NG PROGRAM (CTRP) SYSTEM

OMB No.: 0925-0600
Expiration Date: 08/31/2019

ated to average 30 minutes per response, including the time
and maintain the data needed, and complete and review
nsor, and a person is not required to respond to, a
3 control number. Send comments regarding this burden
luding suggestions for reducing this burden to: NIH, Project
D 20892-7974, ATTN: PRA (0925-0600). Do not return the

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 yo

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 o

Country Codes

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

State and Province Codes

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

Oversight Authorities

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

Trial Status Date Diagram

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

n for Complete Trials

e CTRP Trial Registration system, including the following:

our data and uploading them to the system.

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

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

r is set up for you in columns in the *Sample Trial Data* tab.
nd amended submissions.
ent.
upload of your data.

ata elements:

f the division/program acronyms.

submit clinical trial data to the CTRP system.

ory 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 I

Contact the CTRO
Note: Once you ha

Main Steps f

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2 Prepare t
3 Upload yo

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Note: Son

Uploading Y

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2 Follow the
https://wiki.

oload Clinical Trial Data to the CTRP Trial Registration Sy

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.

or 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
olete (Data Table 4 Funding Sponsor Category is 'National', 'Externally Peer-Reviewed' or 'Institutional') tria
ndments to complete CTRP trials with "Abstraction Verified Response" or "Abstraction Verified No Respons
tes to complete CTRP trials with the processing status "Accepted" and beyond
rials per data file
ole grants per submitted trial
ole IND/IDE per submitted trial
eric contacts for Responsible Party or Sponsor
ole "Other" trial identifiers
Tip: You can add NCT IDs when updating or amending registered trials.

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 ascer

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.
re displayed whenever a drop-down list is available.
ws 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.

t 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.

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
ple, 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.
ne document names (including their extensions) in the file containing the trial data. Up to seven (7) files ca
l-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

ınd email address stored in your CTRP profile.

try/admin/batchUpload.action.

ıses

:t 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 Cha
etailed instructions and best practices for file preparation, refer to the CTRP Registration Site

e single trial record.

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

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

Trial Data Pick List worksheet.

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

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

ssion utility is not supported.

	A	B	C	D	E	F
1	Unique Trial Identifier	Submission Type	NCI Trial Identifier	Amendment Number	Amendment Date	Lead Organization Trial Identifier
2	10	O				53112
3	1000	A	NCI-2009-00001	A1	39938	1234
4	2001	O				12345
5	3000	O				65432
6	4000	O				1233
7	5000	U	NCI-2009-00001			12308

	G	H	I	J	K
1	NCT	Other Trial Identifier	Title	Trial Type	Primary Purpose
2	NCT000123	123;123-A	A Phase I study of Taxol in refractory leukemia in children	Interventional	Treatment
3	NCT00045		Phase III Study of Zoladex Adjuvant to Radiotherapy in Unfavorable Prognosis Carcinoma of the Prostate	Interventional	Treatment
4			A Phase I trial of Ifosfamide and Taxol in refractory Pelvic Malignancies	Interventional	Treatment
5			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	Treatment
6			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	Other
7	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	Treatment

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

	R	S	T	U	V	W
1	[Responsible Party] Investigator Person PO-ID	[Responsible Party] Title	[Responsible Party] Affiliation Organization PO-ID	[Lead Organization] Organization PO-ID	[Principal Investigator] Person PO-ID	Data Table 4 Funding Category
2	1234	Principal Investigator	123		1234	Institutional
3						Institutional
4					87456	Institutional
5	1234	Principal Investigator		12345		Institutional
6					45689	Institutional
7						Institutional

	X	Y	Z	AA	AB
1	[Data Table 4 Funding Sponsor/Source] Organization PO-ID	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			

	AC	AD	AE	AF	AG	AH
1	[NIH Grant] NCI Division/Program Code	Current Trial Status	Why Study Stopped?	Current Trial Status Date	Study Start Date	Study Start Date Type
2	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	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

	AI	AJ	AK	AL	AM	AN	AO
1	Primary Completion Date	Primary Completion Date Type	Study Completion Date	Study Completion Date Type	IND/IDE Type	IND/IDE Number	IND/IDE Grantor
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
7	12/1/2011	Anticipated					

