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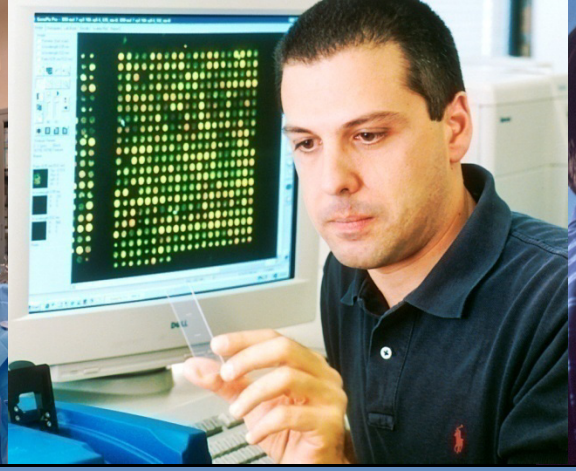



Transforming NCI's Clinical Trials System

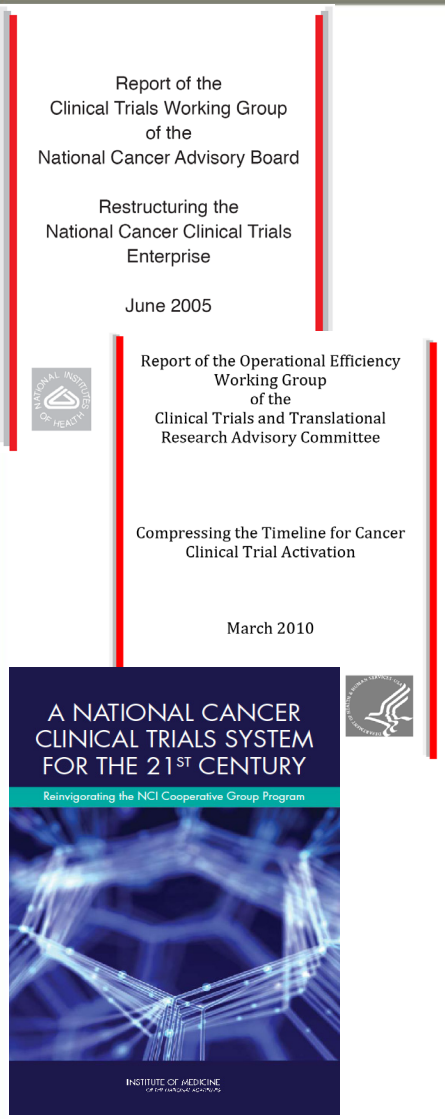
James H. Doroshow, M.D.
Deputy Director for Clinical and Translational Research
National Cancer Institute, NIH

Implementing a National Cancer Clinical Trials System for the 21st Century:
IOM Workshop #2
Washington, DC
February 11, 2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Cancer Institute

Institute of Medicine Report



Emphasized critical need for a public clinical trials system

4 goals for modernization with 12 recommendations

- **Improve speed & efficiency of trial development & activation**
- **Incorporate innovative science and trial design**
- **Improve prioritization, support, and completion of trials**
- **Incentivize participation of patients and physicians**

NCI is implementing a comprehensive approach to transforming its clinical trials system to create a highly integrated network that can address rapid advances in cancer biology based on:

- **Recommendations from the IOM Report**
- **Previous reports (Clinical Trials & Operational Efficiency)**
- **Current stakeholder input**

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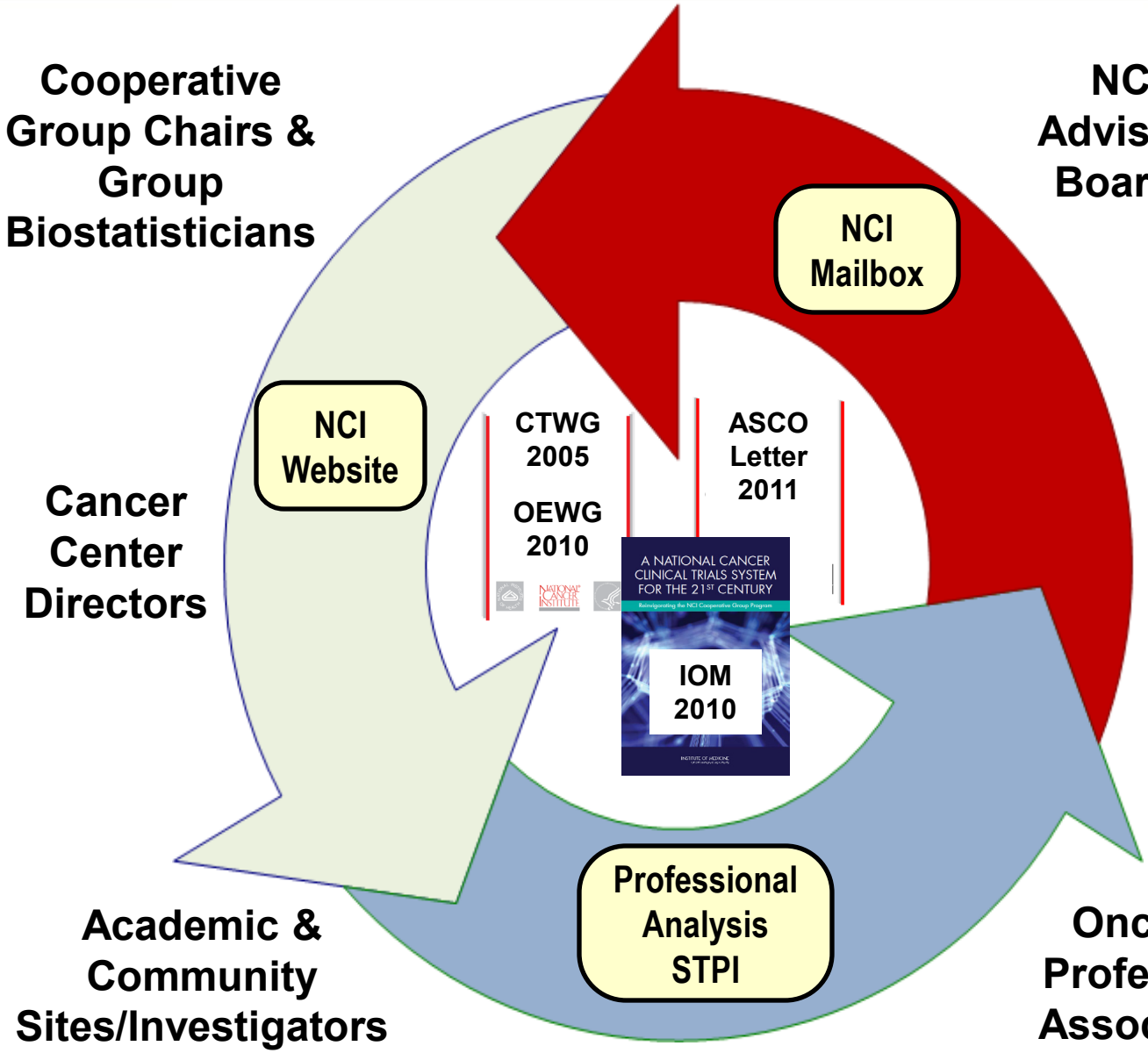
Extensive Review & Stakeholder Input on Revising NCI's Clinical Trials System



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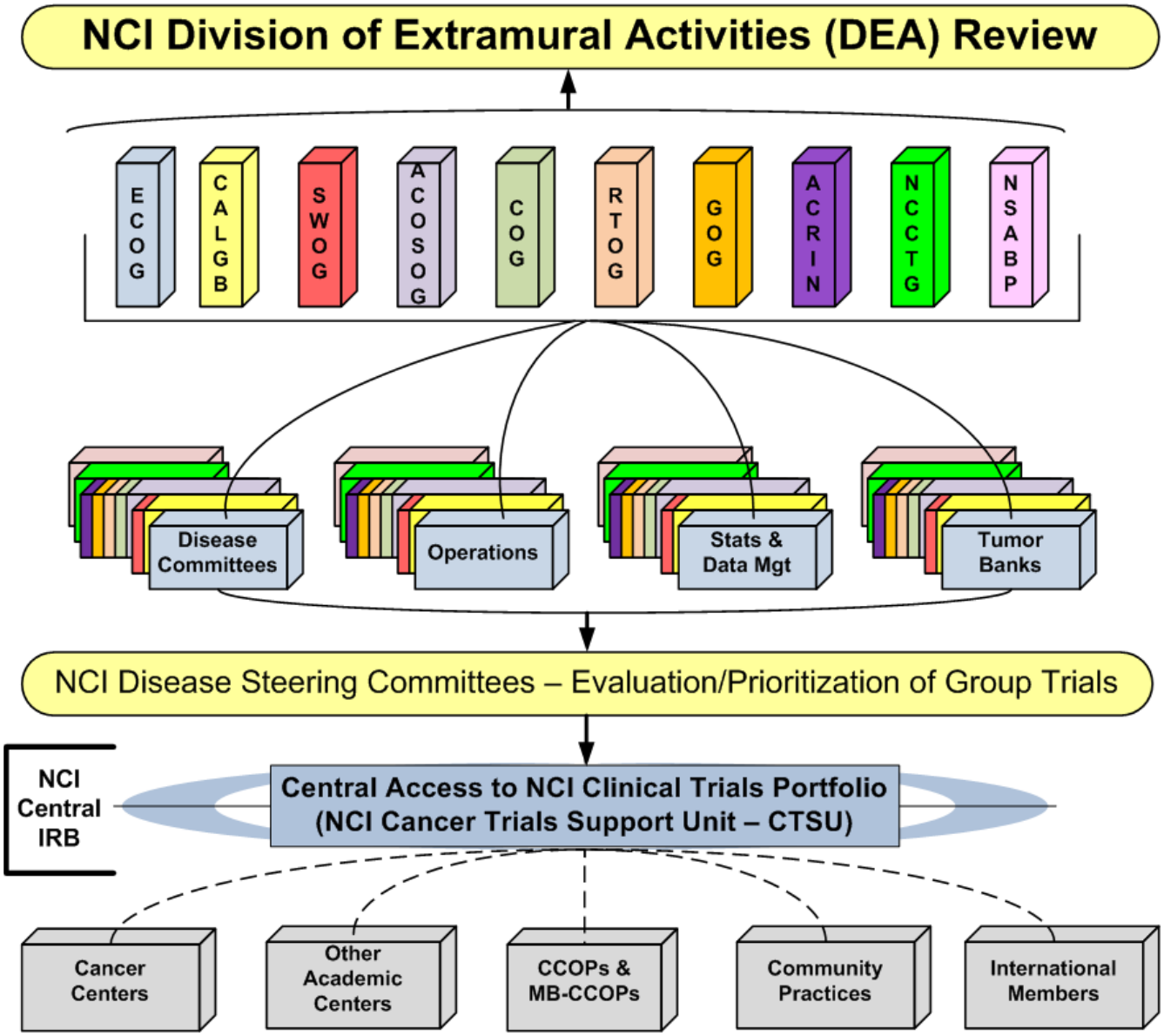
Organizational Structure of Group Program: 2011



