Restructuring the National Cancer Clinical Trials and Translational Research Enterprise

CTWG Informatics Initiatives Implementation Update to CTAC

James H. Doroshow, M.D.
John Speakman
March 10, 2010
CTWG and Related Clinical Trials Initiatives

- Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials (*Doroshow*)

- Promote establishment of national clinical trial information technology infrastructures that are fully interoperable with NCI’s cancer Biomedical Informatics Grid (*Speakman*)

- Achieve industry and FDA concurrence on standard Case Report Forms incorporating Common Data Elements (*Speakman*)

- Develop a credentialing system for investigators and sites (*Speakman*)

- Procurement of an enterprise-wide clinical data management system (*Speakman*)
Rationale: Clinical Trials Reporting Program

- NCI has no electronic database for more than half of its clinical trials portfolio (> 20,000 patients accrued per year)
  - R01s, R21s, P01s, SPOREs etc.
  - Institutionally-supported using CCSG resources
- Currently available databases do not allow NCI and the broader cancer community to:
  - Identify toxicity trends for public safety,
  - Manage portfolio accountably by monitoring accrual, identifying gaps and duplicative studies
  - Effectively prioritize clinical trials
CTWG Goals for Establishment of CTRP

• “Create a comprehensive database containing information on all NCI-funded clinical trials to facilitate better planning and management across clinical trial venues”

• “Create, in partnership with the extramural cancer research community, a national cancer clinical trials information technology infrastructure fully interoperable with NCI’s cancer Bioinformatics Grid to improve cost effectiveness and comparability of results across trials and sites”

• Predates enactment of FDA amendment act by >2 yrs
CTRP Database

- Trial submitter registers with system
  
  Trial is registered (and protocol document uploaded)
  
  NCI abstracts protocol from document

  Submission of Accrual Data

  Comprehensive data accessible
FDA Amendment Act and NIH policy

- **FDA Amendment Act (FDAAA) of 2007**
  - Requires registration of all applicable trials (Phase II/III) with ClinicalTrials.gov
  - Sets rules for determining “Responsible Party” for this activity
  - Penalties for non-registration include large fines and withdrawal of NIH funding
  - Substantive outcomes reporting requirements
  - NIH policy: It is no longer permissible for NIH institutes to register trials on behalf of Responsible Parties (e.g., via any NCI system)

- **NCI is not in control of these requirements**

- **Establishment of need for CTRP in CTWG Report predates FDAAA**
Value-Add of NCI CTRP Registration

2005: Voluntary ClinicalTrials.gov registration from NCI Registry

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

2009: CTRP enhanced to abstract information for ClinicalTrials.gov registration and return file to institutions for independent validation and submission
CTRP Services to the Cancer Community

- Performs abstraction of data that may be suitable for Clinical Trials.gov reporting
  - 40 FTEs funded by NCI
- Provides a data file
  - Data can be uploaded to ClinicalTrials.gov so that dual entry for required elements is unnecessary
  - Data can be used for local data management
- Provide clinical trials management tools for Centers
- Generates Cancer Center “Summary 4” table
- Interoperable with commercial clinical trials systems; NCI will also work with Cancer Centers that have developed own in-house systems
CTRP Reporting Capabilities

- This single portal will meet the NCI’s and the cancer research community’s current and future reporting needs

<table>
<thead>
<tr>
<th>Feature</th>
<th>PDQ</th>
<th>CTRP</th>
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<tbody>
<tr>
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<tr>
<td>Patient level demographic data (CDUS abbreviated)</td>
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<tr>
<td>Patient level outcome data (CDUS complete)</td>
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</table>
ClinicalTrials.gov Capabilities

- The information in ClinicalTrials.gov does not meet the NCI’s or the cancer research communities’ current and future needs

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CTRP Technology Capabilities

- The CTRP system utilizes a state-of-the-art design, developed around structured data that enables integration with Cancer Center systems to automate reporting requirements.

