NOTIFICATION TO RESPOI

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

NDENT OF ESTIMATED BURDEN

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

ct of this collection of information, including suggestions for reducing

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

CTRP Trial Registration Batch Upload Specificatio

About this Document

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

Template Instructions

The Template Instructions worksheet provides detailed instructions for preparing y

Sample Trial Data

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

Note: The worksheet that contains your trial data MUST always be the FIRST work

Trial Data Pick List

The *Trial Data Pick List* worksheet contains sets of valid values for many of the dat
The values are displayed in pick lists when you select an appropriate data element
The pick lists have been provided to assist you in filling out these cells quickly and
However, if you prefer, you can type the values instead.

Note: The drop-down lists will not work if you delete this worksheet.

Trial Data Element Specifications

The specifications worksheet includes the following information:

1 Data elements
2 Order in which the data elements *must be* presented. The element orde
3 Data element requirements. Requirements differ for original, updated, a
4 Valid values. The system accepts only those values listed in this docum
5 Comments. Additional information that helps you to ensure successful

NIH and NCI Values

The NIH & NCI Values worksheet provides all acceptable values for the following d

1 Funding Mechanisms
2 Institute Codes
3 NCI Division/Program Codes
4 NIH Institute Codes

NCI Code Definitions

The NCI Division/Program Code Definitions worksheet lists the long form of each c

Country Codes

The Country Codes worksheet lists the 3-letter country codes for all countries that

State and Province Codes

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

Oversight Authorities

The Oversight Authorities worksheet lists the names of oversight authorities for all

ɔn for Complete Trials

ıe CTRP Trial Registration system, including the following:

ɔur data and uploading them to the system.

ɔad file looks like.
ksheet (tab) in the file.

:a elements in the *(Sample) Trial Data* worksheet.
: cell.
accurately.

er is set up for you in columns in the *Sample Trial Data* tab.
ınd amended submissions.
ıent.
upload of your data.

lata elements:

f the division/program acronyms.

submit clinical trial data to the CTRP system.

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

countries that submit clinical trial data to the CTRP system.

How to Up

Before You

Contact the CTRO
Note: Once you ha

Main Steps f

1 Prepare t
2 Prepare t
3 Upload y

Preparing T

1 Ensure th

* Interv
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* Upda
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* Multi
* Multi
* Gene
* Multi
* Two
* Two

2 Create a

3 Copy the
Most cell

4 Delete th

5 Click the
Arrows a
5a. If arrc
5b. If no a

You mus
* List trial
* Do not c
* Conforn
* Identify

6 Delete th

Preparing T

1 Prepare a
2 To avoid
For exam
If using tr
3 Provide tl
4 Zip all tria
The trial c

Note: Sor

Uploading Y

1 Open yo
2 Follow th
https://wil

oload Clinical Trial Data to the CTRP Trial Registration S

Begin

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 uploads.

for Uploading Your Data

he trial data file.
he trial documents Zip file.
our files to the CTRP system via the NCI Trial Registration application batch upload web page at https://tria

rial Data Files

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

ventional trials
plete (Summary 4 Funding Sponsor Category is 'National', 'Externally Peer-Reviewed' or 'Institutional') trial
ndments to complete CTRP trials with "Abstraction Verified Response" or "Abstraction Verified No Respons
ates to complete CTRP trials with the processing status "Accepted" and beyond
rials per data file
ple grants per submitted trial
ple IND/IDE per submitted trial
eric contacts for Responsible Party or Sponsor
ple "Other" trial identifiers
options for data submission: a) when the XML file for trial submission to ClinicalTrials.gov is required, and
options for providing person and organization-related information: a) PO-ID for the person or organization,

Note: You can request a list of CTRP persons and organizations along with PO-IDs from the CTRO at ncictro@mail.nih.gov.
Or, you can use the search organization/person feature in the CTRP Trial Registration application to asce
IDs.

new Excel spreadsheet (.xls) that will contain the mandatory and optional data for the trial(s) as specified i

Sample Trial Data and *Trial Data Pick List* tabs to your new spreadsheet.
s on the *Sample Trial Data* tab for which there are a defined set of valid values have drop-down lists. Thes

e sample data from the *Sample Trial Data* tab in your new spreadsheet. Optionally, you can rename the ta

cell in which you want to enter data.
ure displayed whenever a drop-down list is available.
ows are displayed next to the cell, click the arrow and select the approprate value from the drop-down list.
arrows are displayed, enter the appropriate information using the valid values in this template.

st adhere to the following requirements:
elements required for registration in the order specified in the *Trial Data Element Spec* tab in this spreads
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.

e *Trial Data Pick List* worksheet from your new file.

rial Document Zip Files

a separate Zip file containing applicable trial documents (e.g. Protocol, IRB approval, Informed Consent, Pa
overwriting existing files when the system extracts your latest upload, rename the document files if they ar
nple, prefix files with a unique trial identifier such as XXXX_document name.doc.
ial identification prefixes, ensure that each of a given trial's document file names is unique.
he document names (including their extensions) in the file containing the trial data. Up to seven (7) files ca
al-related documents. Do not include pathnames in the Zip files.
document Zip file that you intend to upload **MUST NOT** include folders or other Zip files. All trial-related do

me elements will be ignored when updating existing CTRP trials via batch upload.

our Files

ur browser and navigate to the NCI Trial Registration application batch upload web page at https://trials.nc
e intstructions provided on the the Batch Trial Upload web page, or consult the user guide at:
ki.nci.nih.gov/x/7qViAw

ames, and email address stored in your CTRP profile.

ov/registry/admin/batchUpload.action.

on
ing statuses

XML file is not required.
set of mandatory attributes for person or organization

nent.

to select valid values from a list. The sets of valid values for these drop-down lists are derive

e the upload to fail. Similarly, the addition of new/extra trial elements will also cause a failure.
are listed in the *Trial Data Element Spec* or other vaiid value tabs in this spreadsheet.

Sites, Change Memo) for the trials in the data file.
e. For detailed instructions and best practices for file preparation, refer to the CTRP Registrat

ed in one single trial record

ust be Word documents (.doc) or Adobe PDFs (.pdf). No other file types are currently accepte

gistry/admin/batchUpload.action.

d from *Trial Data Pick List* worksheet.

ion Site User Guide at https://wiki.nci.nih.gov/display/CTRP/Trial+Document+Preparation+for

ed.

+Batch+Uploads.

	A	B	C	D	E	F
1	Unique Trial Identifier	Submission Type	NCI Trial Identifier	ClinicalTrials.gov XML Required?	Amendment Number	Amendment Date
2	10	O		Yes		
3	1000	A	NCI-2009-00001	Yes	A1	39938
4	2001	O		Yes		
5	3000	O		No		
6	4000	O		Yes		
7	5000	U	NCI-2009-00001			

	G	H	I	J	K
1	Lead Organization Trial Identifier	NCT	Other Trial Identifier	Title	Trial Type
2	53112	NCT000123	123;123-A	A Phase I study of Taxol in refractory leukemia in children	Interventional
3	1234	NCT00045		Phase III Study of Zoladex Adjuvant to Radiotherapy in Unfavorable Prognosis Carcinoma of the Prostate	Interventional
4	12345			A Phase I trial of Ifosfamide and Taxol in refractory Pelvic Malignancies	Interventional
5	65432			Phase III study of priming with granulocyte-macrophage colony stimulating factor (rhu-gm-csf)and of three induction regimens in adult patients (over 55) with acute non-lymphocytic leukemia	Interventional
6	1233			Phase III Comparison of Methotrexate, Vinblastine, Doxorubicin, and Cisplatin (MVAC) vs. Doxorubicin and Cisplatin (AC) in Women with Advanced Primary or Recurrent Metastatic Carcinoma of the Uterine Endometrium	Interventional
7	12308	NCT009876	321-12	An Open-Labeled, Non-Randomized Phase I Study of Alvocidib (Flavopiridol) Administered with Oxaliplatin and Fluorouracil/Leucovorin in Patients with Advanced Solid Tumors	Interventional

