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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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AACI-NCI
Clinical Trials Reporting Program (CTRP)
Strategic Subcommittee Report

"Reporting Objectives and Implementation Timelines"

Presented to CTAC

July 13, 2011

Kevin Cullen

Sheila Prindiville

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AACI-NCI CTRP Strategic Subcommittee

- AACI leadership met with NCI in 2010 to discuss the reporting requirements and timelines for the Clinical Trials Reporting Program (CTRP).

- CTRP Strategic Subcommittee was formed in fall 2010 and charged to review scope, current and future workload, and timeframe to provide CTRP with data on:
  - Registration (including amendments and updates)
  - Accrual
  - Outcomes.

- The Subcommittee also noted other issues requiring additional consideration.

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AACI-NCI CTRP Strategic Subcommittee Members

- Members of the CTRP Strategic Subcommittee
  - Kevin Cullen, M.D., Co-Chair, Director, University of Maryland Greenebaum Cancer Center
  - Sheila Prindiville, M.D., M.P.H., Co-Chair, Director, Coordinating Center for Clinical Trials, National Cancer Institute
  - Rhoda Arzoomanian, M.S.M., Associate Director, Administration, University of Wisconsin Carbone Cancer Center
  - Jan Buckner, M.D., Professor of Oncology, Mayo Clinic College of Medicine
  - Rob DuWors, M.P.A., Deputy Director, Administration and Finance, Jonsson Comprehensive Cancer Center, UCLA
  - Alyssa K. Gateman, M.P.H., C.C.R.P., Deputy Director, Quality Assurance Office for Clinical Trials, Dana-Farber/Harvard Cancer Center
  - Collette Houston, Director, Clinical Research Operations, Office of Clinical Research, Memorial Sloan-Kettering Cancer Center
  - Nicholas J. Petrelli, M.D., Medical Director, Helen F. Graham Cancer Center at Christiana Care
  - Daniel M. Sullivan, M.D., Executive Vice President/Associate Center Director for Clinical Investigations, Moffitt Cancer Center
  - James Thomas, M.D., Ph.D., Associate Director, Clinical Investigation, Medical College of Wisconsin Cancer Center
- AACI Liaison:
  - Janie Hofacker, R.N., M.S., Director of Programs, Association of American Cancer Institutes

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AACI-NCI CTRP Report: What is CTRP?

- CTRP is a comprehensive database containing regularly updated information on all NCI supported clinical trials.
- It serves as a central repository of trials with information collected using standardized data elements.

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AACI-NCI CTRP Report: Why is CTRP Needed?

- NCI does not have an electronic database for more than half of its clinical trials portfolio, accounting for more than 20,000 patients each year.
  - Most of these trials are conducted with grant support (e.g. R01, R21, P01, SPORE, and Cancer Center institutional trials).

- A comprehensive database of the entire NCI portfolio would help to:
  - Identify gaps in clinical research.
  - Facilitate effective clinical trial prioritization and avoid duplicative studies.
  - Identify toxicity trends across all NCI supported trials if outcomes data were collected.

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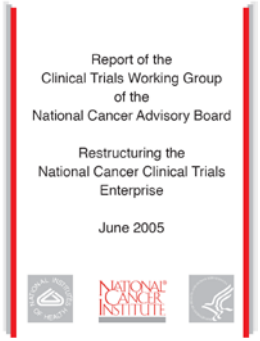
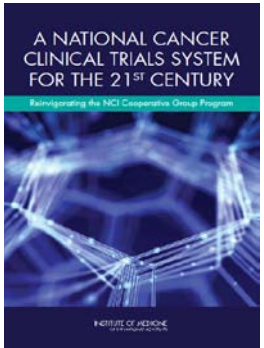
AACI-NCI CTRP Report: Is CTRP a response to the federal law requiring reporting?

- Need for CTRP predates the enactment of FDA Amendment Act (FDAAA) of 2007.
- The CTWG recommended creating a comprehensive database containing information on all NCI-funded clinical trials to facilitate better planning and management (2005).



- The Institute of Medicine (IOM) report reiterated this need (2010).