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<tbody>
<tr>
<td>Relational Database</td>
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<tr>
<td>Web user interface</td>
<td></td>
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<tr>
<td>Reporting capability</td>
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<tr>
<td>Industry Standard Information to allow sharing of data</td>
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<tr>
<td>Electronic reporting standardization aligned with FDA requirements</td>
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<tr>
<td>Open design enabling information exchange with all internal NCI systems</td>
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<tr>
<td>Open design enabling information exchange with Cancer Center clinical trial systems</td>
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## Initial Registration / Reporting Requirements

<table>
<thead>
<tr>
<th></th>
<th>Pre-CTRP</th>
<th>CTRP</th>
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</thead>
<tbody>
<tr>
<td><strong>NCI Cooperative Group Trials</strong></td>
<td>• Trial registration via NCI/CTEP Trial Registry</td>
<td>• Trial registration via NCI Trial Registry (CTRP); No change</td>
</tr>
<tr>
<td><strong>NCI Investigational Drug Trials (N01/U01)</strong></td>
<td>• CDUS Abbreviated*</td>
<td>No change</td>
</tr>
<tr>
<td></td>
<td>• CDUS Complete**</td>
<td>No change</td>
</tr>
<tr>
<td><strong>Other NCI-funded trials (R01, R21, P01, SPORE etc.) and other Institutional Interventional Clinical Trials</strong></td>
<td>• Trial registration via NCI Trial Registry (PDQ; pre-2010) or CT.gov</td>
<td>• Trial registration via NCI Trial Registry (CTRP)</td>
</tr>
<tr>
<td></td>
<td>• Annual reporting of list of trials and accrual for Summary 4</td>
<td>• Accrual data</td>
</tr>
<tr>
<td></td>
<td>*Patient level accrual</td>
<td>• Automated preparation of data for annual Summary 4 reporting</td>
</tr>
<tr>
<td></td>
<td>**Patient level outcomes, toxicity</td>
<td></td>
</tr>
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*CDUS = Clinical Data and Outcome Specified in Symptom Tracking (SDM) System
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<tr>
<td>Cooperative Group</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
</tr>
<tr>
<td>Investigational Drug Trials (N01, U01)</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
<td>Yes (No change)</td>
</tr>
<tr>
<td>Other NCI-funded grant (P01, R21, R01, SPORE etc.)</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutional Investigator-Initiated</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
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<tr>
<td>Industry</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Observational</td>
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</tr>
</tbody>
</table>
## Proposed Future Reporting Specifications by Trial Funding Mechanism (input sought)

<table>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>?</td>
</tr>
<tr>
<td>Industry</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Observational</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
CTRP Implementation

• Pilots at NCI-designated Cancer Centers
  – First for registration, now for accrual
  – Identify issues, estimate workload and refine implementation timeline

• Funding Cancer Centers via CCSG supplements
  – Pilot (n=5) and Early-Adopter Centers (n=19) funded in 2009
  – Budgeted for all Centers in 2010

• Support via phone and e-mail
  – For both Centers and vendors

• Communication:
  – Informational website, mailing list, online forums
  – Weekly/monthly conference calls with Pilot & Early-Adopter sites
  – Regular updates to Cancer Center Directors and Administrators
CTMS Steering Committee and CTRP Subcommittee

• **caBIG Clinical Trials Management Systems (CTMS) Steering Committee**
  – Chairs: Jan Buckner, M.D., (Mayo), Sorena Nadaf (UCSF)
  – Quarterly face to face meeting to provide extramural oversight for the implementation of *all* of the CTWG informatics initiatives
  – CTAC liaison: Dan Sargent, Ph.D.

• **CTMS CTRP Subcommittee**
  – CTRP Subcommittee: conference calls weekly on deployment strategy, reporting capability
  – Provide strategic guidance on efforts with CTRP
  – Identify and discuss potential or existing issues with the CTRP; recently expanded to include Center Directors
## Partnering with the clinical trials community

- **Developing implementation and adoption timelines**

<table>
<thead>
<tr>
<th>Implementation Timeline</th>
<th>Technology</th>
<th>Cancer Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration</td>
<td>Ready</td>
<td>2010</td>
</tr>
<tr>
<td>System Integration (caBIG Enterprise Services)</td>
<td>Ready</td>
<td>?</td>
</tr>
<tr>
<td>Accrual</td>
<td>Ready</td>
<td>?</td>
</tr>
<tr>
<td>Patient level demographics file loader format (CDUS abbreviated)</td>
<td>Q3 2010</td>
<td>?</td>
</tr>
<tr>
<td>Patient level outcomes (CDUS complete)</td>
<td>Q4 2010</td>
<td>?</td>
</tr>
</tbody>
</table>
CTRO Metrics 3/4/10 (2032 Trials Submitted)