	L	M	N	O	P	Q
1	Primary Purpose	[Primary Purpose] Additional Qualifier	[Primary Purpose] Other Text	Phase	Pilot Trial?	[Sponsor] Organization PO-ID
2	Treatment			I		
3	Treatment			III		
4	Treatment			I		654512
5	Treatment			III		
6	Other	Other	Laboratory	NA	Yes	87654
7	Treatment			I		

	R	S	T	U
1	[Sponsor] Organization Name	[Sponsor] Street Address	[Sponsor] City	[Sponsor] State/Province
2	Children's Oncology Group	2115 E Jefferson St	Rockville	MD
3	Radiation Therapy Oncology Group	200 Water Street	New York	NY
4				
5				
6				
7				

	V	W	X	Y
1	[Sponsor] Zip/Postal code	[Sponsor] Country	[Sponsor] Email Address	[Sponsor] Phone
2	20185	USA	test@cog.org	222-444-8888
3	22102	USA	mailto@rtog.com	222-444-8888
4				
5				
6				
7				

	Z	AA	AB	AC	AD	AE
1	[Sponsor] TTY	[Sponsor] FAX	[Sponsor] URL	Responsible Party	Sponsor Contact Type	[Sponsor Contact] Title
2				PI		
3				Sponsor	Personal	
4				Sponsor	Generic	Clinical Study Department
5				PI	Personal	
6				Sponsor	Personal	
7				Sponsor	Generic	Director of Clinical Study Department

	AF	AG	AH	AI	AJ	AK
1	[Sponsor Contact] Person PO-ID	[Sponsor Contact] First Name	[Sponsor Contact] Middle Name	[Sponsor Contact] Last Name	[Sponsor Contact] Street Address	[Sponsor Contact] City
2						
3	23456					
4						
5						
6		Todd		Wright	400 Main St	Handerson
7						

	AL	AM	AN	AO	AP	AQ	AR
1	[Sponsor Contact] State/Province	[Sponsor Contact] Zip/Postal code	[Sponsor Contact] Country	[Sponsor Contact] Email Address	[Sponsor Contact] Phone	[Sponsor Contact] TTY	[Sponsor Contact] FAX
2							
3							
4				mailto@gog.(	240-345-4567		
5							
6	TN	20390	USA	twright@esoc	607-123-1234		
7				twright@esoc	607-123-1234		

	AS	AT	AU	AV	AW	AX
1	[Sponsor Contact] URL	[Lead Organization] Organization PO-ID	[Lead Organization] Name	[Lead Organization] Street Address	[Lead Organization] City	[Lead Organization] State/Province
2			Gynecologic Oncology Group	100 Main St	Fairfax	VA
3			Children's Oncology Group	2115 E Jefferson St	Rockville	MD
4			North Central Cancer Treatment Group	100 Meadow Rd	Hartford	CT
5		12345				
6			Children's Oncology Group	2115 E Jefferson St	Rockville	MD
7						

	AY	AZ	BA	BB	BC	BD
1	[Lead Organization] Zip/Postal code	[Lead Organization] Country	[Lead Organization] Email Address	[Lead Organization] Phone	[Lead Organization] TTY	[Lead Organization] FAX
2	22032	USA	test@cog.org	222-444-8888		
3	20185	USA	test@cog.org	222-444-8888		
4	33333	USA	test@cog.org	222-444-8888		
5						
6	20185	USA	test@cog.org	222-444-8888		
7						

	BE	BF	BG	BH	BI	BJ	BK
1	[Lead Organization] URL	[Lead Organization] Organization Type	[Principal Investigator] Person PO-ID	[Principal Investigator] First Name	[Principal Investigator] Middle Name	[Principal Investigator] Last Name	[Principal Investigator] Street Address
2		cooperative group	1234				
3		cooperative group		Miljenko	B	Pilepich	100 Village Hill Lane
4		cooperative group	87456				
5		cooperative group		Jacob	J	Rowe	100 Old Meadow Rd
6		cooperative group	45689				
7							

	BL	BM	BN	BO	BP	BQ	BR
1	[Principal Investigator] City	[Principal Investigator] State/Province	[Principal Investigator] Zip/Postal code	[Principal Investigator] Country	[Principal Investigator] Email Address	[Principal Investigator] Phone	[Principal Investigator] TTY
2							
3	Natick	MA	01760	USA	MPilepich@mednet.ucla.edu	111-111-1112	
4							
5	Houston	TX	33323	USA	rowe@rambam.health.gov.il	111-111-1114	
6							
7							

	BS	BT	BU	BV	BW	BX
1	[Principal Investigator] FAX	[Principal Investigator] URL	Summary 4 Funding Category	[Summary 4 Funding Sponsor/Source] Organization PO-ID	[Summary 4 Funding Sponsor/Source] Organization Name	[Summary 4 Funding Sponsor/Source] Street Address
2			Institutional		NCI	2115 E Jefferson
3			Institutional		NCI	2115 E Jefferson
4			Institutional		NCI	2115 E Jefferson
5			Institutional		NCI	2115 E Jefferson
6			Institutional		NCI	2115 E Jefferson
7			Institutional		NCI	2115 E Jefferson

	BY	BZ	CA	CB	CC	CD	CE
1	[Summary 4 Funding Sponsor/Source] City	[Summary 4 Funding Sponsor/Source] State/Province	[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
2	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	
3	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	
4	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	
5	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	
6	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	
7	Rockville	MD	20852	USA	mailto@ctrp.or	111-111-1111	

	CF	CG	CH	CI	CJ
1	[Summary 4 Funding Sponsor/Source] FAX	[Summary 4 Funding Sponsor/Source] URL	Program Code	[NIH Grant] Funding Mechanism	[NIH Grant] Institute Code
2				F34	AG
3					
4			IM	K08;CO6	HV;AO
5					
6					
7			BR		

	CK	CL	CM	CN	CO	CP	CQ
1	[NIH Grant] Serial Number	[NIH Grant] NCI Division/Program Code	Current Trial Status	Why Study Stopped?	Current Trial Status Date	Study Start Date	Study Start Date Type
2	72345	CTEP	Complete		8/1/2010	2/1/2009	Actual
3			Temporarily Closed to Accrual	Accrual target was reached for this phase of the study	8/2/2009	1/2/2009	Actual
4	97521;012345	CTEP;CTEP	In Review		8/3/2009	12/3/2010	Anticipated
5			Approved		8/4/2009	12/4/2010	Anticipated
6			Administratively Complete	Closed prematurely	8/5/2009	1/5/2009	Actual
7			Approved		8/1/2009	12/1/2010	Anticipated

	CR	CS	CT	CU	CV	CW	CX
1	Primary Completion Date	Primary Completion Date Type	IND/IDE Type	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	[IND/IDE] NIH Institution
2	08/01/10	Actual					
3	10/02/11	Anticipated					
4	10/3/2011	Anticipated					
5	9/4/2012	Anticipated					
6	8/5/2009	Actual	IND;IND	67899;10,264	CDER;CDER	NIH;NCI	NIA;NA
7	12/1/2011	Anticipated					

	CY	CZ	DA	DB	DC	DD	DE
1	[IND/IDE] NCI Division /Program	[IND/IDE] Has Expanded Access?	[IND/IDE] Expanded Access Status	[IND/IDE] Exempt Indicator	Oversight Authority Country	Oversight Authority Organization Name	FDA Regulatory Information Indicator
2					United States	Federal Government	No
3					United States	Federal Government	No
4					United States	Food and Drug Administratio n	Yes
5							
6	NA;DCP	No;Yes	NA;Approved for marketing	Yes;Yes	United States	Federal Government	No
7					United States	Federal Government	No

