

Children's Oncology Group: NCI Funding

CAC2 Briefing

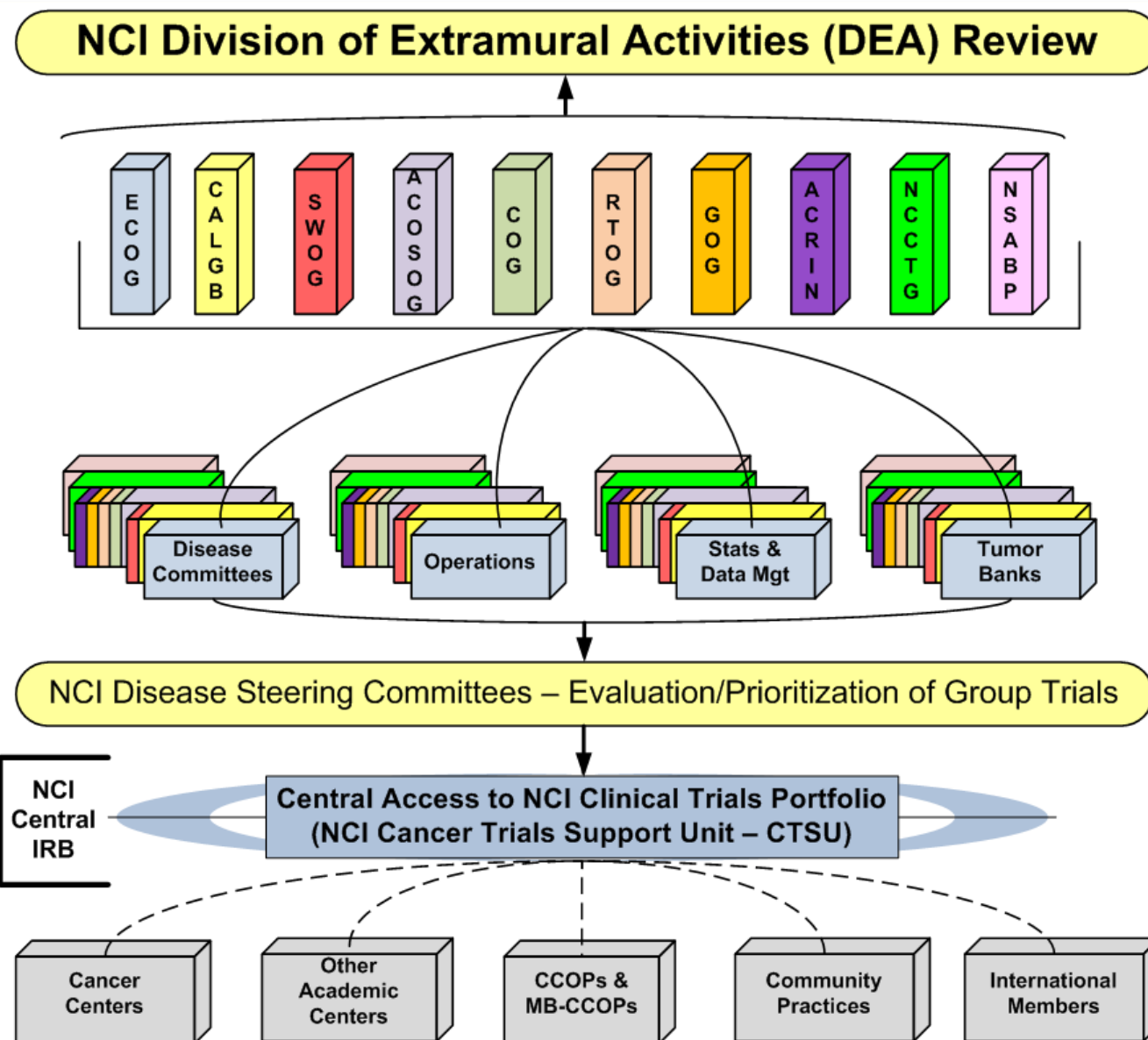
May 22, 2014



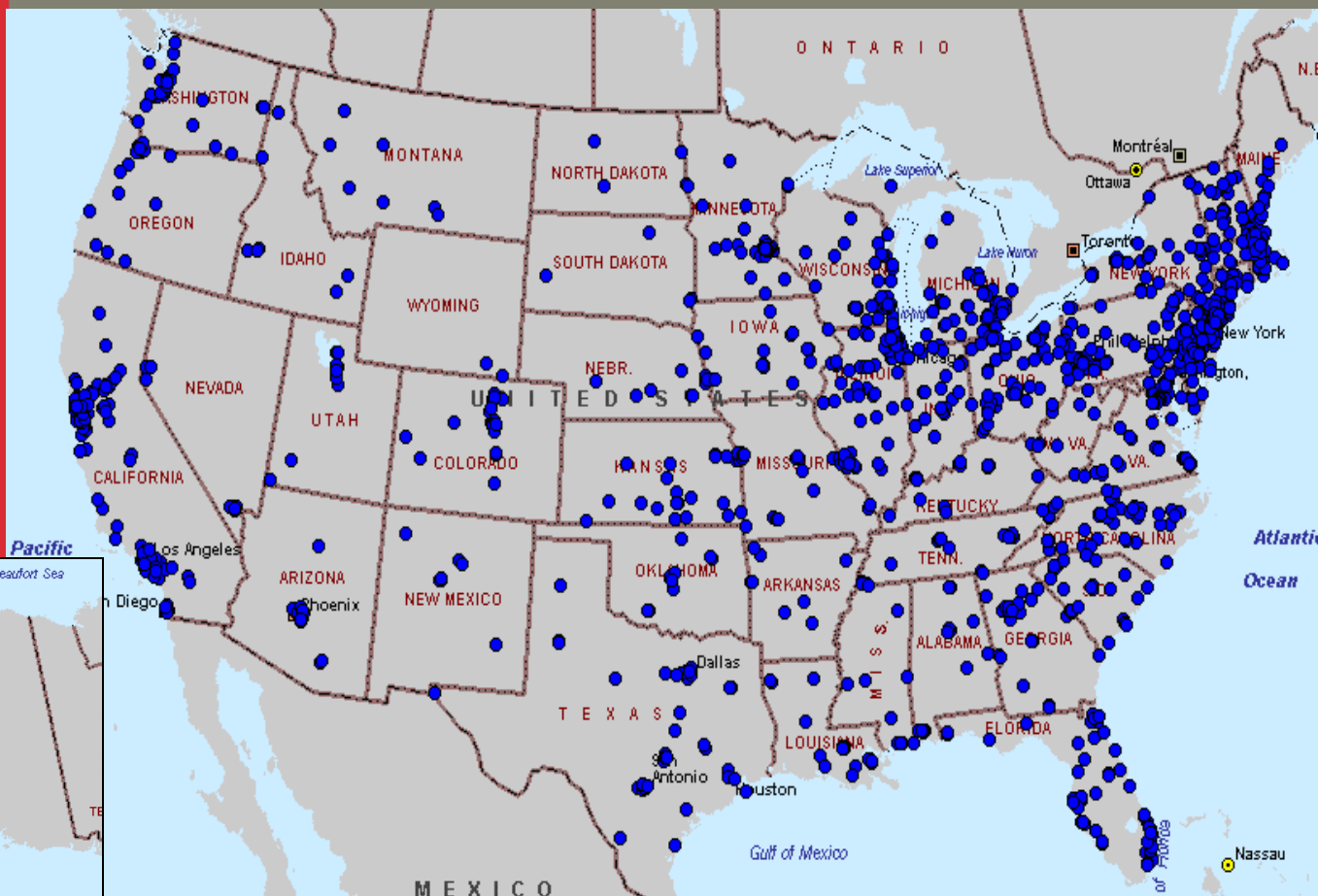
CAC2 Values

- ❖ Put the children and their families **first** in everything we do
- ❖ Support the members and the childhood cancer community while being mindful not to compete with members or to duplicate projects/programs/services that they provide
- ❖ Be accountable and take ownership of one's commitments within the collaborative
- ❖ Be cost effective with resources
- ❖ Be inclusive and collaborative
- ❖ Help give voice to the community, and amplify it in a coordinated fashion
- ❖ Stay action-oriented and flexible

Structure of Program: As of January 2011



Overview of the Current Program



**3,100
Institutions**

**14,000
Investigators**

**About
25,000 pts
enrolled on
tx trials
annually**

Trials	FY2006	FY2007	FY2008	FY2009	FY2010	Accrual Distribution: Phase 3: 83.4% Phase 2: 15.1% Phase 1/Pilot: 1.5%
All Phases: Treatment Trials	27,667	24,715	25,784	29,285	23,468	

COG Primary Funding Mechanisms

- Chair's (Network Operations Center) Grant
- Statistics & Data Center
- Biobank

COG Primary Funding Mechanisms

- Chair's (Network Operations Center) Grant
- Statistics & Data Center
- Biobank

Chair's (Network Operations Center) Grant

- Research & Operations
- Per Case Reimbursement

Chair's (Network Operations Center) Grant

Research & Operations

- Operations Office
- Reference laboratories
- Scientific leadership
- Protocol chairs
- Investigator support at site
- COG Working Meetings
- Biospecimen submission
- Central reviewers
 - Pathology
 - Imaging
 - Radiation therapy

Chair's (Network Operations Center) Grant

- Per Case Reimbursement

- Restricted funding to pay sites for enrolling children on research studies
- For therapeutic trials, \$2000/patient
- For non-therapeutic trials, ~ \$400/patient
- Funds primarily used to pay for clinical research associates (CRAs) or data managers at COG member sites