- **Site-submitted Trials (excluding CTEP/DCP)**
  - Original Submissions 1038
  - Abstracted 984
  - QC 605
  - Trial Summary Report Sent 418
  - Submitted Amendments 47

- **CTEP/DCP Trials**
  - Original Submission 994
  - Abstraction Started 872
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- Procurement of an enterprise-wide clinical data management system (Speakman)
CTWG Initiative: Systems Interoperability and Harmonization

- **Common IT Infrastructure**
  - "The CTWG endorses the universal adoption and deployment of a common, standards-based IT infrastructure for the management of clinical trials across the NCI-supported cancer enterprise that is fully interoperable with the caBIG architecture"

- **Intramural and Extramural**
  - "The long-term goal is for all clinical trial sites either to migrate to the caBIG architecture or to develop interfaces and other required enhancements such that their IT architecture is fully interoperable with the caBIG standards-based architecture"
NCI Enterprise Services (NES): a collection of single, enterprise-wide “sources of record” for key shared items of data, e.g.:

- Protocols
- Organizations
- People (e.g., PIs)
- Diseases
- Agents
NCI Future Term Process

NCI-designated Cancer Centers, Cooperative Group and other participating sites

Industry and other Non-NCI Sponsors

NIH/NLM Clinical Trials.gov

NCI Sponsor System
NCI Participating Site and IRB Mgmt
NCI CTRP
NCI Public Trials Portal

NCI Enterprise Services
Interoperable Infrastructure - Future

- NCI Divisions, Programs, Centers and Offices engaged in clinical trials activities (e.g., CTEP, DCP, OCE, OCC) assembling integration plans
  - Recognizing that NCI’s clinical trials operation is a production process, with many moving parts

- caBIG® Clinical Trials Applications have been re-engineered to leverage NCI Enterprise Services
  - Pre-curated data sources accessible by other applications

- Extramurally developed systems being re-engineered to leverage NCI Enterprise Services
  - First Cancer Centers, vendors engineering systems to leverage services for seamless reporting to CTRP
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Demography CRF Module

Patient Name: __________________

Patient Gender (Check one):
- Male
- Female
- Unknown
- Not Determined

Patient Race (Check all that apply):
- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Unknown
- Not Reported
CTWG Initiative: Develop a Library of Standardized Case Report Form Modules

- Using Common Data Elements
- Reduction of time, cost and effort
- Standardized data capture, cross-trial analysis
- Maximize the capture of critically important data
- Simpler regulatory review
- Leveraging of:
  - past and current NCI standardization work
  - experience of what does and does not secure adoption
Harmonization with Industry

- Clinical Data Acquisition Standards Harmonization (CDASH)
  - Initiative of Clinical Data Interchange Standards Consortium (CDISC)
- Common goal with NCI: harmonizing and standardizing data collection for clinical research
  - CDASH focus: elements that are common to all clinical studies
  - NCI focus: oncology studies
- NCI modules will include all CDASH “mandatory” questions, plus additional oncology content
<table>
<thead>
<tr>
<th>CRF Module Harmonization Workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  NCI CBIIT staff create CRF inventory</td>
</tr>
<tr>
<td>2  Working group aggregates and identifies key content, resolves discrepancies, harmonizes. <strong>Change</strong> – expansion in working group membership to include named POC for all major internal and external clinical trial stakeholders</td>
</tr>
<tr>
<td>3  Working group partitions content - mandatory, conditional, optional</td>
</tr>
<tr>
<td>4  Working group achieves consensus on final list of elements, assures adherence to data standards</td>
</tr>
<tr>
<td>5  Executive summary sent to CTROC</td>
</tr>
<tr>
<td>6  Module circulated for broad community review</td>
</tr>
<tr>
<td>7  Working group reviews and responds to changes from community review. <strong>Change</strong> – POCs for all major internal and external clinical trial stakeholders provide formal approval of CRF elements prior to subsequent review</td>
</tr>
<tr>
<td>8  CRF Subcommittee of the CTMS Steering Committee reviews and approves. <strong>Change</strong> – newly formed subcommittee ensures review by critical external clinical trial stakeholders, e.g., NCI cooperative groups</td>
</tr>
<tr>
<td>9  CTROC reviews and approves</td>
</tr>
<tr>
<td>10 Annual review cycle</td>
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</tbody>
</table>
## Case Report Form Modules – Status

