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

PONDENT OF ESTIMATED BURDEN

nated to average sixty (60) minutes for this questionnaire, including the
r and maintain the data needed, and complete and review the collection of
on is not required to respond to, a collection of information unless it

spect of this collection of information, including suggestions for reducing

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

CTRP Trial Registration Batch Upload Specification for Abl

About this Document

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

Template Instructions

The Template Instructions worksheet provides detailed instructions for preparin

Sample Trial Data

The Sample Trial Data worksheet provides an example of what a typical batch u

Note: A batch upload file must contain only one (1) worksheet (tab)

Batch Upload 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. Requirements differ for original updatec
4. Valid values. The system accepts only those values listed in this doc
5. Comments. Additional information that helps you to ensure success

State and Provence Codes

The State and Province Codes worksheet lists the 2- or 3-letter state/province/t

ɔreviated Trials

RP Trial Registration system, including the following:

g your data and uploading them to the system.

ɹpload file looks like.

l, and amended submissions.
ɔument.
ɜful upload of your data.

erritory codes for the United States, Canada, and Australia.

How to Subr

Before You Be

Contact the CTRO

Note: Once you ha

Main Steps fo

1 Prepare t
2 Email you

Note: CTRO staff v

To transfer trial ow

Preparing Tri

1 Ensure th

* Interv
* Abbr
* Upda
* 100 t

2 Prepare a

You mus

* List trial
* Do not
* Conform
* Identify
* If you pr
* If a trial
* If more
* List pers

Emailing You

Email your file as a

For detailed instruc
https://wiki.

nit Abbreviated Trial Data to the CTRP Trial Registration System

egin

at ncictro@mail.nih.gov to request approval for sending batch files to CTRP. Include your login name, firs
ave received approval, you do not have to request approval for subsequent batches.

r Uploading Your Data

he trial data file
ur files to the CTRO at ncictro@mail.nih.gov

will register your trials using your batch file data. As the trial submitter, the CTRO maintains trial ownership
nership email the CTRO with the first name, last name and email address of the person who will manage y

ial Data Files

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

ventional trials
eviated trials (Summary 4 Funding Sponsor Category is Industrial)
ates to abbreviated CTRP trials with the processing status "Accepted" and beyond
rials per data file

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

t adhere to the following requirements:
elements required for registration in the order specified in the Abbreviated Trial Data Spec tab in this spre
change the spelling of data elements or valid values. Changes to spelling or to the order of the trial elemen
n to the valid values guidelines when entering trial data. Valid values for each of the trial elements, where a
each trial uniquely. For example, append your cancer center unique trial identifier to the file name.
rovide an NCT number the primary purpose, phase, disease and intervention data are not required.
is identified as a duplicate to an existing trial, you can request to add your organization information to the
than one disease or intervention is included, list them on additional lines, one per line when adding local t
sons and organizations with PO-IDs.
Note: You can request a list of CTRP persons and organizations along with PO-IDs from the CTRO at
ncictro@mail.nih.gov.
IDs.

r Files

an attachment to the CTRO at ncictro@mail.nih.gov.

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

ames, and email address stored in your CTRP profile.

red trials. The new owner must be a registered CTRP account holder.

e the upload to fail. Similarly, the addition of new/extra trial elements will also cause a failure.
are listed under Column D in the Abbreviated Trial Data Spec tab in this spreadsheet.

l as a participating site using the same template or create a separate request using the Partic
r to the first column (see Sample Trial Data tab).

:ipating Sites Template for abbreviated trials and email it to the CTRO at ncictro@mail.nih.gov

v.

