CTRP Dictionary - Include v0.1

Version 0.1 DRAFT

This page provides information about CTRP trial attributes, including the data elements exposed to the NCI Clinical Trials API. This dictionary reflects information from version 1.0 of the API and version 4.4 of CTRP.

The following table displays the first seven columns from CTRP-dictionary_508compliant.xlsx. (To download the spreadsheet, click the link and follow your browser's prompts.) For a description of each column on this page and in the spreadsheet, refer to About the CTRP Dictionary.

Element ID	Data Element	Definition	API	TSR	DW	DB
EID 01.01	record_verification_date	Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made. In CTRP, the Last Verified date is the most recent date on which the CTRO confirmed all of a clinical study's information in CTRP as accurate and current.	Yes	Yes	Yes	Yes
EID 02.01	nci_id	The unique ID assigned to the trial by CTRP. Format: NCI followed by YYYY followed by 5 digits <NCI-YYYY-00000>.	Yes	Yes	Yes	Yes
EID 02.02	nct_id	The unique ID assigned to the trial by PRS (ClinicalTrials.gov). Format: NCT followed by 8 numeric characters <NCT00000000>.	Yes	Yes	Yes	Yes
EID 02.03	protocol_id	The unique ID assigned to the trial by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.	Yes	Yes	Yes	Yes
EID 02.04	ccr_id	The unique ID assigned to the trial managed by CCR (Center for Cancer Research).	Yes	Yes	Yes	Yes
EID 02.05	ctep_id	The unique ID assigned to the trial submitted by CTEP (Cancer Therapy Evaluation Program).	Yes	Yes	Yes	Yes
EID 02.06	dcp_id	The unique ID assigned to the trial submitted by DCP (Division of Cancer Prevention).	Yes	Yes	Yes	Yes
EID 02.07	other_ids	Additional IDs assigned to the trial, including unique IDs from other registries, NIH grant numbers, or protocol numbers assigned by the review board.	Yes	Yes	Yes	Yes
EID 02.08	name (component of other_ids)	Name of the other ID.	Yes	No	Yes	Yes
EID 02.09	value	Value of the other ID.	Yes	Yes	Yes	Yes
EID 02.10	amendment_date	Date on which the trial record was last amended. The amendment date is generally entered by the trial submitter.	Yes	Yes	Yes	Yes
EID 02.11	study_protocol_type	The primary investigative techniques used in the protocol. The non-interventional value includes observational and ancillary/correlative studies.	Yes	Yes	Yes	Yes
EID 02.12	study_subtype_code	Subtype of non-interventional trials.	Yes	Yes	Yes	Yes
EID 02.13	category	Category of the trial, as determined by the submission of a full protocol (Complete) or a ClinicalTrials.gov import (Abbreviated).	No	Yes	Yes	Yes
EID 02.14	amendment_number_text	The Amendment Number is a number assigned to the trial submission as specified in the protocol document.	No	Yes	Yes	Yes
EID 03.01	associated_studies	Associated trials, as listed in the API.	Yes	Yes	Yes	Yes
EID 03.02	study_id	The ID of an associated trial.	Yes	Yes	TBD	Yes
EID 03.03	study_id_type	The type of associated trial.	Yes	Yes	Yes	Yes
EID 03.04	study_a	Associated trial, as listed in the data warehouse.	No	Yes	Yes	Yes
EID 03.05	study_b	Associated trial, as listed in the data warehouse.	No	Yes	Yes	Yes
EID 04.01	brief_title	Protocol title intended for the lay public. A title that summarizes the purpose of the trial.	Yes	Yes	Yes	Yes
EID 04.02	official_title	The official name of the protocol provided by the study principal investigator or sponsor.	Yes	Yes	Yes	Yes
EID 04.03	acronym	The abbreviation (initial letters) by which the trial is known. The acronym or initials used to identify a clinical study.	Yes	Yes	Yes	Yes
EID 04.04	keywords	Words or phrases that describe the protocol. A keyword or series of keywords that can help to classify the trial and can help users find studies in the database.	Yes	Yes	Yes	Yes
EID 04.05	brief_summary	Short description of the protocol intended for the lay public. Includes a brief statement of the study hypothesis.	Yes	Yes	Yes	Yes