	AP	AQ	AR	AS	AT	AU	AV
1	IND/IDE Holder Type	[IND/IDE] NIH Institution	[IND/IDE] NCI Division /Program	[IND/IDE] Availability of Expanded Access?	[IND/IDE] Expanded Access Record	Studies a US FDA regulated Drug Product	Studies a US FDA regulated Device Product
2						Yes	
3						Yes	
4						Yes	
5						Yes	
6	NIH;NCI	NIA;NA	NA;DCP	Yes;	NCT01234567;	Yes	
7						Yes	

	AW	AX	AY	AZ	BA	BB
1	Unapproved/ Uncleared Device	Pediatric Post-Market Surveliance	Product Exported from the US	FDA Regulatory Information Indicator	Section 801 Indicator	Data Monitoring Committee Appointed Indicator
2				No		Yes
3				No		Yes
4				Yes	Yes	Yes
5						
6				No		Yes
7				No		Yes

	BC	BD	BE
1	Protocol Document File Name	IRB Approval Document File Name	Participating Sites Document File Name
2	protocol_document_T10.doc	IRB_Approval.doc	Participating_Sites_T10.xls
3	protocol_document_T1000.doc	IRB_Approval_06082007.doc	Participating_Sites_T1000_new.xls
4	protocol_document_T2001.doc	IRB_Approval_T2001.doc	Participating_Sites_T2001.xls
5	3000_protocol_document.doc	3000_IRB_Approval.doc	3000_Participating_Sites.xls
6	4000_protocol_document.doc	4000_IRB_Approval.doc	4000_Participating_Sites.xls
7			

	BF	BG	BH	BI
1	Informed Consent Document File Name	Other Trial Related Document File Name	Change Memo Document Name	Protocol Highlight Document Name
2	10_Informed_Consent.PDF	10_Other_document.doc		
3			Change_memo_doc.doc	
4	Informed_Consent_T2001.PDF	Other_document_T2001.doc		
5	3000_Informed_Consent.PDF	3000_Other_document.doc		
6	4000_Informed_Consent.PDF	4000_Other_document.doc		
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 Code	State Code	Responsible Part	Sponsor Contact Ty	Data Table 4 Funding Categ
Early Phase I	ABW	AK	Principal Investiga	Personal	National
I	AFG	AL	Sponsor	Generic	Externally Peer-Reviewed
I/II	AGO	AR	Sponsor Investigator		Institutional
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
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ZAF
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NIH Grant Funding Mechanis	NIH Grant Institute Cod	NCI Division/Program Code
B01	AA	CCR
B08	AE	CCT/CTB
B09	AF	CTEP
C06	AG	DCB
D43	AI	DCCPS
D71	AM	DCEG
DP1	AO	DTP
DP2	AR	DCP
DP3	AT	DEA
E11	BC	OD
F05	BX	OSB/SPOREs
F30	CA	CIP
F31	CB	CDP
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	
H13	CU	
H23	CX	
H25	DA	
H28	DC	
H50	DD	
H57	DE	
H62	DK	
H64	DP	
H75	EB	
H79	EH	
HD4	EM	
HR!	EP	
I01	ES	
K01	EY	
K02	FD	
K05	GD	
K06	GH	
K07	GM	
K08	GW	
K12	HB	
K14	HC	
K18	HD	
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K22	HI	

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K99	HR
KD1	HS
KL1	HV
KL2	HX
L30	HY
L32	IP
L40	JT
L50	LM
L60	MD
M01	MH
N01	MN
N02	NB
N03	NH
N43	NR
N44	NS
P01	NU
P20	OA
P30	OC
P40	OD
P41	OF
P42	OH
P50	OL
P51	OR
P60	PC
P76	PH
PL1	PR
PN1	PS
PN2	RC
R00	RD
R01	RG
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R04	RR
R06	RX
R08	SC
R13	SF
R15	SH
R17	SM
R18	SP
R21	SU
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R25	TP
R30	TS
R33	TW
R34	VA
R36	WC
R37	WH

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X02
X06
X98
Y01
Y02
Z01
Z02

Current Trial Status	Date Type	IND/IDE Type	IND/IDE Granto	IND/IDE Holder Typ
In Review	Actual	IND	CDER	Investigator
Approved	Anticipated	IDE	CBER	Organization
Active			CDRH	Industry
Closed to Accrual				NIH
Closed to Accrual and Intervention				NCI
Temporarily Closed to Accrual				
Temporarily Closed to Accrual and Intervention				
Complete				
Administratively Complete				
Withdrawn				