	DF	DG	DH	DI
1	Section 801 Indicator	Delayed Posting Indicator	Data Monitoring Committee Appointed Indicator	Protocol Document File Name
2			Yes	protocol_document_T10.doc
3			Yes	protocol_document_T1000.doc
4	Yes	No	Yes	protocol_document_T2001.doc
5				3000_protocol_document.doc
6			Yes	4000_protocol_document.doc
7			Yes	

	DJ	DK	DL	DM
1	IRB Approval Document File Name	Participating Sites Document File Name	Informed Consent Document File Name	Other Trial Related Document File Name
2	IRB_Approval.doc	Participating_Sites_T10.xls	10_Informed_Consent.PDF	10_Other_document.doc
3	IRB_Approval_06082007.doc	Participating_Sites_T1000_new.xls		
4	IRB_Approval_T2001.doc	Participating_Sites_T2001.xls	Informed_Consent_T2001.PDF	Other_document_T2001.doc
5	3000_IRB_Approval.doc	3000_Participating_Sites.xls	3000_Informed_Consent.PDF	3000_Other_document.doc
6	4000_IRB_Approval.doc	4000_Participating_Sites.xls	4000_Informed_Consent.PDF	4000_Other_document.doc
7				

	DN	DO
1	Change Memo Document Name	Protocol Highlight Document Name
2		
3	Change_memo_doc.doc	
4		
5		
6		
7		

Submission Type	Yes_No	Trial Type	Primary Purpose	Primary Purpose Additional Quali
A	No	Interventional	Basic Science	Other
O	Yes	Observational	Diagnostic	
U			Health Service Research	
			Other	
			Prevention	
			Screening	
			Supportive Care	
			Treatment	

Phase	Country Cod	State Code	Responsible Par	Sponsor Contact Ty
0	ABW	AK	PI	Personal
I	AFG	AL	Sponsor	Generic
I/II	AGO	AR		
II	AIA	AZ		
II/III	ALB	CA		
III	AND	CO		
IV	ANT	CT		
NA	ARE	DE		
	ARG	FL		
	ARM	GA		
	ASM	HI		
	ATA	IA		
	ATF	ID		
	ATG	IL		
	AUS	IN		
	AUT	KS		
	AZE	KY		
	BDI	LA		
	BEL	MA		
	BEN	MD		
	BFA	ME		
	BGD	MI		
	BGR	MN		
	BHR	MO		
	BHS	MS		
	BIH	MT		
	BLR	NC		
	BLZ	ND		
	BMU	NE		
	BOL	NH		
	BRA	NJ		
	BRB	NM		
	BRN	NV		
	BTN	NY		
	BVT	OH		
	BWA	OK		
	CAF	OR		
	CAN	PA		
	CCK	RI		
	CHE	SC		
	CHL	SD		
	CHN	TN		
	CIV	TX		
	CMR	UT		
	COG	VA		
	COK	VT		
	COL	WA		
	COM	WI		

CPV	WV
CRI	WY
CUB	AB
CXR	BC
CYM	MB
CYP	NB
CZE	NL
DEU	NS
DJI	NT
DMA	NU
DNK	ON
DOM	PE
DZA	QC
ECU	SK
EGY	YT
ERI	ACT
ESH	NSW
ESP	NT
EST	QLD
ETH	SA
FIN	TAS
FJI	VIC
FLK	WA
FRA	
FRO	
FSM	
FXX	
GAB	
GBR	
GEO	
GHA	
GIB	
GIN	
GLP	
GMB	
GNB	
GNQ	
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GUY	
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LUX
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MAR
MCO
MDA
MDG
MDV
MEX
MHL
MKD
MLI
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MMR
MNG
MNP
MOZ
MRT
MSR
MTQ
MUS

MWI
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MYT
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NCL
NER
NFK
NGA
NIC
NIU
NLD
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NZL
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PRY
PYF
QAT
REU
ROM
RUS
RWA
SAU
SDN
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SVK

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TJK
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TWN
TZA
UGA
UKR
UMI
URY
USA
UZB
VAT
VCT
VEN
VGB
VIR
VNM
VUT
WLF
WSM
YEM
YUG
ZAF
ZAR
ZMB
ZWE

Lead Organization Type	Summary 4 Funding Categ	NIH Grant Funding Mechanis
Institution	National	B01
ordering group	Externally	B08
repository	Peer-Reviewed	B09
research based	Institutional	C06
cooperative group		D43
cancer center		D71
consortium		DP1
drug company		DP2
network		DP3
		E11
		F05
		F30
		F31
		F32
		F33
		F34
		F37
		F38
		G07
		G08
		G11
		G12
		G13
		G20
		G94
		H13
		H23
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		H28
		H50
		H57
		H62
		H64
		H75
		H79
		HD4
		HR!
		I01
		K01
		K02
		K05
		K06
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K99
KD1
KL1
KL2
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L60
M01
N01
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N03
N43
N44
P01
P20
P30
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P41
P42
P50
P51
P60
P76
PL1
PN1
PN2
R00
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T42
T90
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TU2
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U90
UA1
UC1
UC2
UC3
UC6
UC7
UD1
UE1
UE2
UH1
UH2
UH3
UL1
UR1
UR3
UR6
UR8
US3
US4
UT1
UT2
VF1
X01
X02
X06
X98
Y01
Y02
Z01
Z02

NIH Grant Institute Cod	NCI Division/Program Code	Current Trial Status
AA	CCR	In Review
AE	CCT/CTB	Approved
AF	CTEP	Active
AG	DCB	Closed to Accrual
AI	DCCPS	Closed to Accrual and Intervention
AM	DCEG	Temporarily Closed to Accrual
AO	DTP	Temporarily Closed to Accrual and Interventi
AR	DCP	Complete
AT	DEA	Administratively Complete
BC	OD	Withdrawn
BX	OSB/SPOREs	
CA	CIP	
CB	CDP	
CD	TRP	
CE	RRP	
CH	N/A	
CI		
CK		
CL		
CM		
CN		
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CP		
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CU		
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Date Type	IND/IDE Type	IND/IDE Granto	IND/IDE Holder Typ
Actual	IND	CDER	Investigator
Anticipated	IDE	CBER	Organization
		CDRH	Industry
			NIH
			NCI

on

NIH Institution

NEI-National Eye Institute
NHLBI-National Heart, Lung, and Blood Institute
NHGRI-National Human Genome Research Institute
NIA-National Institute on Aging
NIAAA-National Institute on Alcohol Abuse and Alcoholism
NIAID-National Institute of Allergy and Infectious Diseases
NIAMS-National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB-National Institute of Biomedical Imaging and Bioengineering
NICHD-Eunice Kennedy Shriver National Institute of Child Health and Human Develop
NIDCD-National Institute on Deafness and Other Communication Disorders
NIDCR-National Institute of Dental and Craniofacial Research
NIDDK-National Institute of Diabetes and Digestive and Kidney Diseases
NIDA-National Institute on Drug Abuse
NIEHS-National Institute of Environmental Health Sciences
NIGMS-National Institute of General Medical Sciences
NIMH-National Institute of Mental Health
NINDS-National Institute of Neurological Disorders and Stroke
NINR-National Institute of Nursing Research
NLM-National Library of Medicine
CIT-Center for Information Technology
CSR-Center for Scientific Review
FIC-John E. Fogarty International Center for Advanced Study in the Health Sciences
NCCAM-National Center for Complementary and Alternative Medicine
NCMHD-National Center on Minority Health and Health Disparities
NCRR-National Center for Research Resources (NCRR
CC-NIH Clinical Center
OD-Office of the Director

IND/IDE Expanded Access Status

Available
No longer available
Temporarily not available
Approved for marketing

ıment

Trial elements Order	Trial data element	Required for original submission
1	Unique Trial Identifier	Yes
2	Submission Type	Yes
3	NCI Trial Identifier	
4	ClinicalTrials.gov XML Required?	Yes
5	Amendment Number	
6	Amendment Date	
7	Lead Organization Trial Identifier	Yes