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Comparison of CTRP and ClinicalTrials.gov

- CTRP is designed to support NCI's clinical trials portfolio management and inquiries from patients and the scientific communities.
- CTRP facilitates ClinicalTrials.gov submissions, avoiding duplicate data entry.
- Information that CTRP collects or abstracts that is not reported in ClinicalTrials.gov includes:
  - Summary 4 funding category, sponsor, program code, anatomic site (information needed to create Summary 4 reporting from CTRP).
  - Identification of the NIH Institute/NCI division on IND/IDE and grants.
  - Biomarkers: assay type, use, and purpose; tissue specimen type; and collection method.
  - Protocol document for abstraction.
  - Patient accrual is planned for 2012.

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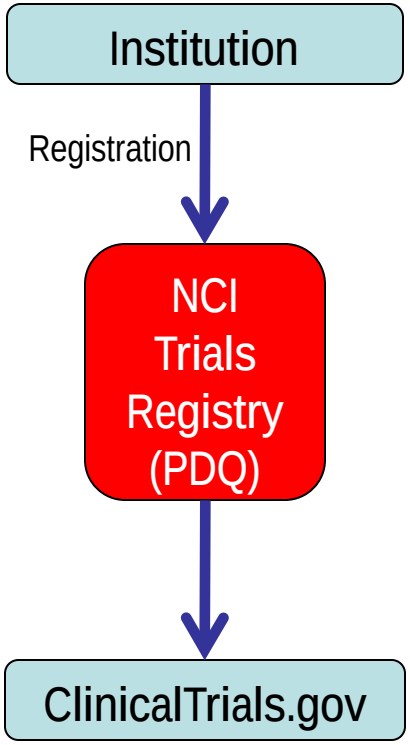
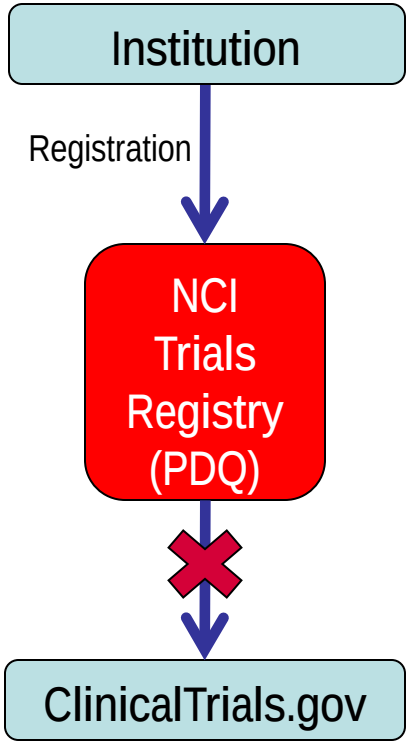
CTRP Facilitation of ClinicalTrials.gov Submissions

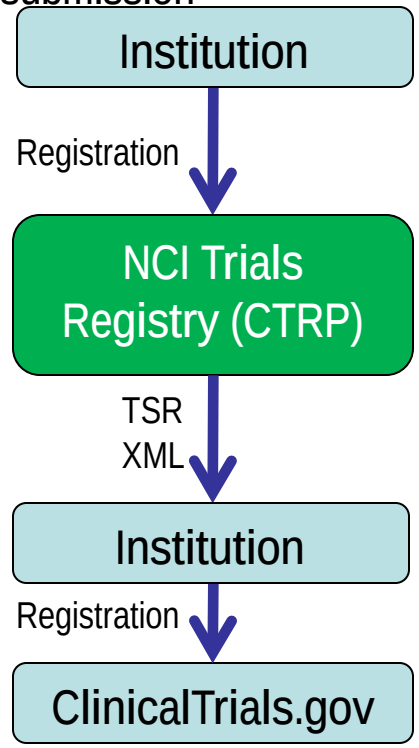
2005: Voluntary ClinicalTrials.gov registration from NCI Registry (PDQ)



2007: FDAAA requires registration and outcomes by Responsible Party. NIH policy prohibits registration by any Federal System



2009: CTRP enhanced to abstract information needed for ClinicalTrials.gov registration and provide a data file to institutions for independent validation and submission



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CTRP Trial Registration

- Scope for trial registration
  - Interventional clinical trials supported by NCI.
  - Open to patient accrual on or after January 1, 2009.
- Types of trial registration
  - CTEP and DCP PIO-managed trials registered by NCI processes; data collected on these trials are transferred internally, avoiding duplicative reporting to NCI.
  - Other trials registered in CTRP by institutions directly.
- Trials categorized to align with Summary 4 trial type (National, Peer-Reviewed, Institutional, Industrial)

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Timeline for Registration

- **NCI-designated Cancer Centers** should complete initial trial registration by October 2011.
- **Other Grantee Institutions** conducting NCI-supported trials should develop processes and complete initial trial registration by January 2012.