National Clinical Trials Network



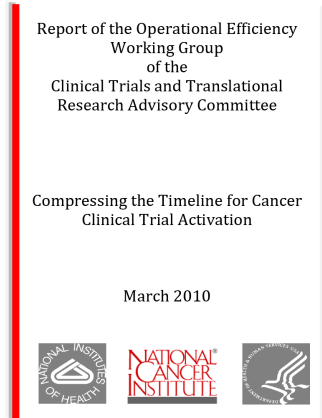
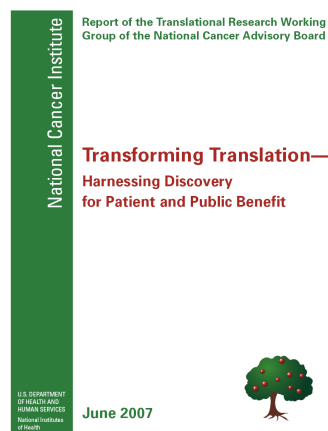
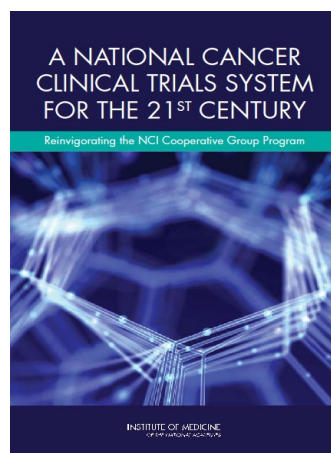
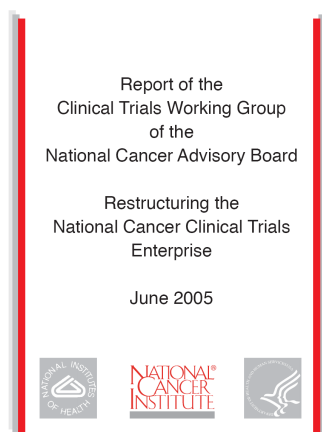
Transforming NCI's Clinical Trials System

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



Cancer Leadership Council
Washington, DC
July 12, 2011

Changing the NCI's Clinical Trials System to Meet the Needs of the 21st Century



Our clinical trials system must reflect the dramatic changes in cancer biology that occurred over the past 15-20 yrs.

What do we need to change?

- Improve the speed and efficiency of the development and conduct of trials
- Incorporate innovative science and trial design into our studies
- Improve prioritization, support, and completion of trials
- Incentivize the participation of patients and physicians in clinical investigations

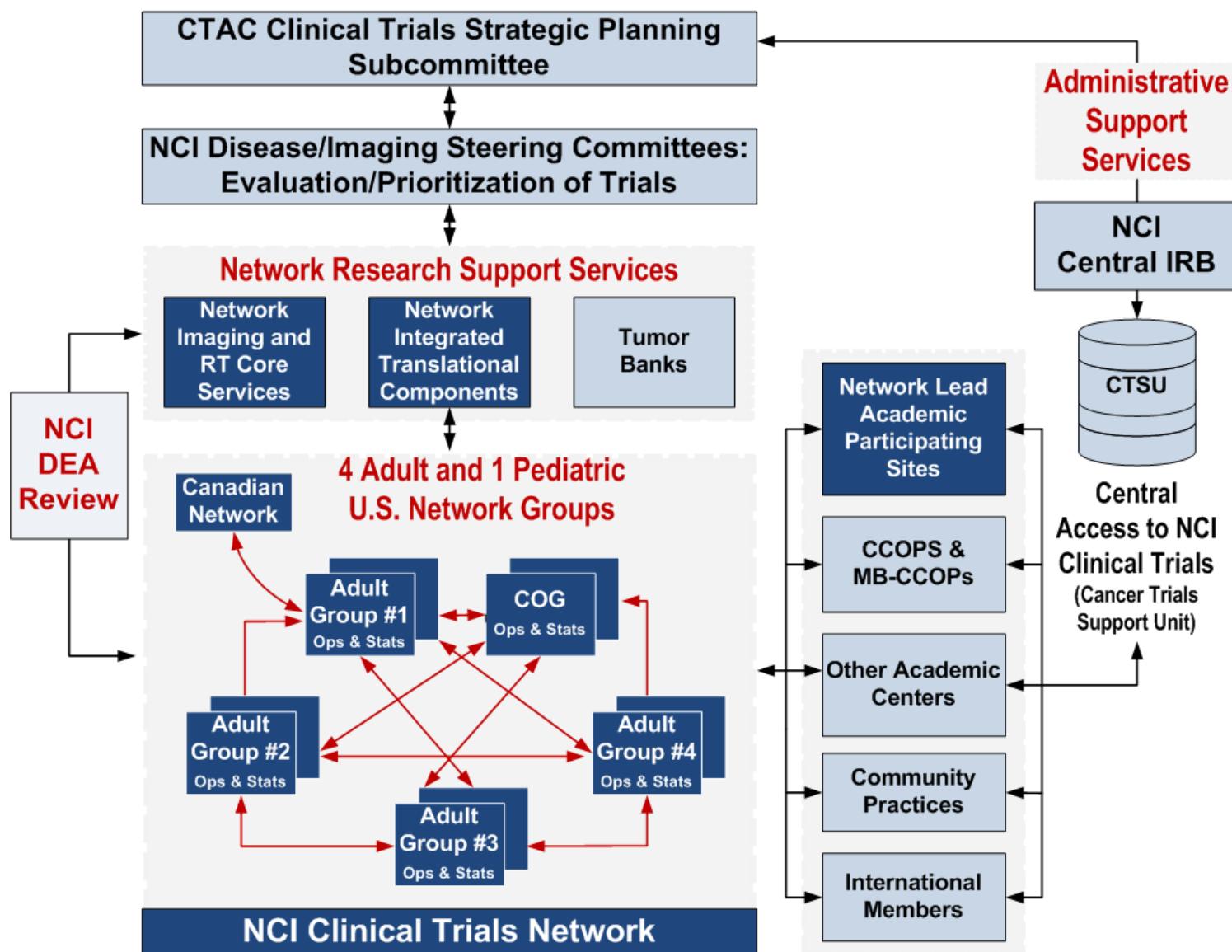
What have we changed?