EID 04.06	detail_description	Extended description of the protocol, including more technical information than the Brief Summary. May include objectives and outline.	Yes	Yes	Yes	Yes
EID 04.07	principal_investigator	Primary medical researcher in charge of carrying out a clinical trial's protocol. Appointed investigator responsible for conducting the clinical trial, or, for multi-site trials, the study chair. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.	Yes	Yes	Yes	TBD
EID 04.08	central_contact	Person providing centralized, coordinated recruitment information for the entire study. The central contact for the trial may be a specific person, or it may be a generic title or role.	Yes	Yes	Yes	Yes
EID 04.09	central_contact_email	The main email address of the central contact person.	Yes	Yes	Yes	Yes
EID 04.10	central_contact_name	The name of the central contact person.	Yes	Yes	Yes	Yes
EID 04.11	central_contact_phone	The main (toll free) phone number of the central contact person.	Yes	Yes	Yes	Yes
EID 04.12	central_contact_type	The contact type.	Yes	No	Yes	TBD
EID 04.13	lead_org	The coordinating/lead center of the trial, responsible for the trial's research protocol. Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial.	Yes	Yes	Yes	TBD
EID 04.14	reporting_method_data_code	Specifies how accruals are submitted to CTRP. Methods used for the principal investigator summary report, as follows: Abbreviated indicates that the trial requires a minimal subset of data for reporting (for example, demographics). Complete indicates that the trial requires a larger set of data (for example, includes outcomes). AE indicates that the trial requires adverse events statistics.	No	Yes	Yes	Yes
EID 04.15	sponsor	Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3.	No	Yes	Yes	TBD
EID 04.16	resp_party_type	The party who is responsible for submitting information about a clinical study and updating that information, as defined by FDAAA. The responsible party can be the sponsor, sponsor-investigator, or sponsor-designated principal investigator.	No	Yes	Yes	Yes
EID 04.17	detail_description_primary	Primary protocol objectives concisely describe what the proposed research or activity intends to accomplish.	No	Yes	Yes	Yes

EID 04.18	detail_description_secondary	Secondary protocol objectives concisely describe what the proposed research or activity may accomplish.	No	Yes	Yes	Yes
EID 04.19	detail_description_tertiary	Protocol outline describes the interventions and procedures administered during the study.	No	Yes	Yes	Yes
EID 05.01	current_trial_status	The current stage or state of a clinical trial or study relative to other stages and its ability to enroll participants / patients. Overall accrual activity for the protocol.	Yes	Yes	Yes	Yes
EID 05.02	current_trial_status_date	The date on which the current trial status became effective.	Yes	Yes	Yes	Yes
EID 05.03	start_date	The date on which the enrollment of participants for a clinical study began (or will begin).	Yes	Yes	Yes	Yes
EID 05.04	start_date_type_code	The type of start date.	Yes	Yes	Yes	Yes
EID 05.05	completion_date	Final date on which data was (or will be) collected.	Yes	Yes	Yes	Yes
EID 05.06	completion_date_type_code	The type of completion date.	Yes	Yes	Yes	Yes
EID 05.07	why_study_stopped	A comment required only for trials at Administratively Complete, Withdrawn, or Temporarily Closed statuses. A brief explanation of why the study has been halted or terminated. For more information, check the trial's Brief Summary or Detailed Description.	No	Yes	Yes	Yes
EID 05.08	primary_completion_date	As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was (or will be) examined or received (or will receive) 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.	No	Yes	Yes	Yes
