

NCI Director's Update

Dr. John E. Niederhuber
Director, National Cancer Institute

Clinical Trials Advisory Committee
July 15, 2009

NCI – July 2009



- **Most-challenging issues**
 - American Recovery and Reinvestment Act of 2009
 - ‘Managing’ the FY09 budget
 - Planning for 2010 and 2011
 - Developing the trans-NIH cancer strategic plan

ARRA: \$10.4 Billion to NIH

- **\$7.4 billion:** Institutes and Centers
 - **\$1.257 billion to NCI**
- **\$1 billion:** extramural construction
- **\$500 million:** NIH construction
- **\$300 million:** shared instrumentation
- **\$400 million:** comparative effectiveness research (\$400M HHS; \$300M AHRQ)
- **\$800 million:** NIH Office of the Director

Definition of CER

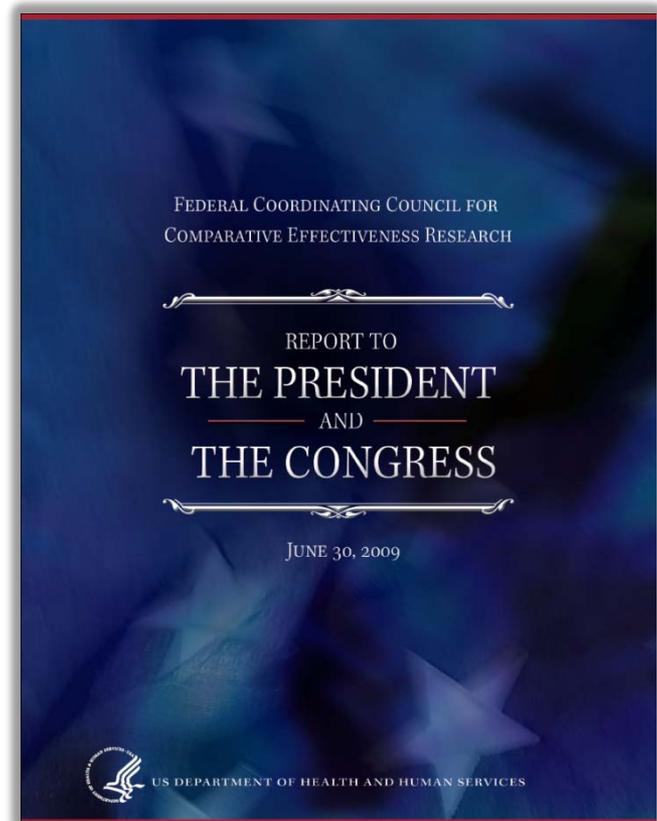
“Comparative effectiveness research is the conduct and synthesis of **research comparing the benefits and harms of different interventions** and strategies to prevent, diagnose, treat and monitor health conditions in ‘real world’ settings.”

Department of Health and Human Services’

Federal **C**oordinating **C**ouncil for **C**omparative **E**ffectiveness **R**esearch