Local Trial Identifier	Submission Type	NCI Trial Identifier	[Submitting Organization] Organization PO-ID	[Submitting Organization] Name	[Submitting Organization] Street Address	[Submitting Organization] City
1	O			Mayo Clinic Hospital	5777 East Mayo Boulevard	Phoeniz
1						

[Submitting Organization] State/Province	[Submitting Organization] Zip/Postal code	[Submitting Organization] Country	[Submitting Organization] Email Address	[Submitting Organization] Phone	[Submitting Organization] TTY	[Submitting Organization] FAX
AZ	85054	United States	ncictepcoppaservices@mail.nih.gov			

[Submitting Organization] URL	[Submitting Organization] Organization Type	Is Submitting Organization a NCI Designated Cancer Center?	[Lead Organization] CTEP Organization PO-ID	[Lead Organization] Name	[Lead Organization] Street Address	[Lead Organization] City
	Research Based	Yes	12345			

[Lead Organization] State/Province	[Lead Organization] Zip/Postal code	[Lead Organization] Country	[Lead Organization] Email Address	[Lead Organization] Phone	[Lead Organization] TTY	[Lead Organization] FAX

[Lead Organization] URL	[Lead Organization] Organization Type	Lead Organization Trial Identifier	NCT Trial Identifier	Title	Trial Type	Primary Purpose	If Primary Purpose is 'Other', describe
	cancer center			Phase III study of priming with granulocyte-macrophage colony stimulatin	Interventional	Other	Laboratory

Phase	Pilot Trial?	[Site Principal Investigator] Person PO-ID	[Site Principal Investigator] First Name	[Site Principal Investigator] Middle Name	[Site Principal Investigator] Last Name
III			Harry		Long

[Site Principal Investigator] Street Address	[Site Principal Investigator] City	[Site Principal Investigator] State/Province	[Site Principal Investigator] Zip/Postal code	[Site Principal Investigator] Country
5777 East Mayo Boulevard	Phoeniz	AZ	85054	United States

[Site Principal Investigator] Email Address	[Site Principal Investigator] Phone	[Site Principal Investigator] TTY	Site [Principal Investigator] FAX	[Site Principal Investigator] URL
Harry.Long@mayo	123-345-7654			

Summary 4 Funding Sponsor/Source Category	[Summary 4 Funding Sponsor/Source] Organization PO-ID	[Summary 4 Funding Sponsor/Source] Organization Name	[Summary 4 Funding Sponsor/Source] Street Address	[Summary 4 Funding Sponsor/Source] City	[Summary 4 Funding Sponsor/Source] State/Province
Industrial		Novartis Pharmaceuticals Corporation	One Health Plaza	East Hanover	NJ

[Summary 4 Funding Sponsor/Source] Zip/Postal code	[Summary 4 Funding Sponsor/Source] Country	[Summary 4 Funding Sponsor/Source] Email Address	[Summary 4 Funding Sponsor/Source] Phone	[Summary 4 Funding Sponsor/Source] TTY	[Summary 4 Funding Sponsor/Source] FAX
07936-1080	United States	ncictepcoppaservices@mail.nih.gov			

[Summary 4 Funding Sponsor/Source] URL	[Submitting Site specific] Program Code	Site Recruitment Status	Site Recruitment Status Date	Date Opened for Accrual	Date Closed for Accrual	Site Target Accrual	Disease Name
		Active	03/01/2009	03/01/2009		50	acute non-lymphocytic leukemia
							stage III non-lymphocytic leukemia

Intervention Type	Intervention Name	Trial Owner First Name	Trial Owner Last Name	Trial Owner Email Address		
Biological /Vaccine	granulocyte-macrophage colony stimulating factor	Mary	Smith	m.smith@		

Trial elements Order	Trial data element	Required?
1	Local Trial Identifier	Yes
2	Submission Type	Yes
3	NCI Trial Identifier	Yes for submitting update only
4	[Submitting Organization] Organization PO-ID	
5	[Submitting Organization] Name	Yes if PO-ID is not provided
6	[Submitting Organization] Street Address	Yes if PO-ID is not provided
7	[Submitting Organization] City	Yes if PO-ID is not provided
8	[Submitting Organization] State/Province	Yes for US/Canada/Australia and if PO-ID is not provided
9	[Submitting Organization] Zip/Postal code	Yes if PO-ID is not provided
10	[Submitting Organization] Country	Yes if PO-ID is not provided
11	[Submitting Organization] Email Address	Yes if PO-ID is not provided
12	[Submitting Organization] Phone	
13	[Submitting Organization] TTY	
14	[Submitting Organization] FAX	
15	[Submitting Organization] URL	
16	[Submitting Organization] Organization Type	
17	Is Submitting Organization a NCI Designated Cancer Center?	Yes
18	[Lead Organization] CTEP Organization PO-ID	
19	[Lead Organization] Name	Yes if PO-ID is not provided

