OMB No.: 0925-0600
Expiration Date: 05/31/2016

NG PROGRAM (CTRP) SYSTEM

nated to average 30 minutes per response, including the
, gathering and maintaining the data needed, and
ncy may not conduct or sponsor, and a person is
nless it displays a currently valid OMB control
y other aspect of this collection of information, including
Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD
ted form to this address.

CTRP Trial Registration Batch Upload Specificatic

About this Document

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

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 upl

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

Trial Data Pick List

The *Trial Data Pick List* worksheet contains sets of valid values for many of the da
The values are displayed in pick lists when you select an appropriate data elemen
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 ord
3 Data element requirements. Requirements differ for original, updated, a
4 Valid values. The system accepts only those values listed in this docun
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 c

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

Trial Status Date Diagram

The Trial Status Date diagram illustrates the relationships between trial start dates

ɔn for Complete Trials

ɲe CTRP Trial Registration system, including the following:

ˈour data and uploading them to the system.

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

ta elements in the *(Sample) Trial Data* worksheet.
t cell.
accurately.

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

data elements:

of the division/program acronyms.

submit clinical trial data to the CTRP system.

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

countries that submit clinical trial data to the CTRP system.

, primary completion dates, and completion dates.

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
* Comp
* Amer
* Upda
* 100 t
* Multi
* Multi
* Gene
* Multi

* Two
* Two

2 Create a

3 Copy the
Most cells

4 Delete th

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

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

6 Delete all

7 Delete th

Preparing T

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

Note: So

Uploading Y

1 Open yo
2 Follow th
https://wiki.

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 (Data Table 4 Funding Sponsor Category is 'National', 'Externally Peer-Reviewed' or 'Institutional') tri
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
Tip: You can add NCT IDs when updating or amending registered trials.
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

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.
ıre displayed whenever a drop-down list is available.
ows are displayed next to the cell, click the arrow and select the appropriate 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.

l empty columns that may appear after the last data element column.

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
ıple, 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 instructions provided on the Batch Trial Upload web page. For more comprehensive information, see the
.nci.nih.gov/x/Ey0ZCQ

and email address stored in your CTRP profile.

stry/admin/batchUpload.action.

uses

e is not required.
andatory attributes for person or organization

ct valid values from a list. The sets of valid values for these drop-down lists are derived from

)load to fail. Similarly, the addition of new/extra trial elements will also cause a failure.
d in the *Trial Data Element Spec* or other valid value tabs in this spreadsheet.

:hange Memo) for the trials in the data file. For trial amendments, you can include either a Ch
etailed instructions and best practices for file preparation, refer to the CTRP Registration Site

ıe single trial record.

Word documents (.doc) or Adobe PDFs (.pdf). No other file types are currently accepted. Zip

dmin/batchUpload.action.
n User's Guide at:

Trial Data Pick List worksheet.

hange Memo document or Protocol Highlight document. **NOTE**: The MacOSX native compre
e User's Guide at https://wiki.nci.nih.gov/x/SwnCBg.

files created with the MAC OS native compression utility may fail.

ession utility is not supported.

	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	AL
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	[Sponsor Contact] State/Province
2							
3	23456						
4							
5							
6		Todd		Wright	400 Main St	Handerson	TN
7							

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

	AT	AU	AV	AW	AX	AY
1	[Lead Organization] Organization PO-ID	[Lead Organization] Name	[Lead Organization] Street Address	[Lead Organization] City	[Lead Organization] State/Province	[Lead Organization] Zip/Postal code
2		Gynecologic Oncology Group	100 Main St	Fairfax	VA	22032
3		Children's Oncology Group	2115 E Jefferson St	Rockville	MD	20185
4		North Central Cancer Treatment Group	100 Meadow Rd	Hartford	CT	33333
5	12345					
6		Children's Oncology Group	2115 E Jefferson St	Rockville	MD	20185
7						

	AZ	BA	BB	BC	BD	BE
1	[Lead Organization] Country	[Lead Organization] Email Address	[Lead Organization] Phone	[Lead Organization] TTY	[Lead Organization] FAX	[Lead Organization] URL
2	USA	test@cog.org	222-444-8888			
3	USA	test@cog.org	222-444-8888			
4	USA	test@cog.org	222-444-8888			
5						
6	USA	test@cog.org	222-444-8888			
7						