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

ment

Trial elements Order	Trial data element	Required for original submission
1	Unique Trial Identifier	Yes
2	Submission Type	Yes
3	NCI Trial Identifier	
4	Amendment Number	
5	Amendment Date	
6	Lead Organization Trial Identifier	Yes
7	NCT	
8	Other Trial Identifier	

9	Title	Yes
10	Trial Type	Yes
11	Primary Purpose	Yes
12	[Primary Purpose] Additional Qualifier	Yes if Primary Purpose is 'Other'
13	[Primary Purpose] Other Text	Yes if Primary Purpose is 'Other'
14	Phase	Yes
15	Pilot Trial?	
16	[Sponsor] Organization PO-ID	Yes
17	Responsible Party	
18	[Responsible Party] Investigator Person PO-ID	Yes if ‘Responsible Party’ is PI or Sponsor Investigator
19	[Responsible Party] Title	Yes if ‘Responsible Party’ is PI or Sponsor Investigator
20	[Responsible Party] Affilliation Organization PO-ID	Yes if ‘Responsible Party’ is PI or Sponsor Investigator
21	[Lead Organization] Organization PO-ID	Yes
22	[Principal Investigator] Person PO-ID	Yes
23	Data Table 4 Funding Category	Yes
24	[Data Table 4 Funding Sponsor/Source] Organization PO-ID	Yes

25	Program Code	
26	[NIH Grant] Funding Mechanism	Yes: if NIH grant exists
27	[NIH Grant] Institute Code	Yes: if NIH grant exists
28	[NIH Grant] Serial Number	Yes: if NIH grant exists
29	[NIH Grant] NCI Division/Program Code	Yes: if NIH grant exists
30	Current Trial Status	Yes
31	Why Study Stopped?	Yes if Current Trial Status is Withdrawn, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention or Administratively Complete
32	Current Trial Status Date	Yes
33	Study Start Date	Yes

34	Study Start Date Type	Yes
35	Primary Completion Date	Yes
36	Primary Completion Date Type	Yes
37	Study Completion Date	
38	Study Completion Date Type	
39	IND/IDE Type	Yes: if IND/IDE trial
40	IND/IDE Number	Yes: if IND/IDE trial
41	IND/IDE Grantor	Yes: if IND/IDE trial
42	IND/IDE Holder Type	Yes: if IND/IDE trial

43	[IND/IDE] NIH Institution	Yes If IND/IDE trial AND (IND/IDE Holder Type) = NIH
44	[IND/IDE] NCI Division /Program	Yes if IND/IDE trial AND If (IND/IDE Holder Type) = NCI
45	[IND/IDE] Availability of Expanded Access Expanded Access?	Yes if IND/IDE trial
46	[IND/IDE] Expanded Access Record	If (Has Expanded Access?) = Yes
47	Studies a US FDA regulated Drug Product	
48	Studies a US FDA regulated Device Product	
49	Unapproved/Uncleared Device	
50	Pediatric Post-Market Surveliance	
51	Product Exported from the US	
52	FDA Regulatory Information Indicator	
53	Section 801 Indicator	Yes if FDA Regulatory Information Indicator is 'Yes'
54	Data Monitoring Committee Appointed Indicator	
55	Protocol Document File Name	Yes

56	IRB Approval Document File Name	Yes
57	Participating Sites Document File Name	
58	Informed Consent Document File Name	
59	Other Trial Related Document File Name	
60	Change Memo Document Name	

61	Protocol Highlight Document Name	

Required for amendment	Required for update	Valid Values
Yes	Yes	
Yes	Yes	O, A, U
Yes	Yes	
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	Early Phase I, I, I/II, II, II/III, III, IV, NA,
		Yes, No
Yes		
		PI, Sponsor, Sponsor Investigator
Yes if 'Responsible Party' is PI or Sponsor Investigator	Yes if 'Responsible Party' is PI or Sponsor Investigator	
Yes if 'Responsible Party' is PI or Sponsor Investigator	Yes if 'Responsible Party' is PI or Sponsor Investigator	
Yes if 'Responsible Party' is PI or Sponsor Investigator	Yes if 'Responsible Party' is PI or Sponsor Investigator	
Yes		
Yes		
Yes	Yes	National, Externally Peer-Reviewed, Institutional
Yes	Yes	

