
40	Contact Email	Yes if generic contact is used
41	Contact Phone	Yes if generic contact is used
42	Contact Phone Extension	
	Personal Contact	
43	Contact Person's PO-ID	
44	Contact Person's First Name	Yes if personal contact is used and PO-ID is not provided
45	Contact Person's Middle Name	
46	Contact Person's Last Name	Yes if personal contact is used and PO-ID is not provided

47	Contact Email	Yes if personal contact is used and PO-ID is not provided
48	Contact Phone	Yes if personal contact is used and PO-ID is not provided
49	Contact Phone Extension	
50	Contact Person's Street Address	Yes if personal contact is used and PO-ID is not provided
51	Contact Person's Zip/Postal Code	Yes if personal contact is used and PO-ID is not provided
52	Contact Person's City	Yes if personal contact is used and PO-ID is not provided
53	Contact Person's State/Province (US/Canada/Australia)	Yes for personal contact and if country is US, Canada, Australia
54	Contact Person's Country	Yes if personal contact is used and PO-ID is not provided
55	Contact Person's TTY	
56	Contact Person's FAX	
57	Contact Person's URL	

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 or organization mandatory attributes is required
	US, Canada, Australia only for the case when PO-ID is not provided
	If exists and phone is provided
Yes/No	Indicate if organization is a NCI designated cancer center
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 Summary 4 program code for NCI designated cancer center
	Several records per one participating site are accepted
	Person PO-ID or all mandatory person attributes is required
	Only initials
	Email address specific to study
	Phone specific to study

	Mandatory if exists and PO-ID is not provided
	Only for US/Canada/Australia in case if PO-ID is not provided
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 or all mandatory person attributes is required
	Several records per one participating site are accepted in case of site-specific contact type
	Only initials

	Email address specific to study
	Phone specific to study
	Mandatory if exists and the phone is provided
	Only for US/Canada/Australia in case if PO-ID is not provided

#	Element	Mandatory?	Value
	Collaborator information	**Optional**	
1	Collaborator #		
3	Collaborator Organization PO-ID		
2	Collaborator Name	Yes if PO-ID is not provided	
4	Collaborator Street Address	Yes if PO-ID is not provided	
5	Collaborator City	Yes if PO-ID is not provided	
6	Collaborator State/Province (US/Canada/Australia)	Yes for US, Canada, Australia and PO-ID is not provided	
7	Collaborator Zip/Postal code	Yes if PO-ID is not provided	
8	Collaborator Country	Yes if PO-ID is not provided	
9	Collaborator Email	Yes if PO-ID is not provided	
10	Collaborator Phone		
11	Collaborator Phone extension		
12	Collaborator TTY		
13	Collaborator FAX		
14	Collaborator URL		
15	Collaborator role on the study	Yes if PO-ID is not provided	Funding Source, Agent Source, Laboratory

Note	
Order in the list of collaborators	
PO-ID or all mandatory organization attributes is required	
US, Canada, Australia only in case if PO-ID is not provided	
If exists and phone is provided	

	1	2	3	4	5
Site info	Site #	Local Trial Identifier	[Site] Organization PO-ID	[Site] Name	[Site] Street Address
Study 1					
	1	LI01		The University of Texas M. D. Anderson Cancer Center	1515 Holcombe Blvd
	1				
	2	LI02		Memorial Sloan-Kettering Cancer C	1275 York Avenue
Study 2					
	1	LI04		Memorial Sloan-Kettering Cancer C	1275 York Avenue
	2	LI06		The University of Texas M. D. Anderson Cancer Center	1515 Holcombe Blvd

6	7	8	9	10	11	12
[Site] City	[Site] State/Province (US/Canada)	[Site] Zip/Postal code (US/Canada)	[Site] Country	[Site] Email	[Site] Phone	[Site] Phone extension
Houston	TX	77030	USA	mailus@mdanderson.org	(713) 792-5410	
New York	NY	10065	USA	info@mskcc.org	212-639-2000	
New York	NY	10065	USA	info@mskcc.org	212-639-2000	
Houston	TX	77030	USA	mailus@mdanderson.org	(713) 792-5410	