	BF	BG	BH	BI	BJ	BK	BL
1	[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	[Principal Investigator] City
2	cooperative group	1234					
3	cooperative group		Miljenko	B	Pilepich	100 Village Hill Lane	Natick
4	cooperative group	87456					
5	cooperative group		Jacob	J	Rowe	100 Old Meadow Rd	Houston
6	cooperative group	45689					
7							

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

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

	BZ	CA	CB	CC	CD	CE	CF
1	[Data Table 4 Funding Sponsor/Source] State/Province	[Data Table 4 Funding Sponsor/Source] Zip/Postal code	[Data Table 4 Funding Sponsor/Source] Country	[Data Table 4 Funding Sponsor/Source] Email Address	[Data Table 4 Funding Sponsor/Source] Phone	[Data Table 4 Funding Sponsor/Source] TTY	[Data Table 4 Funding Sponsor/Source] FAX
2	MD	20852	USA	mailto@ctrp.o	111-111-1111		
3	MD	20852	USA	mailto@ctrp.o	111-111-1111		
4	MD	20852	USA	mailto@ctrp.o	111-111-1111		
5	MD	20852	USA	mailto@ctrp.o	111-111-1111		
6	MD	20852	USA	mailto@ctrp.o	111-111-1111		
7	MD	20852	USA	mailto@ctrp.o	111-111-1111		

	CG	CH	CI	CJ	CK
1	[Data Table 4 Funding Sponsor/Source] URL	Program Code	[NIH Grant] Funding Mechanism	[NIH Grant] Institute Code	[NIH Grant] Serial Number
2			F34	AG	72345
3					
4		IM	K08;CO6	HV;AO	97521;012345
5					
6					
7		BR			

	CL	CM	CN	CO	CP	CQ	CR
1	[NIH Grant] NCI Division/Program Code	Current Trial Status	Why Study Stopped?	Current Trial Status Date	Study Start Date	Study Start Date Type	Primary Completion Date
2	CTEP	Complete		8/1/2010	2/1/2009	Actual	08/01/10
3		Temporarily Closed to Accrual	Accrual target was reached for this phase of the study	8/2/2009	1/2/2009	Actual	10/02/11
4	CTEP;CTEP	In Review		8/3/2009	12/3/2010	Anticipated	10/3/2011
5		Approved		8/4/2009	12/4/2010	Anticipated	9/4/2012
6		Administratively Complete	Closed prematurely	8/5/2009	1/5/2009	Actual	8/5/2009
7		Approved		8/1/2009	12/1/2010	Anticipated	12/1/2011

	CS	CT	CU	CV	CW	CX	CY
1	Primary Completion Date Type	Study Completion Date	Study Completion Date Type	IND/IDE Type	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type
2	Actual						
3	Anticipated						
4	Anticipated						
5	Anticipated						
6	Actual			IND;IND	67899;10,264	CDER;CDER	NIH;NCI
7	Anticipated						

	CZ	DA	DB	DC	DD	DE	DF
1	[IND/IDE] NIH Institution	[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
2						United States	Federal Government
3						United States	Federal Government
4						United States	Food and Drug Administration
5							
6	NIA;NA	NA;DCP	No;Yes	NA;Approved for marketing	Yes;Yes	United States	Federal Government
7						United States	Federal Government

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

	DL	DM	DN	DO
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				

	DP	DQ
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 Services 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	SI	
II	AIA	AZ		
II/III	ALA	CA		
III	ALB	CO		
IV	AND	CT		
NA	ANT	DE		
	ARE	FL		
	ARG	GA		
	ARM	HI		
	ASM	IA		
	ATA	ID		
	ATF	IL		
	ATG	IN		
	AUS	KS		
	AUT	KY		
	AZE	LA		
	BDI	MA		
	BEL	MD		
	BEN	ME		
	BFA	MI		
	BGD	MN		
	BGR	MO		
	BHR	MS		
	BHS	MT		
	BIH	NC		
	BLM	ND		
	BLR	NE		
	BLZ	NH		
	BMU	NJ		
	BOL	NM		
	BRA	NV		
	BRB	NY		
	BRN	OH		
	BTN	OK		
	BVT	OR		
	BWA	PA		
	CAF	RI		
	CAN	SC		
	CCK	SD		
	CHE	TN		
	CHL	TX		
	CHN	UT		
	CIV	VA		
	CMR	VT		
	COD	WA		