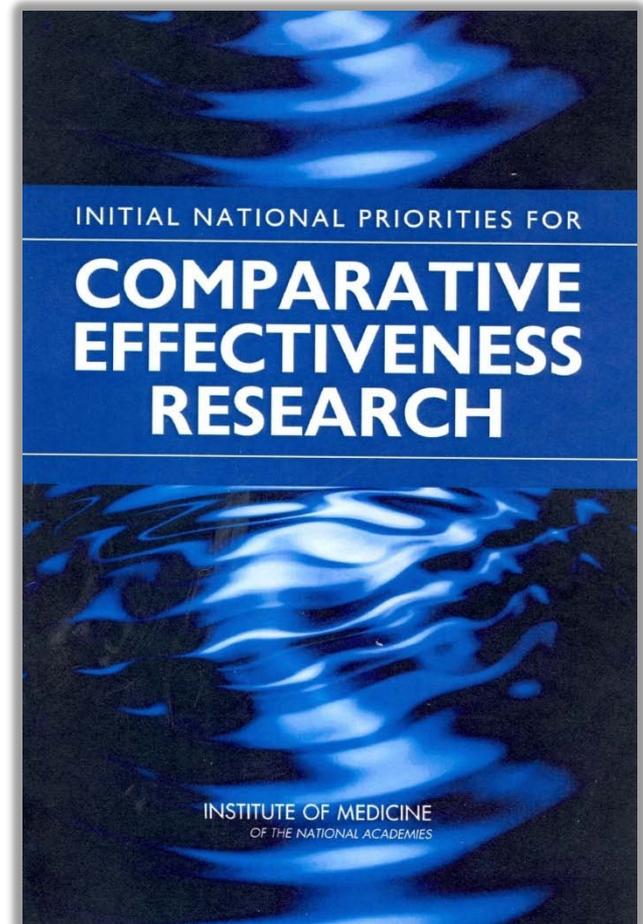
Federal Coordinating Council for CER

- June 30 report by 15 member council recommends:
 - **Invest in dissemination of CER information**
 - Focus CER on priority populations
 - Emphasize high-impact health arenas
 - Invest in data infrastructure



Institute of Medicine CER Report

- **Released June 30, recommends to Congress and the Secretary how to expend CER funds**
- Suggests 100 health topics that should get priority attention and funding from a new national research effort to identify which health care services work best



NCI ARRA Goals

- Meet the “jobs” goal of ARRA
- Fund the best **new science**
- Model one-time dollars to soften out-year problems
- **Invest in science that will make a difference for patients**



