

NCI Director's Update

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Clinical Trials Advisory Committee
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NCI – Nov. 2009



- **Closing out FY2009**
- **The American Recovery and Reinvestment Act**
- **Using ARRA dollars to fund vital science**

NCI FY2009

FY2008 operating budget \$4.83 billion

FY2009 appropriation \$4.96 billion

Change, FY08 to FY09

+2.9% (139 million)

Congratulations to NCI's budget office
for closing the books on FY08 with a
balance of **\$4,432.**

ARRA \$ to NIH

- **\$7.4 billion:** Institutes and Centers
 - **\$1.26 billion** to NCI
 - **\$1 billion:** extramural construction
 - **\$300 million:** shared instrumentation
 - **\$500 million:** NIH construction
 - **\$400 million:** comparative effectiveness research (\$400M HHS; \$300M AHRQ)
 - **\$800 million:** NIH Office of the Director
- } **NCRR**

ARRA Funding: A Once in a Lifetime Opportunity

- Careful and thoughtful planning by the NCI
 - **Strategic foresight:** minimizing the out-year (cliff) effect
 - Maximizing our ability to generate Congressional enthusiasm about investments in cancer research



Payline – ARRA

- **16th percentile:** 2009 RPG payline from appropriated funds
- **16th to 18th percentile:** 4-year grants through stimulus, followed by appropriated do
- **18th to 25th p** and 4-year gran (years)

369 RPGs have been funded due to the extended payline under ARRA

ARRA at NCI

Total NCI ARRA	\$1,256,517,000	% of Total
Grants	\$731,380,000	59%
Supplements to existing awards	341,796,000	
New competing awards	389,584,000	
R&D contracts for the academic community	\$493,837,000	39%
Intramural Equipment	\$6,300,000	0%
Support	\$25,000,000	2%



NIH Funded Cancer Grants

CER (27 awards)	\$61,071,697
Summer (77 awards)	4,503,782
GO (matched 18 awards)	23,802,156
Challenge (18 awards)	17,700,000
Total (140 awards)	\$106,077,635

Training and Faculty Support

Promote re-entry into biomedical & behavioral research careers	\$3.0M
Diversity programs	\$20.6M
Faculty startups	\$76.2M
Supplements: \$58.6M	
Competing: \$17.6M	
Cancer research training, career development, and education	\$11.3M

Dollars cited for two years of ARRA funding.



Clinical/Translational Research ARRA Funding

Examples of programs/projects to be funded via ARRA administrative and competitive supplements and other mechanisms

- Phase I/II therapeutic & imaging clinical trials: **\$47.5M**
- Cancer Genome Characterization Centers **\$13.5M**
- Centers new faculty appointments via Cancer
Centers and Minority Institution Cancer Center
Partnerships **\$56.8M**
- TARGET childhood cancer **\$20.0M**
- NCI Clinical Proteomic Technologies for Cancer **\$2.6M**

Current estimate of ARRA funds for supplements: \$342M

R&D Contracts

- **Examples of programs and projects** funded under contracts (current estimate of ARRA funds: \$494M)
 - Cohort studies
 - **Phase I/II therapeutic & imaging trials**
 - DCTD expansion of Chemical Biology Consortium & overall therapeutics program
 - **caBIG – Knowledge Base**
 - DCTD clinical assay development & molecular characterization centers
 - **TCGA/TARGET/CaHUB**

Challenge Grants

- NIH opted to fund 18 cancer Challenge Grants (\$17.7M) of the 37 NCI sent forward
- **NCI selected an additional 41 high priority**
- Comparison funded 1
- Overall s relevant

20 Challenge Grants for a total of \$9,250,000 went to institutions that are home to NCI-designated Cancer Centers

GO Grants

- NIH **matched** NCI's funding of 18 cancer GO Grants (\$24M)
- **NCI funded 33 additional GO Grants (\$64M)**
 - AIDS: 21 awards, \$21M
 - Functional biology: 5 awards, \$24M
 - Translat
 - Viruses
- Comparativ
funded 12
- Overall suc
reviewed