EID 05.09	primary_completion_date_type_code	The type of primary completion date.	No	Yes	Yes	Yes
EID 06.01	oversight_authority_country	(Retired: Deprecated by FDAAA Final Rule April 2017)	No	(Retired)	(Retired)	(Retired)
EID 06.02	oversight_authority_organization_name	(Retired: Deprecated by FDAAA Final Rule April 2017)	No	(Retired)	(Retired)	(Retired)
EID 06.03	fdaregulated_indicator	Indicates whether this trial includes an intervention subject to US FDA regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug and Cosmetic Act: 505, 510(k), 515, 520(m), and 522.	No	Yes	Yes	Yes
EID 06.04	section_801_indicator	If this trial includes an FDA regulated intervention, then this element becomes relevant. Indicates whether this is an 'applicable clinical trial' as defined in US Public Law 110-85, which was enacted on September 27, 2007. Section 801 of US Public Law 110-85 amends Section 402 of the US Public Health Service Act to expand the clinical study registry known as ClinicalTrials.gov and create a clinical study results database. Briefly, applicable drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Applicable device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance.	No	Yes	Yes	Yes
EID 06.05	delayed_posting_indicator	Unapproved/Uncleared Device: If this is a Section 801 applicable clinical trial, then this element becomes relevant. Indicates whether this trial includes a device not previously approved or cleared by the US FDA for any use as specified in the US Public Law 110-85, Title VIII, Section 801.	No	Yes	Yes	Yes
EID 06.06	data_monitoring_committee_appointed_indicator	Indicates whether a data monitoring committee has been appointed for this study. The data monitoring committee is group of independent scientists appointed to monitor the safety and scientific integrity of a human research intervention. The group can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also known as a data safety and monitoring board (DSMB).	No	Yes	Yes	Yes
EID 06.07	fda_regulated_drug	Indicates whether the trial studies one or more U.S. FDA-regulated drug or biologic products (a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act).	TBD	Yes	Yes	Yes
EID 06.08	fda_regulated_device	Indicates whether the trial studies one or more U.S. FDA-regulated device products (a device subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act).	TBD	Yes	Yes	Yes
EID 06.09	post_prior_to_approval	Indicates whether the responsible party authorizes posting of the study record on ClinicalTrials.gov prior to U.S. FDA approval/clearance of device product.	TBD	Yes	Yes	Yes
EID 06.10	ped_postmarket_surv	Indicates whether the U.S. FDA has ordered a pediatric post-market surveillance of the device product.	TBD	Yes	Yes	Yes
EID 06.11	exported_from_us	Indicates whether the product is manufactured in the U.S. or one of its territories and exported for study in a clinical trial in another country.	TBD	Yes	Yes	Yes
EID 07.01	irb_approval_status	Approval status as specified by the human subjects review board.	No	Yes	Yes	Yes
EID 07.02	irb_approval_number	Number assigned by the human subjects review board upon approval of the protocol. The value may be a number or the date of approval in mm/dd/yyyy format.	No	Yes	Yes	Yes
EID 07.03	irb_name	Full name of the approving human subjects review board.	No	Yes	Yes	TBD
EID 07.04	irb_organization_affiliation	Official name of organizational affiliation of the approving human subjects review board.	No	Yes	Yes	TBD
EID 08.01	ind_ide_type_code	Specifies that the trial involves an IND or an IDE under US FDA regulations. IND indicates the trial involves an Investigational New Drug Application. IDE indicates the trial involves an Investigational Device Exemption.	No	Yes	Yes	Yes