8	NCT	
9	Other Trial Identifier	
10	Title	Yes
11	Trial Type	Yes
12	Primary Purpose	Yes
13	[Primary Purpose] Additional Qualifier	Yes if Primary Purpose is 'Other'
14	[Primary Purpose] Other Text	Yes if Primary Purpose is 'Other'
15	Phase	Yes
16	Pilot Trial?	
17	[Sponsor] Organization PO-ID	PO-ID or all mandatory organization attributes are not NULL AND if ‘ClinicalTrials.gov XML Required?”=’Yes’
18	[Sponsor] Organization Name	Yes if Sponsor’s PO-ID is NULL AND if ‘ClinicalTrials.gov XML Required?”=’Yes’
19	[Sponsor] Street Address	Yes if Sponsor’s PO-ID is NULL AND if ‘ClinicalTrials.gov XML Required?”=’Yes’
20	[Sponsor] City	Yes if Sponsor’s PO-ID is NULL AND if ‘ClinicalTrials.gov XML Required?”=’Yes’

21	[Sponsor] State/Province	Yes for US/Canada/Australia Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes' and for US/Canada/Australia
22	[Sponsor] Zip/Postal code	Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'
23	[Sponsor] Country	Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'
24	[Sponsor] Email Address	Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'
25	[Sponsor] Phone	
26	[Sponsor] TTY	
27	[Sponsor] FAX	
28	[Sponsor] URL	
29	Responsible Party	Yes if ClinicalTrials.gov XML Required? is set to 'Yes'
30	Sponsor Contact Type	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor
31	[Sponsor Contact] Title	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Generic'
32	[Sponsor Contact] Person PO-ID	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'. Sponsor's Contact PO-ID or all person-specific mandatory attributes must be provided
33	[Sponsor Contact] First Name	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor's Contact PO-ID is NULL
34	[Sponsor Contact] Middle Name	

35	[Sponsor Contact] Last Name	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL
36	[Sponsor Contact] Street Address	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL
37	[Sponsor Contact] City	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL
38	[Sponsor Contact] State/Province	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL and for USA, Canada or Australia
39	[Sponsor Contact] Zip/Postal code	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL
40	[Sponsor Contact] Country	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL
41	[Sponsor Contact] Email Address	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'
42	[Sponsor Contact] Phone	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'
43	[Sponsor Contact] TTY	
44	[Sponsor Contact] FAX	
45	[Sponsor Contact] URL	

46	[Lead Organization] Organization PO-ID	PO-ID or all mandatory organization specific attribute are required
47	[Lead Organization] Name	Yes if Lead Organization PO-ID is NULL
48	[Lead Organization] Street Address	Yes if Lead Organization PO-ID is NULL
49	[Lead Organization] City	Yes if Lead Organization PO-ID is NULL
50	[Lead Organization] State/Province	Yes for US/Canada/Australia and if Lead Organization PO-ID is NULL
51	[Lead Organization] Zip/Postal code	Yes if Lead Organization PO-ID is NULL
52	[Lead Organization] Country	Yes if Lead Organization PO-ID is NULL
53	[Lead Organization] Email Address	Yes if Lead Organization PO-ID is NULL
54	[Lead Organization] Phone	
55	[Lead Organization] TTY	
56	[Lead Organization] FAX	
57	[Lead Organization] URL	
58	[Lead Organization] Organization Type	
59	[Principal Investigator] Person PO-ID	PO-ID or all person-specific mandatory attributes
60	[Principal Investigator] First Name	Yes if Principal Investigator PO-ID is NULL
61	[Principal Investigator] Middle Name	
62	[Principal Investigator] Last Name	Yes if Principal Investigator PO-ID is NULL
63	[Principal Investigator] Street Address	Yes if Principal Investigator PO-ID is NULL
64	[Principal Investigator] City	Yes if Principal Investigator PO-ID is NULL
65	[Principal Investigator] State/Province	Yes for US/Canada/Australia and if Principal Investigator PO-ID is NULL

66	[Principal Investigator] Zip/Postal code	Yes if Principal Investigator PO-ID is NULL
67	[Principal Investigator] Country	Yes if Principal Investigator PO-ID is NULL
68	[Principal Investigator] Email Address	Yes if Principal Investigator PO-ID is NULL
69	[Principal Investigator] Phone	Yes if Principal Investigator PO-ID is NULL
70	[Principal Investigator] TTY	
71	[Principal Investigator] FAX	
72	[Principal Investigator] URL	
73	Summary 4 Funding Category	Yes
74	[Summary 4 Funding Sponsor/Source] Organization PO-ID	PO-ID or all mandatory organization specific attribute are required
75	[Summary 4 Funding Sponsor/Source] Organization Name	Yes if Organization PO-ID is NULL
76	[Summary 4 Funding Sponsor/Source] Street Address	Yes if Organization PO-ID is NULL
77	[Summary 4 Funding Sponsor/Source] City	Yes if Organization PO-ID is NULL
78	[Summary 4 Funding Sponsor/Source] State/Province	Yes if Organization PO-ID is NULL and for US/Canada/Australia
79	[Summary 4 Funding Sponsor/Source] Zip/Postal code	Yes if Organization PO-ID is NULL
80	[Summary 4 Funding Sponsor/Source] Country	Yes if Organization PO-ID is NULL
81	[Summary 4 Funding Sponsor/Source] Email Address	Yes if Organization PO-ID is NULL
82	[Summary 4 Funding Sponsor/Source] Phone	
83	[Summary 4 Funding Sponsor/Source] TTY	
84	[Summary 4 Funding Sponsor/Source] FAX	
85	[Summary 4 Funding Sponsor/Source] URL	
86	Program Code	

87	[NIH Grant] Funding Mechanism	Yes: if NIH grant exists
88	[NIH Grant] Institute Code	Yes: if NIH grant exists
89	[NIH Grant] Serial Number	Yes: if NIH grant exists
90	[NIH Grant] NCI Division/Program Code	Yes: if NIH grant exists
91	Current Trial Status	Yes
92	Why Study Stopped?	Yes if Current Trial Status is Withdrawn, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention or Administratively Complete
93	Current Trial Status Date	Yes
94	Study Start Date	Yes

95	Study Start Date Type	Yes
96	Primary Completion Date	Yes
97	Primary Completion Date Type	Yes
98	IND/IDE Type	Yes: if IND/IDE trial
99	IND/IDE Number	Yes: if IND/IDE trial
100	IND/IDE Grantor	Yes: if IND/IDE trial
101	IND/IDE Holder Type	Yes: if IND/IDE trial

102	[IND/IDE] NIH Institution	Yes If IND/IDE trial AND (IND/IDE Holder Type) = NIH
103	[IND/IDE] NCI Division /Program	Yes if IND/IDE trial AND If (IND/IDE Holder Type) = NCI
104	[IND/IDE] Has Expanded Access?	Yes if IND/IDE trial
105	[IND/IDE] Expanded Access Status	If (Has Expanded Access?) = Yes
106	[IND/IDE] Exempt Indicator	Yes
107	Oversight Authority Country	Yes if ClinicalTrials.gov XML Required? is set to 'Yes'
108	Oversight Authority Organization Name	Yes ClinicalTrials.gov XML Required? is set to 'Yes'
109	FDA Regulatory Information Indicator	Yes ClinicalTrials.gov XML Required? is set to 'Yes'
110	Section 801 Indicator	Yes if FDA Regulatory Information Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'
111	Delayed Posting Indicator	Yes if section 801 Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'
112	Data Monitoring Committee Appointed Indicator	
113	Protocol Document File Name	Yes

114	IRB Approval Document File Name	Yes
115	Participating Sites Document File Name	
116	Informed Consent Document File Name	
117	Other Trial Related Document File Name	
118	Change Memo Document Name	

119	Protocol Highlight Document Name	

Required for amendment	Required for update	Valid Values
Yes	Yes	
Yes	Yes	O, A, U
Yes	Yes	
Yes		Yes, No
Yes		
Yes		