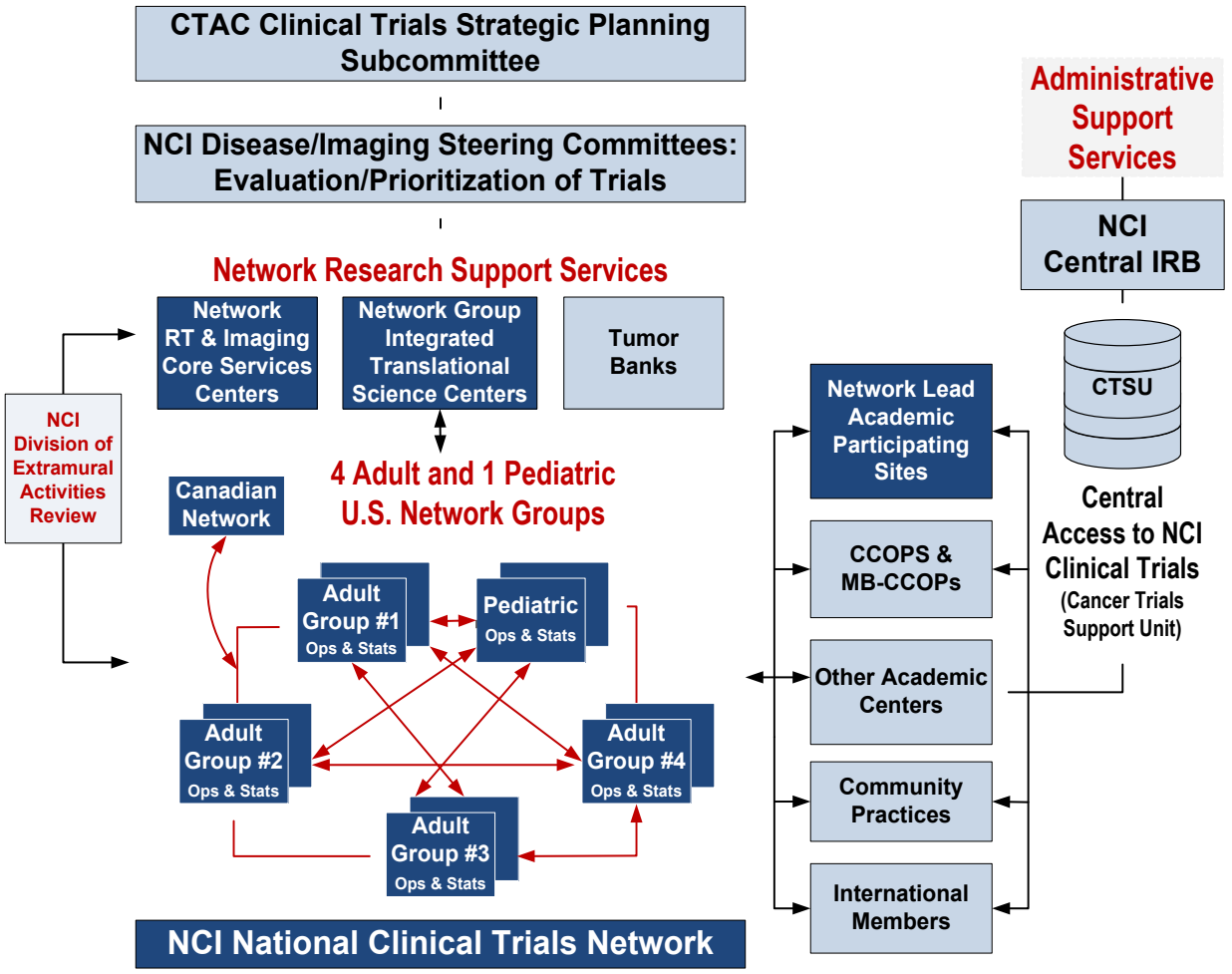
IOM Goal 1: Improve Speed & Efficiency of the Design, Launch, and Conduct of Clinical Trials

Recommendation 1: ***Facilitate some consolidation of Group "front-office" operations by reviewing & ranking Groups with defined metrics on similar timetable & by linking funding to review scores***

Progress:

- New Program with up to 4 adult & 1 pediatric Network Groups
- Peer-review focused on overall research strategy, collaboration, & operational efficiency
- Support for trials designed with integral molecular screening
- Integrated translational science & Lead Academic Participating Site awards
- Core RT/Imaging services
- Strategic planning & trial prioritization at national level
- Adult and pediatric Central IRBs; consent template
- Common IT data mgt system
- Centralized 24/7 patient registration

New Program: NCI National Clinical Trials Network (NCTN)



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IOM Goal 1: Improve Speed and Efficiency

Recommendation 2: *Require/facilitate consolidation of Group "back-office" operations & working with extramural community, make process improvement in operations & organizational management a priority*

Progress

- **Centralized 24/7 patient registration, regulatory support & site verification of trial participation by Cancer Trials Support Unit**
- **Implementation of timelines for study review & development with major time savings for trial activation**
- **Implementation of common IT data management system for trial development and conduct instituted for all new clinical trials activated in 2013**

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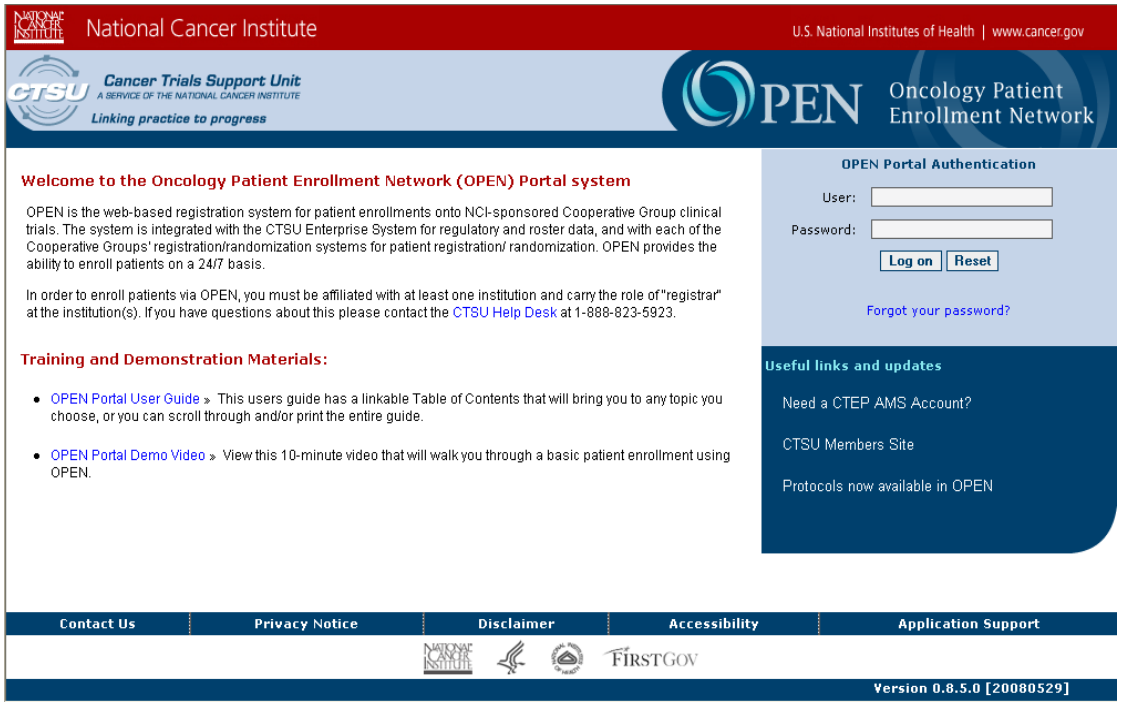
CTSU: A National Infrastructure for Patient Enrollment on NCI-Supported Clinical Trials

Cancer Trials Support Unit (CTSU) has expanded centralized administrative & regulatory functions for clinical trials

- Over 57,000 patients enrolled via CTSU since 2002
- Cross-Group accrual available for all phase 3 & select phase 2 tx trials
- Expansion of services to other NCI trial networks & collaborative trials
- Provides a range of critical services in support of the national system

- ✓ Patient registration
- ✓ Accrual reimbursement
- ✓ Protocol Coordination
- ✓ Clinical Data Operations
- ✓ Regulatory Support Service
- ✓ Financial Management
- ✓ Site Auditing
- ✓ Site QA
- ✓ CTSU Help Desk
- ✓ CTSU Web Site
- ✓ Education & Trial Promotion