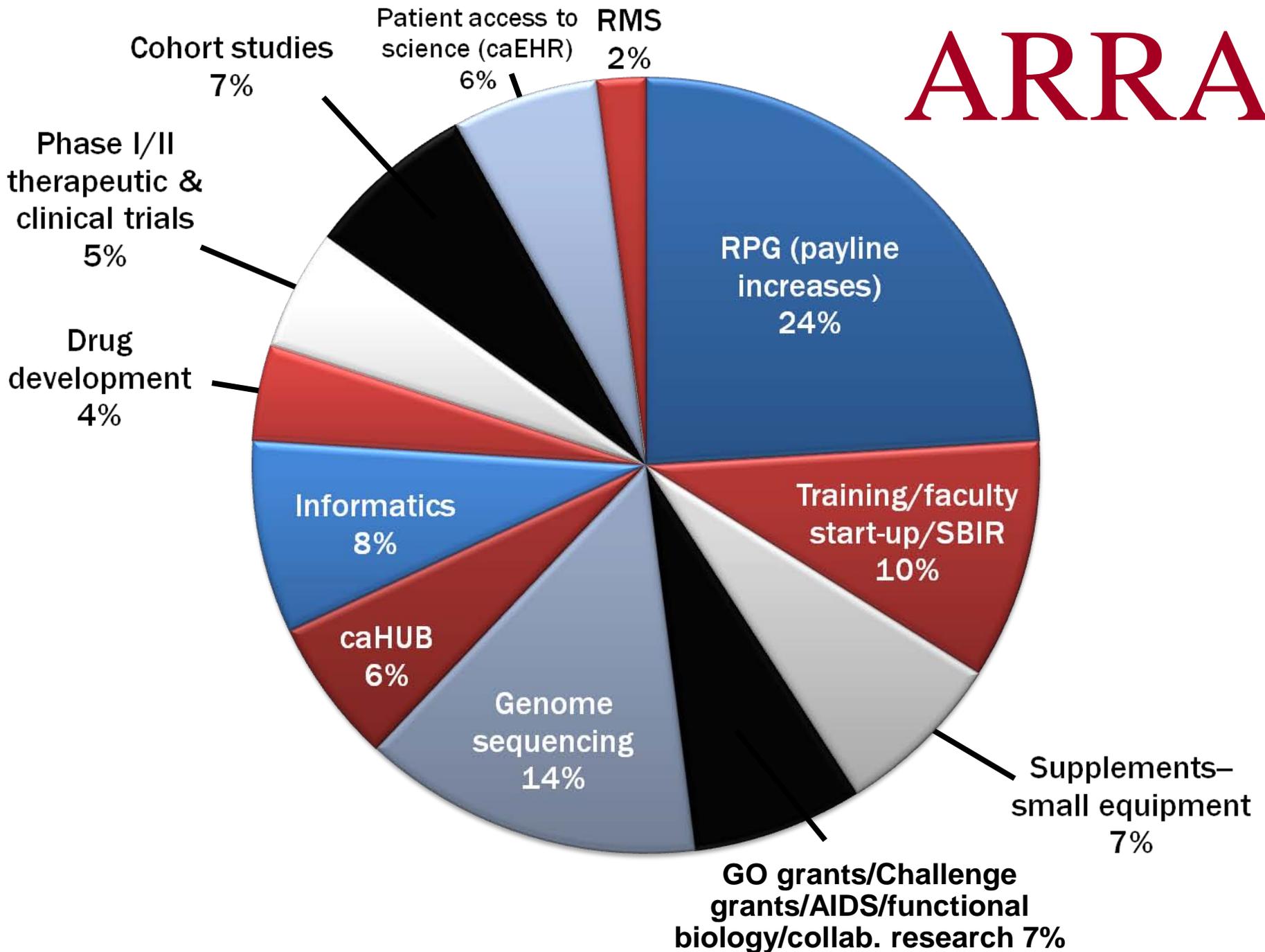
Supporting Individual Investigators

- **16th percentile:** 2009 RPG payline from appropriated funds
- **16th to 18th percentile:** 4-year grants through stimulus, followed by appropriated dollars
- **18th to 25th percentile:** Mix of 2-year and 4-year grants (stimulus for first 2 years)

ARRA Funding Applications Received

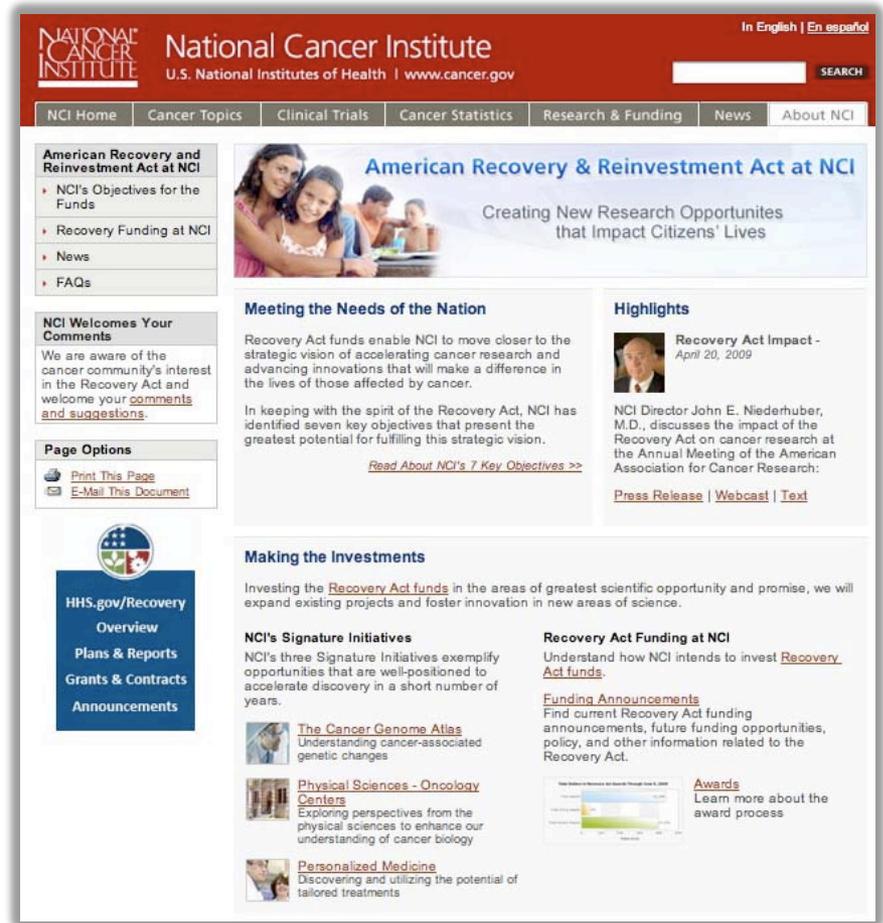
Funding Opportunity	NIH total	NCI total	Status
NCI - Activities to Promote Research Collaborations		~167	Closed
Challenge Grants	~20,000	~4,398	Closed
Competitive Revisions	~2,123	~500	Closed
GO Grants	~2,500	~568	Closed
P30 Staff Grants	~550	~56	Closed
Administrative Supplements		2,500-3,000	Closed

