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
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.
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
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.
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.
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).
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.
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
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)
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.
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.
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.
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.
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**.
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.
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.
Timelines for NCI-Supported Clinical Trial Reporting

NCI-designated Cancer Centers

- Complete Initial Trial Registration
- Ongoing New Trial Registration
- Amendment and Update Reporting
- Patient Accrual Reporting

Other Grantee Institutions

- Complete Initial Trial Registration
- Ongoing New Trial Registration
- Amendment and Update Reporting
- Patient Accrual Reporting

NCI and Extramural Community

Future CTRP reporting requirements including:
- Registration of non-interventional trials
- Feasibility/requirements for outcomes reporting
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.
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.
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)
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
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.
DATA ELEMENTS
### Registration Data Elements

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## Registration Data Elements
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**Accrual Data Elements**  
National, Peer-Reviewed, Institutional Trials

| Protocol Administrative Data Elements                  | Mandatory = M  
|--------------------------------------------------------|---------------  
| 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  
| 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             |
## 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 |