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Clinical Trials Reporting Program (CTRP): 2013 Update

Presented to CTAC
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Sheila A. Prindiville, MD, MPH
for CCCT and CBIIT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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NCI's Clinical Trials Reporting Program

- Overview
- Progress since last report to CTAC (July, 2011)
- Future considerations for CTRP data capture and reporting
- CTAC Clinical Trials Informatics Subcommittee: addressing future considerations and unresolved policy issues

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What is CTRP?

- Comprehensive database containing regularly updated information on all NCI supported clinical trials, including accrual
- Central repository of trials with information collected using standardized data elements
- System designed to support NCI's clinical trials portfolio management

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Added Value of CTRP to NCI

- Collects information not available in ClinicalTrials.gov that enhances NCI's clinical trials portfolio management; including:
  - Patient and site accrual data
  - Biomarkers: assay type, purpose, tissue specimen type and collection method
  - Protocol document for abstraction (except industrial trials)
  - Data needed to create Cancer Center Support Grant (CCSG) Data Table 4 (e.g., funding category, funding sponsor, anatomic site)
- Search of trial data enhanced by consistent terminology including disease terms, interventions and biomarkers
- Enhances ClinicalTrials.gov compliance
  - Facilitates ClinicalTrials.gov submissions, avoiding duplicate data entry by NCI awardees.
  - Supports management of NCI's ClinicalTrials.gov account and compliance with the FDA Amendment Act of 2007 for NCI sponsored trials.

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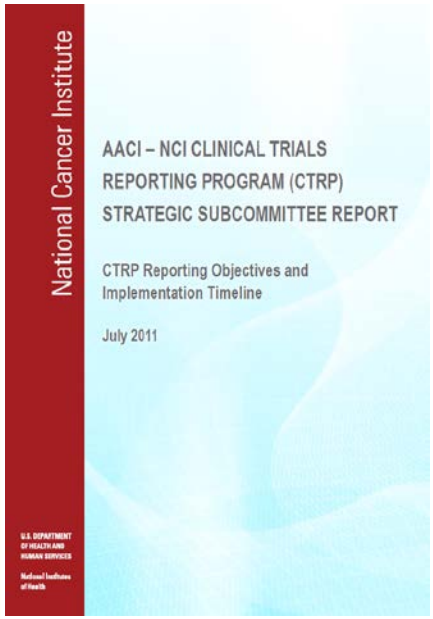
AACI* – NCI CTRP Strategic Subcommittee July 2011



- CTRP Reporting Requirements
  - Registration
  - Amendments
  - Updates/status changes
  - Accrual
  - Outcome reporting
- Timelines

*Association of American Cancer Institutes (AACI)

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Timelines*: AACI – NCI CTRP Strategic Subcommittee Report, July 2011

- Initial registration of interventional trials open to accrual on or after January 1, 2009 to be completed by September 2011
- Ongoing registration of new trials beginning September 2011
- Submit trial amendments and updates beginning March 2012
- Submit subject accrual reporting, with quarterly updates, beginning September 2012
- Defer observational trials and outcome data reporting for 3 to 5 years

*Timelines for NCI-Designated Cancer Centers

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Progress: Trial Registration

- Initial registration of interventional trials open as of January 1, 2009 has been completed by NCI-Designated Cancer Centers, CTEP, DCP, and CCR
- Registration of new trials is ongoing
- Registration of non-interventional (i.e., observational/ancillary/correlative) trials is accepted
- Registration of trials by other NCI awardees has not consistently begun