<table>
<thead>
<tr>
<th>Round</th>
<th>Work Groups</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Demography</td>
<td>Complete</td>
</tr>
<tr>
<td>2</td>
<td>Adverse Events; Participant ID; Enrollment; Registration; Protocol Violation; Medical History; Physical Examination</td>
<td>Broad community review complete – awaiting expanded workgroup review</td>
</tr>
<tr>
<td>3</td>
<td>Concomitant Agents; Study Agents; Prior and Post Therapy Agents; Drug Accountability; Lab Results; Outcomes; Extent of Disease/Staging</td>
<td>Broad community review complete – awaiting expanded workgroup review</td>
</tr>
<tr>
<td>4</td>
<td>Imaging; Off Treatment, Diagnosis; Footer/Header; Eligibility; Non-Agent Interventions; Vital Signs</td>
<td>Expanded workgroups to consider before broad community review</td>
</tr>
<tr>
<td>5</td>
<td>Any remaining elements</td>
<td>Convene after above</td>
</tr>
</tbody>
</table>
Future

- Community adoption essential for success

- Plan for ongoing maintenance includes annual review of the total library of CRFs for necessary changes

- Modifications will be requested by, and changes will be vetted by, community and NCI
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CTWG Recommendation: Investigator and Site Credential Repository

- **Simplify and speed trial initiation**
  - Eliminate the need to endlessly reestablish credentials each time a trial is initiated (or annually in the case of CTEP)

- **Facilitate rapid communication of:**
  - new regulations and changes to the clinical research community
  - changes in the status of individual investigators and sites to sponsors

- **Partner with relevant federal agencies, professional societies and trade associations**
  - As appropriate, pursue links to clinical investigator community outside of cancer research

- **Leverage FIREBIRD**
  - Federal Investigator REgistry of Biomedical Informatics Research Data
• Product of the Interagency Oncology Task Force (IOTF) - NCI-FDA partnership

• Automates and centralizes “FDA 1572 Form” investigator registration process
  – Eliminates paper-based, manual process, need for wet signatures
  – Investigators register online with trial sponsors (NCI and/or commercial) via web interface to secure, central repository
  – Maintains accreditation information profile, can automatically be applied to multiple registrations and/or sponsors
  – Standardizes collection of registration information across multiple sponsors and FDA

• FIREBIRD has completed Operational Pilot, in limited production with NCI Division of Cancer Prevention
2010 NCI Implementation

- **Establish NCI/professional society/trade association partnership**
  - Approach FDA, professional societies (e.g., ASCO, AACR, AACI, ONS, SoCRA, ACRP), trade associations (e.g., PhRMA, BIO)

- **Form task force to define and establish credentialing criteria for both investigators and sites**
  - Start with FDA 1571/1572 forms
  - Develop formal investigator and site credentialing process for oncology clinical trials, based on criteria established by task force
  - Incorporate/harmonize information from professional organizations that provide certification/training programs

- **Establish and maintain data repository**
  - Based on Federal Investigator Registry of Biomedical Informatics Research Data (FIREBIRD)
  - Incorporating NCI Enterprise Services (NES)
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CDMS Procurement

- NCI has purchased licensing rights for a commercial clinical data management system (CDMS) software product
- Will be made available free of charge to all organizations in the NCI Clinical Research Enterprise
  - (i.e., all non-profit NCI-supported organizations conducting clinical trials)
- Can be used under license terms for all cancer trials
  - Not just NCI-sponsored trials
  - Including industry, investigator-initiated, etc.
- Cannot be used for non-cancer trials under license terms
  - If an organization wanted to extend the license to allow use in non-cancer trials, a business discussion between the organization and the vendor (not involving NCI) would be required
CDMS Procurement: Purpose

- Respond to need expressed by Cooperative Groups for a single Remote Data Entry system
  - “...a unique responsibility and opportunity to develop a uniform, paperless, RDE system for over 1700 trial sites, 30,000 new accruals per year, more than 100,000 patients in active follow up”

- Deliver full-function clinical data management capability to entire NCI-supported clinical research community
  - Irrespective of ability to pay

- Allow researchers to share information
  - with other caBIG® compatible systems, within organizations, with other organizations and with NCI