ARRA



Obligating ARRA Funds

- ARRA funds must be spent by the end of FY2010
- Some grant specialists are working solely on ARRA awards
- **Like other ICs, NCI is simultaneously administering its annual appropriation**



The screenshot displays the National Cancer Institute (NCI) website's page for the American Recovery & Reinvestment Act. The header includes the NCI logo, the text "National Cancer Institute U.S. National Institutes of Health | www.cancer.gov", and language options "In English | En español". A search bar is located in the top right. The main navigation menu contains links for "NCI Home", "Cancer Topics", "Clinical Trials", "Cancer Statistics", "Research & Funding", "News", and "About NCI".

The main content area features a large banner titled "American Recovery & Reinvestment Act at NCI" with the subtitle "Creating New Research Opportunities that Impact Citizens' Lives". Below the banner, there are several sections:

- American Recovery and Reinvestment Act at NCI**: A sidebar menu with links for "NCI's Objectives for the Funds", "Recovery Funding at NCI", "News", and "FAQs".
- NCI Welcomes Your Comments**: A section inviting the cancer community to share their interest in the Recovery Act and provide comments and suggestions.
- Page Options**: Links for "Print This Page" and "E-Mail This Document".
- Meeting the Needs of the Nation**: A section discussing the strategic vision of accelerating cancer research and advancing innovations that will make a difference in the lives of those affected by cancer. It includes a link to "Read About NCI's 7 Key Objectives >>".
- Highlights**: A section featuring a photo of NCI Director John E. Niederhuber, M.D., and a link to "Recovery Act Impact - April 20, 2009". It also includes a link to "Press Release | Webcast | Text".
- Making the Investments**: A section stating that NCI will expand existing projects and foster innovation in new areas of science.
- NCI's Signature Initiatives**: A section listing three initiatives: "The Cancer Genome Atlas", "Physical Sciences - Oncology Centers", and "Personalized Medicine".
- Recovery Act Funding at NCI**: A section providing information on how NCI intends to invest Recovery Act funds, including links for "Funding Announcements" and "Awards".

At the bottom left, there is a blue box with the text "HHS.gov/Recovery Overview Plans & Reports Grants & Contracts Announcements".

NCI FY 2009 Operating Budget Development

FY 2008 operating budget (with \$25M supplemental)	\$4,830,647
FY 2009 Omnibus Appropriations Bill	\$4,968,973
Difference, FY08 to FY09	\$138,326
Percent change, FY08 to FY09	+2.9%

(dollars in thousands)



FY2010 President's Budget Proposal

- “The President proposes to invest

over \$6

across

of an e

cancer

– \$5.1

■ ~

- **Hearings:** no indication there will be additional hearings on NIH 2010 budget
- **House:** Chairman Obey’s plan is to act on all 12 appropriations bills before the August recess, with Labor, HHS, Education bill to the House floor July 22
- **Senate:** No dates set; Chairman Inouye stated intention to pass all 12 bills before end of FY09



COMMITTEE ON APPROPRIATIONS

DAVID R. OBEY, CHAIRMAN

FOR IMMEDIATE RELEASE
Friday, July 10, 2009

CONTACT: Ellis Brachman
(202) 225-2771

PREPARED STATEMENT OF CHAIRMAN DAVID R. OBEY
2010 LABOR-HHS-EDUCATION APPROPRIATIONS BILL
SUBCOMMITTEE MARKUP

July 10, 2009

*"... whatever you did for one of the least of these brothers of mine, you did for me."
- Mathew 25:40*

“...\$31.3 billion for the NIH, rejecting the Administration’s targeted funding approach and ensuring that all institutes and centers receive funding to offset biomedical research inflation.”

