

National Cancer Institute

NCI Director's Update

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Director, National Cancer Institute

National Cancer Advisory Board
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U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

National Institutes
of Health

FY 2008

- RPGs funded at the 14th percentile plus extensive exceptions (20% success rate)
- *R01s funded at the 19th percentile extended payline plus exceptions (236 awards)
- NCI funded 1,284 competing RPGs in FY08 (including supplemental appropriation)
- NCI added 1 new Cancer Center
 - Greenebaum Cancer Center, University of Maryland

Congratulations to NCI's budget office for closing the books on FY08 with a balance of \$3,302.

NCI FY 2009 Operating Budget Development

FY 2008 operating budget (w/supplemental)	\$4,830,647
FY 2009 <u>Continuing Resolution</u>	\$4,805,088
Difference, FY08 to FY09	-\$25,559
Percent change, FY08 to FY09	-0.5%

(dollars in thousands)

NCI FY 2009 Operating Budget Development

	<u>Amount (in thousands)</u>	<u>Percent change</u>
Subtotal Available	-\$25,559	-0.5%
Less est. NIH taps/assessments incr.	-15,000	
• Potential NIH Director's 1% transfer	?	
• Potential HHS Secretary's transfer	?	
• GEI transfer	?	
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Subtotal available	-40,559	-0.8%

NCI FY 2009 Operating Budget Development

	Amount (in thousands)	Percent change
Subtotal Available	- \$40,559	-0.8%
NCI-wide Requirements:		
• Mandated salary increases	- 21,500	
• Rent/lease/utilities/renovations incr.	- 10,900	
• AIDS redirections	- 15,000	
• Small Business Program increase	0	
NCI Director's Reserve	- 35,000	
Return FY08 SAIC division recoveries from contract closeout	-52,209	
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Subtotal Available	- 175,168	-3.6%

NCI FY 2009 Operating Budget Development

	<u>Amount (in thousands)</u>	<u>Percent change</u>
Subtotal Available	- \$175,168	-3.6%
Research Project Grants:		
• Noncompeting/Admin Supps	29,873	
• Competing (12 th % under CR)	26,362	
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Subtotal Available	- 118,933	-2.5%

NCI FY 2009 Operating Budget Development

	<u>Amount (in thousands)</u>	<u>Percent change</u>
Subtotal Available	- \$118,933	- 2.5%
Potential Recoveries/Redeployments:		
• Phaseouts/Reductions Res DOCs	25,169	
• Phaseouts/Reductions Infrastructure	3,425	
• Other Research Grants – 3% Reduction	1,989	
• NCI-Frederick Contract Transition	70,000	
• Division One Time Recoveries	17,476	
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Subtotal Available	-874	- 0%

NCI FY 2009 Operating Budget Development

	<u>Amount (in thousands)</u>	<u>Percent change</u>
Subtotal Available	-\$874	- 0%
<p>At this date what spendable resources do we have?</p>		
RPG RFA Pool	65,000	
Director's Reserve	35,000	
Facilities Setaside	10,000	
Available for Requests under <u>CR</u>	\$109,126	

There are also dollars in division base budgets for division-controllable RFA reissuances

What Else **Might** Happen?

- Available for requests under CR: **\$109 million**
- Available under a potential 2.2% increase: **\$189 million**
 - Includes **\$10 million for facilities**
 - Assumes higher payline and better COLAs for noncompeting
 - Covers the higher-than-anticipated federal payraise
- Economic stimulus could add another **\$125 million a year for 2 years**
 - Anticipate funds would be highly directed, through Challenge Grants
 - NCI could get comparative effectiveness research funds
 - NCI could benefit from additional renovation money

Economic Stimulus

Senate Finance Comm. began mark-up on its version Jan. 29.
Sen. Specter may propose adding \$10B over 2 years to NIH.