As of 2011, 24/7 enrollment for all Group Tx trials



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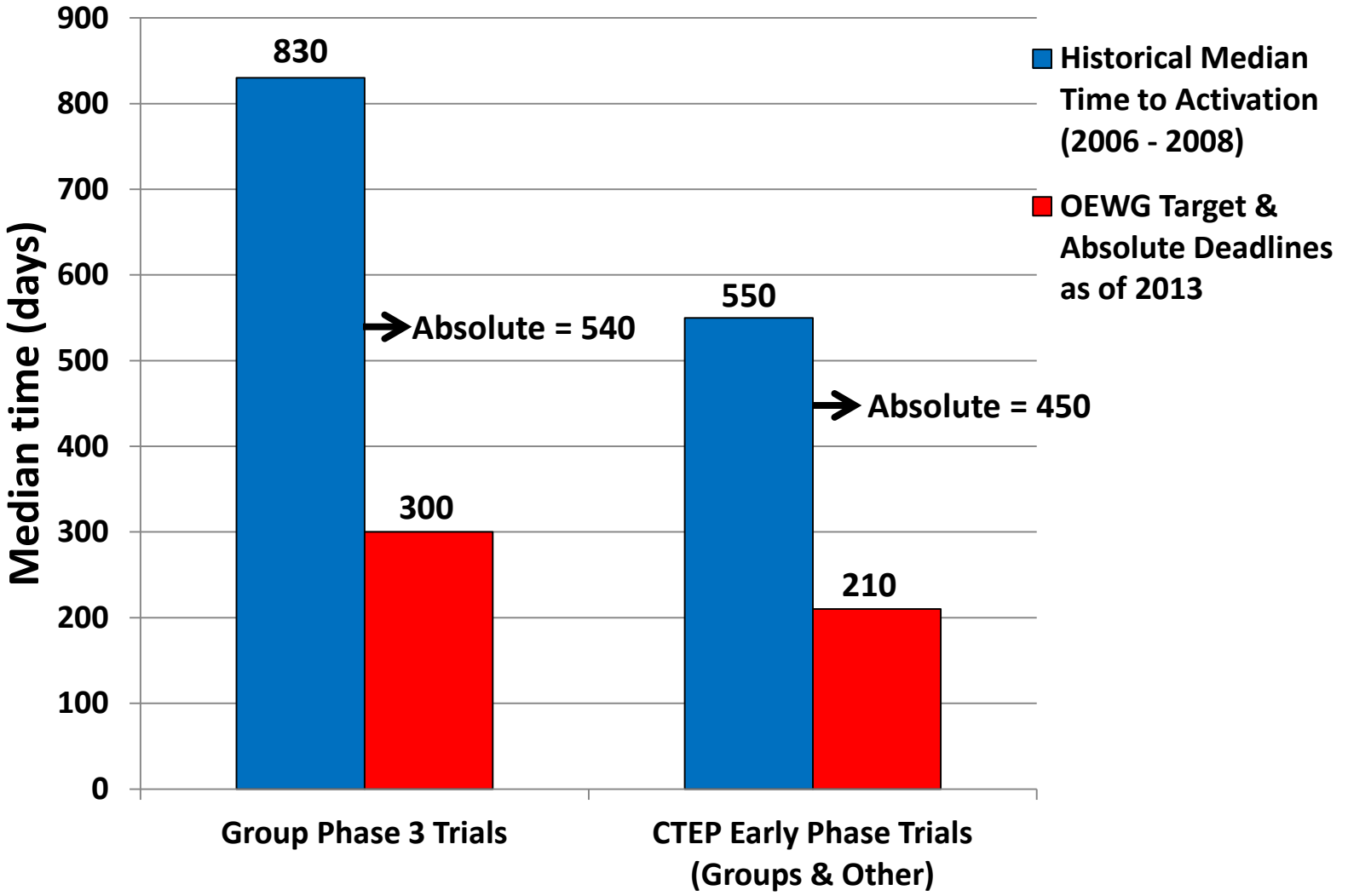
Implementation of Operational Efficiency Timelines



Protocol terminated if absolute timelines not achieved

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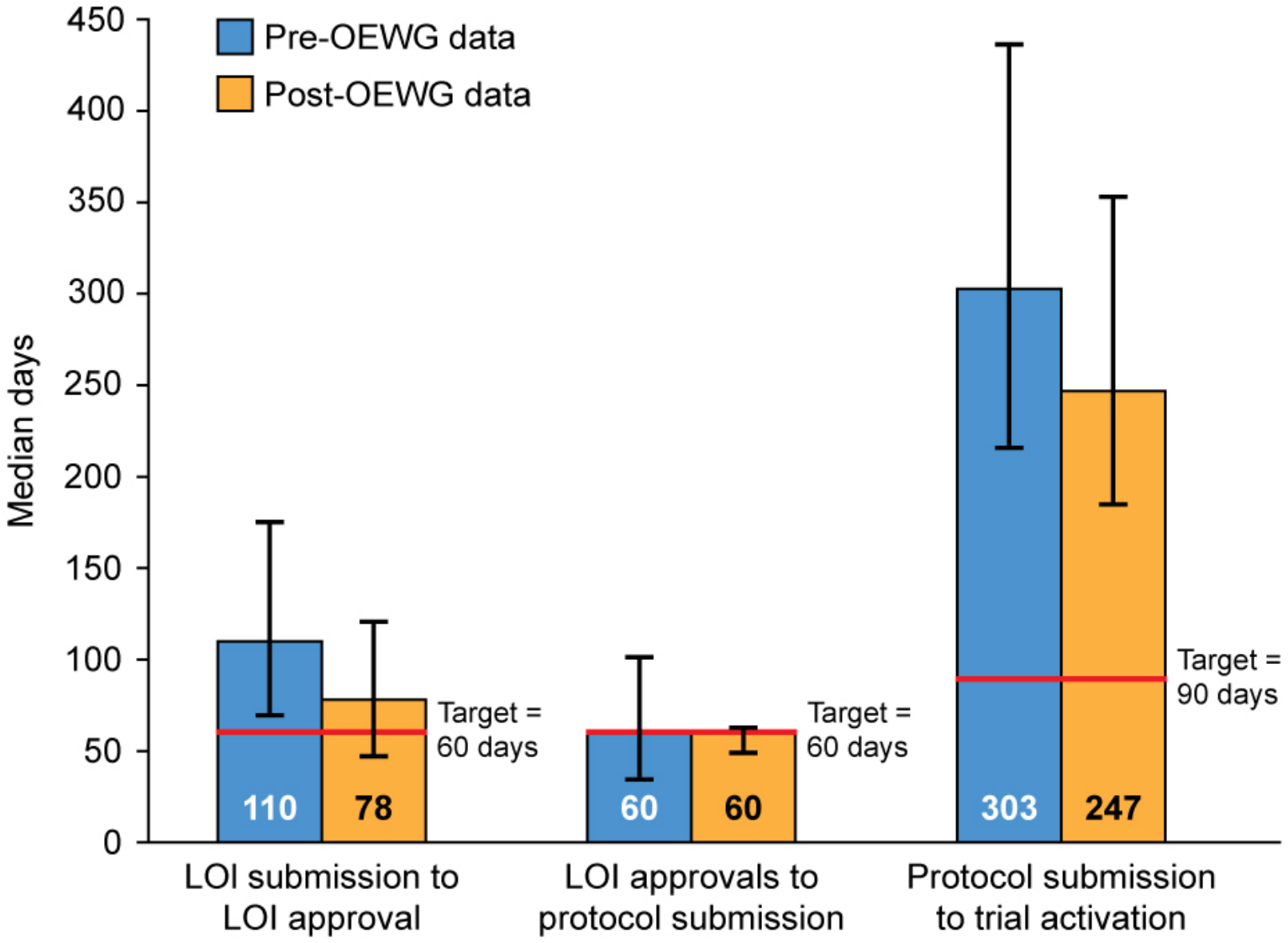
Breakdown of Study Development Stages

Early Phase Trials



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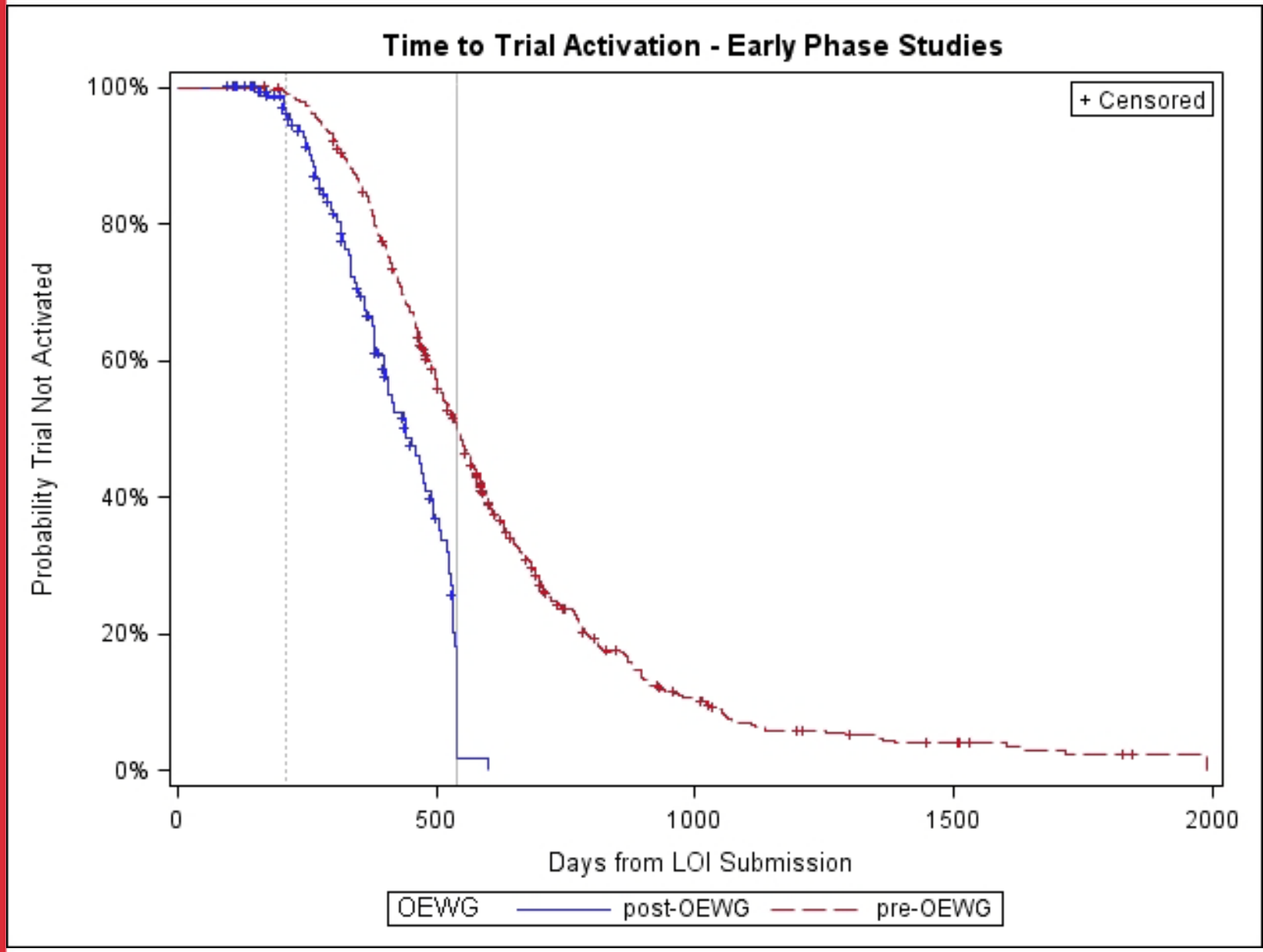
Timeline Comparison Early Phase Trials

Historical vs Post-OEWG (Apr 2010 – Aug 2012)