Developing the Trans-NIH Cancer Strategic Plan

- Drs. Niederhuber and Katz (NIAMS) appointed by NIH to chair committee to develop plan (May 14)
- All NIH ICs conducting cancer research submitted information (24 of 27)
- Report submitted to NIH June 30

Strategic Plan to Double the NIH Cancer Research Budget

Co-Chairs:

John E. Niederhuber, M.D.
Director, National Cancer Institute

Stephen I. Katz, M.D., Ph.D.
Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases

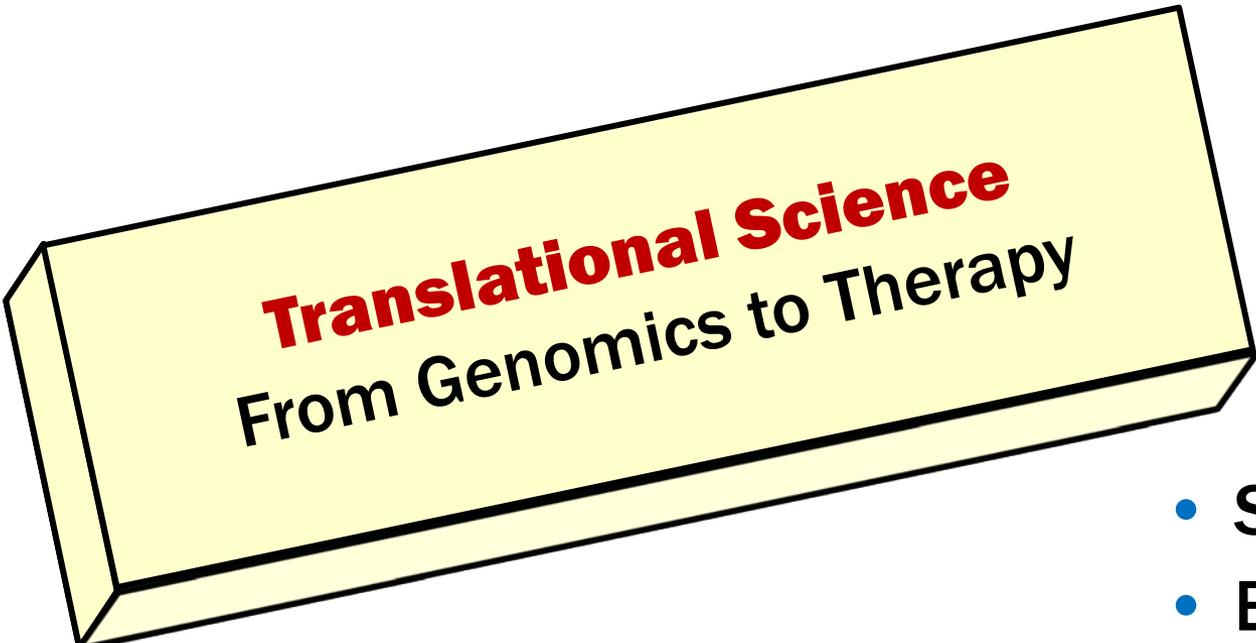
June 30, 2009

21st Century Cancer Medicine

Prevention and Treatment

- Derive a functional understanding of the causal defect/dependence; e.g. Wnt, P13K, NF- κ B...
 - Distinguish passenger defects from true drivers
- Determine dependence of cancer cells and micro-environment cells on genes that are amplified, translocated, mutated or epigenetically altered
 - “Oncogene addiction”
- Find genes to which cancer cells are addicted but that are not mutated, translocated or amplified
 - “Non-oncogene addiction”

