NCI's Clinical Trials Reporting Program (CTRP)

Data Table 4

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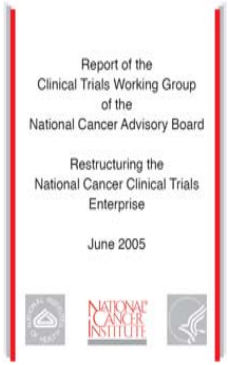
What is CTRP?

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

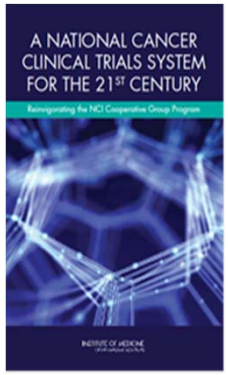
http://www.cancer.gov/about-nci/organization/ccct/ctrp

CTRP – Rationale



Key conclusions of 2005 Clinical Trials Working Group (CTWG) and 2010 Institute of Medicine reports

- NCI had no electronic database that captured all NCI supported trials and their accrual.
- R01s, R21s, P01s, SPORE grants and institutionally-supported trials using NCI-funded Cancer Center infrastructure resources were particularly difficult to identify



Available databases did not allow NCI and the broader cancer community to:

- Manage the portfolio accountably by monitoring accrual, identifying gaps and duplicative studies
- Effectively prioritize clinical trials

CTRP Development Timeline

2009	Registration of interventional trials piloted by NCI Designated Cancer Centers
2009	CTRP Trials Reporting Office (CTRO) established to abstract protocol information
2010	Registration of interventional trials open to patient accrual on or after 1/1/09 begins at all NCI Designated Cancer Centers
2011	AACI and NCI collaboratively define CTRP reporting objectives and implementation timeline for submitting clinical trial registration and accrual
2012	Amendment and updating reporting begins in March; quarterly accrual in September
2013	"Upload from NCI CTRP" introduced by NLM to support ClinicalTrials.gov reporting
2013	CTRP data submission requirement added to CCSG P30 Terms of Award
2014	Begin assessment of accuracy of CTRP data compared to selected CCSG DT4s
2015	CTRP is the source of clinical trial abstracts on the Cancer.gov website
2015	Clinical Trials Informatics Working Group of the NCI Clinical Trials and Translational Research Advisory Committee (CTAC) is formed

CTRP – Key Attributes

Expands beyond data already contained in ClinicalTrials.gov

- Standardized abstraction of protocol information
- Consistent terminology and coding to optimize search and retrieval of cancer trials information
- Biomarker and patient-level accrual data
- Standardized person and organization data elements

Designed to minimize duplicative data entry

- Integration with ClinicalTrials.gov facilitates compliance with FDA Amendments Act (FDAAA) of 2007
- Includes information that can be used to generate reports needed for Cancer Center Data Table 4 submissions

CTRP – Trial Registration

All NCI Supported Interventional[1] Clinical Trials

- NOTE: All trials conducted at an NCI Designated Cancer Center are ***NCI Supported***.
- Each trial registration record includes all sources of NCI/NIH grant support (P30 #, RO1, etc.)

[1] Studies in human beings in which individuals are assigned by an investigator, based on a protocol, to receive specific interventions. Subjects may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The individuals are followed and biomedical and/or health outcomes are assessed. (Source: http://prsinfo.clinicaltrials.gov/definitions.html and http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf

CTRP Trial Registration: Categories

(Aligned with CCSG Data Table 4 definition of Study Source)

- **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
- **Institutiona**l: 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
- **Industrial**: The design and implementation of these clinical research studies is controlled by the pharmaceutical company or other institution

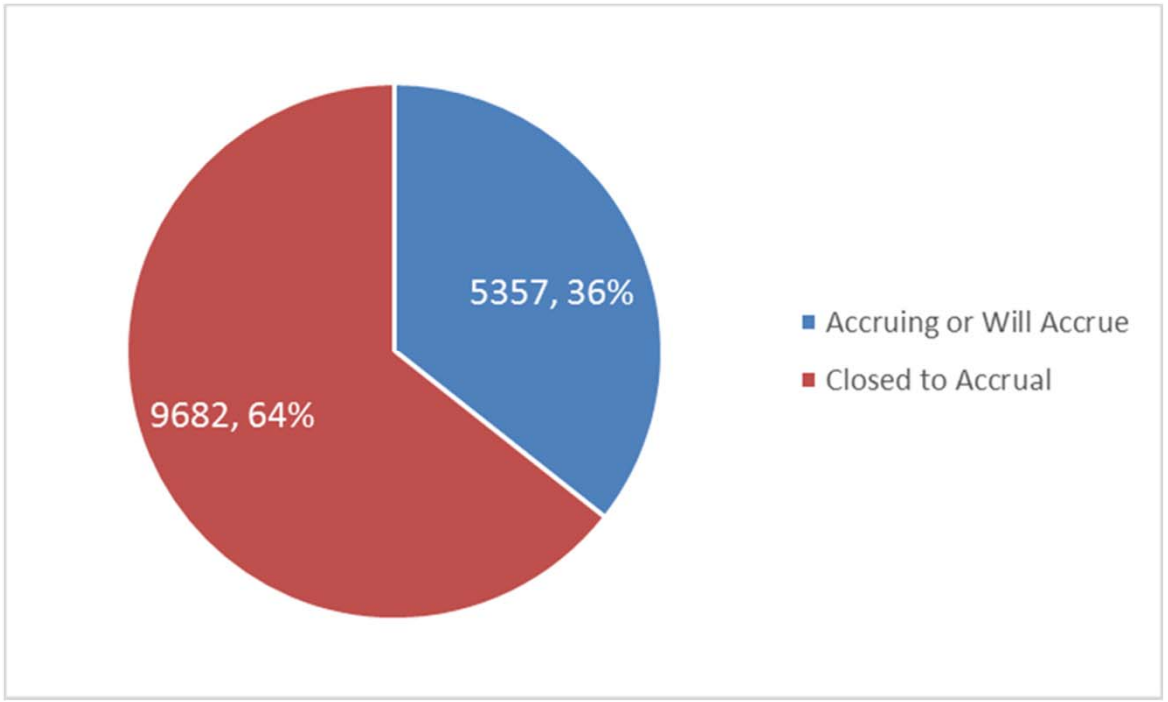
http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf

CTRP Trial Registration

CTRP supports, but does not require at this time, registration of non-interventional trials.

- **Non-interventional trials -** Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study. (Source: http://prsinfo.clinicaltrials.gov/definitions.html)
  - **Observational trials** - Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants.
  - **Ancillary-Correlative** - A subgroup of non-interventional trials, defined as a trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.

Trials Registered in CTRP – March, 2016



Total number of trials: 15,039

as of March 2016

CTRP and Data Table 4

Rationale for Use of CTRP – Data Table 4

- Minimizes duplicate reporting by NCI Designated Cancer Centers to NCI
  - CTRP reuses data already submitted to NCI.
  - CTEP, DCP, CCR trials transferred within NCI to CTRP
  - Information about NCI Designated Cancer Center trials in CTRP
- Ensures consistency:
  - Reduces potential for duplicate trial registration, accrual reporting
  - Consistent data, e.g., protocol IDs, trial phase, title, and sponsor
    - GOG-0086P
      - vs GOG 0086P, GOG0086P, GOG 86P, GOG 86p, 0086-P, 0086P, 86P, 11-404, 09-115
  - Supports accurate accounting of:
    - The number of trials in NCI designated cancer centers.
    - Accrual to each trial ongoing in NCI designated cancer centers.

CTRP –Interventional Trial Data Table 4 Progress to Date

- Development of CTRP Data Table 4 for interventional trials is well underway
- In 2014, NCI staff reviewed a CTRP DT4 and the CCSG DT 4 report for the same time period with each NCI Designated Cancer Center in a teleconference
- Centers were asked to review the discrepancies that arose during the review and update data in CTRP (e.g., correcting trial status, adding or deleting participation in a National or Industrial trial) as needed
- Centers were also asked to verify organizational components and affiliates so that accrual in the CTRP DT4 record is correctly represented.

CTRP DT4 compared to OCC DT4
General Observations – Interventional trials

- Registration:
  - Virtually all trials reported on CCSG DT4 are in CTRP
  - Difficult to match trials in CTRP with OCC DT4 without NCT number
  - Trials missing from CTRP DT4 include:
    - Out of scope
    - Inconsistencies due to status history
      - Closed prior to the reporting period
      - Status history incorrect
    - Not registered in CTRP (mostly institutional, industrial)
    - Ongoing in organizational component not part of cancer center
  - Additional trials listed on CTRP DT4 reports:
    - Status history incomplete (e.g., industrial trials prior to 12/13)
    - Participating site status may differ from overall trial status

CTRP DT4 compared to CCSG DT4
General Observations – Interventional trials

- Accrual:
  - Increased consistency between CTRP and OCC DT4 for more recent reporting periods.
  - Reasons for inconsistencies include:
    - Lead organization did not report accrual for all participating sites.
    - Accrual is not correctly attributed because a participating site is not represented as part of the cancer center
    - Site has not reported accrual for industrial trials on which it is participating
    - Industrial trials report cumulative accrual; a report for an interval prior to the initial accrual reporting date does not contain accrual.

CTRP DT4 – Current Status

- Registration
  - Most interventional trials in CCSG DT4 are registered in CTRP
    - Ongoing efforts to harmonize trial status and participating sites in CTRP with CCSG DT4
    - Efforts are complicated by absence of NCTIDs in CCSG DT4
- Accrual
  - Ongoing efforts to work with centers to complete accrual reporting

CTRP DT4 – Next Steps

- Timeline for implementation of CTRP generated DT4 has not been established
- Continued efforts to harmonize registration and accrual reporting for interventional trials reported in CCSG DT4 and CTRP DT4
- CTAC Clinical Trials Informatics Working Group has been formed to provide input regarding NCI's clinical trials informatics activities
- How best to define the organizational components of a cancer center and maintain them?

Summary

- CTRP supports NCI's clinical research enterprise by providing a registry of consistently written, regularly updated, clinical trial abstracts
  - Coding terms are tailored to optimize the search and retrieval of cancer clinical trials
- CTRP is designed to minimize duplicate data entry, e.g.,
  - CTRP data can be used to produce CTRP Data Table 4 reports
  - Supporting the registration of trials in ClinicalTrials.gov by the sponsor
- CTRP data is the source of clinical trial abstracts on NCI's Website, Cancer.gov
- Future enhancements to CTRP, including a reporting capability, are planned with broad input

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