COG	WI
COK	WV
COL	WY
COM	AB
CPV	BC
CRI	MB
CUB	NB
CXR	NL
CYM	NS
CYP	NT
CZE	NU
DEU	ON
DJI	PE
DMA	QC
DNK	SK
DOM	YT
DZA	ACT
ECU	NSW
EGY	NT
ERI	QLD
ESH	SA
ESP	TAS
EST	VIC
ETH	WA
FIN	
FJI	
FLK	
FRA	
FRO	
FSM	
GAB	
GBR	
GEO	
GGY	
GHA	
GIB	
GIN	
GLP	
GMB	
GNB	
GNQ	
GRC	
GRD	
GRL	
GTM	
GUF	
GUM	
GUY	
HKG	

HMD
HND
HRV
HTI
HUN
IDN
IMN
IND
IOT
IRL
IRN
IRQ
ISL
ISR
ITA
JAM
JEY
JOR
JPN
KAZ
KEN
KGZ
KHM
KIR
KNA
KOR
KWT
LAO
LBN
LBR
LBY
LCA
LIE
LKA
LSO
LTU
LUX
LVA
MAC
MAF
MAR
MCO
MDA
MDG
MDV
MEX
MHL
MKD
MLI

MLT
MMR
MNE
MNG
MNP
MOZ
MRT
MSR
MTQ
MUS
MWI
MYS
MYT
NAM
NCL
NER
NFK
NGA
NIC
NIU
NLD
NOR
NPL
NRU
NZL
OMN
PAK
PAN
PCN
PER
PHL
PLW
PNG
POL
PRI
PRK
PRT
PRY
PSE
PYF
QAT
REU
ROU
RUS
RWA
SAU
SDN
SEN
SGP

SGS
SHN
SJM
SLB
SLE
SLV
SMR
SOM
SPM
SRB
STP
SUR
SVK
SVN
SWE
SWZ
SYC
SYR
TCA
TCD
TGO
THA
TJK
TKL
TKM
TLS
TON
TTO
TUN
TUR
TUV
TWN
TZA
UGA
UKR
UMI
URY
USA
UZB
VAT
VCT
VEN
VGB
VIR
VNM
VUT
WLF
WSM
YEM

ZAF
ZMB
ZWE

Lead Organization Type	Data Table 4 Funding Categ	NIH Grant Funding Mechanis
Institution	National	B01
ordering group	Externally Peer-Reviewed	B08
repository	Institutional	B09
research based		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
		H25
		H28
		H50
		H57
		H62
		H64
		H75
		H79
		HD4
		HR!
		I01
		K01
		K02
		K05
		K06
		K07
		K08
		K12
		K14
		K18

K21
K22
K23
K24
K25
K26
K30
K99
KD1
KL1
KL2
L30
L32
L40
L50
L60
M01
N01
N02
N03
N43
N44
P01
P20
P30
P40
P41
P42
P50
P51
P60
P76
PL1
PN1
PN2
R00
R01
R03
R04
R06
R08
R13
R15
R17
R18
R21
R24
R25
R30

R33
R34
R36
R37
R41
R42
R43
R44
R49
R55
R56
R90
RC1
RC2
RC3
RC4
RL1
RL2
RL5
RL9
RS1
S06
S10
S11
S21
S22
SC1
SC2
SC3
T01
T02
T03
T06
T09
T14
T15
T32
T34
T35
T36
T37
T42
T90
TL1
TU2
U01
U09
U10
U11

U13
U14
U17
U18
U19
U1A
U1Q
U1S
U1T
U1V
U21
U22
U23
U24
U27
U2G
U2R
U30
U32
U34
U36
U38
U41
U42
U43
U44
U45
U47
U48
U49
U50
U51
U52
U53
U54
U55
U56
U57
U58
U59
U60
U61
U62
U65
U66
U75
U79
U81
U82

U83
U84
U87
U88
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		
CO		
CP		
CR		
CT		
CU		
CX		
DA		
DC		
DD		
DE		
DK		
DP		
EB		
EH		
EM		
EP		
ES		
EY		
FD		
GD		
GH		
GM		
GW		
HB		
HC		
HD		