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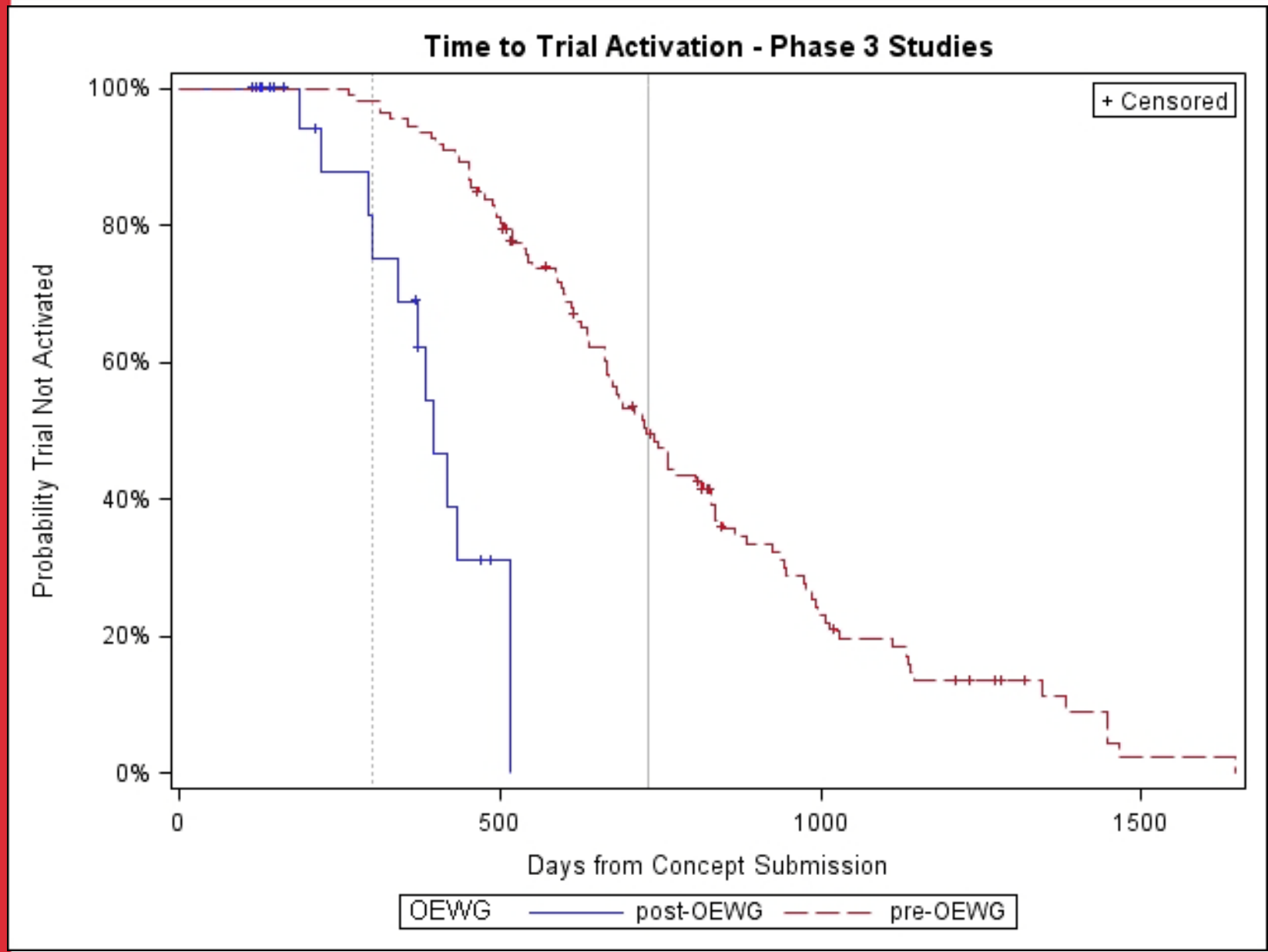
Timeline Comparison Phase 3 Trials

Historical vs Post-OEWG (Apr 2010 – Aug 2012)



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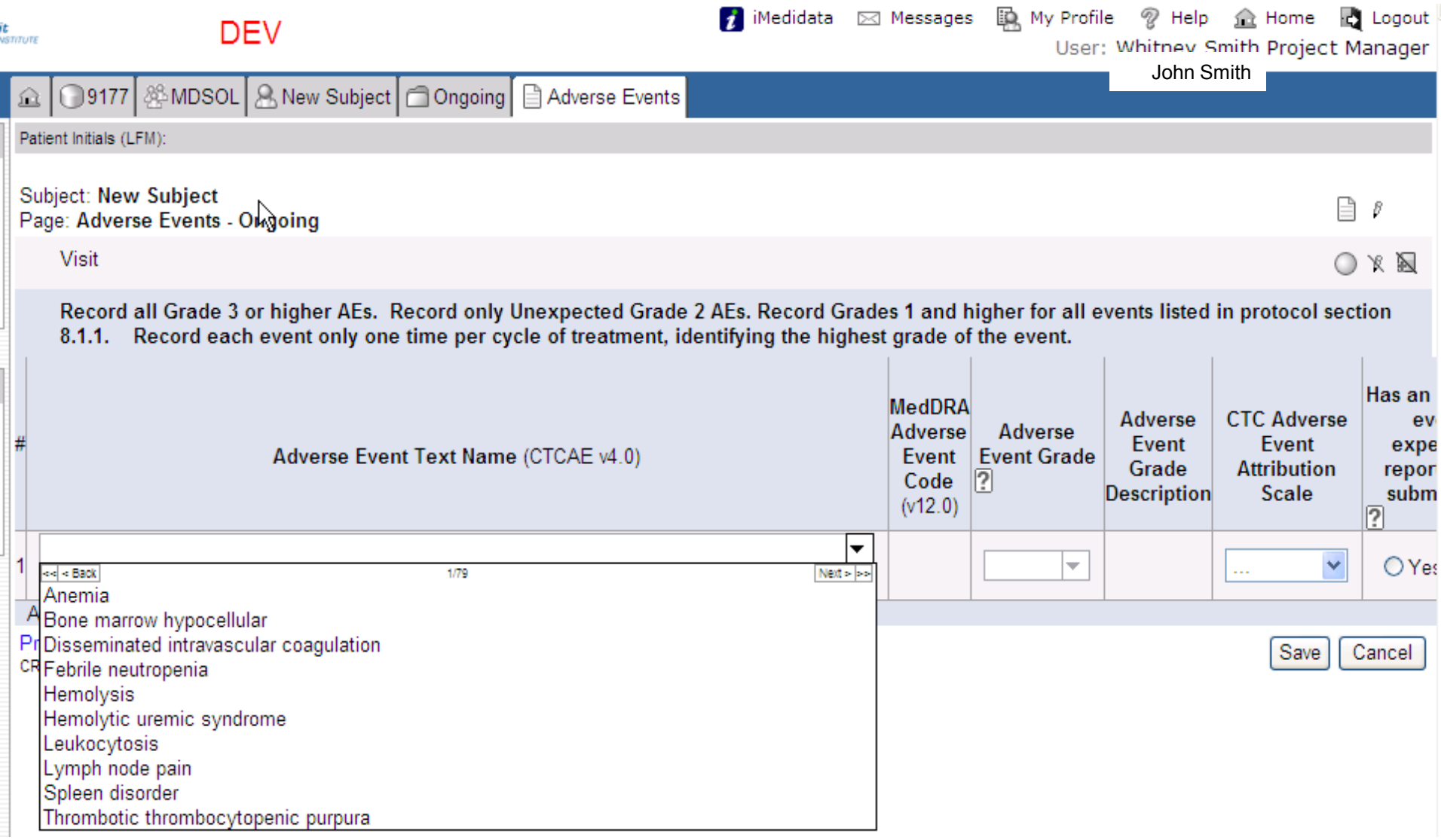
Common IT Data Management System (CDMS)

- **Electronic tool(s) or processes that support**
  - ✓ Data collection: Remote Data Capture (RDC)
  - ✓ Data coding: Standard libraries - Common Toxicity Criteria
  - ✓ Data management: Discrepancy, delinquency, communication, correction & preparation of data for analysis
- **Core benefits of CDMS on NCI-supported multicenter trials**
  - ✓ Reduces training costs & cost of overall cost of data management
  - ✓ Reduces risk of data delinquency and/or discrepancy
  - ✓ Reduces time/effort to correct/complete data
  - ✓ Reduces delays in obtaining Science and Safety results & improves trial management & decision-making
- **Other Benefits to NCI-supported multicenter trials**
  - ✓ Supports/complements transformation of Groups into new 'Network' program
  - ✓ Meets FDA & other Federal requirements for e- data capture, security & transfer
  - ✓ Promotes data sharing
  - ✓ Sets stage for further infrastructure improvements such as integration with expedited Serious AE reporting, remote auditing, electronic filing for FDA reports

Medidata RAVE® Toxicity (Adverse Event) Page



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IOM Goal 1: Improve Speed and Efficiency

Recommendation 3: *HHS should lead a trans-agency effort to streamline and harmonize government oversight and regulation of cancer clinical trials*

Progress

- Established interagency agreement with FDA for rapid review of approved Group phase 3 tx trials at concept stage
- Developed coordinated processes for development/review of trials under FDA Special Protocol Assessment (SPA)
- Developed adult & pediatric NCI Central IRBs with major improvement in review timelines & AAHRRP accreditation
- Working with CDRH/FDA to coordinate early review of investigational devices (biomarkers)

NCI CIRB Profile – Enrollment: Current Model

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Enrollment of Institutions/IRBs reviewing Group Studies: Facilitated Review

- **Number of Signatory Institutions Enrolled** **330**
  - *Number of Institutions using Adult CIRB only* *183*
  - *Number of Institutions using Pediatric CIRB only* *42*
  - *Number of Institutions using both Adult & Pediatric CIRB* *105*
- **Total Number of Enrolled Signatory Institutions, Affiliates, and Components** **1,023**
- **Number of NCI Designated Cancer Centers** **43**
- **Number of CCOPs** **35**
- **Number of MBCCOPs** **10**