- Resources for the development of predictive biomarkers
- Clinical trial prioritization
- Operational efficiency standards for trial development
- Regulatory & administrative support
- Modernized clinical trial IT infrastructure

Where do we go from here?

Introducing A New Organizational Structure

NCI Clinical Trials Network




National Clinical Trials Network

Request for Applications (RFA)

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI)
Funding Opportunity Title	NCI National Clinical Trials Network - Network Group Operations Centers (U10)
Activity Code	U10 Cooperative Clinical Research – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-CA-12-010
Companion Funding Opportunity	RFA-CA-12-011 ; RFA-CA-12-012 ; RFA-CA-12-013 ; RFA-CA-12-014 ; RFA-CA-12-504
Number of Applications	Only one application from an eligible institution is allowed as defined in Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.394, 93.395
Funding Opportunity Purpose	This funding opportunity announcement (FOA) solicits applications from institutions/organizations that propose to establish Network Group Operations Centers for the NCI National Clinical Trials Network (NCTN). The goal of the NCTN is to develop and conduct state-of-the-art cancer treatment and advanced imaging clinical trials, especially large, definitive multi-institutional trials evaluating

Department of Health and Human Services Public Health Services Grant Application <i>Do not exceed character length restrictions indicated.</i>		LEAVE BLANK—FOR PHS USE ONLY.			
		Type	Activity	Number	
		Review Group		Formerly	
		Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT <i>(Do not exceed 81 characters, including spaces and punctuation.)</i> COG NCTN Network Group Operations Center					
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> X YES <i>(If "Yes," state number and title)</i> Number: RFA-CA-12-010 (U10) Title: NCI National Clinical Trials Network – Network Group Operations Centers					
3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR					
3a. NAME (Last, first, middle) Adamson, Peter C.		3b. DEGREE(S) MD		3h. eRA Commons User Name ADAMSONP	
3c. POSITION TITLE Chair, Children's Oncology Group		3d. MAILING ADDRESS <i>(Street, city, state, zip code)</i> 3615 Civic Center Blvd Philadelphia, PA 19104-4318 			
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics					
3f. MAJOR SUBDIVISION Pharmacology					
3g. TELEPHONE AND FAX <i>(Area code, number and extension)</i> TEL: 215-590-6359 FAX:		E-MAIL ADDRESS: adamson@email.chop.edu			
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		4a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes			
4b. Federal-Wide Assurance No. 00000459		4c. Clinical Trial <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		4d. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes			5a. Animal Welfare Assurance No. A3442		
6. DATES OF PROPOSED PERIOD OF SUPPORT <i>(month, day, year—MM/DD/YY)</i> From 3/1/2014 Through 2/28/2019		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) \$35,949,359		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 8a. Direct Costs (\$) \$177,754,341	
		7b. Total Costs (\$) \$38,082,294		8b. Total Costs (\$) \$188,580,025	
9. APPLICANT ORGANIZATION Name The Children's Hospital of Philadelphia Address Research Institute 3615 Civic Center Boulevard Philadelphia, PA 19104-4318		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input checked="" type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged			
		11. ENTITY IDENTIFICATION NUMBER 23-1352166 DUNS NO. 0737576270000 Cong. District PA-002			

National Clinical Trials Network

Peer Review: Summary Statement

PROGRAM CONTACT:
Margaret Mooney
240.276.6560
mooneym@mail.nih.gov

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 07/26/2013
Revised Date: 07/30/2013

Application Number: 1 U10 CA180886-01

Principal Investigator

ADAMSON, PETER C MD

Applicant Organization: CHILDREN'S HOSPITAL OF PHILADELPHIA

Review Group: ZCA1 GRB-I (O1)
National Cancer Institute Special Emphasis Panel
National Clinical Trial Network Groups