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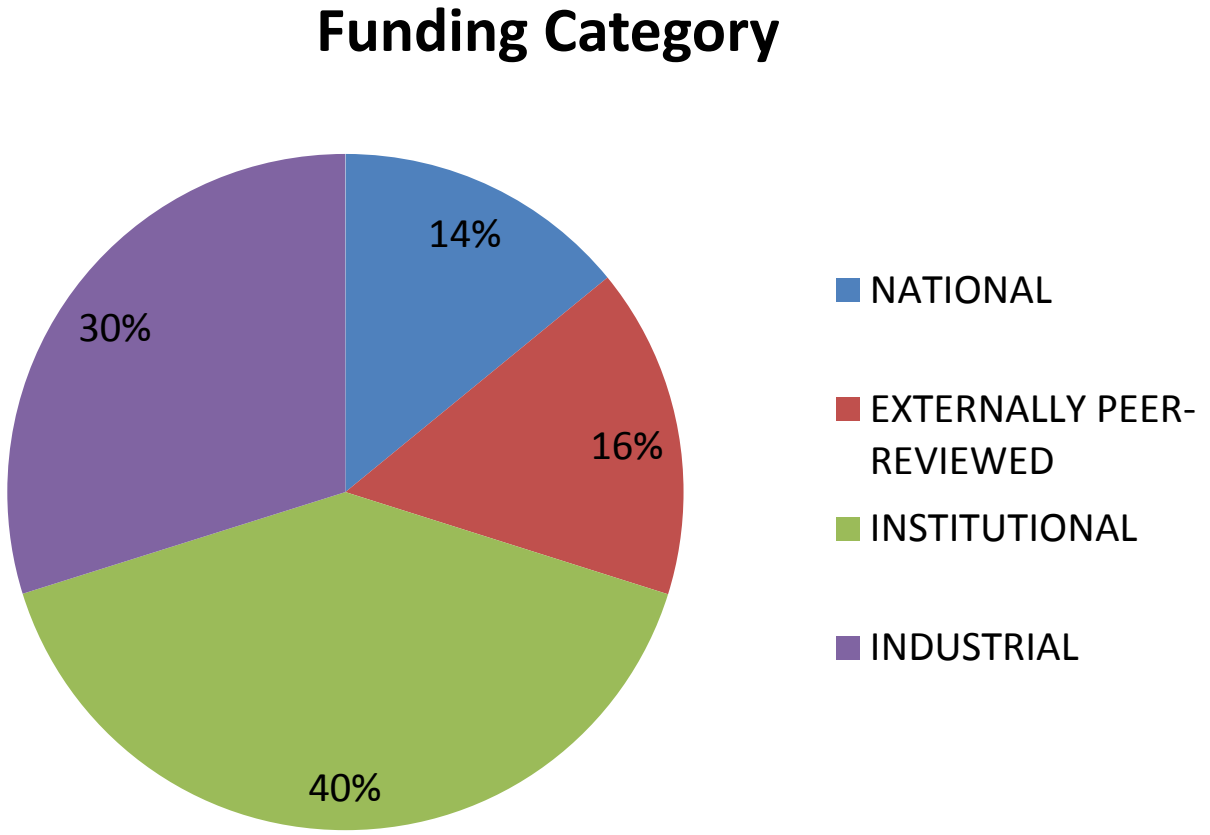
Registered Trials by Funding Category

10,257 Trials Registered and Abstracted (November 2013)



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Progress: Amendments and Updates

- NCI-Designated Cancer Centers are reporting amendments, updates, and status changes
- Timing of submissions:
  - Amendments: within 20 days of IRB approval
  - Status changes: within 30 days of the change
  - Updates: annually
- CTRP will implement an automated process for a yearly reminder to facilitate update reporting

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Accrual Reporting – Work in Progress

- Import of accrual data on NCI managed trials (CTEP, DCP, CCR) underway
- Cancer Centers reporting patient level accrual on institutional trials where they are the lead organization is in progress
- Cancer Centers report summary accrual count on Industrial trials where they are participating is in progress

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Progress: CCSG Data Table 4

- Initial CTRP automated CCSG Data Table 4 reports developed

- Beginning in January 2014, initial CTRP-generated Data Table 4 reports will be reviewed with each NCI-Designated Cancer Center to ensure:
  - The list of registered trials is accurate and complete
  - Accrual is complete and correctly reported for the Cancer Center and its affiliates