As of 4/30/2012

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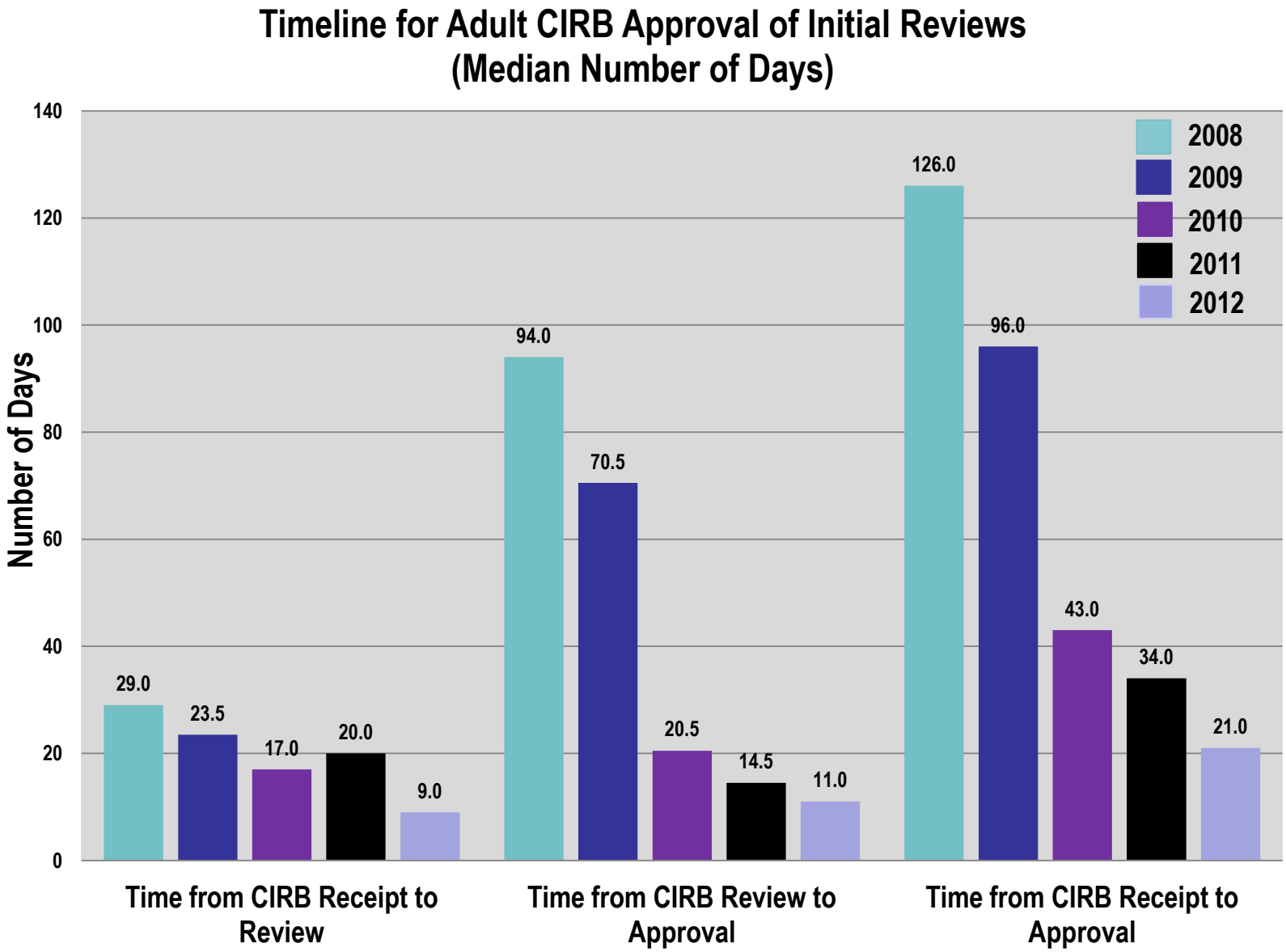
NCI CIRB: Changes in Initial Review Timeline



NCI Adult & Pediatric CIRB Independent Model

- **Received full accreditation by Association for Accreditation of Human Research Participant Protection Programs (AAHRPP) in December 2012**
- **New institutions being added and current institutional members of CIRB being transitioned to independent model**
- **Participation in NCTN trials will require use of CIRB**
  (with waiver exemption possible for sites demonstrating similar local IRB review timelines)
- **Being expanded to include study review of other NCI-supported clinical trials networks & potential expansion to other types of studies**
  - ✓ Experimental Therapeutics Clinical Trials Network; other NCI Networks
  - ✓ DCP-supported cancer control & prevention studies

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IOM Goal 1: Improve Speed and Efficiency

Recommendation 4: *NCI should take steps to facilitate more collaboration among the various stakeholders in cancer clinical trials*

Progress

- NCI has harmonized all guidelines for programs engaged in the conduct of clinical trials so that the appropriate incentives are in place for collaboration (SPORES, Cancer Centers, Groups)
- In collaboration with CEO Roundtable on Cancer, developed Standard Terms of Agreement for Research Trials (START) clauses for company and academic collaborations to speed clinical trial negotiations
- Revised IP option on all CTEP Cooperative Research and Development Agreements (CRADAs) relating to drug development (CTEP Intellectual Property Option to Collaborator; Pages 13404-13410 [FR DOC# 2011-5609]): Biomarkers/Tissues—no blocking IP; royalty-free non-exclusive licenses
- CRADA negotiations with Pharma: 6 month absolute deadline

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IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

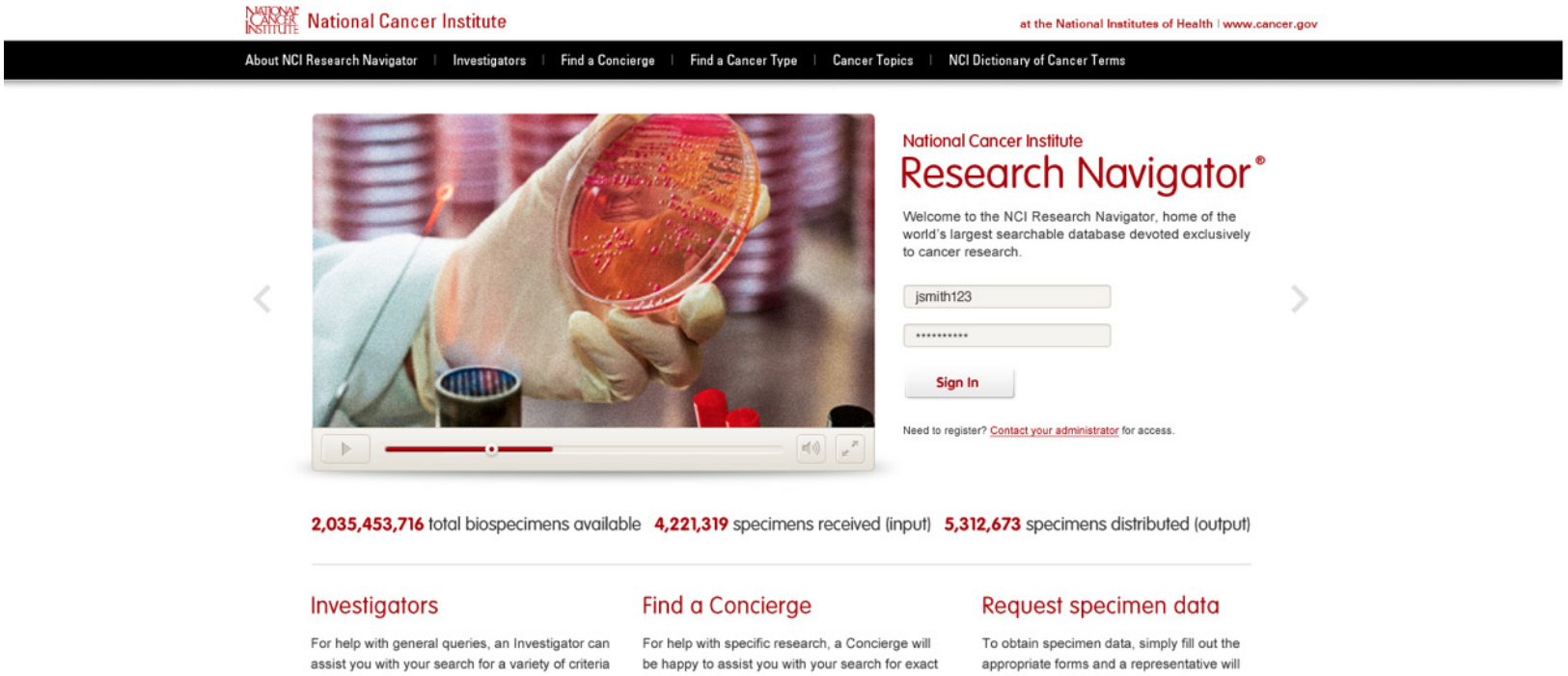
Recommendation 5: *NCI should mandate submission of annotated biospecimens to high-quality, standardized central biorepositories when samples are collected from patients in the course of Group trials and should implement new funding mechanisms and policies to support the management and use of those resources for retrospective correlative science*

Progress

- **Revising RFA for U24 grants for National Specimen Banks for NCTN Groups to include common operating procedures for samples collected from patients Group and other NCI supported trials**
- **Developing common process & procedures for requesting biospecimens banked from NCI clinical trials**
- **Developing shared IT infrastructure to enhance specimen inventories**

Integrated National Biospecimen Banks for NCTN

Biospecimen *Navigator*



- ✓ Provide consolidated inventory of biospecimens across NCTN trials
- ✓ Connect biospecimen inventory data with associated trial data and (where possible) clinical data – as aggregate counts – to allow for assessment of biospecimen availability based on trial design / end points
- ✓ Provide tools and standards definitions to facilitate automated data loading from multiple systems
- ✓ Provide secure, role-based, highly functional user interface performing data queries & reporting to meet needs of various stakeholders
- ✓ Provide user interface & data model for tracking biospecimen requests, utilization, & scientific productivity
- ✓ Create an extensible system to serve similar biospecimen inventory / query & request tracking needs beyond NCTN Groups as needed

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IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

Recommendation 6

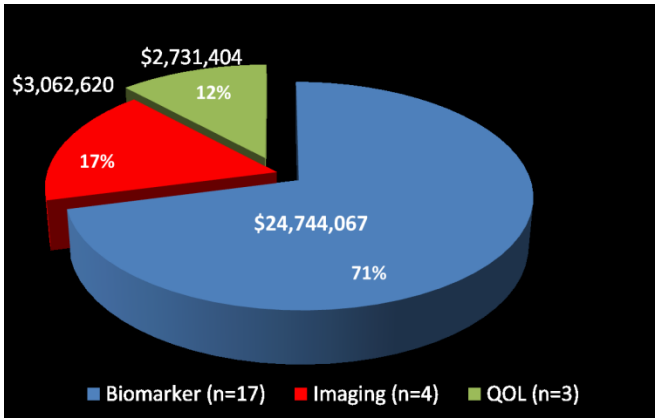
Cooperative Groups should lead the development and assessment of innovative designs for clinical trials that evaluate cancer therapeutics and biomarkers (including combinations of therapies).