EID 08.02	grantor_code	US FDA center to which the IND or IDE was submitted. Valid values for IND are Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER). Valid values for IDE are Center for Devices and Radiological Health (CDRH) or Center for Biologics Evaluation and Research (CBER).	No	Yes	Yes	Yes
EID 08.03	ind_ide_number	Number assigned to an IND or IDE.	No	Yes	Yes	Yes
EID 08.04	holder_type_code	The type of IND/IDE holder.	No	Yes	Yes	Yes
EID 08.05	expanded_access_indicator	Availability of Expanded Access: Indicate whether any non-protocol access is to be provided for the investigational drug or device.	No	Yes	Yes	Yes
EID 08.06	expanded_access_status_code	The status of the drug or device access when the drug or device is available outside any clinical trial protocol.	No	(Retired)	Yes	Yes
EID 08.07	exempt_indicator	(Retired: Deprecated by FDAAA Final Rule April 2017)	No	(Retired)	(Retired)	(Retired)
EID 08.08	funding_mechanism_code	A unique ID, a three-character code used to identify areas of extramural research activity applied to funding mechanisms.	No	Yes	Yes	Yes
EID 08.09	nih_institution_code	A two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative.	No	Yes	Yes	Yes
EID 08.10	serial_number	The number assigned sequentially to a series within an Institute, Center, or Division.	No	Yes	Yes	Yes
EID 08.11	nci_division_or_program	The NCI organizational unit that provides funding for the study.	No	Yes	Yes	Yes

EID 08.12	expanded_access_record	Specifies the ClinicalTrials.gov identifier (NCT ID) for the associated Expanded Access record.	TBD	Yes	Yes	Yes
EID 09.01	anatomic_sites	A comma-delimited list of the anatomic site(s) on which the trial or study is focused.	Yes	Yes	Yes	Yes
EID 09.02	summary_4_funding_category	The type of Data Table 4 funding sponsorship.	No	Yes	Yes	Yes
EID 09.03	specific_funding_source	Sponsor or source of the funding mechanism.	No	Yes	Yes	TBD
EID 09.04	program_code	The alphanumeric code that identifies the clinical research program.	No	Yes	Yes	Yes
EID 10.01	collaborators	A collaborator is an organization other than the sponsor that provides support for a clinical study. This support may include funding, design, implementation, data analysis, or reporting.	Yes	Yes	Yes	Yes
EID 10.02	functional_role	The type of organization that provides support.	Yes	Yes	Yes	TBD
EID 10.03	name (component of collaborators)	Name of the collaborator organization.	Yes	Yes	Yes	TBD
EID 11.01	diseases	Disease or condition. Diseases are neoplastic or nonneoplastic conditions, disorders, syndromes, illnesses, or injuries. Conditions include any health issue that is the subject of a clinical protocol.	Yes	Yes	Yes	Yes
EID 11.02	disease_code	Unique ID assigned to the disease or condition.	Yes	No	Yes	Yes
EID 11.03	inclusion_indicator (component of diseases)	Indicates whether the system includes the disease/condition.	Yes	No	Yes	TBD
EID 11.04	lead_disease_indicator	(Not implemented.)	Yes	No	Yes	Yes
EID 11.05	nci_thesaurus_concept_id (component of diseases)	A concept unique ID within the NCI Enterprise Vocabulary Service's (EVS) NCI Thesaurus (NCIt).	Yes	No	Yes	TBD
EID 11.06	preferred_name	Standard name. Word or phrase that the NCIt uses by preference to refer to the disease or condition.	Yes	Yes	Yes	TBD
EID 11.07	display_name	The name that is used in the “reported” diseases domain. Some diseases are reported and therefore are included in the reported disease hierarchy. Others are too specific to report and are not included in the reported disease domain. The name of a reported disease in the domain can differ from the preferred name.	Yes	No	Yes	TBD
EID 11.08	parents	A comma-delimited list of concepts in the hierarchy above the disease/condition concept. Also known as super-concepts.	Yes	No	Yes	Yes
EID 11.09	synonyms (component of diseases)	A comma-delimited list of alternative names for the preferred name of the disease or condition.	Yes	No	TBD	TBD