Yes		Max 4000 characters
Yes	Yes	Interventional, Observational
Yes	Yes	Treatment, Prevention, Supportive Care, Screening, Diagnostic, Health Service Research, Basic Science, Other
Yes if Primary Purpose is 'Other'	Yes if Primary Purpose is 'Other'	Other
Yes if Primary Purpose is 'Other'	Yes if Primary Purpose is 'Other'	
Yes	Yes	0, I, I/II, II, II/III, III, IV, NA,
		Yes, No
PO-ID or all mandatory organization attributes are not NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		

Yes for US/Canada/Australia Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes' and for US/Canada/Australia		2-letter state/province code required for US/Canada, 2-3 letter code required for Australia
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		3-letter country code required
Yes if Sponsor's PO-ID is NULL AND if 'ClinicalTrials.gov XML Required?"='Yes'		
Yes if ClinicalTrials.gov XML Required? is set to 'Yes'		PI, Sponsor
Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party value is Sponsor	Personal, Generic
Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Generic'	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Generic'	
Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'. Sponsor's Contact PO-ID or all person-specific mandatory attributes must be provided	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'. Sponsor's Contact PO-ID or all person-specific mandatory attributes must be provided	
Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor's Contact PO-ID is NULL	Yes if 'ClinicalTrials.gov XML Required?"='Yes' and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor's Contact PO-ID is NULL	

Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL and for USA, Canada or Australia	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL and for USA, Canada or Australia	2-letter state/province code required for US/Canada, 2-3 letter code required for Australia
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal' and Sponsor’s Contact PO-ID is NULL	3-letter country code required
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'	
Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'	Yes if ‘ClinicalTrials.gov XML Required?”=’Yes’ and if Responsible Party is Sponsor and Sponsor Contact Type is 'Personal'	

PO-ID or all mandatory organization specific attribute are required		
Yes if Lead Organization PO-ID is NULL		
Yes if Lead Organization PO-ID is NULL		
Yes if Lead Organization PO-ID is NULL		
Yes for US/Canada/Australia and if Lead Organization PO-ID is NULL		2-letter state/province code required for US/Canada, 2-3 letter code required for Australia
Yes if Lead Organization PO-ID is NULL		
Yes if Lead Organization PO-ID is NULL		3-letter country code required
Yes if Lead Organization PO-ID is NULL		
		Institution, ordering group, repository, research based,
PO-ID or all person-specific mandatory attributes		
Yes if Principal Investigator PO-ID is NULL		
Yes if Principal Investigator PO-ID is NULL		
Yes if Principal Investigator PO-ID is NULL		
Yes if Principal Investigator PO-ID is NULL		
Yes for US/Canada/Australia and if Principal Investigator PO-ID is NULL		2-letter state/province code required for US/Canada, 2-3 letter code required for Australia

Yes if Principal Investigator PO-ID is NULL		
Yes if Principal Investigator PO-ID is NULL		3-letter country code required
Yes if Principal Investigator PO-ID is NULL		
Yes if Principal Investigator PO-ID is NULL		
Yes	Yes	National, Externally Peer-Reviewed, Institutional
PO-ID or all mandatory organization specific attribute are required	PO-ID or all mandatory organization specific attribute are required	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	
Yes if Organization PO-ID is NULL and for US/Canada/Australia	Yes if Organization PO-ID is NULL and for US/Canada/Australia	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	
Yes if Organization PO-ID is NULL	Yes if Organization PO-ID is NULL	

Yes: if NIH grant exists	Yes: if NIH grant exists	Refer Funding Mechanism in Valid Values worksheet.
Yes: if NIH grant exists	Yes: if NIH grant exists	Refer Institute Code in Valid Values worksheet.
Yes: if NIH grant exists	Yes: if NIH grant exists	format: 5 or 6 digits
Yes: if NIH grant exists	Yes: if NIH grant exists	Refer NCI Division/Program Code in Valid Values worksheet. Specify only the code.
Yes	Yes	In Review, Approved, Active, Closed to Accrual, Closed to Accrual and Intervention , Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Complete, Administratively Complete are
Yes if Current Trial Status is Withdrawn, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention or Administratively Complete	Yes if Current Trial Status is Withdrawn, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention or Administratively Complete	
Yes	Yes	
Yes	Yes	

Yes	Yes	Actual, Anticipated
Yes	Yes	
Yes	Yes	Actual, Anticipated
Yes: if IND/IDE trial	Yes: if IND/IDE trial	IND, IDE
Yes: if IND/IDE trial	Yes: if IND/IDE trial	
Yes: if IND/IDE trial	Yes: if IND/IDE trial	CDER, CBER, CDRH
Yes: if IND/IDE trial	Yes: if IND/IDE trial	Investigator, Organization, Industry, NIH, NCI

Yes If IND/IDE trial AND (IND/IDE Holder Type) = NIH	Yes If IND/IDE trial AND (IND/IDE Holder Type) = NIH	Refer NIH Institution in Valid Values worksheet.
Yes if IND/IDE trial AND If (IND/IDE Holder Type) = NCI	Yes if IND/IDE trial AND If (IND/IDE Holder Type) = NCI	Refer NCI Division/Program Code in Valid Values worksheet.
Yes if IND/IDE trial	Yes if IND/IDE trial	Yes, No
If (Has Expanded Access?) = Yes	If (Has Expanded Access?) = Yes	Available, No longer available, Temporarily not available, Approved for marketing
		Yes, No
Yes if ClinicalTrials.gov XML Required? is set to 'Yes'	Yes if ClinicalTrials.gov XML Required? is set to 'Yes'	see Oversight Authority tab
Yes ClinicalTrials.gov XML Required? is set to 'Yes'	Yes ClinicalTrials.gov XML Required? is set to 'Yes'	see Oversight Authority tab
Yes ClinicalTrials.gov XML Required? is set to 'Yes'	Yes ClinicalTrials.gov XML Required? is set to 'Yes'	Yes, No
Yes if FDA Regulatory Information Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'	Yes if FDA Regulatory Information Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'	Yes, No
Yes if section 801 Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'	Yes if section 801 Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'	Yes, No
		Yes, No
Yes		

Yes		
Yes		

Comments
O - original submission (including the first submission to CTRP); A - amendment submission to the already published trial in CTRP; U - update to the CTRP trial. Amendment submission can be accepted only if the trial processing status is 'Abstraction Verified Response' or 'Abstraction Verified No Response'. Update can be submitted for trials that have been accepted or have processing status other than 'Submitted' and 'Rejected'. See Processing Status Transition tab for information about trial processing statuses
This element is applicable to amendment submission and update to the CTRP trials only. This is the trial identifier assigned by the CTRP. Amendment can only be accepted for trials that have 'Abstraction Verified Response' or 'Abstraction Verified No Response' processing status in CTRP. Update can be submitted for trials that have 'Accepted' status and above.
Indicates whether XML generation for trial submitting in ClinicalTrials.gov is required. If Indicator is assigned to 'No', responsible Party information and Regulatory Information is not required (will be ignored if provided). This value is ignored in update submission
This element is applicable to amendment submission only. Use amendment number that is recorded in user's system.
This element is applicable to amendment submission only. Use date of amendment as documented in the amended protocol document . Format mm/dd/yyyy.
AS IS in the protocol document & assigned by the lead organization (unique in the lead organization system)

Unique identifier assigned to the published trials in PRS (ClinicalTrials.gov)
If more than one exists, provide them in one column separated with semicolon (;)
Title from the protocol document
Currently only Interventional trials are accepted
Use value 'Other' if Primary Purpose value is 'Other' (this applies to interventional trials only)
Provide description if Primary Purpose is 'Other' (col 13)
Will be recorded only if Phase value is NA. Default: No

Include Phone Extension if any in the same field. Use XXX-XXX-XXXX format for USA and Canada
Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Used for defining contact type for the Responsible Party Sponsor (see 27)
Applicable to the Responsible Party=Sponsor Generic Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only

Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Applicable to the Responsible Party=Sponsor Personal Contact only
Include Phone Extension if any in the same field. Use XXX-XXX-XXXX format for USA and Canada

Include Phone Extension if any in the same field. Use XXX-XXX-XXXX format for USA and Canada

Include Phone Extension if any in the same field. Use XXX-XXX-XXXX format for USA and Canada
Provide PO-ID or all organization related mandatory attributes
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Provide if PO-ID is NULL
Include Phone Extension if any in the same field. Use XXX-XXX-XXXX format for USA and Canada
Summary 4 element, no LOV exists, codes are specific to cancer centers

If more than one grant is recorded provide this value for all grants separated by semicolon (;)
If more than one grant is recorded provide this value for all grants separated by semicolon (;)
If more than one grant is recorded provide this value for all grants separated by semicolon (;)
Defaults to N/A if not specified. If more than one grant is recorded provide this value for all grants separated by semicolon (;)
1) Trials with current trial status 'Withdrawn' are not accepted for the original submission. 2) Submission of amendment or update to existing study with Completed, Administratively Completed, Withdrawn and Disapproved current trial status are not accepted. 3)
Mandatory if Current Trial Status is Withdrawn, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention or Administratively Complete
Date when the status has came in effect. Format: mm/dd/yyyy
Date that enrollment to the protocol begins. Format: mm/dd/yyyy

Only current/past date (in respect to batch upload date) is accepted for actual type and only future date is accepted for anticipated type. 'Anticipated' type is valid for 'In Review' and 'Approved' and 'Withdrawn' current trial status only. 'Actual' type is valid for any other current trial status besides 'In Review', 'Approved' and 'Withdrawn'. For more information check State-Dates tab in this file.
Date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. Format: mm/dd/yyyy
Only current/past date (in respect to batch upload date) is accepted for actual type and only future date is accepted for anticipated type. 'Actual' type is valid for 'Administratively Complete' or 'Complete' current trial statuses only. 'Anticipated' type is valid for any other current trial status besides 'Administratively Complete' or 'Complete'. For more information check State-Dates tab in this file.
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;).
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;)
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;)
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;)

If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;). If NIH institution is not applicable to a single IND/IDE, provide NA as replacement for the value
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;). If NCI division/program is not applicable to a single IND/IDE, provide NA as replacement for the value
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;).
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;). If expanded access is not applicable to a single IND/IDE, provide NA as replacement for the value
If more than one IND/IDE is recorded provide this value for all IND/IDE separated by semicolon (;). Default: 'No'
Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Must be 'Yes; if trial includes IND/IDE. Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Must be not NULL if FDA Regulatory Information Indicator is 'Yes'. Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Must be not NULL if section 801 Indicator is 'Yes'. Delayed Posting Indicator is applicable only to study that includes device intervention. Ignored if ClinicalTrials.gov XML Required? is set to 'No'
Ignored if ClinicalTrials.gov XML Required? is set to 'No'
1) Include file extension. 2) If you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name). 3) Submit amended protocol for amendment submission.

1) Include file extension. 2) if you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name). 3) Submit dummy file if IRB approval is not required with the statement 'IRB' approval is not required'. 4) Submit dummy file with the following info: name of Review Board (address, phone, email) and Board Affiliation name in case of pre-IRB approved studies submission. 5) One IRB Approval is only needed.
1) Include file extension. 2) f you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name). 3) Requited if case of multi-site trial and if the participation sites information is not included in the protocol document. 4) If participating site changes (recruitment status, program code) or collaborator's info change occur, submit this document for amendment or update
1) Requited if is not included in the protocol document.2) Include file extension. 3) f you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name).
1) Include file extension. 2) f you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name).
1) This element is applicable to the amendment only and includes the changes that occurred in the protocol document due to amendment. 2) Include file extension. 3) f you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name).

1) This element is applicable to the amendment only and includes the protocol document with highlighted changes from the previous version. 2) Include file extension. 3) f you have at least two files with the same name, rename files (ex. prefix unique trial identifier to document name).

NOTE: These are the valid values for the data elements. Although they are presented in ve

Funding Mechanism	Institute Code	NCI Division/Program Code
B01	AA	CCR
B08	AE	CTEP
B09	AF	CIP
C06	AG	CDP
DP1	AI	CCT/CTB
DP2	AM	DCB
DP3	AO	DCCPS
D43	AR	DCEG
D71	AT	DTP
E11	BC	DCP
F05	BX	DEA
F30	CA	OD
F31	CB	OSB/SPOREs
F32	CD	TRP
F33	CE	RRP
F34	CH	N/A
F37	CI	
F38	CK	
G07	CL	
G08	CM	
G11	CN	
G12	CO	
G13	CP	
G20	CR	

G94	CT
HD4	CU
HR!	CX
	DA
H13	DC
H23	DD
H25	DE
H28	DK
H50	DP
H57	EB
H62	EH
H64	EM
H75	EP
H79	ES
I01	EY
KD1	FD
KL1	GD
KL2	GH
K01	GM
K02	GW
K05	HB
K06	HC
K07	HD
K08	HG
K12	HI
K14	HK
K18	HL
K21	HM
K22	HO
K23	HP
K24	HR
K25	HS
K26	HV
K30	HX
K99	HY
L30	IP
L32	JT
L40	LM
L50	MD
L60	MH
M01	MN
N01	NB
N02	NH
N03	NR

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X02
X06
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Y01
Y02
Z01
Z02

ertical format, there is no correlation between the columns.

NIH Institution
NEI-National Eye Institute
NHLBI-National Heart, Lung, and Blood Institute
NHGRI-National Human Genome Research Institute
NIA-National Institute on Aging
NIAAA-National Institute on Alcohol Abuse and Alcoholism
NIAID-National Institute of Allergy and Infectious Diseases
NIAMS-National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB-National Institute of Biomedical Imaging and Bioengineering
NICHD-Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDCD-National Institute on Deafness and Other Communication Disorders
NIDCR-National Institute of Dental and Craniofacial Research
NIDDK-National Institute of Diabetes and Digestive and Kidney Diseases
NIDA-National Institute on Drug Abuse
NIEHS-National Institute of Environmental Health Sciences
NIGMS-National Institute of General Medical Sciences
NIMH-National Institute of Mental Health
NINDS-National Institute of Neurological Disorders and Stroke
NINR-National Institute of Nursing Research
NLM-National Library of Medicine
CIT-Center for Information Technology
CSR-Center for Scientific Review
FIC-John E. Fogarty International Center for Advanced Study in the Health Sciences
NCCAM-National Center for Complementary and Alternative Medicine
NCMHD-National Center on Minority Health and Health Disparities

NCRR-National Center for Research Resources (NCRR
CC-NIH Clinical Center
OD-Office of the Director

NCI Division/Program Code
CCR
CCT/CTB
CTEP
DCB
DCCPS
DCEG
DTP
DCP
DEA
OD
OSB/SPOREs
CIP
CDP
TRP
RRP
N/A

Definition
Center for Cancer Research
Center for Cancer Training / Cancer Training Branch
Cancer Therapy Evaluation Program
Division of Cancer Biology
Division of Cancer Control and Population Sciences
Division of Cancer Epidemiology and Genetics
Developmental Therapeutics Program
Division of Cancer Prevention
Division of Extramural Activities
Office of the Director, NCI, NIH
Organ Systems Branch (OSB) /Specialized Programs of Research Excellence (SPOREs)
Cancer Imaging Program
Cancer Diagnosis Program
Translational Research Program
Radiation Research Program
Not applicable