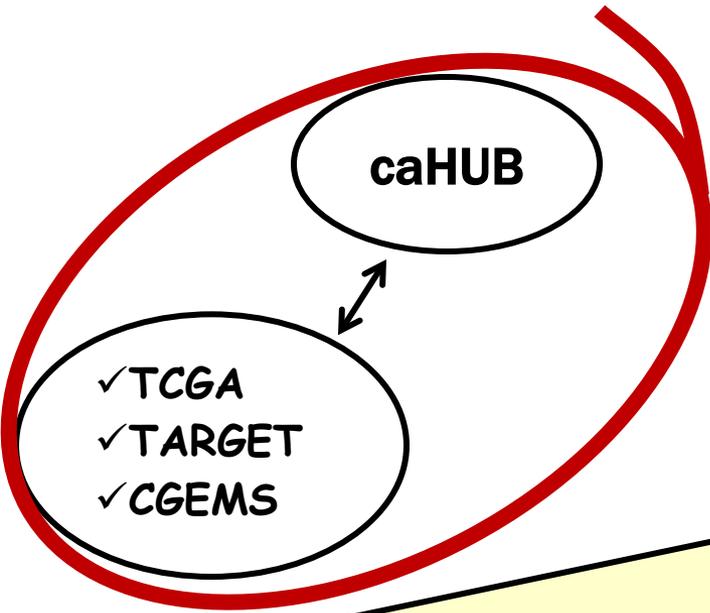
NCI Therapeutics Platform



Translational Science
From Genomics to Therapy

- Small molecules
- Biologics
- Biomarkers