- **\$300M for NCRR:** shared instrumentation and capital research equipment
- **\$2.7B for the NIH OD:** half to the ICs., for efforts that can be completed in 2 years. Priority on grants on specific scientific challenges; new research expanding the scope of ongoing projects; research on public health priorities; and stem cell research
- **\$500 million to the B&F** for constructing, improving and repairing NIH buildings and facilities
- **Comparative effectiveness research:** \$300M to AHRQ, \$400M to NIH, 400M to HHS

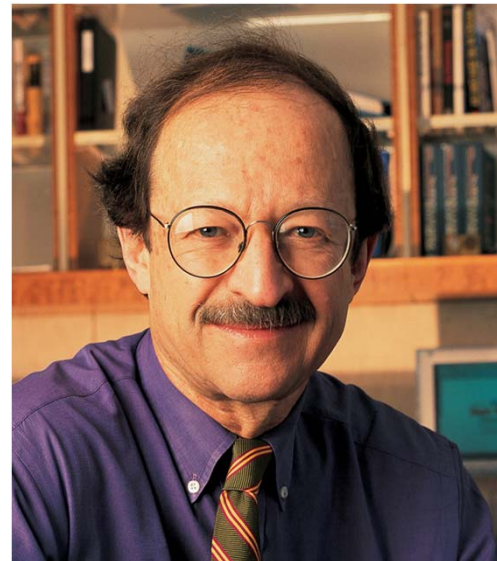
Obama Administration



- Tom Daschle, Secretary of Health and Human Services
- William Corr, Deputy Secretary
- Steven Chu, Energy Secretary
- John Holdren, Science Advisor



Eric Lander, co-chair of the President's Council of Advisors on Science and Technology



Harold Varmus, co-chair of the President's Council of Advisors on Science and Technology

Transition Team

Five Strategies for Accelerating the War on Cancer
in an Era of Budget Deficits

James H. Doroshow, Robert T. Croyle, and John E. Niederhuber
“The Oncologist” Commentary – 2009; 14

Prototyping A Twenty-First-Century Biomed
System Through Cancer

Kenneth H. Buetow, John E. Niederhuber
“Health Affairs,” Jan. 19, 2009

Facilitating Patient-Centered Center Research and
a New Era of Drug Discovery

John E. Niederhuber (in press)

Vision for the Future of FDA

Brookings Institute Conference, Wash., D.C., Sept. 26, 2008
Remarks by David Epstein, President & CEO, Novartis Oncology (in press)

Four Important Steps Toward 21st Century Care
for Patients with Cancer

Mark McClellan and Joshua S. Benner (in press)

Priorities of New Administration

- **Healthcare coverage and affordability**
- **Access and quality of care**
- **Innovation through science**
- **Attracting and training the next generation**
 - **Cancer Centers network**
 - **NCCCP network**
 - **BIG Health™ Consortium and IT history (caBIG®)**
 - **Biology to translation infrastructure**
 - **Clinical applications based on evidence**

Meeting with Mark McClellan

Follow-on to Sept. 26, 2008 Brookings
Institution Conference on Clinical
Cancer Research

- **Cancer can serve as a model: clinical applications based on evidence, IT infrastructure, basic biology, etc.**
 - **We must continue chipping away at barriers to clinical research and build a new model for development of targeted therapies**
- **It will be important to talk about the changes required in biomedical research within in the context of the new administration's priorities**

Meeting with Mark McClellan

- Cancer is the arena for the investigation of molecular medicine
 - No other disease type has the necessary expertise and infrastructure
- Need to build partnerships to develop knowledge around molecular medicine in real-time situations
- Partnerships with CMS should be developed, to pay for diagnostic tests within a set of identified circumstances to allow for further study
- The opportunity to co-develop diagnostic and preventive interventions should be further explored – including effective biomarker validation

National Cancer Institute

The Nation's Investment in Cancer Research



Connecting the Nation's
Cancer Community

AN ANNUAL PLAN AND BUDGET PROPOSAL FISCAL YEAR 2010

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

EC Scientific Retreat



EC Retreat: Robert Austin

Keynote Address: "Is Cancer a Disease?"