HG
HI
HK
HL
HM
HO
HP
HR
HS
HV
HX
HY
IP
JT
LM
MD
MH
MN
NB
NH
NR
NS
NU
OA
OC
OD
OF
OH
OL
OR
PC
PH
PR
PS
RC
RD
RG
RM
RR
RX
SC
SF
SH
SM
SP
SU
TI
TP
TS

TW
VA
WC
WH
WT

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	Data Table 4 Funding Category	Yes
74	[Data Table 4 Funding Sponsor/Source] Organization PO-ID	PO-ID or all mandatory organization specific attribute are required
75	[Data Table 4 Funding Sponsor/Source] Organization Name	Yes if Organization PO-ID is NULL
76	[Data Table 4 Funding Sponsor/Source] Street Address	Yes if Organization PO-ID is NULL
77	[Data Table 4 Funding Sponsor/Source] City	Yes if Organization PO-ID is NULL
78	[Data Table 4 Funding Sponsor/Source] State/Province	Yes if Organization PO-ID is NULL and for US/Canada/Australia
79	[Data Table 4 Funding Sponsor/Source] Zip/Postal code	Yes if Organization PO-ID is NULL
80	[Data Table 4 Funding Sponsor/Source] Country	Yes if Organization PO-ID is NULL
81	[Data Table 4 Funding Sponsor/Source] Email Address	Yes if Organization PO-ID is NULL
82	[Data Table 4 Funding Sponsor/Source] Phone	

83	[Data Table 4 Funding Sponsor/Source] TTY	
84	[Data Table 4 Funding Sponsor/Source] FAX	
85	[Data Table 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	Study Completion Date	
99	Study Completion Date Type	
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'). Note: Effective September 2015, modifying the value of this indicator has been restricted to the CTRO. CTRP accepts only a 'No' value for this indicator. If you submit a 'Yes' value, the system reverts it to 'No' and sends you a warning message to that effect in the registration confirmation email. In addition, the system automatically notifies the CTRO that a 'Yes' value was submitted for the trial, the CTRO then sets the indicator's value accordingly. To change the value of this indicator, submit a request to the CTRO at ncictro@mail.nih.gov.
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 applicable to original submission, amendment and update. Withdrawn status is only applicable to Update functionality.
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'). Note: Effective September 2015, modifying the value of this indicator has been restricted to the CTRO. CTRP accepts only a 'No' value for this indicator. If you submit a 'Yes' value, the system reverts it to 'No' and sends you a warning message to that effect in the registration confirmation email. In addition, the system automatically notifies the CTRO that a 'Yes' value was submitted for the trial, the CTRO then sets the indicator's value accordingly. To change the value of this indicator, submit a request to the CTRO at ncictro@mail.nih.gov.	Yes (if section 801 Indicator is 'Yes' and ClinicalTrials.gov XML Required? is set to 'Yes'). Note: Effective September 2015, modifying the value of this indicator has been restricted to the CTRO. CTRP accepts only a 'No' value for this indicator. If you submit a 'Yes' value, the system reverts it to 'No' and sends you a warning message to that effect in the registration confirmation email. In addition, the system automatically notifies the CTRO that a 'Yes' value was submitted for the trial, the CTRO then sets the indicator's value accordingly. To change the value of this indicator, submit a request to the CTRO at ncictro@mail.nih.gov.	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

Data Table 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) Please use 'In Review' status at submission of pre-IRB approved study.
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 v

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

N43
N44
PL1
PN1
PN2
P01
P20
P30
P40
P41
P42
P50
P51
P60
P76
RC1
RC2
RC3
RC4
RL1
RL2
RL5
RL9
RS1
R00
R01
R03
R04
R06
R08
R13
R15
R17
R18
R21
R24
R25
R30
R33
R34
R36
R37
R41
R42
R43

NS
NU
OA
OC
OD
OF
OH
OL
OR
PC
PH
PR
PS
RD
RX
SC
SF
SH
SM
SP
SU
TI
TP
TS
WH
RC
RG
RM
RR
TW
WT
VA
WC

R44
R49
R55
R56
R90
SC1
SC2
SC3
S06
S10
S11
S21
S22
TL1
TU2
T01
T02
T03
T06
T09
T14
T15
T32
T34
T35
T36
T37
T42
T90
UA1
UC1
UC2
UC3
UC6
UC7
UD1
UE1
UE2
UH1
UH2
UH3
UL1
UR1
UR3
UR6