Progress

- **Initiated the Biomarker, Imaging, and Quality of Life Studies Funding Program to ensure that critical correlative studies could be incorporated in a timely manner into phase 3 and large, multi-institutional phase 2 trials during the process of concept development .**

- **From mid-2008 thru 12/27/12, 24 of 88 concepts submitted incorporating integral and integrated biomarker, imaging, QOL, and CEA studies have been supported for a total commitment of $30,538,091.**

BIQSFP-Funded Studies



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Approved BIQSFP Studies: Examples

Cooperative Group/CCOP	Funded Study Type	Cancer Site	Assay/Test/ Assessment
SWOG	Integral Biomarker	Breast	OncoType DX
COG	Integrated QOL	Peds ALL	vincristine-associated neuropathy & motor function
COG	Integral & Integrated Biomarkers	Peds AML	FLT3/ITD, KIT, MRD, WT1, RUNX1, TET2, MLL-PTD, c-CBL, CEBPα, CD74, PSMB5
RTOG/ACRIN	Integrated Imaging	Glioblastoma	MRI
RTOG	Integral Biomarker	Esophageal	HER2
NCCTG	Integral Biomarker	Glioma	translocation of 1p:19q
CALGB	Integral & Integrated Biomarkers	Lung	COX-2, urinary PGE-M
COG	Integral Biomarker	Peds AML	FLT3/ITD, MRD, CEBPα
NSABP	Integrated QOL	Breast	fatigue, behavioral & health outcomes
GOG	Integrated QOL	Uterine	PROMIS 7 (HRQOL)

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IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

- **NCI worked with Investigational Drug Steering Committee on evaluation of innovative clinical trial designs as well as other key issues related to cancer therapeutics:**

  - ✓ **"Design of phase II clinical trials testing cancer therapeutics: consensus recommendations from the clinical trial design task force of the NCI investigational drug steering committee. Clin. Cancer Res. 16: 1764-1769, 2010**

  - ✓ **"Novel designs and endpoints for phase II clinical trials. Clin. Cancer Res. 15: 1866-1872, 2009**

  - ✓ **"Approaches to phase I clinial trial design focused on safety, efficiency, and selected patient populations: a report from the clinical trial design task force of the NCI investigational drug steering committee. Clin. Cancer Res. 16: 1726-1736, 2010**

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IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

- **NCI is revising Early Therapeutics Clinical Trials System:**
  - ✓ ***Team Science*** **focused approach for Early Experimental Therapeutics Program**
  - ✓ ***Molecular profiling*** **of patient tumors from early experimental therapeutics clinical trials**
  - ✓ ***Enhanced collaboration*****, both within NCI/DCTD (PD Lab, CRADA collaboration, CDP, CIP, RRP) and with other NCI-sponsored programs, including SPORES, Centers, mouse models consortia, grantees (P01s)**
  - ✓ ***Streamline the timeline for study development*** **by identifying processes that can be better synchronized and/or performed simultaneously; provide core services**

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IOM Goal 3: Improve Prioritization, Selection, Support, and Completion of Cancer Clinical Trials

Recommendation 8: ***NCI should re-evaluate its role in the clinical trials system***

Progress

- Initiated Clinical Trials and Translational Research Advisory Committee (CTAC) with specific responsibilities for evaluating NCI's clinical trials programs strategic vision
- CTAC Strategic Planning Working Group: Evaluate the overall effectiveness of studies conducted by NCTN
- Revamped prioritization process for phase 3 and large phase 2 treatment & control trials through disease and modality-specific Steering Committees to ensure most important trials are given highest priority
- NCI represents Institute priorities for the public program on the Steering Committees and facilitates implementation of prioritized clinical trials

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NCTN Program Cooperative Agreements: 6 Funding Opportunity Announcements Released

Network Component	Mechanism (Duration)	Est. Max. # Grants	Frequency New Application Accepted?	Multiple PI Option?
Group Operations Centers	U10 (5 Yrs)	5	Every 5 Years	Yes
Group Statistical & Data Mgt Centers	U10 (5 Yrs)	5	Every 5 Years	Yes
Lead Academic Participating Sites	U10 (5 Yrs)	30 to 40	Possible Additional Date After 2 Years within 5 Year Period	Yes
Integrated Translational Science Awards	U10 (5 Yrs)	5 to 7	Every 5 Years	Yes
RT and Imaging Core Services	U24 (5 Yrs)	1	Every 5 Years	Yes
Canadian Collaborating Network	U10 (5 Yrs)	1	Every 5 Years	Yes

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Timeline for Implementation of NCTN Program

NCI Board of Scientific Advisors Review	Nov 2011
NCI & NIH Review FOA/Guidelines	Nov 2011 – July 2012
New FOAs & Guidelines Released	July 23, 2012
Letter of Intents Due	December 15, 2012
Receipt Competing Applications Due	January 15, 2013
Review Competing Applications	June 2013
National Cancer Advisory Board Review	October 2013
Rollout of Awards in FY2014	March 2014 (tentative)

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Vision for Transformed Network

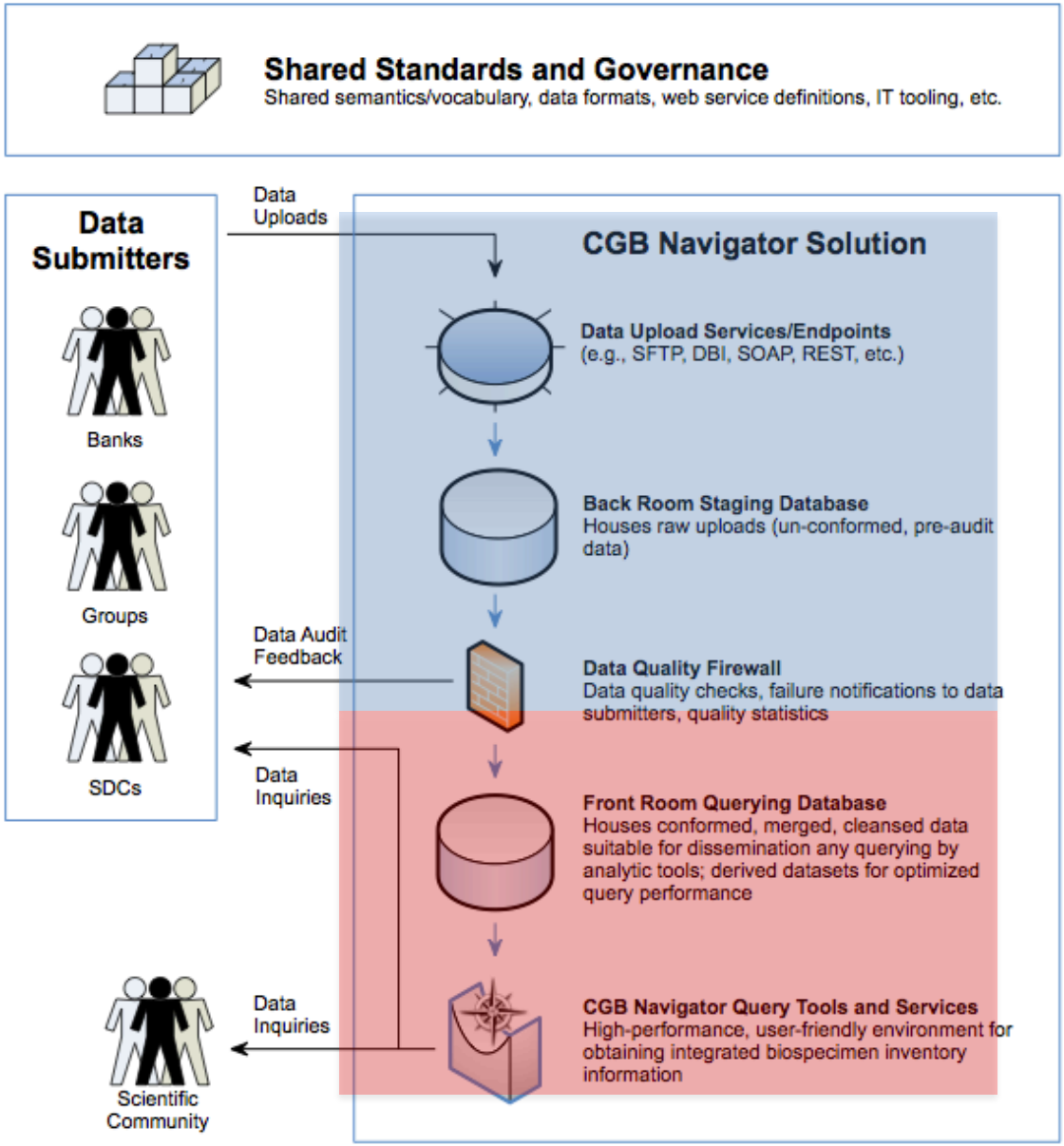
- **Provide essential infrastructure for NCI trials in treatment, control, screening, diagnosis, & prevention across all NCI clinical research programs**
- **Launch trials rapidly and complete accrual according to defined guidelines through integrated national network of performance sites**
- **Promote user-friendly, harmonized processes to extramural community (investigators, patients, advocates, & industry)**
- **Provide functional platform to perform large scale testing of increasingly smaller subsets of molecularly-defined cancers & focus on questions not well supported in a commercial environment**

