

# **CTMS Steering Committee Report to CTAC December 8, 2008**

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Co-Chair, CTMS Steering Committee

Chair, North Central Cancer Treatment Group

# The Four Informatics Initiatives

- **Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials**
- **Achieve industry and FDA concurrence on standard Case Report Forms incorporating Common Data Elements**
- **Promote establishment of national clinical trial information technology infrastructures that are fully interoperable with NCI's cancer Biomedical Informatics Grid (caBIG™)**
- **Develop a credentialing system for investigators and sites that is recognized and accepted by NCI, industry sponsors, clinical investigators, and clinical trial sites**

# caBIG Workspaces

## caBIG Program Management and Contracting

**Clinical Trials  
Management  
Systems**

**Integrative  
Cancer  
Research**

*In Vivo*  
**Imaging**

**Tissue Banks  
& Pathology  
Tools**

**Strategic  
Planning**

**Documentation  
and Training**

**Data Sharing  
& Intellectual  
Capital**

**Vocabularies and Common Data Elements**

**caGrid**

# Charge to Steering Committee

- **Provide strategic guidance and direction to caBIG™ on Clinical Trials Management Workspace activities**
- **Give input and feedback on Workspace projects and their prioritization**
- **Review and prioritize Task Force activities**
- **Work with caBIG™ to ensure the Workspace's strategy and priorities align with NCI's broader goals and objectives**

# Steering Committee Participants

## Trialists

- Principal Investigators
  - Academic institutions
  - Pharmaceutical industry
- Statisticians, Data Managers, Nurses

## Informaticists

- Cooperative Groups, Cancer Centers
- Subject matter experts

## Patient Advocates

## Governmental Representatives

- NCI (DCTD, DCP, Centers, CBIIT)
- FDA

# Meeting Conduct & Content

- Quarterly
- Agenda established collaboratively
- Format
  - Presentation → Round Table Discussion
- Focus & Content
  - CTWG recommendation implementation
- Action items established by consensus

# Strengths

- Bidirectional communication
  - NCI and extramural investigators
  - Clinical trialists and informaticists
  - Cooperative Groups & Cancer Centers
- Mutual accountability (if you will, then...)
- Pragmatic prioritization
- Anticipatory troubleshooting

# Weaknesses

- Lack of continuity meeting to meeting
- FDA participation minimal
- No OHRP representation
- Implementation plans incompletely developed



# Opportunities

- CDMS deployment
- Implementation/integration caBIG™ tools
- Clinical Trial Reporting Program
- CTSA engagement

# Threats

- Immaturity of implementation plans
- Policy quagmires
  - Data sharing
  - Intellectual policy
- Workspace silos
- Lack of internal NCI cohesion
  - Tools
  - Policies



**NCCTG**

**NORTH CENTRAL CANCER TREATMENT GROUP**

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**Questions?**