UR8
US3
US4
UT1
UT2
U01
U09
U10
U11
U13
U14
U17
U18
U19
U1A
U1Q
U1S
U1T
U1V
U21
U22
U23
U24
U27
U2G
U2R
U30
U32
U34
U36
U38
U41
U42
U43
U44
U45
U47
U48
U49
U50
U51
U52
U53
U54
U55

U56
U57
U58
U59
U60
U61
U62
U65
U66
U75
U79
U81
U82
U83
U84
U87
U88
U90
VF1
X01
X02
X06
X98
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
Aland Islands	ALA
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
Congo, Democratic Republic of th	COD
Cook Islands	COK
Costa Rica	CRI
Cote D Ivoire	CIV
Croatia	HRV
Cuba	CUB
Cyprus	CYP
Czech Republic	CZE
Denmark	DNK
Djibouti	DJI
Dominica	DMA
Dominican Republic	DOM
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
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
Guernsey	GGY
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
Isle of Man	IMN
Israel	ISR
Italy	ITA
Jamaica	JAM
Japan	JPN
Jersey	JEY
Jordan	JOR
Kazakhstan	KAZ
Kenya	KEN
Kiribati	KIR
Korea, Democratic Peoples Republic of	PRK
Korea, Republic of	KOR
Kuwait	KWT
Kyrgyzstan	KGZ
Lao Peoples Democratic Republic	LAO
Latvia	LVA
Lebanon	LBN
Lesotho	LSO
Liberia	LBR
Libyan Arab Jamahiriya	LBY
Liechtenstein	LIE
Lithuania	LTU

Luxembourg	LUX
Macau	MAC
Macedonia	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
Montenegro	MNE
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
Palestinian Territory	PSE
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	ROU
Russian Federation	RUS
Rwanda	RWA
Saint Barthelemy	BLM
Saint Helena	SHN
Saint Kitts And Nevis	KNA
Saint Lucia	LCA
Saint Martin (French Part)	MAF
Saint Pierre and Miquelon	SPM
Saint Vincent And The Grenadines	VCT
Samoa	WSM
San Marino	SMR
Sao Tome And Principe	STP
Saudi Arabia	SAU
Senegal	SEN
Serbia	SRB
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 Isla	SGS
Spain	ESP
Sri Lanka	LKA
Sudan	SDN
Suriname	SUR
Svalbard And Jan Mayen Islands	SJM
Swaziland	SWZ
Sweden	SWE
Switzerland	CHE

Syrian Arab Republic	SYR
Taiwan	TWN
Tajikistan	TJK
Tanzania	TZA
Thailand	THA
Timor-Leste	TLS
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
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	
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
NB
NL
NT
NS
NU
ON
PE
QC
SK
YT

ACT
NSW
NT
QLD
SA
TAS
VIC
WA

Oversight Authority Country
Afghanistan
Algeria
Argentina
Argentina
Australia
Australia
Australia
Austria
Austria
Austria
Austria
Bangladesh
Bangladesh
Bangladesh
Belarus
Belgium
Belgium
Belgium
Belgium
Belgium
Bolivia
Bolivia
Brazil
Brazil
Brazil
Bulgaria
Bulgaria
Burkina Faso
Burkina Faso
Cambodia
Cameroon
Canada
Canada
Canada
Canada
Chile
Chile
China
China
China
Colombia
Colombia
Croatia
Croatia

Czech Republic
Czech Republic
Denmark
Denmark
Denmark
Denmark
Denmark
Denmark
Denmark
Dominican Republic
Ecuador
Egypt
Egypt
Estonia
Ethiopia
Finland
Finland
Finland
France
France
France
France
France
France
France
Gambia
Gambia
Georgia
Germany
Germany
Germany
Germany
Germany
Ghana
Ghana
Greece
Greece
Greece
Guinea-Bissau
Hong Kong
Hong Kong
Hong Kong
Hungary
Iceland
Iceland
India
India
India
India

India
India
India
Ireland
Ireland
Ireland
Israel
Israel
Israel
Israel
Italy
Italy
Italy
Italy
Italy
Italy
Jamaica
Japan
Japan
Japan
Japan
Japan
Jordan
Kazakhstan
Kenya
Kenya
Kenya
Latvia
Lebanon
Lebanon
Liechtenstein
Lithuania
Lithuania
Macedonia
Malawi
Malawi
Malaysia
Mali
Mauritius
Mexico
Mexico
Mexico
Mexico
Mexico
Mexico
Morocco
Mozambique