EID 12.01	classification_code	(Retired: Deprecated by FDAAA Final Rule April 2017)	Yes	(Retired)	(Retired)	(Retired)
EID 12.02	interventional_model	Interventional Study Model: The general design of the strategy for assigning interventions to participants in a clinical study.	Yes	Yes	Yes	Yes
EID 12.03	study_model_code	The study model is the primary strategy for subject identification and follow-up. Applies to non-interventional trials.	Yes	Yes	Yes	Yes
EID 12.04	study_model_other_text	A detailed description of the trial’s study model, if the study model code is Other.	Yes	Yes	Yes	Yes
EID 12.05	bio_specimen	For Ancillary-Correlative trials that indicate that biospecimens will be retained.	Yes	Yes	Yes	Yes
EID 12.06	bio_specimen_description	All types of biospecimens to be retained (such as whole blood, serum, white cells, urine, or tissue).	Yes	Yes	Yes	Yes
EID 12.07	bio_specimen_retention_code	The DNA retention indicator. Applies to Ancillary-Correlative trials that indicate biospecimens will be retained.	Yes	Yes	Yes	Yes
EID 12.08	f1	A bio_specimen element.	Yes	No	TBD	TBD
EID 12.09	f2	A bio_specimen element.	Yes	No	TBD	TBD
EID 12.10	f3	A bio_specimen element.	Yes	No	TBD	TBD
EID 12.11	f4	A bio_specimen element.	Yes	No	TBD	TBD
EID 12.12	primary_purpose	The reason for the protocol.	Yes	Yes	Yes	Yes
EID 12.13	primary_purpose_code	The reason for the protocol.	Yes	Yes	Yes	Yes
EID 12.14	primary_purpose_other_text	A description of the trial’s primary purpose, if the primary purpose code is Other.	Yes	Yes	Yes	Yes
EID 12.15	primary_purpose_additional_qualifier_code	Additional qualifier code for the trial’s primary purpose.	Yes	No	Yes	Yes
EID 12.16	phase	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs.	Yes	Yes	Yes	Yes
EID 12.17	phase (component of phase)	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs.	Yes	Yes	Yes	Yes
EID 12.18	phase_other_text	Other text for the trial phase.	Yes	No	Yes	Yes
EID 12.19	phase_additional_qualifier_code	This element indicates whether the trial is a pilot.	Yes	Yes	Yes	Yes
EID 12.20	masking	A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions.	Yes	Yes	Yes	Yes
EID 12.21	masking (component of masking)	(Retired: Deprecated by FDAAA Final Rule April 2017)	Yes	(Retired)	(Retired)	(Retired)
EID 12.22	masking_allocation_code	The clinical trial design strategy used to assign participants to an arm of a study.	Yes	Yes	Yes	Yes

EID 12.23	masking_role_investigator	This element indicates that the investigator is blind to the intervention assignments.	Yes	Yes	Yes	Yes
EID 12.24	masking_role_outcome_assessor	This element indicates that the outcome assessor is blind to the intervention assignments.	Yes	Yes	Yes	Yes
EID 12.25	masking_role_subject	This element indicates that the subject is blind to the intervention assignments.	Yes	Yes	Yes	Yes
EID 12.26	masking_role_caregiver	This element indicates that the caregiver is blind to the intervention assignments.	Yes	Yes	Yes	Yes
EID 12.27	minimum_target_accrual_number	The anticipated (target) number of subjects in the trial.	Yes	Yes	Yes	Yes
EID 12.28	number_of_arms	Number of intervention groups in the trial.	Yes	Yes	Yes	Yes
EID 12.29	secondary_purpose_name	Optional secondary reason for conducting the trial.	No	Yes	Yes	Yes
EID 12.30	secondary_purpose_other_text	A description of the trial's secondary purpose, if the secondary purpose code is Other.	No	Yes	Yes	Yes
EID 12.31	time_perspective_code	The temporal relationship of observation period to time of subject enrollment. Applies to non-interventional trials.	No	Yes	Yes	Yes
EID 12.32	time_perspective_other_text	A description of the trial's time perspective, if the time perspective code is Other.	No	Yes	Yes	Yes
EID 12.33	number_of_groups	The number of intervention groups/cohorts associated with the trial. Applies to non-interventional trials.	No	Yes	Yes	Yes
EID 12.34	model_description	This element provides any available details about the Interventional Study Model.	TBD	Yes	Yes	Yes