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Definitions: 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 are changes in the 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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Frequency of Submission of Amendments, Status Changes, and Updates

- Amendments : within 20 days of IRB approval.
- Status changes: within 30 days of the change.
- Updates: annually.

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Timeline for Amendments and Updates

- The reporting of amendments and updates is to begin 9 months after the specification is made available (released June 2011).
- **NCI-designated Cancer Centers** should develop processes and begin submitting amendments, updates and status changes by March 2012.
- **Other Grantee Institutions** conducting NCI-supported trials should develop processes and begin submitting amendments, updates and status changes by June 2012.

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CTRP Patient Accrual Reporting

- Data Elements Based on CDUS Abbreviated
  - Patient-level data elements consistent with standard Case Report Form (CRF) Demography elements.
- Methods
  - CTRP Web Site for manual entry.
  - Batch and Service specification for automated submission of patient accrual targeted for completion by September, 2011.
- Guidelines for Patient Accrual Reporting
  - Patient–level Accrual will be reported for National, Peer-Reviewed, and Institutional trials. The Lead Organization will report patient accrual for all participating sites on a trial.
  - Summary Accrual (cumulative count) will be reported for Industrial trials by the Participating Organization.
  - Patient accrual reported quarterly.

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Timeline for Accrual

- The specification for automated patient accrual is targeted for finalization in September, 2011.

- The reporting of patient accrual is to begin 1 year after the specification is made available.
  - NCI-designated Cancer Centers should develop processes and begin submitting accrual September 2012.
  - Other Grantee Institutions conducting NCI-supported trials should develop processes and begin submitting accrual by January 2013.

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CTRP Outcomes Reporting

- The CTWG report discussed elements of outcome reporting, including toxicity and adverse event reporting.
- The CTRP Strategic Subcommittee recommended deferring capture of outcomes data for 3-5 years.
- During that time, a group with extramural representation, should work with NCI to identify the outcomes data elements, the proposed implementation and cost, and the timeframe for implementation.

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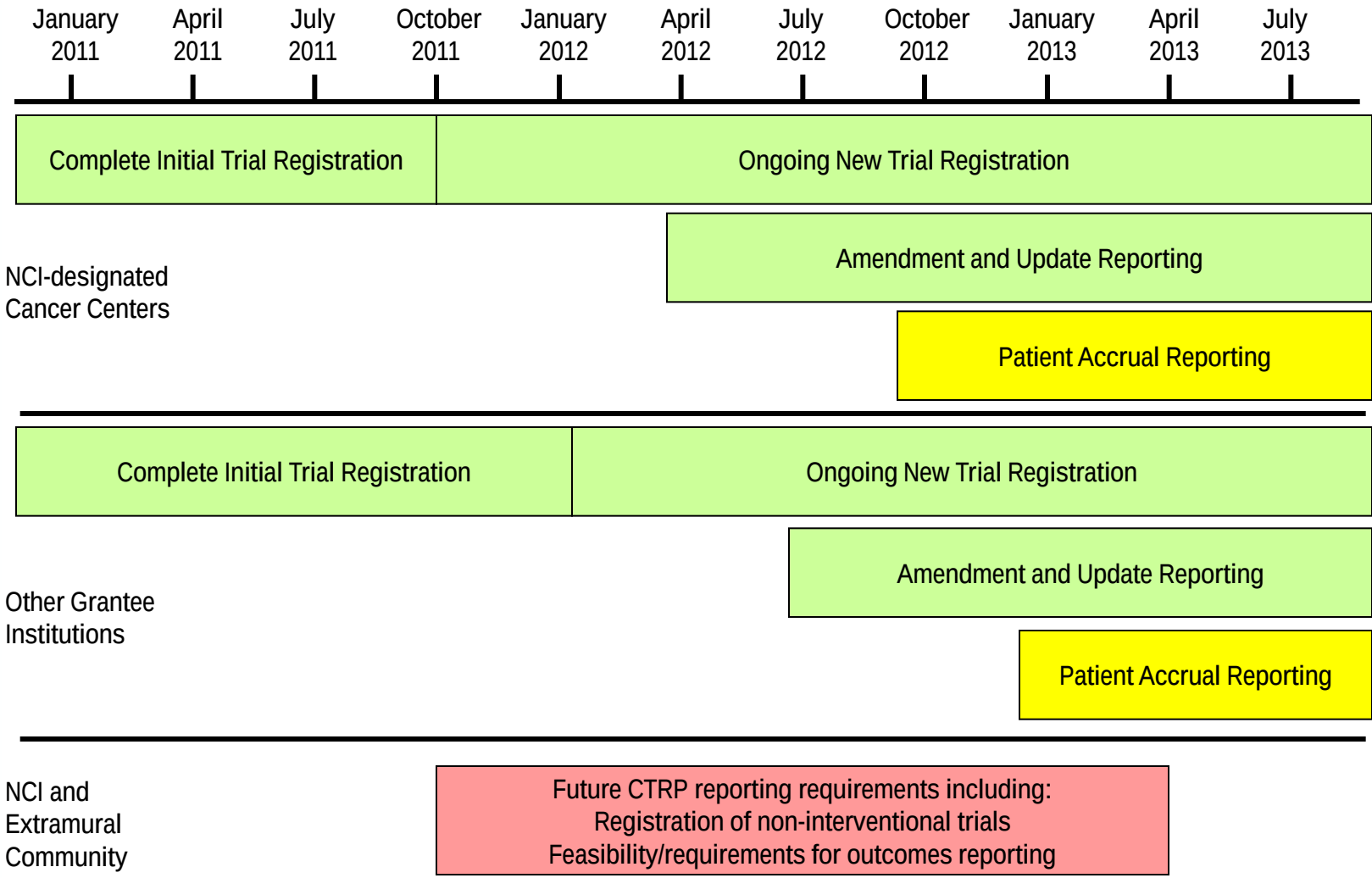
Timelines for NCI-Supported Clinical Trial Reporting