Netherlands

Netherlands
Netherlands
Netherlands
Netherlands
New Zealand
New Zealand
New Zealand
New Zealand
New Zealand
Nigeria
Norway
Norway
Norway
Norway
Norway
Norway
Pakistan
Pakistan
Panama
Peru
Peru
Peru
Philippines
Philippines
Poland
Poland
Poland
Poland

Portugal
Portugal
Portugal
Romania
Romania
Saudi Arabia
Saudi Arabia
Senegal
Serbia
Sierra Leone
Singapore
Singapore
Singapore
Slovenia
Slovenia
South Africa
South Africa

South Africa
Spain
Spain
Spain
Spain
Spain
Sri Lanka
Sudan
Sweden
Sweden
Sweden
Sweden
Sweden
Switzerland
Switzerland
Switzerland
Switzerland
Taiwan
Taiwan
Taiwan
Tanzania
Tanzania
Tanzania
Thailand
Thailand
Thailand
Thailand
Tunisia
Tunisia
Turkey
Turkey
Uganda
Uganda
Uganda
Ukraine
Ukraine
United Arab Emirates
United Arab Emirates

United Kingdom
United Kingdom
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)

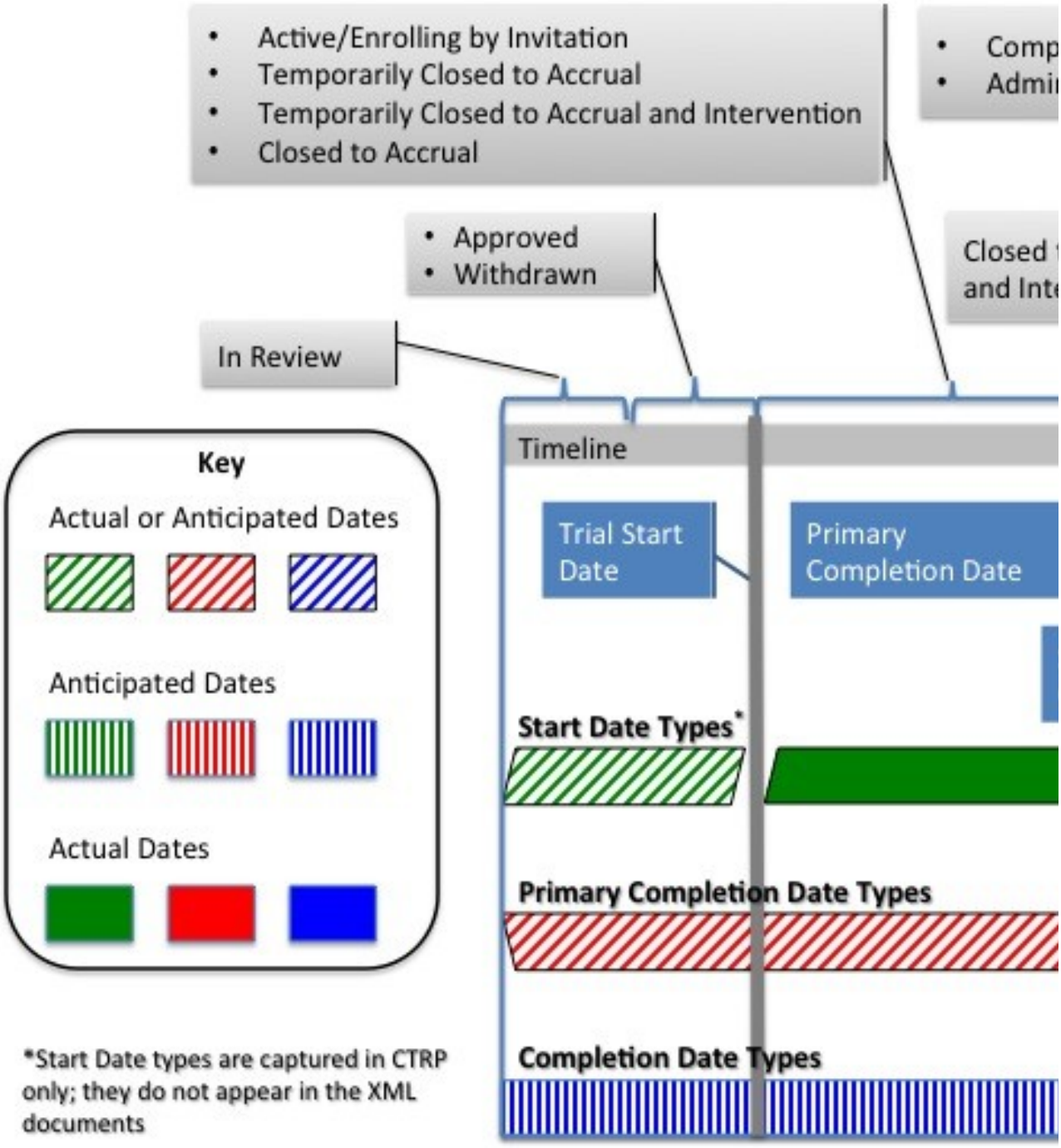
The Central Committee on Research Involving Human Subjects (CCMO)