EID 12.35	masking_description	This element provides any available details about the masked parties.	TBD	Yes	Yes	Yes
EID 12.36	no_masking	This element indicates that all people involved in the study know the identity of the intervention assignment.	TBD	Yes	Yes	Yes
EID 13.01	accepts_healthy_volunteers_indicator	Indicate whether healthy volunteers may participate in the study. Healthy volunteers are people who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements.	Yes	Yes	Yes	Yes
EID 13.02	study_population_description	A description of the population from which the groups or cohorts will be selected (such as primary care clinic, community sample, or residents of a certain town). Applies to observational studies only.	Yes	Yes	Yes	Yes
EID 13.03	sampling_method_code	The sampling method code indicating the processes to select the study population. Applies to observational studies only. For details, check the trial's Detailed Description.	Yes	Yes	Yes	Yes
EID 13.04	eligibility	Eligibility criteria.	Yes	Yes	Yes	Yes
EID 13.05	structured	Structured eligibility criteria.	Yes	Yes	Yes	Yes
EID 13.06	gender	Physical gender of individuals who may participate in the protocol.	Yes	Yes	Yes	TBD
EID 13.07	max_age	Maximum age of participants. The value "999 Years" represents no maximum age.	Yes	Yes	Yes	TBD
EID 13.08	max_age_number	Provide a number for the maximum age of participants.	Yes	Yes	Yes	TBD
EID 13.09	max_age_unit	Select a unit of time for the maximum age of participants.	Yes	Yes	Yes	TBD
EID 13.10	max_age_in_years	Maximum age of participants, expressed in years.	Yes	No	TBD	TBD
EID 13.11	min_age	Minimum age of participants. The value "0 Years" represents no minimum age.	Yes	Yes	Yes	TBD
EID 13.12	min_age_number	Provide a number for the minimum age of participants.	Yes	Yes	Yes	TBD
EID 13.13	min_age_unit	Select a unit of time for the minimum age of participants.	Yes	Yes	Yes	TBD
EID 13.14	min_age_in_years	Minimum age of participants, expressed in years.	Yes	No	TBD	TBD
EID 13.15	unstructured	Unstructured eligibility criteria.	Yes	Yes	Yes	Yes
EID 13.16	display_order	The order in which the trial lists unstructured eligibility criteria.	Yes	No	Yes	TBD
EID 13.17	inclusion_indicator (component of unstructured)	Indicates whether the specified criterion (population description) is an inclusion indicator (t) or exclusion indicator (f) for participation in this trial.	Yes	No	Yes	TBD
EID 13.18	description	A description of the population included or exluded from the trial.	Yes	Yes	Yes	TBD
EID 13.19	gender_based	Indicates whether participant eligibility is based on self-representation of gender identity.	TBD	Yes	Yes	Yes
EID 13.20	gender_description	This element provides any available information about gender eligibility.	TBD	Yes	Yes	Yes
EID 14.01	interventions	The interventions being studied (administered) in the arm.	Yes	Yes	Yes	Yes
EID 14.02	intervention_name	The standard name of the intervention being studied. For a drug, this is the generic name. For an investigational new drug that does not yet have a generic name, this may be the chemical name, company code, or serial number.	Yes	Yes	Yes	Yes
EID 14.03	intervention_type	The general category or mode of the intervention being studied.	Yes	Yes	Yes	Yes
EID 14.04	intervention_code	The code (NCI Thesaurus Concept ID) of the intervention being studied.	Yes	No	Yes	Yes
EID 14.05	intervention_description	Succinctly describes the key details of the intervention. For drug interventions, a summary of the drug's chemical nature and (potential) mechanism of action, and/or details such as dosage form, dosage, frequency, and duration. For other interventions, a summary of the procedure or device that provides key details that distinguish it from similar interventions.	Yes	Yes	Yes	Yes