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, Unknown
If (Has Expanded Access?) = Yes	If (Has Expanded Access?) = Yes	
		Yes, No,
		Yes, No,
		Yes, No,
		Yes, No,
		Yes, No,
		Yes, No
Yes if FDA Regulatory Information Indicator is 'Yes'	Yes if FDA Regulatory Information Indicator is '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.
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

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 (;).
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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
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

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N44
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P76
RC1
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R42
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SC1
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TU2
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UA1
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UH3
UL1

UR1
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UR6
UR8
US3
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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 Islan	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 code	State/Province
UNITED STATES	USA	
		Alabama
		Alaska
		Arizona
		Arkansas
		California
		Colorado
		Connecticut
		Delaware
		Florida
		Georgia
		Hawaii
		Idaho
		Illinois
		Indiana
		Iowa
		Kansas
		Kentucky
		Louisiana
		Maine
		Maryland
		Massachusetts
		Michigan
		Minnesota
		Mississippi
		Missouri
		Montana
		Nebraska
		Nevada
		New Hampshire
		New Jersey
		New Mexico
		New York
		North Carolina
		North Dakota
		Ohio
		Oklahoma
		Oregon
		Pennsylvania
		Rhode Island
		South Carolina
		South Dakota
		Tennessee

		Texas
		Utah
		Vermont
		Virginia
		Washington
		West Virginia
		Wisconsin
		Wyoming
CANADA	CAN	
		Alberta
		British Columbia
		Manitoba
		New Brunswick
		Newfoundland and Labrador
		Northwest Territories
		Nova Scotia
		Nunavut
		Ontario
		Prince Edward Island
		Quebec
		Saskatchewan
		Yukon
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	
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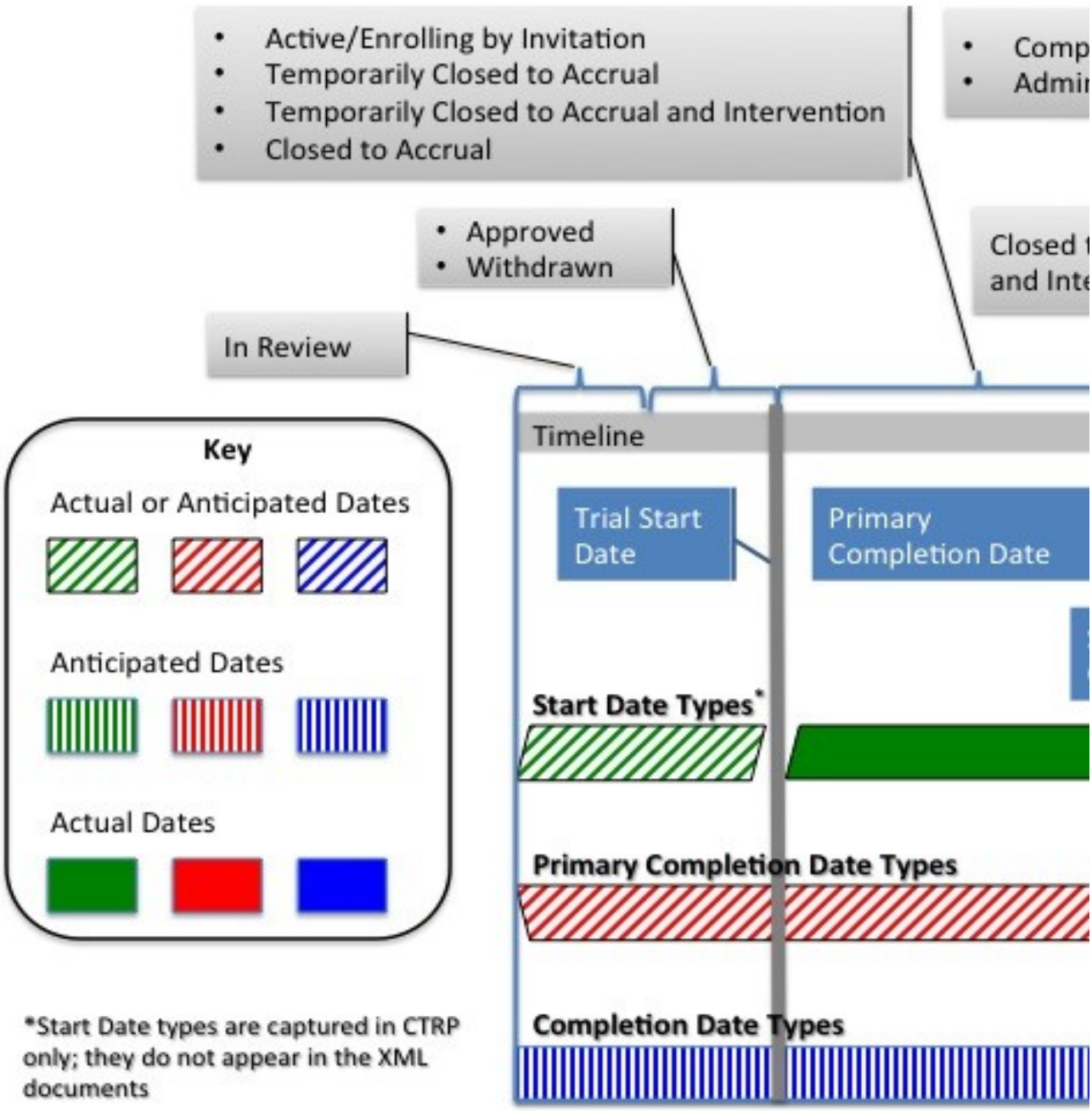
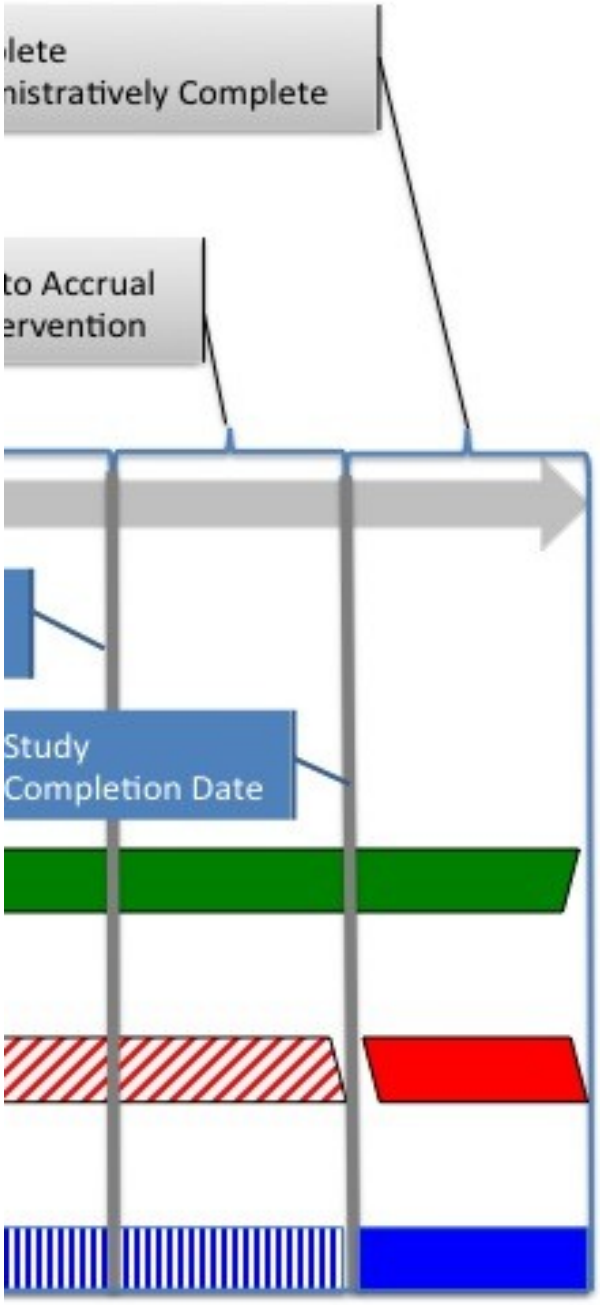
Trial Start, Primary Completion, and Completion Dates

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Study
Completion Date