Implementation of IOM Report

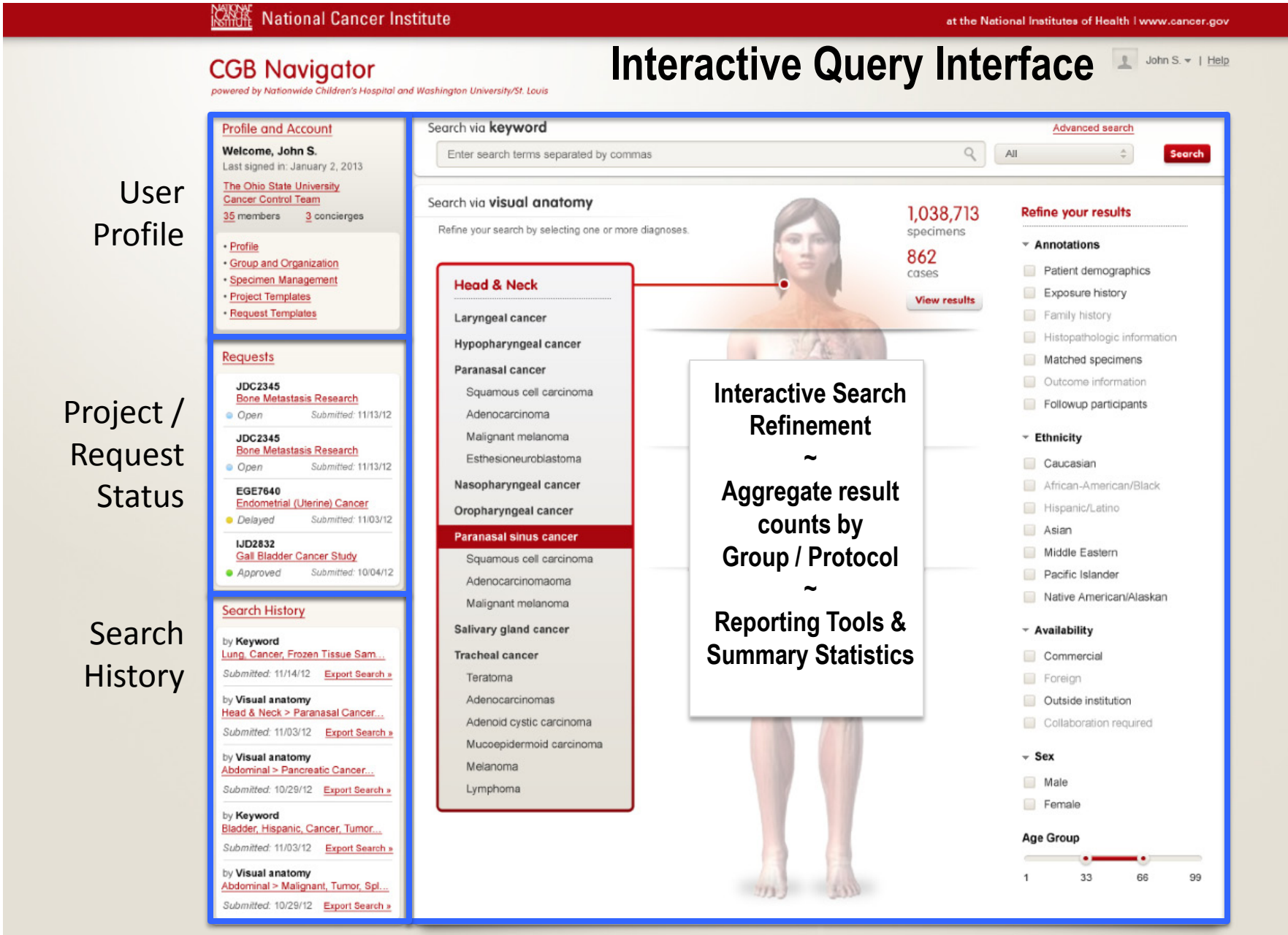
Additional Slides

Integrated National Biospecimen Banks for NCTN

Biospecimen *Navigator*



User Interface Design Concept - Investigator Page



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Approved BIQSFP Studies

Cooperative Group/CCOP	Funded Study Type	Cancer Site	Assay/Test/ Assessment
RTOG	Integrated Biomarker	Pancreas	SMAD4
ECOG	Integral & Integrated Biomarker	Adult ALL	MRD
Alliance	Integrated Imaging	Prostate	PET/CT
RTOG	Integral Biomarkers	Head & Neck	P16 & EGFR
COG	Integral Biomarker	JMML	DNA Sequencing
SWOG	Integral Biomarker	Gastric	ERCC-1
ACOSOG	Integral Biomarker	Breast	Ki67
CALGB	Integral Biomarker & Imaging	Esophageal	central pathology & PET-CT
RTOG	Integral Biomarker	Oropharynx	p16
COG	Integrated Biomarker	Peds ACL	galactomannan & β-D-glucan
COG	Integrated Biomarkers	Peds ACL	bacterial isolates from stool/perirectal swabs
COG	Integrated Imaging	Peds ALL (osteonecrosis)	MRI
SWOG	Integral & Integrated	NSCLC	KRAS, EGFR

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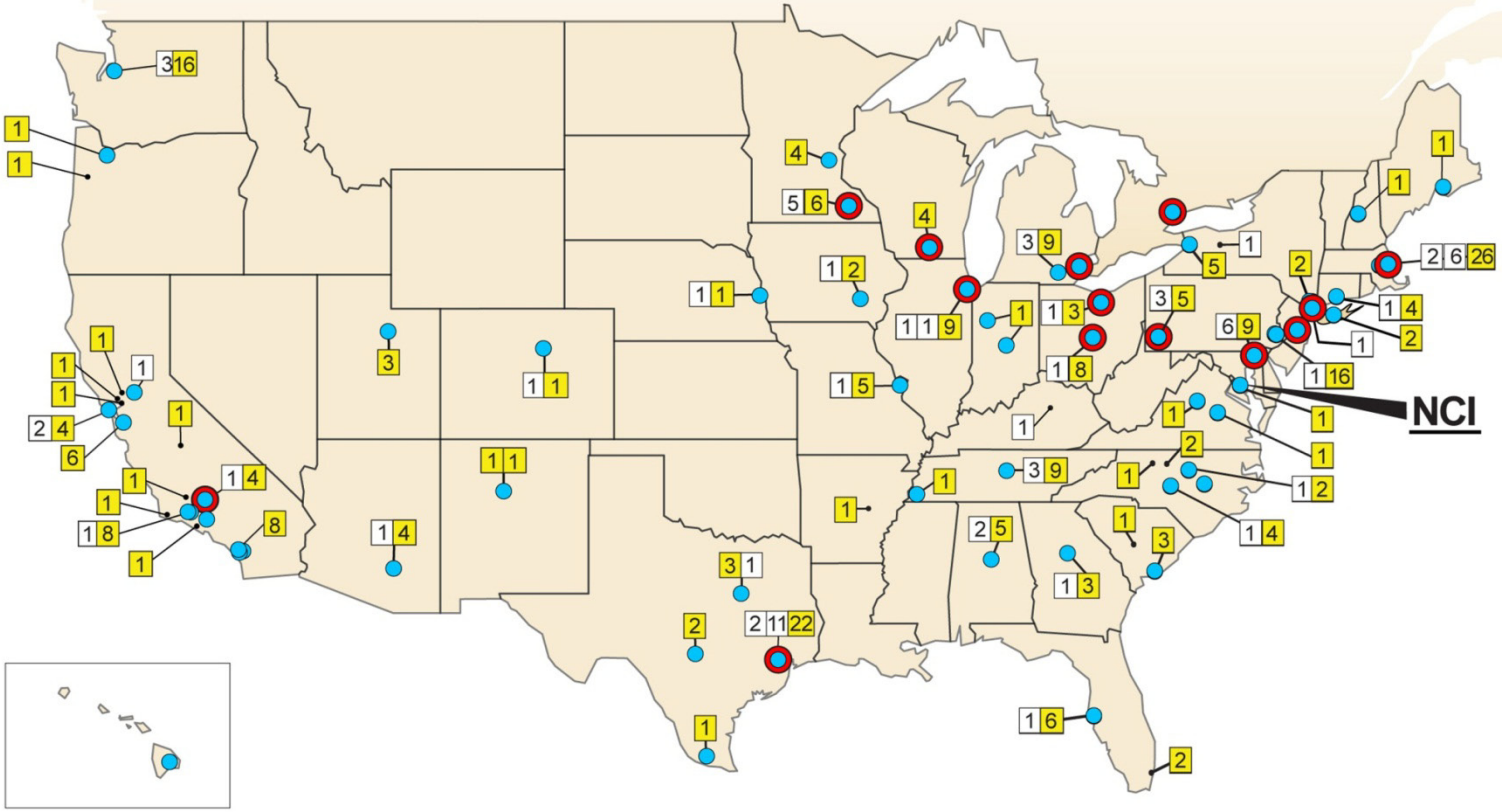
IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

Integration of NCI-Sponsored Programs Using Early Experimental Therapeutics Program: Network Collaborations of All Sites



Program Project Grant Sites

NCI-Designated Cancer Centers

U01 Sites

Specialized Programs of Research Excellence Sites

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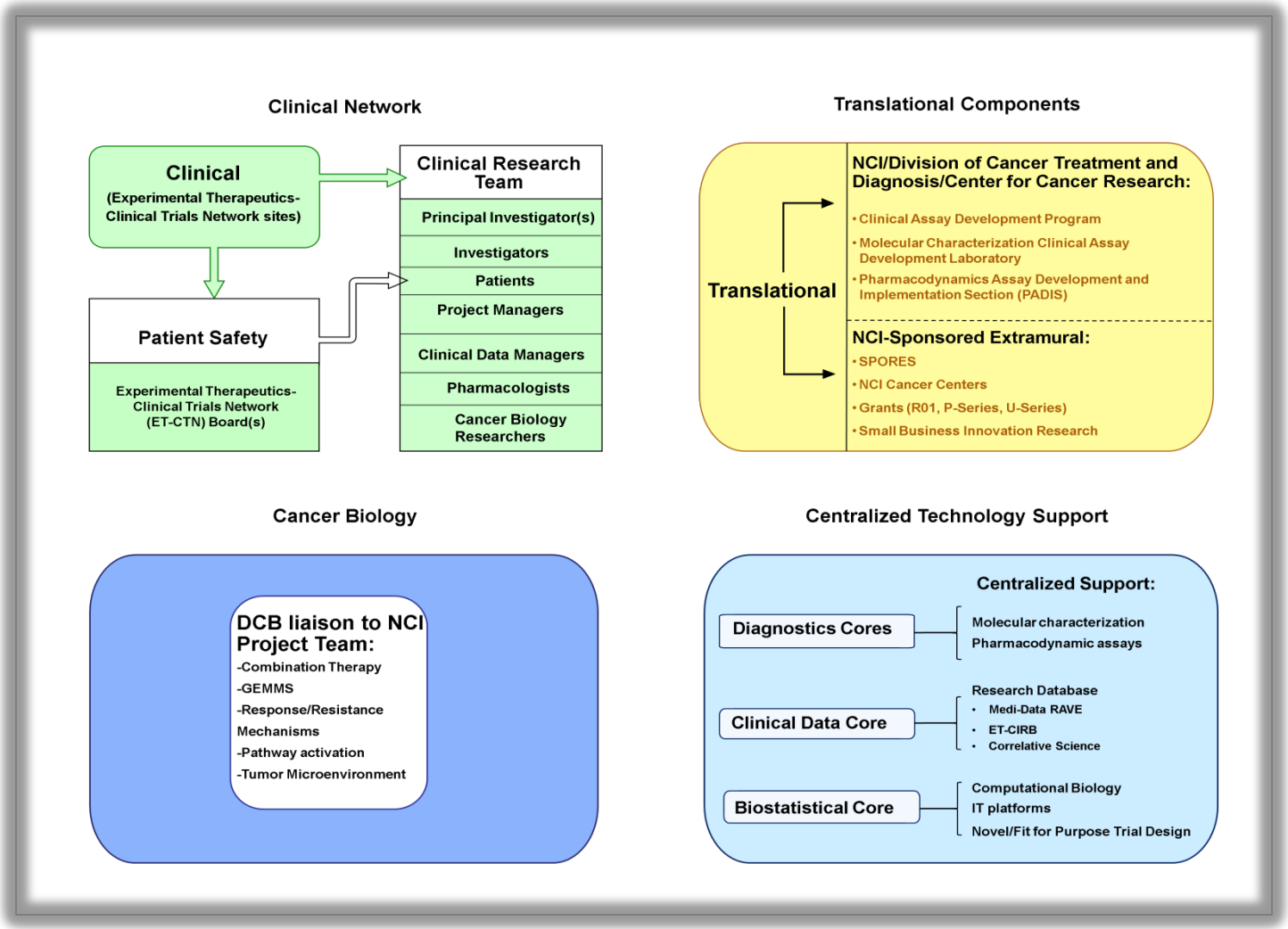
IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