- Ordinary Darwinian evolution (random SNP mutations followed by natural selection) is unlikely to lead to complex organisms
- Evolution works most efficiently by large scale genomic changes/rearrangements, not SNPs
- The price of high evolution rates is cancer
- Cancer is necessary for high rates of evolution and is **not** a disease

2009 EC Retreat

Build interdisciplinary teams

Study individuals who are at high risk for cancer are a resistance dev

Identify predictive

Create a Google for

Integrate all 'omics'

- Real time assays of the **stressors and responses** that initiate and sustain cancer
- Model the **evolution of cancer** with a focus on alterations in the stroma/niche/microenvironment
- Understand the **epigenetic changes** that control the type and number of cancer cells

Invent the academic approach to science
eers/change
ward systems

Measure and model sequence of stresses in a multi-cellular system

Co
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Improve real-time imaging of cancer

Supplement high risk projects

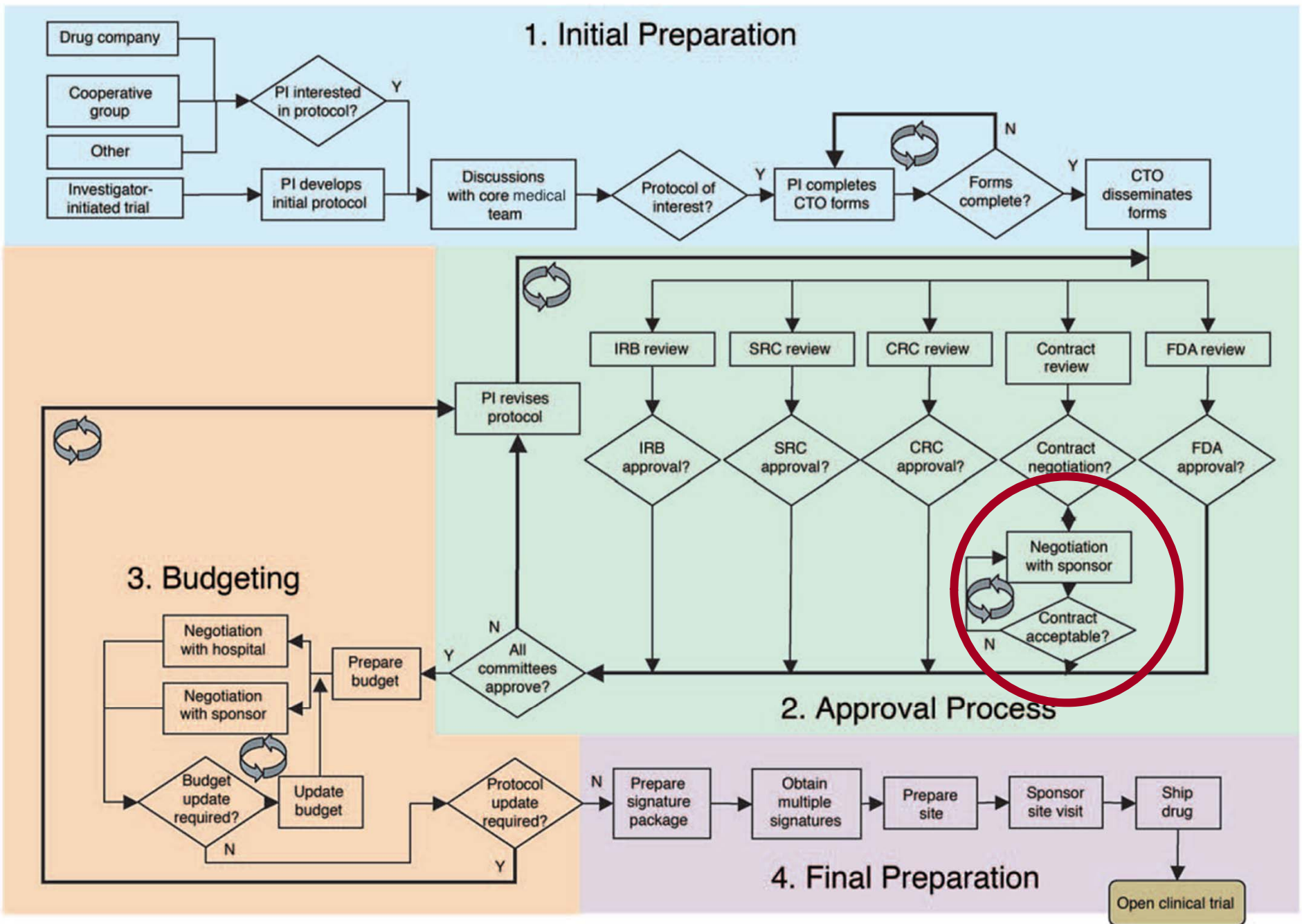
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populations based
cohort studies