13	14	15	16	17	18	19	20
[Site] TTY	[Site] FAX	[Site] URL	Is it NCI designated cancer center?	Study Current Recruitment Status at site	Study Current Recruitment Status date	Site Target Accrual	Program Code
		http://www.mdanderson.org	YES	recruiting	10/20/2008	55	BM3
		http://www.mskcc.org	YES	recruiting	11/2/2008	125	
		http://www.mskcc.org	YES	recruiting	11/2/2008	125	
		http://www.mdanderson.org	YES	recruiting	10/20/2008	55	BM3

	21	22	23	24	25
Site Investigator	Investigator's Person PO-ID	Investigator's First Name	Investigator's Middle name	Investigator's Last Name	Investigator's Email
		Mary	A	Simpson	msimpson@mdanderson.org
		Brandy	S	White	bwhite@mdanderson.org
		Helen	T	Harold	hharold@mskcc.org
		Helen	T	Harold	hharold@mskcc.org
		Mary	A	Simpson	msimpson@mdanderson.org

26	27	28	29	30	31	32
Investigator's Phone	Investigator's Phone Extension	Investigator's Street Address	Investigator's Zip/Postal Code (US/Canada)	Investigator's City	Investigator's State/Province (US/Canada)	Investigator's Country
(713) 792-5410	235	1515 Holcombe Blvd	77030	Houston	TX	USA
(713) 792-5410	254	1515 Holcombe Blvd	77030	Houston	TX	USA
212-639-2000	3224	1275 York Avenue	10065	New York	NY	USA
212-639-2000-145	3224	1275 York Avenue	10065	New York	NY	USA
(713) 792-5410	235	1515 Holcombe Blvd	77030	Houston	TX	USA

33	34	35	36	37		38	
Investigator's TTY	Investigator's FAX	Investigator's URL	Investigator's Role in the study	Use investigator as site contact for the study	Site Contact Info	Contact type	Genetic Contact
			Principal Investigator	YES		Site-Specific	
			Sub-investigator	NO			
			Principal Investigator	NO		Site-Specific	
			Principal Investigator	NO		Study_specific	
			Principal Investigator	NO			

39	40	41	42		43	44	45	46
Title	Contact Email Address	Contact Phone	Contact Phone Extension	Personal Contact	Contact Person's PO-ID	Contact Person's First Name	Contact Person's Middle Name	Contact Person's Last Name
						Terry		Smith
Clinical Study Department	clinicalstudydept@mskcc.org	212-639-2000	123					

47	48	49	50	51	52	53	54	55
Contact Email	Contact Phone	Contact Phone Extension	Contact Person's Street Address	Contact Person's Zip/Postal Code (US/Canada)	Contact Person's City	Contact Person's State/Province (US/Canada)	Contact Person's Country	Contact Person's TTY
info@mskc	212-639-2000	4444	1275 York Avenue	10065	New York	NY	USA	

56	57			
Contact Person's FAX	Contact Person's URL		**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	3	2	4	5	6
Collaborator #	**Collaborator Organization PO-ID**	**Collaborator Name**	**Collaborator Street Address**	**Collaborator City**	**Collaborator State/Province (US/Canada)**
1		Publitek, Inc. dba Fotosearch	21155 Watertown Road	Waukesha	WI
2		AstraZeneca International	P.O. Box 15437	Wilmington	DE

7	8	9	10	11	12
Collaborator Zip/Postal code (US/Canada)	**Collaborator Country**	**Collaborator Email**	**Collaborator Phone**	**Collaborator Phone extension**	**Collaborator TTY**
53186-1898	USA	mailus@fotosearch.com	1-800-827-3920		
19850-5437	UK	info@astrazeneca-us.com	1 302 886 3000		

13	14	15
Collaborator FAX	**Collaborator URL**	**Collaborator role on the study**
262-717-0745	http://www.fotosearch.com	Laboratory
302 886 2972	www.astrazeneca-us.com	Agent Source