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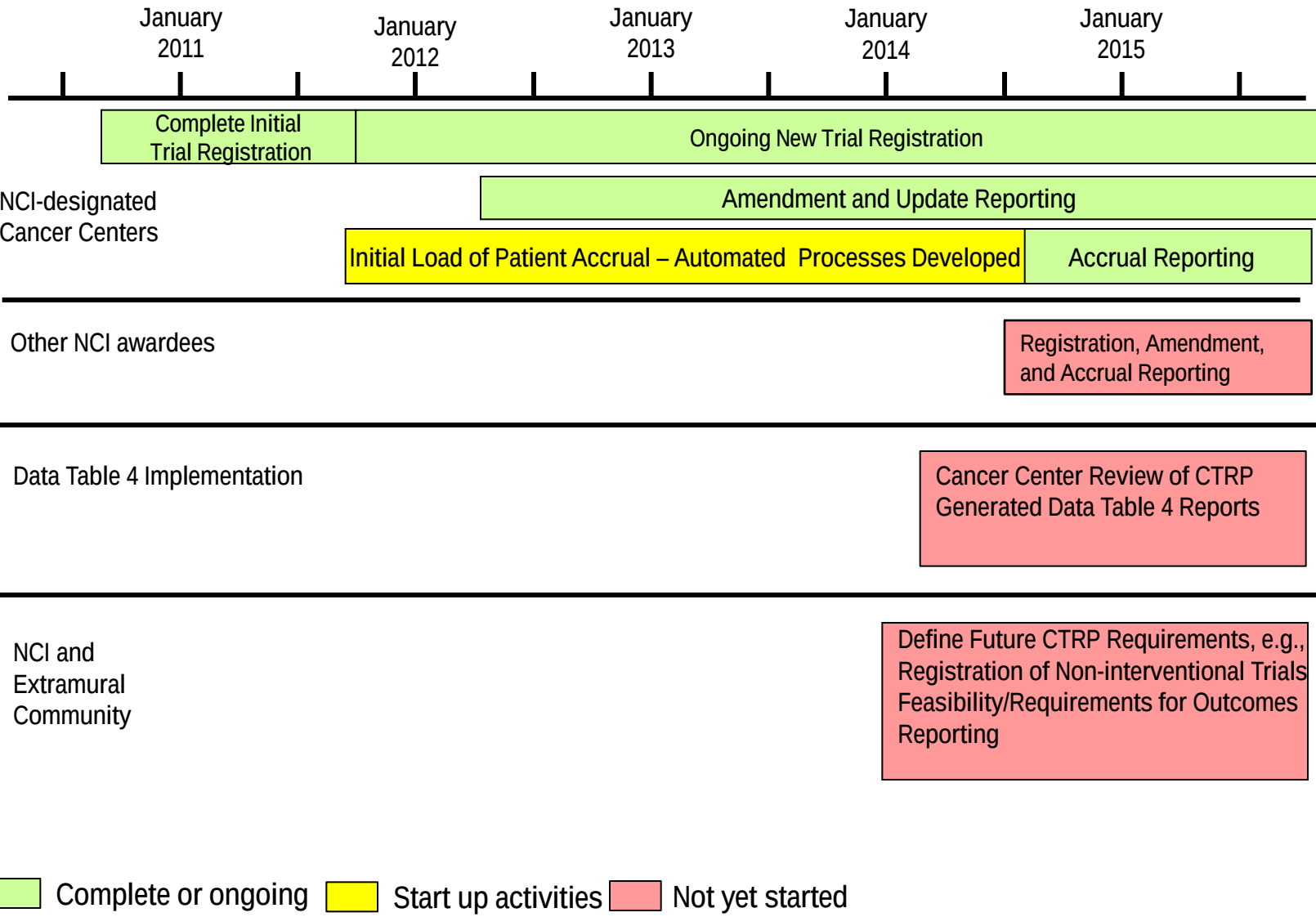
CTRP Timeline as of October 2013



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CTRP - A Collaborative Effort Within the NIH/NCI

- Collaborative effort within NCI
  - Involved many groups within NCI (CTEP, DCP, OCC, CCR, DCCPS) to initiate data transfer and integration activities
- Collaborative effort with NIH/NLM
  - Regular meetings to facilitate NCI and extramural community compliance with FDAAA reporting requirements to ClinicalTrials.gov
  - Developed and implemented “Upload from CTRP” function which allows sponsors to retrieve CTRP data for trial registration for upload to ClinicalTrials.gov
  - CTRP registration and amendment timelines make data available for upload well within timelines defined by ClinicalTrials.gov