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NCI Support

- The NCI will continue to support NCI grantees and software vendors to facilitate registration and the reporting of accrual.

- Examples of NCI support include:
  - Funding supplements to NCI-designated Cancer Center grants to support start-up costs of CTRP reporting requirements.
    - 2011 supplement request issued in June; applications due July 22.
  - Professionally written abstracts following clinical trial registration, and a data file suitable for posting in Clinicaltrials.gov after review.
  - Technical support, user calls, etc., to support the CTRP community.

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Topics requiring additional consideration (1)

- Reporting non-interventional trials in CTRP
  - Registration of non-interventional trials needed for complete Summary 4 reporting; recommended reporting these trials after registration of interventional trials is completed.
- Patient-level disease coding for accrual
  - Harmonization of Summary 3 ICD-9 terminology with CTEP's Simplified Disease Code terminology is recommended to simplify reporting.
- Summary 4 Reports
  - It will be critical to design the accrual reporting specifications in such a way that each cancer center's accrual to a study is appropriately counted.

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Topics requiring additional consideration (2)

- Centers without automated systems
  - Some sites do not have a commercial or homegrown clinical data management system and they may need additional support or more liberal timelines for meeting reporting guidelines.

- Process for changing CTRP technical specifications
  - Recommended a working group to evaluate any future changes to registration and accrual specifications and to work with affected stakeholders to assure timely and accurate implementation.
  - Membership to include:
    - CDMS vendors plus any sites developing and/or maintaining in-house CDMS's
    - NCI
    - Cancer Centers (at least 2)

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Key Communications

- July 11, 2011 – Announcement of report to AACI membership, NCI-designated Cancer Center Directors, and caBIG CTMS Steering Committee members
- July 13, 2011 – Clinical Trials and Translational Research Advisory Committee (CTAC) Presentation
- July 14, 2011 – AACI Clinical Research Initiative Presentation
- Webinars
  - Cancer Center Clinical Trials Operations Leadership
  - CTRP Users

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Further Information

- NCI CTRP User Meeting – Monthly Conference Call
  - Teleconference: 866-709-2465 Code: 5305410 http://cbiit.acrobat.com/ncictrp
  - Next Call: August 3rd, 2:00 p.m. ET
- CTRP Website
  - Information and resources to assist you in understanding NCI's Clinical Trials Reporting Program (CTRP) and to prepare you for registering clinical trials.
  - http://www.cancer.gov/clinicaltrials/conducting/ncictrp/main
- CTRP Resources Website
  - User guides, templates
  - http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources
- CTRP mailbox
  - NCICTRO@mail.nih.gov.

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DATA ELEMENTS

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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