Meeting Date: 07/16/2013
Council: OCT 2013
Requested Start: 03/01/2014

RFA/PA: CA12-010
PCC: M8CH

Project Title: COG NCTN Network Group Operations Center

SRG Action: Impact Score: 12

Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 1A-Both genders, scientifically acceptable

Minority: 1A-Minorities and non-minorities, scientifically acceptable

Children: 1A-Both Children and Adults, scientifically acceptable

NIH Defined Phase III Clinical trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	34,345,943	38,026,178
2	34,024,052	37,669,796
3	33,516,539	37,107,902
4	33,984,536	37,626,046
5	34,457,875	38,150,104
TOTAL	170,328,945	188,580,025

NIH Peer Review

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses
Minor Weakness: An easily addressable weakness that does not substantially lessen impact Moderate Weakness: A weakness that lessens impact Major Weakness: A weakness that severely limits impact		

Network Group Operations Centers

- COG 12
- N,R,G 23
- Alliance 26
- SWOG 26
- ECOG/ACRIN 31

National Clinical Trials Network

Notice of Award (NOA)

5-Year Annual Funding Request for NCI Clinical Trials Network

Category for Base Division Set-Aside for Network Program	Annual Total Cost for FY14 to FY18 Based on 20% Reduction in Accrual Compared to Average Accrual Over Last 6 Years (Approx. 20,000 Treatment Trial Enrollments)
Funding Based on FY2011 Levels:	\$ 152,644,335
Group Operations & Statistical Centers (includes Capitation), Lead Academic Participating Sites, and Core Services	
Funding Request Based on New Funding Model & BIQSFP:	
Increase Capitation to "High-Performance" DCTD-funded Sites	\$ 11,520,000
Increase Capitation to "High-Performance" DCP-funded CCOPs & MB-CCOPs	\$ 10,080,000
Increase Funding for Integral and Integrated Markers (BIQSPF)	\$ 4,000,000
Subtotal:	\$ 25,600,000
Grand Total:	\$ 178,244,335 *

* The 5-Year Total Cost Funding Request for FY2014 to FY2018 for the NCTN is \$891,221,675

- All external reviews of the NCI clinical trials system emphasized need to provide increased research reimbursement to ensure continued participation of sites in the public program
- **Base “per-case” reimbursement for patient enrollment in the program has remained fixed at \$2,000 per patient in treatment trials for over a decade**
 - 2006 estimate for average per patient cost in industry trials was \$4,700 for phase 3 & \$8,450 for phase 2 Trials (& some industry trials at \geq \$15,000)
 - Survey in 2009 of Group sites found that of those planning to limit participation in the program (32% of respondents), 75% cited inadequate reimbursement for the decline in their level of participation
- “High-Performance” sites incur additional infrastructure costs due to the number of patients they accrue & additional funding is especially needed to compensate these sites for their large patient follow-up burden -
(propose additional \$2,000 /pt for these sites for total of ~\$4,000/pt)



COOPERATIVE CLINICAL RESEARCH AGREEMENT
Department of Health and Human Services
National Institutes of Health
NATIONAL CANCER INSTITUTE

Notice of Award

Issue Date: 04/11/2014



Grant Number: 1U10CA180886-01
FAIN: U10CA180886

Principal Investigator(s):
PETER C ADAMSON, MD

Project Title: COG NCTN Network Group Operations Center

STEVEN WILEY
DIRECTOR, RESEARCH FINANCE
THE CHILDREN'S HOSPITAL OF PHILADELPHIA
RESEARCH INSTITUTE
3615 CIVIC CTR BLVD
PHILADELPHIA, PA 191044318

Award e-mailed to: stokes@email.chop.edu

Budget Period: 04/11/2014 – 02/28/2015
Project Period: 04/11/2014 – 02/28/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$23,865,844 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSP OF PHILADELPHIA in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number U10CA180886. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

SECTION I – AWARD DATA – 1U10CA180886-01**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$234,204
Fringe Benefits	\$58,552
Supplies	\$4,610
Travel Costs	\$692,220
Other Costs	\$136,775
Consortium/Contractual Cost	\$21,593,283