EID 14.06	synonyms (component of interventions)	A comma-delimited list of alternative names for the intervention, including brand names, abbreviations, code names, and chemical structure.	Yes	Yes	Yes	Yes
EID 15.01	arms	A group or subgroup of participants in a clinical trial that receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins. Applies to interventional trials.	Yes	Yes	Yes	Yes
EID 15.02	arm_name	Label (short name) used to identify the arm or comparison group.	Yes	Yes	Yes	Yes
EID 15.03	arm_type	Function of the arm.	Yes	Yes	Yes	Yes

EID 15.04	arm_description	Brief description of the arm or comparison group, to distinguish it from other arms/groups in the trial.	Yes	Yes	Yes	Yes
EID 16.01	name	The name (or title) of an outcome measure. Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors, or treatment. The title is a concise name for the specific measure.	Yes	Yes	Yes	Yes
EID 16.02	description	Additional information about the outcome measure, if needed for clarification.	Yes	Yes	Yes	Yes
EID 16.03	timeframe	Time point(s) at which the outcome measure is assessed.	Yes	Yes	Yes	Yes
EID 16.04	safety_indicator	(Retired: Deprecated by FDAAA Final Rule April 2017)	No	(Retired)	(Retired)	(Retired)
EID 16.05	type_code	Indicates the outcome measure type.	Yes	Yes	Yes	Yes
EID 17.01	group_code	The label of a group or subgroup of participants in a clinical trial that receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins.	No	Yes	Yes	Yes
EID 17.02	description	Specific subgroup stratification factors.	No	Yes	Yes	Yes
EID 18.01	biomarkers	Biomarkers for the trial.	Yes	Yes	Yes	Yes
EID 18.02	assay_purpose	Why the biomarker is being measured.	Yes	Yes	Yes	Yes
EID 18.03	long_name	Long name of the biomarker.	Yes	No	Yes	TBD
EID 18.04	name (component of biomarkers)	Name of biomarker in caDSR.	Yes	Yes	Yes	TBD
EID 18.05	synonyms (component of biomarkers)	Alternative names for the biomarker.	Yes	No	TBD	TBD
EID 18.06	hugo_biomarker_code	A unique ID for the biomarker within the Human Genome Organisation (HUGO) Gene Nomenclature Committee (HGNC) database.	Yes	No	Yes	TBD
EID 18.07	nci_thesaurus_concept_id (component of biomarkers)	A unique ID for the biomarker within the NCI Enterprise Vocabulary Service's (EVS) NCI Thesaurus (NCIt).	Yes	No	Yes	TBD
EID 18.08	evaluation_type_code	Method of biomarker evaluation.	No	Yes	Yes	Yes
EID 18.09	assay_type_code	How the biomarker is being measured.	No	Yes	Yes	Yes
EID 18.10	assay_use	How the biomarker is used in the trial.	No	Yes	Yes	Yes
EID 18.11	type_code	Describes the type of biospecimen for the biomarker.	No	Yes	Yes	Yes
EID 19.01	sites	Participating sites for a trial.	Yes	Yes	Yes	Yes
EID 19.02	contact_email	The email address for a specified participating site contact on a trial.	Yes	Yes	Yes	Yes
EID 19.03	contact_name	The name of a specified participating site contact on a trial.	Yes	Yes	Yes	TBD
EID 19.04	contact_phone	The office phone number for a specified participating site contact on a trial.	Yes	Yes	Yes	Yes
EID 19.05	generic_contact	Primary contact for a participating site.	Yes	Yes	Yes	TBD
EID 19.06	recruitment_status	The current stage or state of a participating site relative to other stages and its ability to enroll participants / patients. Protocol accrual activity at a facility.	Yes	Yes	Yes	Yes
EID 19.07	recruitment_status_date	The date associated with the participating site's current site recruitment status.	Yes	Yes	Yes	Yes
EID 19.08	local_site_identifier	The unique ID assigned to the trial by the participating site.	Yes	No	Yes	Yes
EID 19.09	org_address_line_1	The first part of an address for the participating site.	Yes	No	Yes	Yes
EID 19.10	org_address_line_2	The second part of an address for the participating site.	Yes	No	Yes	Yes
EID 19.11	org_city	The city of the participating site.	Yes	Yes	Yes	Yes
EID 19.12	org_country	The country of the participating site.	Yes	Yes	Yes	Yes