- **Major Components of Revised Early Experimental Therapeutics Program**



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IOM Goal 2: Incorporate Innovative Science and Trial Design Into Cancer Clinical Trials

Recommendation 7: *NCI, in cooperation with other agencies, should establish a consistent, dynamic process to oversee development of national unified standards*

Progress

- **Under auspices of Clinical and Translational Research Advisory Committee (CTAC), developed definitions of integral & integrated studies for biomarkers, imaging, and quality of life investigations associated with Group trials**

- **Working with the NLM and the AACI to develop the Cancer Trials Reporting Program (CTRP) database to provide accrual information related to all NCI-supported clinical trials with full accrual reporting to begin in 2013**

Steering Committee Leadership

Disease Specific Steering Committee

Steering Committee	Co-Chairs
Gastrointestinal (GISC)	Dan Haller, MD, Bruce Minsky, MD, & Neal Meropol, MD
Gynecologic (GCSC)	David Gershenson, MD; Gillian Thomas, MD; Michael Birrer, MD
Head & Neck (HNSC)	David Adelstein, MD; David Brizel, MD; & Drew Ridge, MD, Ph.D
Genitourinary (GUSC)	Eric Klein, MD; Robert Dreicer, MD; & Anthony Zietman, MD
Breast (BCSC)	Thomas Buchholz, MD; & Nancy Davidson, MD
Thoracic (TMSC)	William Blackstock, MD; David Harpole, MD; & Mark Socinski, MD
Leukemia (LKSC)	Wendy Stock, MD; & Jerry Radich, MD
Lymphoma (LYSC)	Oliver Press, MD; & Julie Vose, MD
Myeloma (MYSC)	Morie Gertz, MD; & Nikhil Munshi, MD
Brain (BMSC)	Ian Pollack, MD; & W.K. (Al) Yung, MD
Pediatric Leukemia & Lymphoma (PLLSC)	David Poplack, MD; & Robert Arceci, MD
Pediatric & Adolescent Solid Tumor (PASTSC)	Mark Bernstein, MD, & Kate Matthay, MD

Steering Committee Leadership

Non-Disease Specific Steering Committee

Steering Committee	Co-Chairs
Investigational Drug SC (IDSC)	Lillian Siu, MD & Miguel Villalona, MD
Symptom Management & Health Related QoL SC (SxQOL SC)	Deborah Bruner, RN, PhD & Michael Fisch, MD, MPH
Patient Advocate SC (PASC)	Elizabeth Frank & Mary Jackson Scroggins
Clinical Imaging SC (CISC)	Steve Larson, MD & Neil M. Rofsky, MD

Concept Evaluation Summary ~ (as of 12/31/2012)

Steering Committee	Total Concept Evaluated	Total Concept Approved	Total OPEN to Accrual
GISC	45	23	17
GCSC	43	26	24
HNSC	13	8	4
SxQOL SC	58	24	17
GUSC	19	9	7
BCSC	29	13	6
TMSC	24	7	4
LKSC	9	6	2
LYSC	15	6	5
MYSC	8	3	1
BMSC	14	9	4
CISC	3	2	1
PLLSC	5	3	1
PASTSC	8	5	0
	293	**144 (49%)**	**93 (65%)**

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IOM Goal 3: Improve Prioritization, Selection, Support, and Completion of Cancer Clinical Trials

Recommendation 9: *NCI, Groups, and physicians should take steps to increase the speed, volume, and diversity of patient accrual and to ensure high-quality performance at all sites participating in Group trials*

Progress

- **Modernizing clinical trials IT infrastructure by implementing common clinical data management system to be used across NCI-supported clinical trials system**
- **Enhancing trial participant diversity through support for Minority-based Community Clinical Oncology Programs, Patient Navigator Research Program, & other NCI programs**
- **Working with patient advocates in concept development and accrual planning, along with Groups, Disease Steering Committees, and Patient Advocate Steering Committee**

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IOM Goal 3: Improve Prioritization, Selection, Support, and Completion of Cancer Clinical Trials

- **Update of NCI Informed Consent Document (ICD) Template to address concerns regarding patient understanding of clinical trials presented to them by their treating physicians**

- **Process put in place to assess status current ICDs in NCI trials & address concerns of stakeholders across the oncology community**

  'Snapshot' Audit: Length of Phase 3 CTEP Tx Trials
  97 studies - Range: 5 to 35 pages - Median: 16 pages

- **Series of Working Groups to address key aspects of the ICD created in order to update and streamline/shorten the NCI ICD Template**

- **Anticipated implementation date in 2nd Quarter 2013**

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Update NCI Consent Template: Working Group Co-chairs & Federal Regulatory Advisors

- **Working Group 1 (Background, required tests, intervention sections):**
  - *Shlomo Koyfman, MD – clinical investigator*
  - *Joan Westendorp, RN, MSN, OCN, CCRA – protocol coordinator*
- **Working Group 2 (Risks and benefits sections):**
  - *Roy Smith, MD – former CIRB Chair*
  - *Michael Paasche-Orlow, MD, MA, MPH – ICD expert*
- **Working Group 3 (Alternatives, privacy, injury, cost, rights, signature):**
  - *Edward Goldman, JD – ICD expert*
  - *Nancy Morton, MT, MPH – protocol coordinator*
- **Working Group 4 (Possible attachments):**
  - *Barbara LeStage, MPH – patient advocate*
  - *Mary McCabe, RN, MA – ICD expert*
- **Working Group 5 (Companion studies):**
  - *Lisa Carey, MD – clinical investigator*
  - *Laura Beskow, MPH, PhD – translational investigator*
- **FDA Advisors:** *Sandra Casak, MD; Ruthann Giusti, MD; Joanne Less, PhD; Shan Pradhan, MD; Sara Goldkind, MD, MA*
- **OHRP Advisors:** *Jerry Menikoff, JD, MPP, MD; Julie Kaneshiro, MA; Lisa Rooney, JD; Lisa Buchanan, MA*

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New NCI ICD Template Features

- Text examples for different types & phases of studies
  - *Includes chemoprevention and imaging trials*
- Section page/length limits
- Text provided for mandatory specimen collection, within primary consent, and optional specimen collection, located before signature line
- Contact information for study doctor
  - *Easy to find for study participants with one location to ask questions, discuss concerns, report side effects or injuries*
- More text examples for optional studies, e.g., imaging correlatives
- Text for biobanking, optional research biopsy, and future studies
- Complies with new FDA regulation, 21 CFR 50.25(c)
- Meets new CTEP electronic submission requirements, FDA mandate

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New NCI ICD Template – Risk Presentation

- **Recommendations for risks section**
  - ***Risks described from study participant perspective***
    - Easy to understand, meaningful
    - Changes in specific lab values not included
  - ***Similar frequency categories as previous Templates***
    - Clearer definition of frequency – "x out of one hundred" rather than percentage
  - ***Format risks into tables – "Tables of Possible Side Effects"***
    - Use different tables for experimental and standard arms; grouping by regimen
    - List risks by body system, keeping description at a general level using lay terms
  - ***Three tasks for DCTD/CTEP***
    - Translate DCTD/CTEP's risk profiles of IND agents into more general lay terms
    - Develop repository of "Tables of Possible Side Effects" for CTEP IND agents
    - Develop repository of "Tables of Possible Side Effects" for commonly used commercial drugs and regimens

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IOM Goal 3: Improve Prioritization, Selection, Support, and Completion of Cancer Clinical Trials

Recommendation 10: *NCI should allocate a larger portion of its research portfolio to the Clinical Trial Group Program to ensure that the Program has sufficient resources to achieve its unique mission*

Progress

- **NCI developed targeted initiatives that have increased reimbursement to sites for patients on large phase 2 studies & additional funding provided for select phase 3 trials based on complexity as well as the funding for critical biomarker, imaging & QOL studies**

- **Changes in the funding model for new RFA:**
  - ✓ **Increased reimbursement for high-performing sites (~aimed at 40% accrual)**
  - ✓ **Need for additional infrastructure support with proposed RFA budget increased to support better reimbursement but lower level of accrual**
  - ✓ **Increase in core resources for genomic correlative studies**

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IOM Goal 4: Incentivize the Participation of Patients and Physicians in Clinical Trials

Recommendation 11: ***All stakeholders should work to ensure that clinical investigators have adequate training and mentoring, paid protected research time, the necessary resources, and recognition***

Progress

- **NCI created Clinical Investigator Team Leadership Award to promote collaborative science & recognize outstanding clinical investigators with annual awards made since 2009**

2012 Awardees

Dr. Lyudmila Bazhenova	UC San Diego Moores Cancer Center
Dr. Lisa Bomgaars	Baylor College of Medicine, Lester and Sue Smith Clinic at Texas Children's CC
Dr. Alberto Broniscer	St. Jude Children's Research Hospital
Dr. Daniel DeAngelo	Dana-Farber Cancer Institute
Dr. Konstantin Dragnev	Dartmouth-Hitchcock Norris Cotton Cancer Center
Dr. Shirish Gadgeel	Wayne State University Karmanos Cancer Institute
Dr. Shannon Puhalla	University of Pittsburgh
Dr. Bart Lee Scott	Fred Hutchinson Cancer Research Center; University of Washington
Dr. B. Douglas Smith	Johns Hopkins University, Sidney Kimmel Comprehensive Cancer Center
Dr. Jonathan Strosberg	H. Lee Moffitt Cancer Center
Dr. Antoinette Tan	Cancer Institute NJ/UMDNJ-Robert Wood Johnson Medical School
Dr. Jason Zell	UC Irvine Chao Family Comprehensive Cancer Center

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IOM Goal 4: Incentivize the Participation of Patients and Physicians in Clinical Trials

Recommendation 12: *Health care payment policies should value the care provided to patients in clinical trials and adequately compensate that care*

Progress

- NCI continues to work with the NIH as well as across HHS Agencies and with other federal Agencies to help define and shape national policy on clinical trials and reimbursement a well as to educate patients and payers regarding the benefit of clinical trials

- Working with FDA to facilitate incorporation of genomic tests into definitive clinical trials and the development of companion diagnostics