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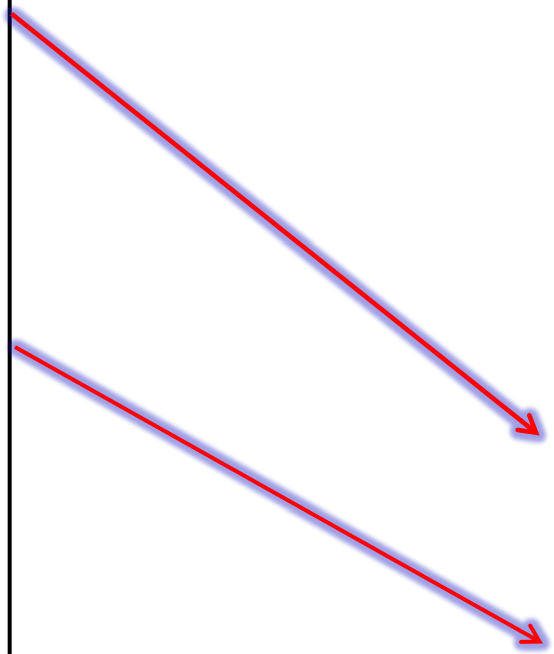
"Upload from CTRP" and ClinicalTrials.gov

- CTRP-ClinicalTrials.gov Upload function allows trial sponsors to register and maintain trial information in ClinicalTrials.gov from CTRP data
  - NCI-sponsored Trials: NCI ClinicalTrials.gov account for NCI sponsored trials
  - Other-sponsored Trials: Sponsors can upload CTRP data directly into their ClinicalTrials.gov account from CTRP via the Upload Service
- CTRP imports Industrial trial data from ClinicalTrials.gov for trials that Cancer Centers have indicated participation
  - The CTRP Clinical Trials Reporting Office (CTRO) performs scientific abstraction for cancer disease and interventions on Industrial trials to enable search and reporting across all trial categories

Main Menu

XML Upload

Upload from NCI CTRP



ClinicalTrials.gov
Protocol Registration System

Send message to ClinicalTrials.gov PRS

Help us improve: PRS Survey

Main Menu

Standard Functions

Protocol Records
- Create
- Modify
- View
- **QA Review Comments**
- **Problems: ncictro Records**
- Undelete

User Account
- Change password
- Modify Information
- PRS Administrator(s)

Help
- **Quick Start Guide**
- Frequently Asked Questions (FAQ)
- Responsible Party FAQ
- What's New **Jan 24, 2013**
- User's Guide

- Protocol Data Element Definitions
- Protocol Review Criteria

- Results Data Element Definitions
- Results Review Criteria
- Simple Results Templates
- About Results Data Entry

- FDAAA 801 Requirements
- FDAMA 113 Requirements

XML Upload
- Upload protocol records
- Check upload status
- Protocol XML Schema
- Results XML Schema
- Results Pick-list Normalization
- External Upload API
- Upload from NCI CTRP

Session
- Logout

Administrative Functions

Protocol Records
- **Problems: NCI Records**
- Validate all records
- Release all records
- Check release status
- Change owner
- Publication Report
- Transfer NIH Record (NIH)

User Accounts
- Create
- Modify
- Enable/disable

Organization Account
- Modify
- Groups
- Email Addresses
- Product Information

Help
- **Admin Quick Reference**

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CTRP: Future Considerations

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CTRP: Future Considerations

- Should the scope of trials required for reporting to CTRP be expanded to include submission of non-interventional trials?
  - CTRP currently accepts observational and ancillary/correlative studies but submission is not required
  - Current CCSG Data Table 4 format requires observational and ancillary/correlative studies; is this necessary going forward?
    - What data elements and accrual should be reported for these trials if CTRP required submission?
- The AACI/NCI 2011 report recommended deferral of outcome reporting to CTRP for 3-5 years
  - Is outcome reporting feasible and of value to NCI and the oncology community?