Country	3-letter code
AFGHANISTAN	AFG
ALBANIA	ALB
ALGERIA	DZA
AMERICAN SAMOA	ASM
ANDORRA	AND
ANGOLA	AGO
ANGUILLA	AIA
ANTARCTICA	ATA
ANTIGUA AND BARBUDA	ATG
ARGENTINA	ARG
ARMENIA	ARM
ARUBA	ABW
AUSTRALIA	AUS
AUSTRIA	AUT
AZERBAIJAN	AZE
BAHAMAS	BHS
BAHRAIN	BHR
BANGLADESH	BGD
BARBADOS	BRB
BELARUS	BLR
BELGIUM	BEL
BELIZE	BLZ
BENIN	BEN
BERMUDA	BMU
BHUTAN	BTN
BOLIVIA	BOL
BOSNIA AND HERZEGOWINA	BIH
BOTSWANA	BWA
BOUVET ISLAND	BVT
BRAZIL	BRA
BRITISH INDIAN OCEAN TERRITORY	IOT
BRUNEI DARUSSALAM	BRN
BULGARIA	BGR
BURKINA FASO	BFA
BURUNDI	BDI
CAMBODIA	KHM
CAMEROON	CMR
CANADA	CAN
CAPE VERDE	CPV
CAYMAN ISLANDS	CYM
CENTRAL AFRICAN REPUBLIC	CAF
CHAD	TCD
CHILE	CHL
CHINA	CHN

CHRISTMAS ISLAND	CXR
COCOS (KEELING) ISLANDS	CCK
COLOMBIA	COL
COMOROS	COM
CONGO	COG
COOK ISLANDS	COK
COSTA RICA	CRI
COTE D'IVOIRE	CIV
CROATIA (local name: Hrvatska)	HRV
CUBA	CUB
CYPRUS	CYP
CZECH REPUBLIC	CZE
DENMARK	DNK
DJIBOUTI	DJI
DOMINICA	DMA
DOMINICAN REPUBLIC	DOM
EAST TIMOR	TMP
ECUADOR	ECU
EGYPT	EGY
EL SALVADOR	SLV
EQUATORIAL GUINEA	GNQ
ERITREA	ERI
ESTONIA	EST
ETHIOPIA	ETH
FALKLAND ISLANDS (MALVINAS)	FLK
FAROE ISLANDS	FRO
FIJI	FJI
FINLAND	FIN
FRANCE	FRA
FRANCE, METROPOLITAN	FXX
FRENCH GUIANA	GUF
FRENCH POLYNESIA	PYF
FRENCH SOUTHERN TERRITORIES	ATF
GABON	GAB
GAMBIA	GMB
GEORGIA	GEO
GERMANY	DEU
GHANA	GHA
GIBRALTAR	GIB
GREECE	GRC
GREENLAND	GRL
GRENADA	GRD
GUADELOUPE	GLP
GUAM	GUM
GUATEMALA	GTM
GUINEA	GIN

GUINEA-BISSAU	GNB
GUYANA	GUY
HAITI	HTI
HEARD AND MC DONALD ISLANDS	HMD
HOLY SEE (VATICAN CITY STATE)	VAT
HONDURAS	HND
HONG KONG	HKG
HUNGARY	HUN
ICELAND	ISL
INDIA	IND
INDONESIA	IDN
IRAN (ISLAMIC REPUBLIC OF)	IRN
IRAQ	IRQ
IRELAND	IRL
ISRAEL	ISR
ITALY	ITA
JAMAICA	JAM
JAPAN	JPN
JORDAN	JOR
KAZAKHSTAN	KAZ
KENYA	KEN
KIRIBATI	KIR
KOREA, DEMOCRATIC PEOPLE'S REPUBLIC OF	PRK
KOREA, REPUBLIC OF	KOR
KUWAIT	KWT
KYRGYZSTAN	KGZ
LAO PEOPLE'S DEMOCRATIC REPUBLIC	LAO
LATVIA	LVA
LEBANON	LBN
LESOTHO	LSO
LIBERIA	LBR
LIBYAN ARAB JAMAHIRIYA	LBY
LIECHTENSTEIN	LIE
LITHUANIA	LTU
LUXEMBOURG	LUX
MACAU	MAC
MACEDONIA, THE FORMER YUGOSLAV REPUBLIC	MKD
MADAGASCAR	MDG
MALAWI	MWI
MALAYSIA	MYS
MALDIVES	MDV
MALI	MLI
MALTA	MLT
MARSHALL ISLANDS	MHL
MARTINIQUE	MTQ
MAURITANIA	MRT

MAURITIUS	MUS
MAYOTTE	MYT
MEXICO	MEX
MICRONESIA, FEDERATED STATES OF	FSM
MOLDOVA, REPUBLIC OF	MDA
MONACO	MCO
MONGOLIA	MNG
MONTSERRAT	MSR
MOROCCO	MAR
MOZAMBIQUE	MOZ
MYANMAR	MMR
NAMIBIA	NAM
NAURU	NRU
NEPAL	NPL
NETHERLANDS	NLD
NETHERLANDS ANTILLES	ANT
NEW CALEDONIA	NCL
NEW ZEALAND	NZL
NICARAGUA	NIC
NIGER	NER
NIGERIA	NGA
NIUE	NIU
NORFOLK ISLAND	NFK
NORTHERN MARIANA ISLANDS	MNP
NORWAY	NOR
OMAN	OMN
PAKISTAN	PAK
PALAU	PLW
PANAMA	PAN
PAPUA NEW GUINEA	PNG
PARAGUAY	PRY
PERU	PER
PHILIPPINES	PHL
PITCAIRN	PCN
POLAND	POL
PORTUGAL	PRT
PUERTO RICO	PRI
QATAR	QAT
REUNION	REU
ROMANIA	ROM
RUSSIAN FEDERATION	RUS
RWANDA	RWA
SAINT KITTS AND NEVIS	KNA
SAINT LUCIA	LCA
SAINT VINCENT AND THE GRENADINES	VCT
SAMOA	WSM

SAN MARINO	SMR
SAO TOME AND PRINCIPE	STP
SAUDI ARABIA	SAU
SENEGAL	SEN
SEYCHELLES	SYC
SIERRA LEONE	SLE
SINGAPORE	SGP
SLOVAKIA (Slovak Republic)	SVK
SLOVENIA	SVN
SOLOMON ISLANDS	SLB
SOMALIA	SOM
SOUTH AFRICA	ZAF
SOUTH GEORGIA AND THE SOUTH SANDWICH IS	SGS
SPAIN	ESP
SRI LANKA	LKA
ST. HELENA	SHN
ST. PIERRE AND MIQUELON	SPM
SUDAN	SDN
SURINAME	SUR
SVALBARD AND JAN MAYEN ISLANDS	SJM
SWAZILAND	SWZ
SWEDEN	SWE
SWITZERLAND	CHE
SYRIAN ARAB REPUBLIC	SYR
TAIWAN, PROVINCE OF CHINA	TWN
TAJIKISTAN	TJK
TANZANIA, UNITED REPUBLIC OF	TZA
THAILAND	THA
TOGO	TGO
TOKELAU	TKL
TONGA	TON
TRINIDAD AND TOBAGO	TTO
TUNISIA	TUN
TURKEY	TUR
TURKMENISTAN	TKM
TURKS AND CAICOS ISLANDS	TCA
TUVALU	TUV
UGANDA	UGA
UKRAINE	UKR
UNITED ARAB EMIRATES	ARE
UNITED KINGDOM	GBR
UNITED STATES	USA
UNITED STATES MINOR OUTLYING ISLANDS	UMI
URUGUAY	URY
UZBEKISTAN	UZB
VANUATU	VUT

VENEZUELA	VEN
VIET NAM	VNM
VIRGIN ISLANDS (BRITISH)	VGB
VIRGIN ISLANDS (U.S.)	VIR
WALLIS AND FUTUNA ISLANDS	WLF
WESTERN SAHARA	ESH
YEMEN	YEM
YUGOSLAVIA	YUG
ZAIRE	ZAR
ZAMBIA	ZMB
ZIMBABWE	ZWE

Country	Country 3-letter cod	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 Labrado
		Northwest Territories
		Nova Scotia
		Nunavut
		Ontario
		Prince Edward Island
		Quebec
		Saskatchewan
		Yukon
AUSTRALIA	AUT	
		Australian Capital Territory
		New South Wales
		Northern Territory
		Queensland
		South Australia
		Tasmania
		Victoria
		Western Australia