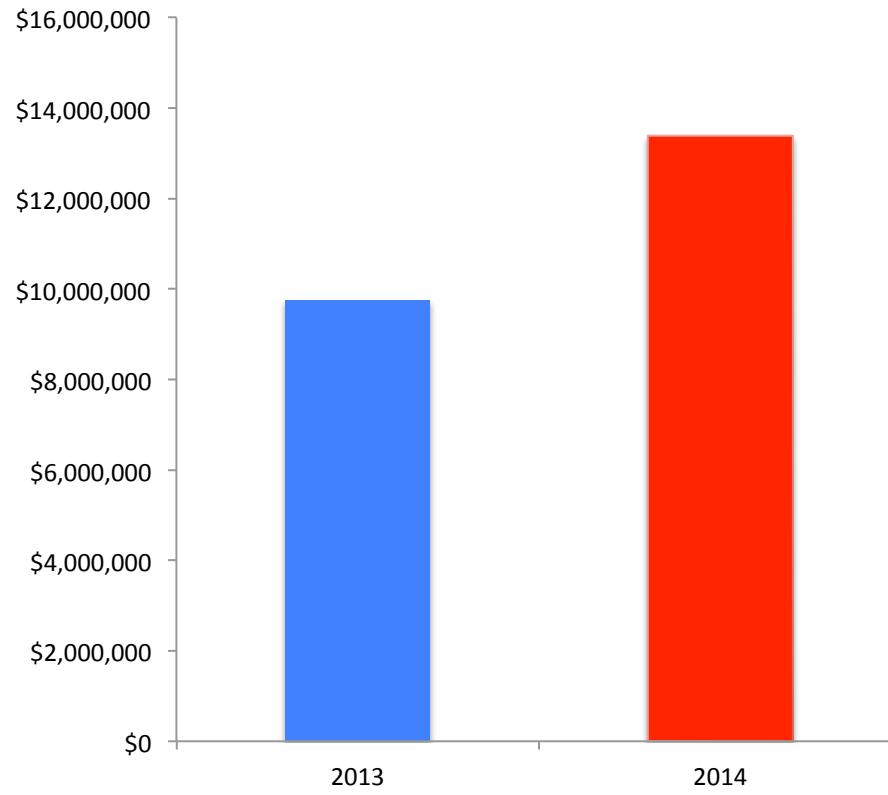
Federal Direct Costs	\$22,719,644
Federal F&A Costs	\$1,146,200
Approved Budget	\$23,865,844
Federal Share	\$23,865,844
TOTAL FEDERAL AWARD AMOUNT	\$23,865,844

AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$23,865,844
--	---------------------

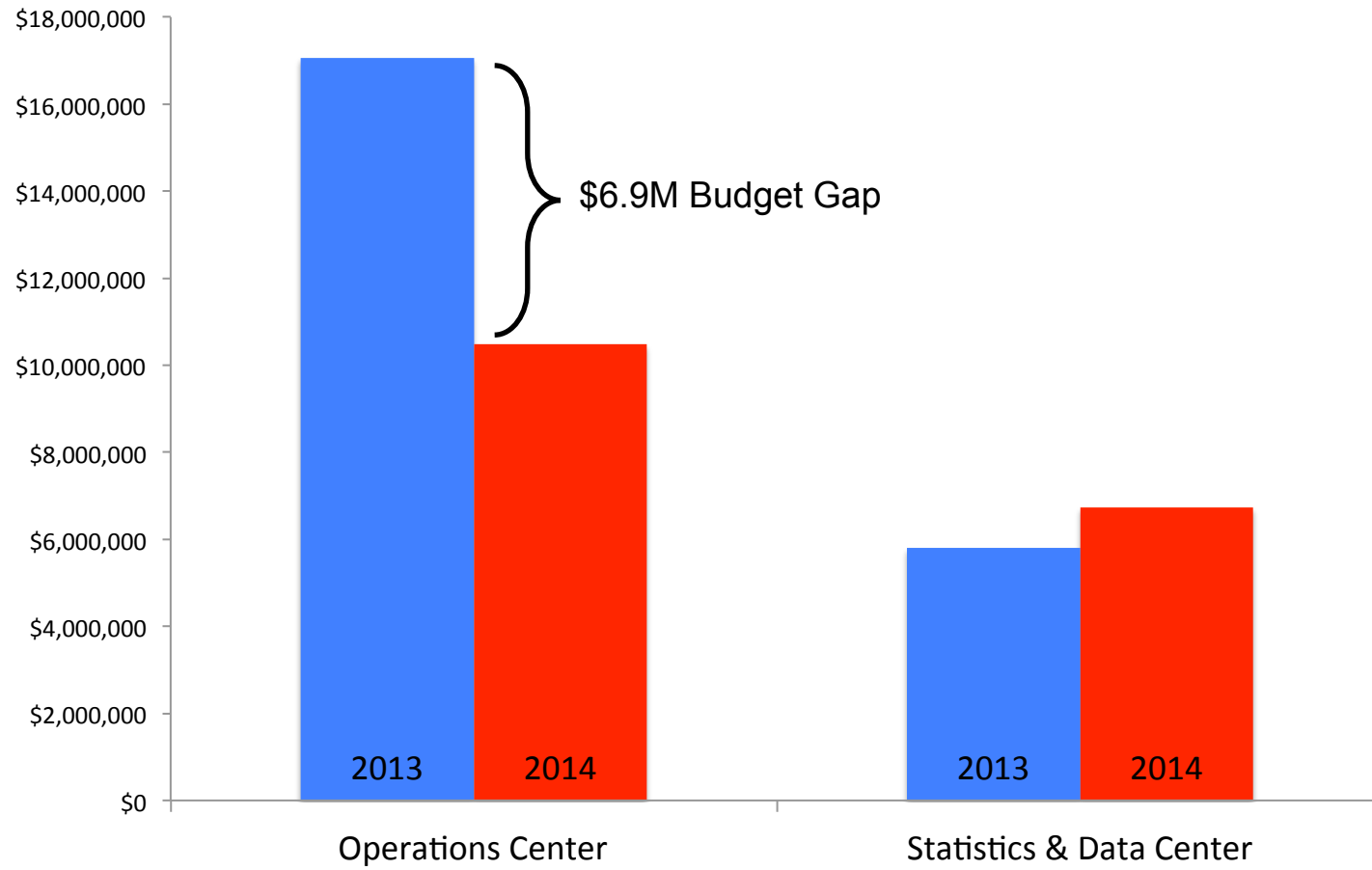
SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$23,865,844	\$23,865,844
2	\$11,624,217	\$11,624,217
3	\$11,631,132	\$11,631,132
4	\$11,624,217	\$11,624,217
5	\$11,624,217	\$11,624,217