EID 19.13	org_email	The email address of the participating site.	Yes	No	Yes	Yes
EID 19.14	org_family	The organization family of the participating site.	Yes	No	Yes	Yes
EID 19.15	org_fax	The fax number of the participating site.	Yes	No	Yes	TBD
EID 19.16	org_name	The full name of the participating site (the organization where the protocol is being conducted).	Yes	Yes	Yes	Yes
EID 19.17	org_to_family_relationship	The relationship of the participating site organization to its family.	Yes	No	Yes	Yes
EID 19.18	org_phone	The phone number of the participating site.	Yes	No	Yes	Yes
EID 19.19	org_postal_code	The postal code of the participating site.	Yes	Yes	Yes	Yes
EID 19.20	org_state_or_province	The two-letter abbreviation for the participating site's state or province.	Yes	Yes	Yes	Yes
EID 19.21	org_status	The organization status of the participating site.	Yes	No	Yes	Yes
EID 19.22	org_status_date	The date associated with the participating site's organization status.	Yes	No	Yes	Yes
EID 19.23	org_tty	The TTY number of the participating site.	Yes	No	Yes	TBD
EID 19.24	org_coordinates	The geographic coordinates of the participating site.	Yes	No	TBD	TBD
EID 19.25	org_po_id	Unique ID for the participating site organization, assigned by CTRP.	No	Yes	Yes	Yes
EID 19.26	investigator_last_name	The principal investigator for a trial at a participating site.	No	Yes	Yes	Yes
EID 19.27	target_accrual	The anticipated (target) number of subjects in the trial at the participating site.	No	Yes	Yes	Yes
EID 20.01	code_system	The disease terminology code currently in use for accruals.	No	No	Yes	Yes

EID 20.02	subject_identifier	Unique ID assigned to the patient for the study.	No	No	Yes	Yes
EID 20.03	zip	The study subject's postal code. In the US, the postal code is the string of characters used to identify the five-digit Zone Improvement Plan (ZIP) code, assigned by the US Postal Service to facilitate mail delivery. If the subject is a US resident, the postal code is mandatory.	No	No	TBD	Yes
EID 20.04	country	The study subject's country. The name of a country from which a person or their biological family had previous residence or ancestors. If the subject is not a US resident, the country is mandatory.	No	No	Yes	Yes
EID 20.05	birth_date	The study subject's month and year of birth.	No	No	TBD	Yes
EID 20.06	gender	Text designations that identify the study subject's gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles.	No	No	Yes	Yes
EID 20.07	race	Text designations that identify the study subject's race, based on the Office of Management and Budget (OMB) categories.	No	No	Yes	Yes
EID 20.08	ethnicity	Text designations that identify the study subject's ethnicity, based on the Office of Management and Budget (OMB) categories.	No	No	Yes	Yes
EID 20.09	payment_method	Text designations that identify the study subject's payment method. An entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service.	No	No	Yes	Yes
EID 20.10	registration_date	Date the subject was registered for the study.	No	No	Yes	Yes
EID 20.11	registration_group	Unique ID assigned by CTRP (PO ID) to the organization that originally registered the patient for the study.	No	No	Yes	Yes
EID 20.12	site_org_id	Unique ID (numeric or alphanumeric) assigned to the study site.	No	No	Yes	Yes
EID 20.13	preferred_name	The study subject's diagnosed disease or condition. Diseases are neoplastic or nonneoplastic conditions, disorders, syndromes, illnesses, or injuries. Conditions include any health issue that is the subject of a clinical protocol.	No	No	Yes	Yes
EID 20.14	accrual_count	The actual number of subjects accrued on the trial at the participating site to date.	No	No	Yes	Yes
EID 20.15	targeted_accrual	The anticipated (target) number of subjects for the trial for all participating sites in a Cancer Center Family.	No	No	Yes	Yes