2-3 letter state/province cod	Old values
AL	
AK	
AZ	
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CA	
CO	
CT	
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FL	
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HI	
ID	
IL	
IN	
IA	
KS	
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Oversight Authority Country
Afghanistan
Algeria
Argentina
Argentina
Australia
Australia
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Austria
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Bangladesh
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Bulgaria
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Burkina Faso
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Dominican Republic

Ecuador
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Morocco

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Tunisia
Tunisia
Turkey
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Uganda
Uganda
Uganda
Ukraine
Ukraine
United Arab Emirates
United Arab Emirates

United Kingdom
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United Kingdom
United Kingdom
United Kingdom
United States
United States
United States

Zambia
Zambia
Zimbabwe

Oversight Authority Organization Name
Ministry of Public Health
Ministry of Health
Human Research Bioethics Committee
Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica
Department of Health and Ageing Therapeutic Goods Administration
Human Research Ethics Committee
National Health and Medical Research Council
Ethikkommission
Agency for Health and Food Safety
Federal Ministry for Health and Women
Federal Office for Safety in Health Care
Bangladesh Medical Research Council
Directorate of Drug Administration
Ethical Review Committee
Ministry of Health
Institutional Review Board
Directorate general for the protection of Public health: Medicines
Federal Agency for Medicinal Products and Health Products
Ministry of Social Affairs, Public Health and the Environment
The Federal Public Service (FPS) Health, Food Chain Safety and Environment
Ethics Committee
Ministry of Health
National Health Surveillance Agency
Ministry of Health
National Committee of Ethics in Research
Ministry of Health
Bulgarian Drug Agency
Ministry of Health
Ministry for Higher Education and Research
Ministry of Health
Ministry of Public Health
Canadian Institutes of Health Research
Ethics Review Committee
Health Canada
Ministry of Health & Long Term Care, Ontario
Comisi?n Nacional de Investigaci?n Cient?fica y Tecnol?gica
Instituto de Salud Publica de Chile
Ethics Committee
Ministry of Health
State Food and Drug Administration
INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos
Institutional Review Board
Minister of Science, Education and Sports

Ministry of Health and Social Care
Ethics Committee
State Institute for Drug Control
Danish Dataprotection Agency
Danish Medicines Agency
Ethics Committee
National Board of Health
The Danish National Committee on Biomedical Research Ethics
The Ministry of the Interior and Health
The Regional Committee on Biomedical Research Ethics
Secretar?a del Estado de Salud P?blica y Asistencia Social (SESPAS)

Public Health Ministry
Institutional Review Board
Ministry of Health and Population
The State Agency of Medicine
Ethiopia Science and Technology Commission
Ethics Committee
Ministry of Social Affairs and Health
National Agency for Medicines
Afssaps - French Health Products Safety Agency
Direction G?n?rale de la Sant?
French Data Protection Authority
Institutional Ethical Committee
Ministry of Health
National Consultative Ethics Committee for Health and Life Sciences
Department of State for Health and Social Welfare
MRC Ethics Committee
Ministry of Health
Federal Ministry of Food, Agriculture and Consumer Protection
Federal Ministry of Education and Research
Federal Institute for Drugs and Medical Devices
Ethics Commission
Paul-Ehrlich-Institut
Committee on Human Research
Ministry of Health
National Organization of Medicines
Ethics Committee
Ministry of Health and Welfare
Ministry of Health
Joint CUHK-NTEC Clinical Research Ethics Committee
Ethics Committee
Department of Health
National Institute of Pharmacy
Ministry of Health and Social Security
Icelandic Medicines Control Agency
Science and Engineering Research Council
Institutional Review Board

Ministry of Science and Technology
Ministry of Health
Department of Atomic Energy
Drugs Controller General of India
Indian Council of Medical Research
Ministry of Health
Medical Ethics Research Committee
Irish Medicines Board
Ethics Commission
Ministry of Health
Israeli Health Ministry Pharmaceutical Administration
The Israel National Institute for Health Policy Research and Health
Ministry of Health
National Monitoring Centre for Clinical Trials - Ministry of Health
Ethics Committee
National Institute of Health
National Bioethics Committee
The Italian Medicines Agency
Ministry of Health
Foundation for Biomedical Research and Innovation
Pharmaceuticals and Medical Devices Agency
Ministry of Health, Labor and Welfare
Ministry of Education, Culture, Sports, Science and Technology
Institutional Review Board
Ethical Committee
Ethical Commission
Ethical Reveiw Committee
Institutional Review Board
Ministry of Health
State Agency of Medicines
Ministry of Public Health
Institutional Review Board
Control Authority for Medicinal Products
Bioethics Committee
State Medicine Control Agency - Ministry of Health
Ethics Committee
National Health Sciences Research Committee
College of Medicine Research and Ethics Committee
Ministry of Health
Ministry of Health
Ministry of Health and Quality of Life
National Council of Science and Technology
Ethics Committee
Federal Commission for Protection Against Health Risks
Ministry of Health
National Institute of Public Health, Health Secretariat
Federal Commission for Sanitary Risks Protection
Ministry of Public Health

Ministry of Health (MISAU)
The Central Committee on Research Involving Human Subjects (CCMO)

Dutch Health Care Inspectorate
Medical Ethics Review Committee (METC)
Medicines Evaluation Board (MEB)
Independent Ethics Committee
Health Research Council
Food Safety Authority
Health and Disability Ethics Committees
Institutional Review Board
Medsafe
The National Agency for Food and Drug Administration and Control
Data Inspectorate
The National Committees for Research Ethics in Norway
Norwegian Medicines Agency
Norwegian Institute of Public Health
Directorate for Health and Social Affairs
Norwegian Social Science Data Services
Ministry of Health
Research Ethics Committee
Ministry of Health
Ethics Committee
Ministry of Health
General Directorate of Pharmaceuticals, Devices, and Drugs
Bureau of Food and Drugs
Department of Health
Ministry of Scientific Research and Information Technology
Drug Institute
Ministry of Health
Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Ethics Committee for Clinical Research
National Pharmacy and Medicines Institute
Health Ethic Committee
National Medicines Agency
State Institute for Drug Control
Research Advisory Council
Ministry of Health
Ministere de la sante
Ethics Committee
Ministry of Health and Sanitation
Health Sciences Authority
Domain Specific Review Boards
Clinical Trials & Epidemiology Research Unit (CTERU)
Agency for Medicinal Products - Ministry of Health
Ministry of Health
National Health Research Ethics Council

Medicines Control Council
Department of Health
Ministry of Health
Spanish Agency of Medicines
Ministry of Health and Consumption
Comit? ?tico de Investigaci?n Cl?nica
Ethics Committee
Ministry of Healthcare & Nutrition
Ministry of Health
Medical Products Agency
The National Board of Health and Welfare
Swedish National Council on Medical Ethics
Regional Ethical Review Board
Institutional Review Board
Ethikkommision
Federal Office of Public Health
Swissmedic
Laws and standards
Department of Health
National Bureau of Controlled Drugs
Institutional Review Board
National Institute for Medical Research
Food & Drug Administration
Ministry of Health
Ethical Committee
Khon Kaen University Ethics Committee for Human Research
Food and Drug Administration
Ministry of Public Health
Office of Pharmacies and Medicines
Ministry of Public Health
Ethics Committee
Ministry of Health
Research Ethics Committee
Ministry of Health
National Council for Science and Technology
State Pharmacological Center - Ministry of Health
Ministry of Health
General Authority for Health Services for Abu Dhabi
Drug Control Department - Medicines and Pharmacy Control - Ministry of Health
Food Standards Agency
Medicines and Healthcare Products Regulatory Agency
Research Ethics Committee
National Health Service
Department of Health
Federal Government
Institutional Review Board
Food and Drug Administration

Research Ethics Committee
Ministry of Health
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