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Per Case Reimbursement Budgets



Funding to COG FY13 - FY14



THE CANCER LETTER

April 4, 2014

• www.cancerletter.com

• Vol. 40 No. 14



Group Chairs: Research in "Crisis"

ASCO Says NCTN Budgets Cut by 40 Percent, Warns of "Dangerous Disruption of Cancer Care"

By Paul Goldberg

The chairs of the adult clinical trials groups that make up the NCI National Clinical Trials Network said in a letter that recent budget cuts have triggered a "crisis" in clinical research.

Simultaneously, a statement by the president of the American Society of Clinical Oncology, Clifford Hudis, amplified the concerns of the group chairs, and pointed to a separate problem in NCI's transition to the new structure of clinical research: a three-month gap in funding for community oncology clinics engaged in institute-funded research.

(Continued to page 2)

Research in Crisis

The Letter to Varmus
From NCTN Group Chairs
... Page 3

The ASCO Statement
... Page 4

Community Oncologists
Tell Congress Practices
Are Not Adequately
Reimbursed
... Page 6

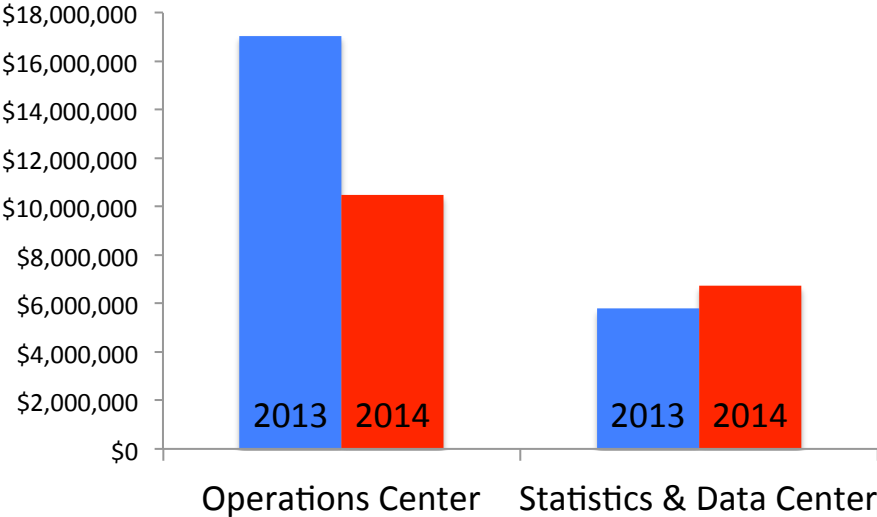
In Brief

PCORI Forms Clinical
Trials Advisory Panel
... Page 8

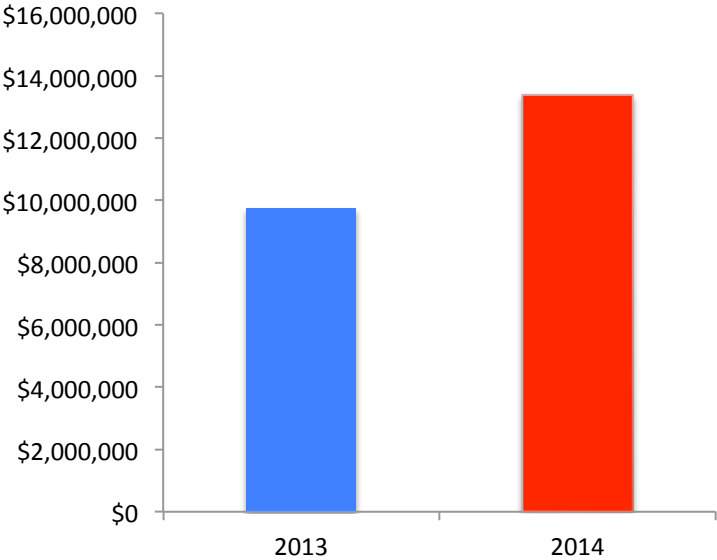
Two Foundations Offer
\$300,000 in Awards For
Neuroendocrine Tumor
Cell Lines
... Page 10