29 GO Grants for a total of \$26,861,000 went to institutions that are home to NCI-designated Cancer Centers

ACTNOW

- **Accelerating Clinical Trials of Novel Oncologic Pathways (\$31M)**

- 37 early phase clinical trials of new treatment regimens

- Awarded to
and
within

11 NCI-designated cancer centers and 6 Cooperative Groups among those funded by ACTNOW

ARRA at NIH in FY10

- NCI does not have funds set aside for most NIH initiatives slated for FY10 ARRA funds
- There will be several opportunities for grantees to compete for **FY10 NIH-funded ARRA opportunities**
 - Check the NIH website for announcements
- Currently open: Building Community-linked Infrastructure to Enable Health Science Research
 - Closes 12/11/09; NIH funds available, \$30M

ARRA at NCI in FY10

- NCI **obligated** or **committed** all available ARRA funds prior to Sept. 30, 2009
- Rema
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limite
 - **2010 NCI ARRA opportunities**
 - **TCGA/TARGET**
 - **To be discussed today:**
Implementation of Operational Efficiency Working Group recommendations at NCI's Cooperative Groups and Cancer Centers
- Spec
 - Pro
 - R&

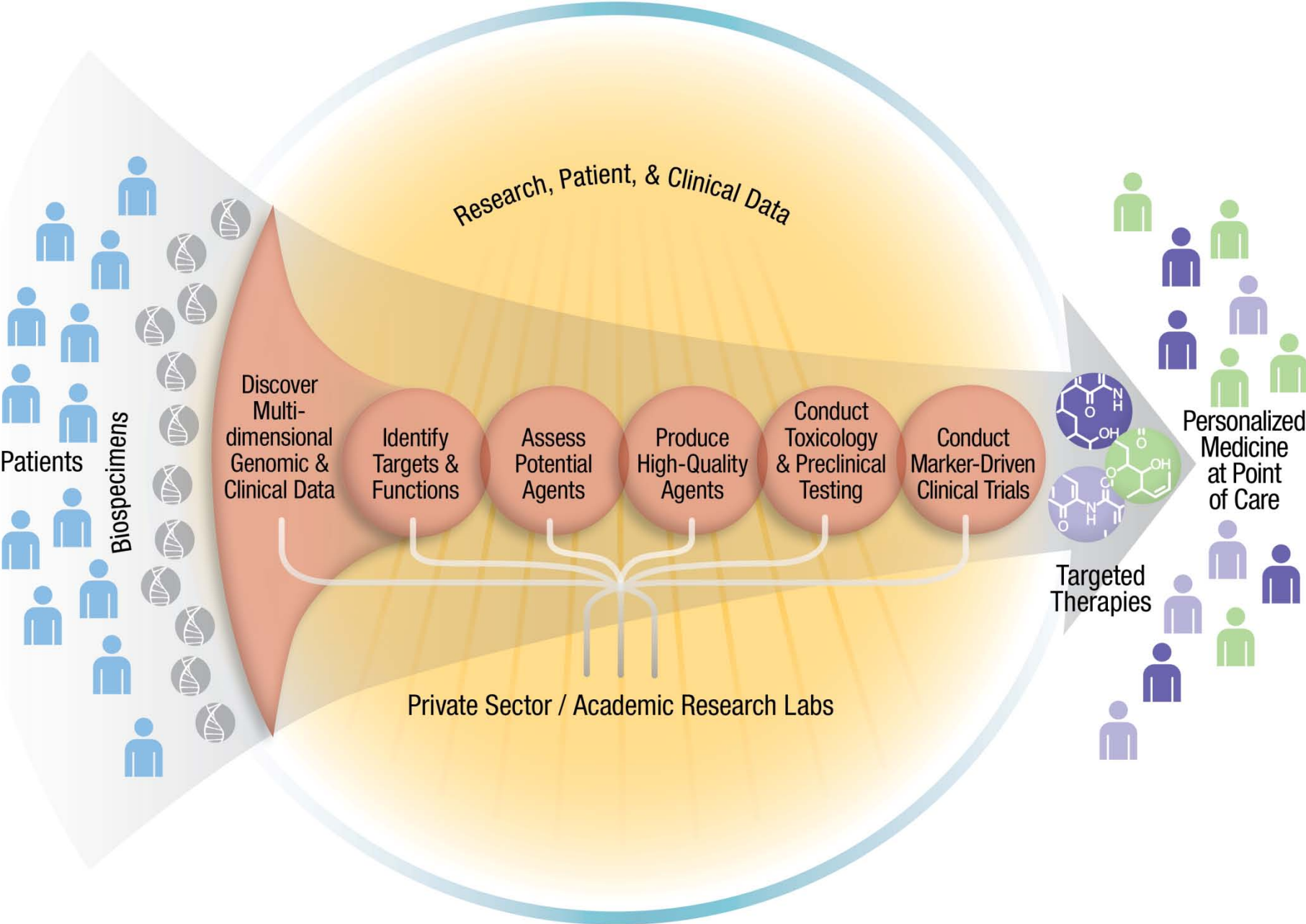
TCGA

- NIH Signature Project (one of seven)
- Identification of relevant genetic alterations in cancer
- Involves >24 institutions and >100 scientists
- **ARRA funding has allowed expansion up to 25 tumors**