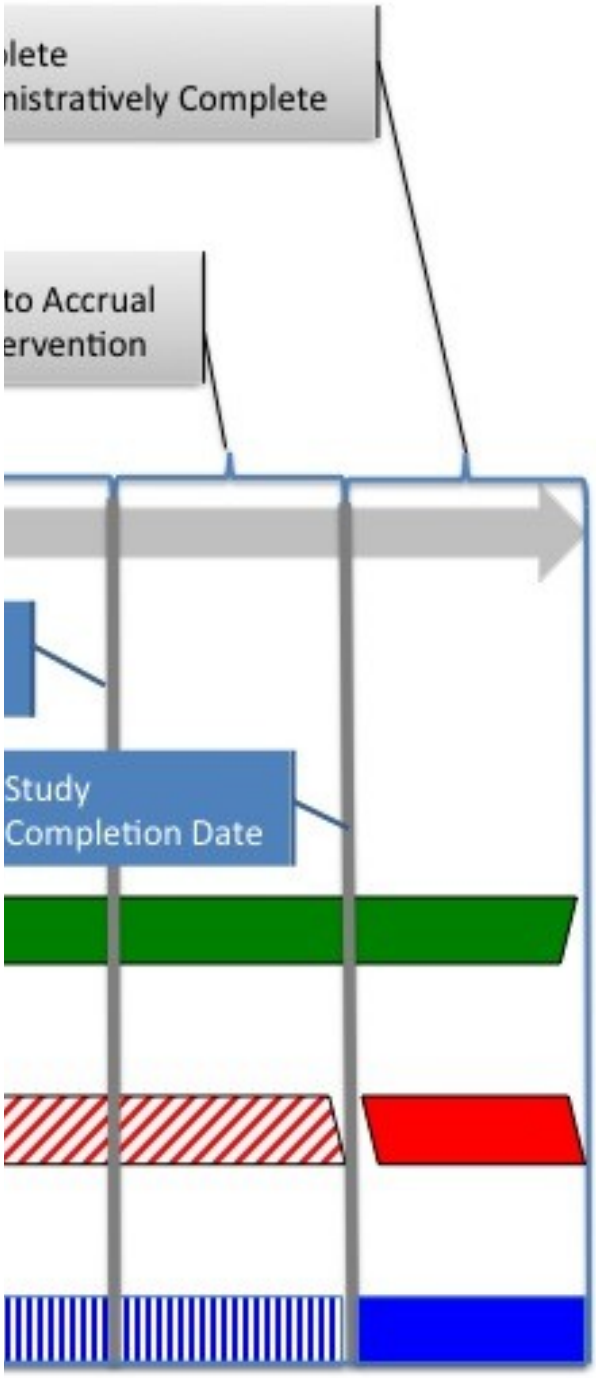
Dutch Health Care Inspectorate
Medical Ethics Review Committee (METC)
Medicines Evaluation Board (MEB)
Independent Ethics Committee
Health Research Council
Food Safety Authority
Health and Disability Ethics Committees
Institutional Review Board
Medsafe
The National Agency for Food and Drug Administration 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
Medical Research Council

Trial Start, Primary Completion, and Completion Dates




lete
nistratively Complete
to Accrual
ervention
Study
Completion Date