Funding to COG FY13 - FY14



Per Case Reimbursement Budgets

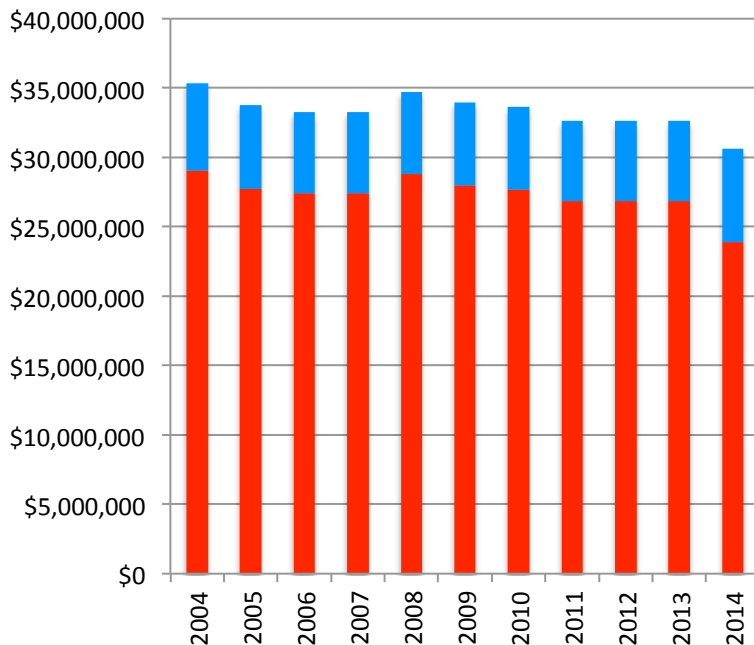


COG Funding

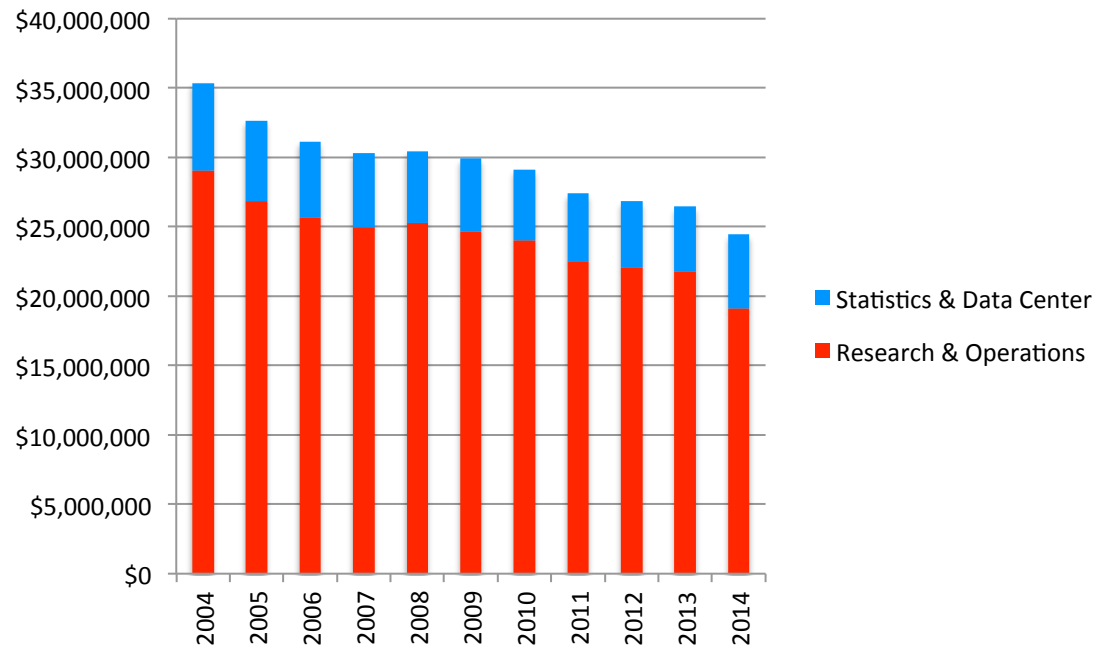
Historical Trends

COG Historical Base Funding

Annual Budget



Annual Budget
(CPI adjusted - 2004 Dollars)



NCI data on base funding to the COG via its two main grant mechanisms. The COG was also successful in receiving additional funding (not shown) through NCI supplements. Dollars figures in the right panel are adjusted for inflation using the Consumer Price Index.