actual/real
translational
projects

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with
mechanisms
of cancer

NCI Clinical Trials System: Current Status

- **System is inefficient, time consuming, and under-funded**
- **In an era of targeted therapy, the system is geared toward the testing of non-specific regimens**
 - **Lacks the capacity to highly characterize each patient and carefully match that patient profile to targeted therapeutic combinations**



Life Sciences Consortium

Common language

IP

Antitrust

CEO Roundtable on Cancer

- **Founded in 2001 by Pres. George H.W. Bush**
 - “Do something bold and venturesome about cancer”
 - **28 members; 20 honorary members**
 - **Life Sciences Consortium**
 - **11 companies**
 - **Chair: Dr. Gregory Curt of AstraZeneca**



CEO ROUNDTABLE
ON CANCER

Project Structure

- Involved legal and business representatives from participants
 - 17 reps. from LSC companies
 - 26 reps. from NCI-Designated Cancer Centers
- Obtained copies of 78 clinical trial agreements from participating organizations
 - 49 redacted copies of final negotiated agreements
 - 29 agreement templates
 - Approximately equal numbers of agreements from LSC companies and Cancer Centers
 - Agreements included company-sponsored and investigator-initiated trials

Agreement Analysis

- Identified 45 key concepts in the 7 clause categories
- Captured exact language that embodied these concepts for all 78 agreements
- Organized agreement language into categories representing embodied concept
- Analyzed results for similarities and differences in key concepts across final negotiated agreements
- Analyzed template agreements for key differences with negotiated agreements


Key Clauses

- Through discussions with legal and business representatives, identified:
 - Intellectual property
 - Study data
 - Subject injury
 - Indemnification
 - Confidentiality
 - Publication rights
 - Biological samples

Intellectual Property

- **Company-Sponsored Trials**
 - Inventions owned by company
 - Research institution retains right to use inventions for non-commercial research and education
- **Investigator-Initiated Trials**
 - Inventions owned by research institution
 - Research institution grants company a royalty-free, non-exclusive license and an option to obtain a royalty-bearing exclusive license

Life Sciences Consortium



“The Department of Justice announced today that it will not oppose a proposal by the CEO Roundtable on Cancer to develop and publicize model contract language for clinical trials of potential new cancer treatments.”

Department of Justice press release
Wednesday Sept. 17, 2008

Moving Beyond Common Language

**Life Sciences Consortium,
CEO Roundtable, NCI, FDA,
and academia must tackle
“common data elements”**

NCI's Challenges

- **Anticipate science:** know where science and technology are leading us
- **Improve our portfolio:** fill the gaps and strengthen by soliciting and incentivizing
- **Conduct science** at the intersection of disciplines
- **Facilitate our ability** to maximally work across divisions
- **Optimally use precious resources**
- **Ultimately, translate our findings**



www.cancer.gov