20	[Lead Organization] Street Address	Yes if PO-ID is not provided
21	[Lead Organization] City	Yes if PO-ID is not provided
22	[Lead Organization] State/Province	Yes for US/Canada/Australia and if PO-ID is not provided
23	[Lead Organization] Zip/Postal code	Yes if PO-ID is not provided
24	[Lead Organization] Country	Yes if PO-ID is not provided
25	[Lead Organization] Email Address	Yes if PO-ID is not provided
26	[Lead Organization] Phone	Yes if PO-ID is not provided
27	[Lead Organization] TTY	
28	[Lead Organization] FAX	
29	[Lead Organization] URL	
30	[Lead Organization] Organization Type	
31	Lead Organization Trial Identifier	Yes
32	NCT Trial Identifier	
33	Title	Yes
34	Trial Type	Yes
35	Primary Purpose	Yes, if NCT number is not provided
36	If Primary Purpose is 'Other', describe	Yes, if Primary Purpose value is 'Other'

37	Phase	Yes, if NCT number is not provided
38	Pilot Trial?	
39	[Site Principal Investigator] Person PO-ID	
40	[Site Principal Investigator] First Name	Yes if PO-ID is not provided
41	[Site Principal Investigator] Middle Name	
42	[Site Principal Investigator] Last Name	Yes if PO-ID is not provided
43	[Site Principal Investigator] Street Address	Yes if PO-ID is not provided
44	[Site Principal Investigator] City	Yes if PO-ID is not provided
45	[Site Principal Investigator] State/Province	Yes for US/Canada/Australia and if PO-ID is not provided
46	[Site Principal Investigator] Zip/Postal code	Yes if PO-ID is not provided
47	[Site Principal Investigator] Country	Yes if PO-ID is not provided
48	[Site Principal Investigator] Email Address	Yes if PO-ID is not provided
49	[Site Principal Investigator] Phone	Yes if PO-ID is not provided
50	[Site Principal Investigator] TTY	
51	Site [Principal Investigator] FAX	
52	[Site Principal Investigator] URL	
53	Summary 4 Funding Sponsor/Source Category	Yes
54	[Summary 4 Funding Sponsor/Source] Organization PO-ID	PO-ID or the rest of mandatory attribute for the organization is mandatory
55	[Summary 4 Funding Sponsor/Source] Organization Name	Yes if PO-ID is not provided
56	[Summary 4 Funding Sponsor/Source] Street Address	Yes if PO-ID is not provided

57	[Summary 4 Funding Sponsor/Source] City	Yes if PO-ID is not provided
58	[Summary 4 Funding Sponsor/Source] State/Province	Yes if PO-ID is not provided and for the following courtiers: USA, Canada and Australia
59	[Summary 4 Funding Sponsor/Source] Zip/Postal code	Yes if PO-ID is not provided
60	[Summary 4 Funding Sponsor/Source] Country	Yes if PO-ID is not provided
61	[Summary 4 Funding Sponsor/Source] Email Address	Yes if PO-ID is not provided
62	[Summary 4 Funding Sponsor/Source] Phone	
63	[Summary 4 Funding Sponsor/Source] TTY	
64	[Summary 4 Funding Sponsor/Source] FAX	
65	[Summary 4 Funding Sponsor/Source] URL	
66	[Submitting Site specific] Program Code	Yes for NCI designated cancer center
67	Site Recruitment Status	Yes
68	Site Recruitment Status Date	Yes
69	Date Opened for Accrual	Yes if study is or was opened for accrual
70	Date Closed for Accrual	Yes if study is or was closed for accrual
71	Site Target Accrual	Yes for NCI designated Cancer Center
72	Disease Name	Yes if NCT number is not provided
73	Intervention Type	Yes if NCT number is not provided

74	Intervention Name	Yes if NCT number is not provided
75	Trial Owner First Name	Yes
76	Trial Owner Last Name	Yes
77	Trial Owner Email Address	Yes