- Cooperative Groups have agreed to use the CDMS’ Electronic Data Capture (EDC) functionality
  - Optional use of other CDMS features/sub-components
  - Other organizations (e.g., Cancer Centers, Consortia) may choose to use the CDMS
CDMS Procurement: License

- NCI-hosted or locally hosted
- **Unlimited-user, perpetual license, including:**
  - On-site installation, administrator training, user training materials
  - Telephone / e-mail support
  - Periodic software upgrades
- **Does NOT include:**
  - Custom integration with existing / legacy systems
  - Migration of legacy data
  - Infrastructure for locally hosted option (system administration staff, hardware, etc.)
- **Request for Letters of Intent, November 2009**
  - Total LOIs received: 43
- **Full implementation has been delayed because of vendor protests**
• **Communications will be sent to**
  - caBIG® ANNOUNCE mailing list  
    ([CABIG ANNOUNCE@LIST.NIH.GOV](mailto:CABIG ANNOUNCE@LIST.NIH.GOV))
  - caBIG® Clinical Trials mailing list ([CABIG CTMS-L@LIST.NIH.GOV](mailto:CABIG CTMS-L@LIST.NIH.GOV))
  - caBIG® Clinical Data Management System  
    ([CABIG CDMS@LIST.NIH.GOV](mailto:CABIG CDMS@LIST.NIH.GOV))

• **Communications will come from**
  - [ncicabigcdms@mail.nih.gov](mailto:ncicabigcdms@mail.nih.gov)
Questions / Contacts on CDMS Procurement

- Questions regarding the contract, protests, etc.:
  - Louis Gilden, Contracting Officer, US Department of the Interior: louis.gilden@aqd.nbc.gov

- Questions regarding CDMS Procurement
  - George A. Komatsoulis, Ph.D., Deputy Director, NCI Center for Biomedical Informatics and Information Technology (CBIIT) at komatsog@mail.nih.gov
  - John Speakman, Associate Director, Clinical Trials Products and Programs, NCI Center for Biomedical Informatics and Information Technology (CBIIT) at john.speakman@nih.gov

- Questions regarding CDMS Deployment
  - Neesha Desai, CDMS Project Manager, NCI Center for Biomedical Informatics and Information Technology (CBIIT) at neesha.desai@nih.gov
CTRP User Resources

• Trial registration website:
  https://trials.nci.nih.gov/registry/
  – Register trials with the NCI’s CTRP, search CTRP registered trials

• CTRP informational website:
  http://www.cancer.gov/ncictrp
  – Resources include FAQs, Glossary, and a CTRP User’s Guide

  – Ask questions of the CTRP team and other CTRP users

• CTRP-USERS-L@list.nih.gov – CTRP mailing list
• NCICTRP@mail.nih.gov – Program questions
• NCICTRO@mail.nih.gov – Clinical Trials Reporting Office
Cancer Center Adoption Timeline

- **Pilot NCI-designated Cancer Centers**
  - January 2009: New trials
  - July 2009: New and existing trials, amendments
  - October 2009: Ongoing Registrations

- **“Early Adopter” NCI-designated Cancer Centers**
  - January 2009: New trials, amendments
  - July 2009: New and existing trials, amendments
  - October 2009: Ongoing Registrations

- **All Remaining NCI-designated Cancer Centers**
  - January 2009: New trials, amendments
  - July 2009: New and existing trials, amendments
  - October 2009: Ongoing Registrations

- **Non-Cancer Center Grantees**
  - January 2009: New trials, amendments
  - July 2009: New and existing trials, amendments
  - October 2009: Ongoing Registrations

- **All NCI Grantees**
  - March 2010: Ongoing Registrations
  - September 2010: Observational / Ancillary / Correlative?
Why not just take the data from ClinicalTrials.Gov into CTRP?

- Several key concepts are not structured in the ClinicalTrials.Gov specifications (e.g., eligibility criteria)
- NCI, patients and physicians need data elements to be more finely grained for retrieval of trials
  - within conditions (e.g., clinical stage, histological type, grade of tumor)
  - Other qualifiers (e.g., again using cancer as an example, “unresectable”, “localized”, “recurrent”)
- CTRP Database enables investigators to update current data elements quarterly in near-real-time
  - ClinicalTrials.Gov waits until two years after study closure
- As the data elements relating to outcomes are finalized, NCI expects the scope of information needed will be much broader and more detailed