- Long-term goal of including all major cancer types and subtypes
- **TARGET utilizes the TCGA approach in childhood cancers**

caHUB

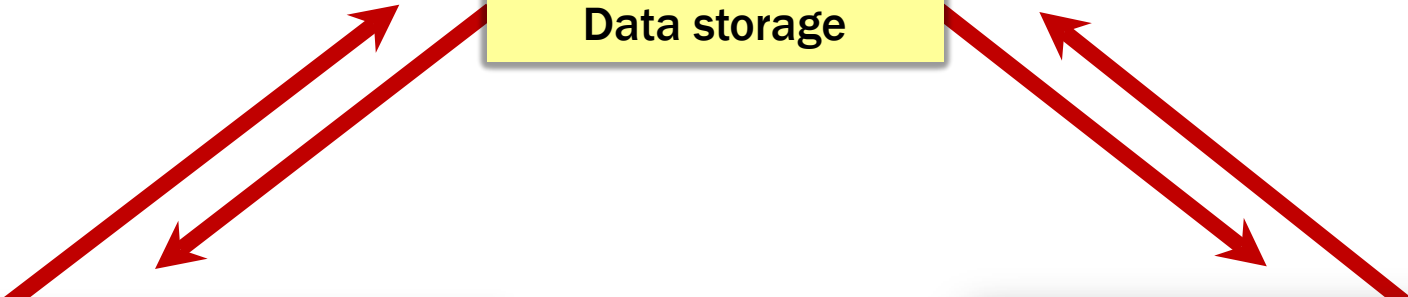
- A unique, centralized, public resource to **ensure the adequate and continuous supply of human biospecimens** and associated data
- caHUB Implementation
 - Tissue procurement (tumor and normal)
 - Pathology reference center/core biospecimen resource
 - Biospecimen R&D
- ARRA funds: \$60M

NCI Therapeutics Platform



Pilot study
**Patient and tumor
characterization center**

Data storage



- NCI Cancer Centers
- NCCCP
- SPOREs
- CCOPs
- Cooperative Groups

NCI structure

Translation



Practicing oncologists

Point of Care Diagnostics

Dr. Francis Collins' Five Themes as NIH Director

- Apply high-throughput technologies to understand fundamental biology and uncover causes of specific disease states
- Translation: develop strategies, and t
- Put science to w
- **A greater focus**
- Reinvigorate and research commu

The National Cancer Program has long been committed to making a difference in these areas.

How Do We Move Ahead?

- Obama administration supports science
- Emphasis not on what we've done or on capacity, but on **seeing science impact patients and decrease cost**
 - Economic impact is a key factor
- But there is tremendous pressure on the discretionary portion of the federal budget
 - **Will support translate into new resources?**