Valid Values	Comments	Definition
	Trial identifier as assigned by the submitting organization	
O, U	O- Original is default. U- update	Original submission is the first time submission of a trial to CTRP. Update means submitting an update to the already registered trial in CTRP.
	Ignored in case of original submission	
	PO-ID or all organization mandatory 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		
yes, no	no is default	
	PO-ID or all organization mandatory attributes is 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		
	AS IS in the protocol document & assigned by the lead organization	
	This value or at least one disease and one intervention record are required in attached proprietary trial template	
Max 4000 characters	Title from the protocol document	
Interventional, Observational	Currently only Interventional trials are accepted	
Treatment, Prevention, Supportive Care, Screening, Diagnostic, Health Service Research, Basic Science, Other	Mandatory if value in row 32 is NULL (if NCT number is NULL)	
	Provide free text value if Primary Purpose value is 'Other'. Not aplicable if Primary Purpose is not 'Other'	

0, I, I/II, II, II/III, III, IV, N/A	Mandatory if value in row 32 is NULL (if NCT number is NULL)	
Yes, No	Only applicable if Phase is 'N/A; Default is No	
	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		
	Include Phone Extension if any in the same field	
Industrial		

2-letter state/province code required for US/Canada, 2-3 letter code required for Australia		
Submitting Site specific	Submitting Site specific, 'Not specified' is default. Mandatory if value in row 17 is 'yes'.	
Not yet recruiting; Recruiting; Enrolling by invitation; Active, not recruiting; Completed; Suspended; Terminated; Withdrawn		
	Date when the recruitment status has come in effect	
	Mandatory if value in row 17 is 'yes'. '0' can be used if value is unknown	
	If more that one disease is provided, use the additional line for a new disease (see Trial Data Sample)	
Drug, Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Other	If more that one intervention is provided, use the additional line for an additional intervention (see Trial Data Sample)	

	If more that one intervention is provided, use the additional line for an additional intervention (see Trial Data Sample)	
	This information is required for trial ownership transfer. Note: user must be registered in CTRP	
	This information is required for trial ownership transfer. Note: user must be registered in CTRP	
	This information is required for trial ownership transfer. Note: user must be registered in CTRP	

Country	Country 3-letter code	State/Province
UNITED STATES	USA	
		Alabama
		Alaska
		Arizona
		Arkansas
		California
		Colorado
		Connecticut
		Delaware
		Florida
		Georgia
		Hawaii
		Idaho
		Illinois
		Indiana
		Iowa
		Kansas
		Kentucky
		Louisiana
		Maine
		Maryland
		Massachusetts
		Michigan
		Minnesota
		Mississippi
		Missouri
		Montana
		Nebraska
		Nevada
		New Hampshire
		New Jersey
		New Mexico
		New York
		North Carolina
		North Dakota
		Ohio
		Oklahoma
		Oregon
		Pennsylvania
		Rhode Island
		South Carolina
		South Dakota
		Tennessee
		Texas
		Utah
		Vermont
		Virginia
		Washington
		West Virginia

		Wisconsin
		Wyoming
CANADA	CAN	
		Alberta
		British Columbia
		Manitoba
		New Brunswick
		Newfoundland and Labrador
		Northwest Territories
		Nova Scotia
		Nunavut
		Ontario
		Prince Edward Island
		Quebec
		Saskatchewan
		Yukon
AUSTRIA	AUT	
		Australian Capital Territory
		New South Wales
		Northern Territory
		Queensland
		South Australia
		Tasmania
		Victoria
		Western Australia

2-3 letter state/province code	Old values
AL	
AK	
AZ	
AR	
CA	
CO	
CT	
DE	
FL	
GA	
HI	
ID	
IL	
IN	
IA	
KS	
KY	
LA	
ME	
MD	
MA	
MI	
MN	
MS	
MO	
MT	
NE	
NV	
NH	
NJ	
NM	
NY	
NC	
ND	
OH	
OK	
OR	
PA	
RI	
SC	
SD	
TN	
TX	
UT	
VT	
VA	
WA	
WV	

WI
WY

AB
BC
MB
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NL
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NS
NU
ON
PE
QC
SK
YT

ACT
NSW
NT
QLD
SA
TAS
VIC
WA