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CTRP: Reporting Requirements

- CTRP trial information is designed for NCI portfolio analysis on a number of data dimensions:
  - Cancer Center
  - Disease and Intervention
  - Biomarkers
  - Target and Actual Accrual
- Initial reporting focus has been on Data Table 4
- Need stakeholder input for future reporting requirements (within NCI and extramural)
- Policies for information access and corresponding user privileges needs to be established

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CTAC Clinical Trials Informatics Subcommittee Responsibilities

- Review progress on the implementation of CTWG and other clinical trials informatics initiatives
- Provide advice on CTRP topics needing additional consideration such as:
  - CCSG Data Table 4 report design
  - Reporting non-interventional trials in CTRP
  - Assessment of whether additional data elements should be captured in CTRP (e.g. outcome data)
- Working groups may be formed to accomplish specific tasks

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Data Elements/Definitions

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Trial Categorization: Definitions
NCI Office of Cancer Centers - Data Table 4

- **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks

- **Externally Peer-Reviewed:** R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or an approved peer-reviewed funding organization

- **Institutional:** In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results
  - It is acceptable for industry and other entities to provide support (*e.g.,* drug, device, other funding) but the trial should clearly be the intellectual product of the center investigator.
  - This category may also include:
    - Institutional studies authored and implemented by investigators at another Center
    - Multi-Institutional studies authored and implemented by investigators at your Center

- **Industrial:** The design and implementation of these clinical research studies is controlled by the pharmaceutical company

http://cancercenters.cancer.gov/grants_funding/index.html

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AACI – NCI CTRP Strategic Subcommittee Amendments and Updates

- Amendments are changes that:
  1. Substantively alter the treatment administered; and/or
  2. The study design; and/or
  3. The sites in which patients are being enrolled on the trial

- Status changes: changes in overall status of the trial (e.g., a change from active to closed to accrual).

- Updates: Other changes to the protocol.

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Registration Data Elements
National, Peer-Reviewed, Institutional Trials

Registration Data Elements	Mandatory =M Optional = O Conditional = C
Lead Organization	M
NCT Number	O
Other Identifiers	O
Title	M
Phase	M
Trial Type	M
Purpose	M
Principal Investigator	M
Sponsor and Responsible Party	C (Mandatory if XML is requested)
Trial Submission Category	M
Summary 4 Funding Sponsor	M
Program Code	O
NIH Grant Information	O
Current Trial Status and Status Dates	M
IND/IDE Information	O
Protocol Document	M
IRB Approval	M
List of Participating Sites	O
Informed Consent Document	M
Regulatory Information	C (Mandatory if XML is requested)

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Registration Data Elements Industrial Trials

Registration Data Elements	Mandatory =M Optional = O Conditional = C
Lead Organization	M
NCT Number	O
Lead Org Trial Identifier Number	M
Title	M
Submitting Organization Name	M
Submitting Organization Local Trial Identifier	M
Phase	M
Trial Type	M
Purpose	M
Site Principal Investigator	M
Confirmation that Trial Submission Category is Industrial	M
Summary 4 Funding Sponsor Type	M
Site Specific Program Code	O
Current Site Specific Trial Status	M
Date Reporting Site Open to Accrual	C (M when date known)
Date Reporting Site Closed to Accrual	C (M when date known)
Trial related documents	O

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Accrual Data Elements
National, Peer-Reviewed, Institutional Trials

Protocol Administrative Data Elements	Mandatory =M Optional = O Conditional = C
NCI Protocol Number	M
CTEP/DCP Protocol Number	C (Mandatory if CTEP/DCP PIO managed trial)
Date Report Submitted	M
Cut-Off Date for Data	M
Current Protocol Status	M
Submitter Name and Contact Information	O
Patient Demographic Information	Mandatory =M Optional = O Conditional = C
Patient ID	M
Patient Zip Code	C (Mandatory if US)
Patient Country Code	C (Mandatory if not US)
Patient Birth Date (Month/Year)	M
Patient Gender	M
Patient Ethnicity	M
Patient Method of Payment	O
Date of Patient Entry	M
Patient Disease Code	C (Mandatory for all trials except DCP PIO trials registered in CTRP by NCI
Patient Race	M

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Accrual Data Elements
Industrial Trials

Protocol Administrative Data Elements	Mandatory =M Optional = O Conditional = C
NCI Protocol Number	M
CTEP/DCP Protocol Number	C (Mandatory if CTEP/DCP PIO managed trial)
Date Report Submitted	M
Cut-Off Date for Data	M
Current Protocol Status	M
Submitter Name and Contact Information	O
Accrual during reporting period	Mandatory =M Optional = O Conditional = C
Number of patients accrued at site	M