Data Elements Included in NCI As Sponsor Trials Report - Include 20170905

The following table describes the data elements displayed in the NCI As Sponsor Trials report for each trial:

Data Element	Description
NCI ID	The unique ID assigned to the trial by the CTRP.
Lead Org 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. For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
Title	The official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document). For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
Lead Organization PO ID	The unique ID assigned to the lead organization by the CTRP. For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
Lead Organization	The name of the organization responsible for the trial's research protocol, and responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial. For information, refer to Abstracting Sponsors and Responsible Parties.
NCT ID	The unique ID assigned to the trial by the National Clinical Trial program (ClinicalTrials.gov) for trials that have been submitted to ClinicalTrials.gov Protocol Registration System (PRS) previously. This ClinicalTrials.gov ID appears as "NCT" followed by 8 numeric characters (such as NCT12345678). For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
CTEP ID	The unique ID assigned to the trial submitted by CTEP (Cancer Therapy Evaluation Program). For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
DCP ID	The unique ID assigned to the trial submitted by DCP (Division of Cancer Prevention). For information, refer to Abstracting Trial Descriptions, Titles, and Identifiers.
Funding Mechanism	A unique three-character code. NIH assigns one of these codes to each area of extramural research activity. This code identifies the funding mechanism of a grant on a trial. For information, refer to Funding Mechanism Code Values or Abstracting Funding.
NCI Division /Program	The NCI division or program identified in an IND, IDE, or grant record, as the NCI organizational unit that provides funding for the trial. For information, refer to NCI Division and Program Values, Abstracting INDs and IDEs, or Abstracting Funding.
Institution Code	The NIH institution associated with the trial, as identified in an IND, IDE, or grant record. For information, refer to NIH Institution Code Values, NIH Grant Institute Code Values, Abstracting INDs and IDEs, or Abstracting Funding.

IND/IDE Grantor	The US FDA center to which the IND or IDE was submitted, and that holds the IND/IDE approval:
	• For IND:
	  ○ Center for Drug Evaluation and Research (CDER)
	  ○ Center for Biologics Evaluation and Research (CBER)
	• For IDE:
	  ○ Center for Devices and Radiological Health (CDRH)
	  ○ Center for Biologics Evaluation and Research (CBER)
	
	For information, refer to Abstracting INDs and IDEs.

IND/IDE Holder Type	The type of organization that holds the IND/IDE approval for the trial: • Investigator • Organization • Industry • NIH • NCI For information, refer to Abstracting INDs and IDEs.
IND/IDE Number	The number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). For information, refer to Abstracting INDs and IDEs.
IND/IDE Types	A value indicating whether 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. For information, refer to Abstracting INDs and IDEs.

Section 801 Indicator	A value indicating whether the FDA-regulated interventional trial is an applicable trial as defined in US Public Law 110-85, Title VIII, Section 801. For information, refer to Abstracting Regulatory Information.
Principal Investigator	The Unable to render {include} The included page could not be found. For information, refer to Abstracting Sponsors and Responsible Parties.
Sponsor Org	The name of the primary organization that oversees the implementation of the study and is responsible for data analysis, as defined in 21 CFR 50.3. For information, refer to Abstracting Sponsors and Responsible Parties.
Responsible Party	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. For information, refer to Abstracting Sponsors and Responsible Parties.
Summary 4 Funding Sponsor	The CTRP organizations listed as Data Table 4 Funding Sponsor for the trial. Sponsor or source of the funding mechanism. For information, refer to Abstracting Sponsors and Responsible Parties.
Trial Status	The current stage or state of a clinical trial or study relative to its ability to enroll participants/patients. For information, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Abstracting Trial Statuses.
Trial Status Date	The date on which the current trial status became effective. For information, refer to Abstracting Trial Statuses.
Trial Start Date	The date on which the enrollment of participants for a clinical study began (or will begin). For information, refer to Abstracting Trial Statuses.
Primary Completion Date	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 (as specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial). For information, refer to Abstracting Trial Statuses.
Primary Completion Date Type	A value indicating whether the completion date is the one on which the trial is expected to complete (Anticipated), or the date on which it actually completed (Actual). For information, refer to Abstracting Trial Statuses.
Submitting Org Name	The name of the organization that submitted the trial.
Current Processing Status	The current status of the trial in the CTRP trial processing work flow. For information, refer to Trial Processing Statuses and Abstracting Trial Statuses.
Study Category	The category of the trial, as determined by the submission of a full protocol (Complete) or a ClinicalTrials.gov import (Abbreviated). For information, refer to CTRP Trial Categories, Study Sources or Abstracting NCI-Specific Information.
Submission Number	A number identifying the trial record in the sequence of submissions for that trial. An original submission is submission 1. For information, refer to Processing Trial History Information.
Trial Submission Type	A value indicating whether the trial is an original submission or an amendment. For information, refer to Processing Trial History Information.
Trial Summary Report Sent Date	The date on which the system sent the Trial Summary Report (TSR) to the principal investigator or trial submitter. For information, refer to Processing Trial Milestones.