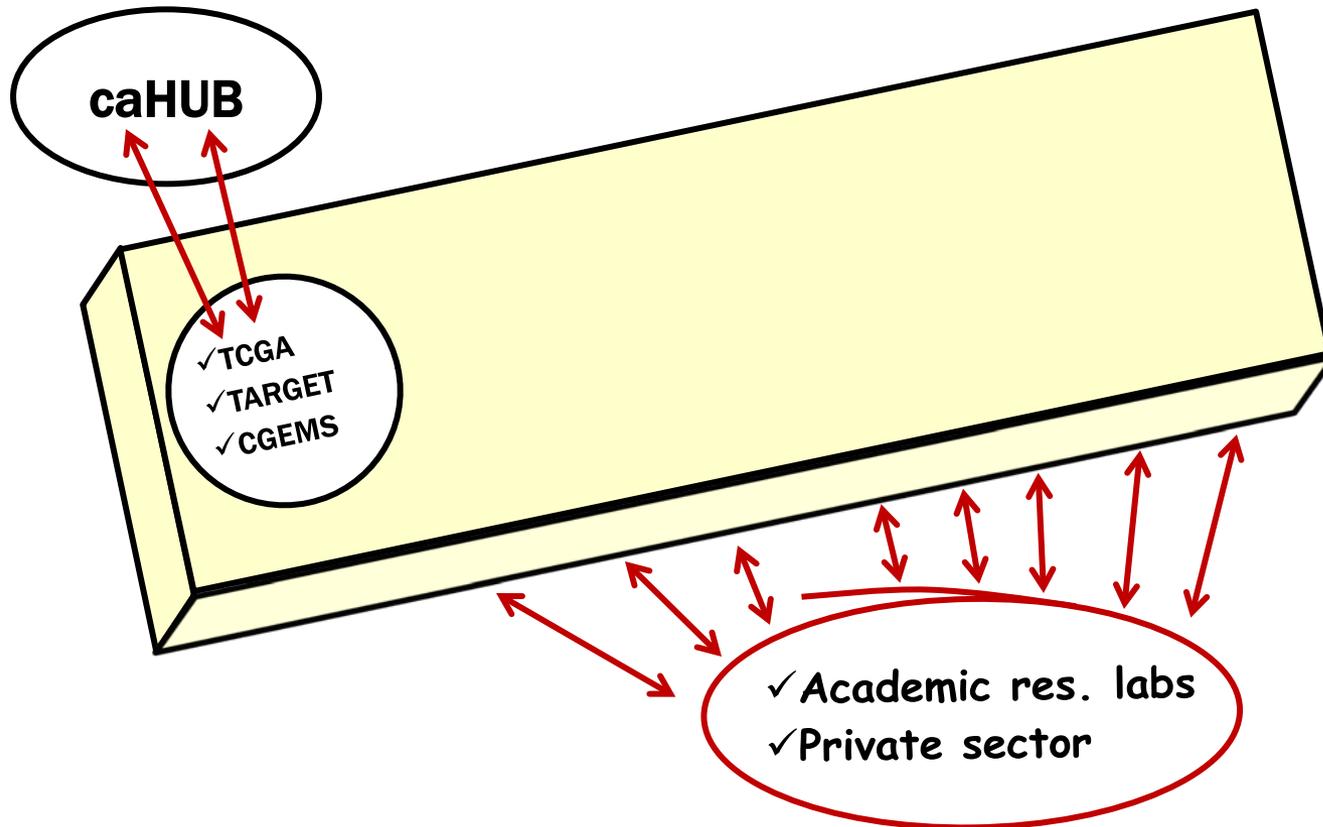
NCI Therapeutics Platform



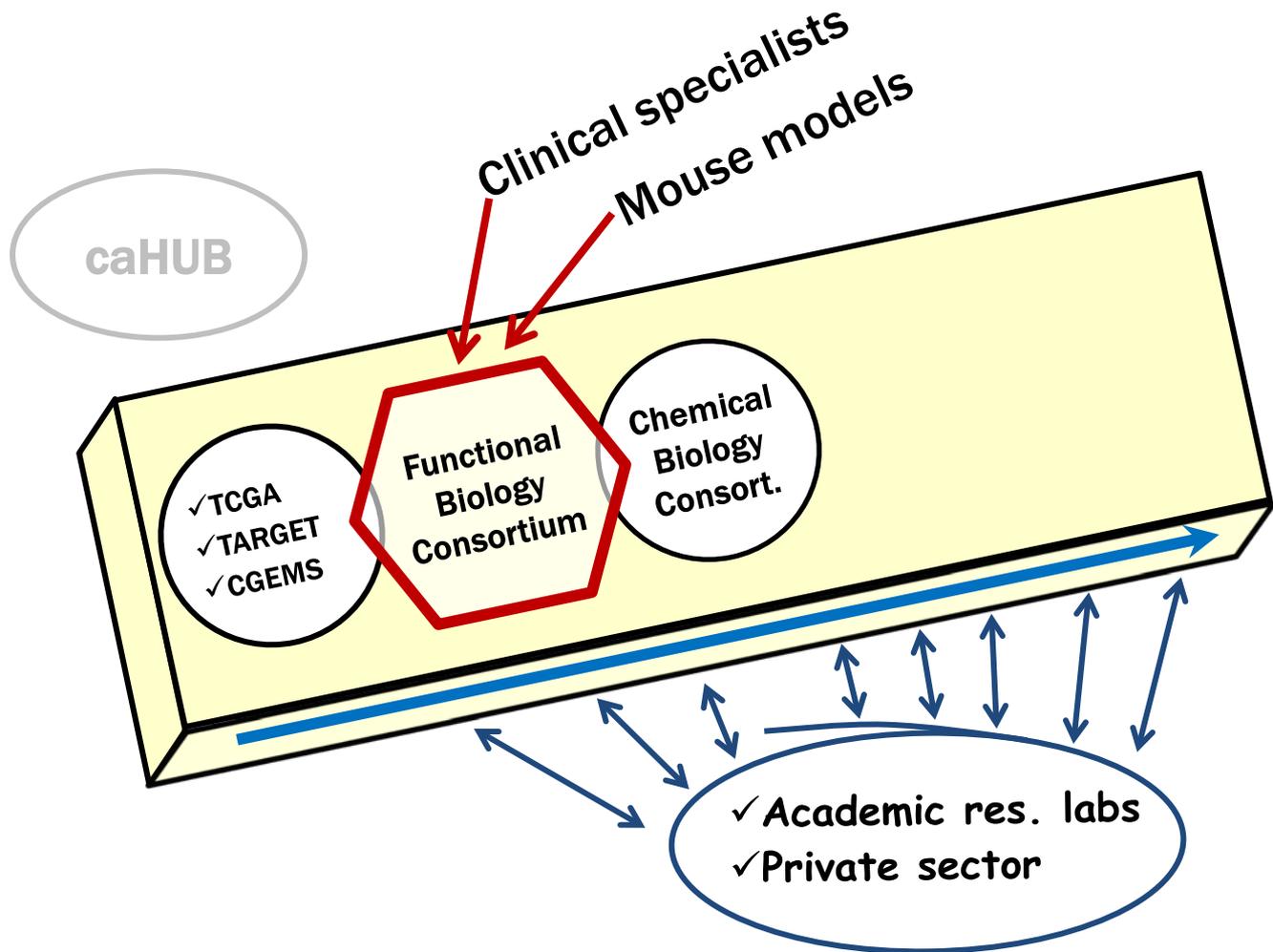
Translational Science
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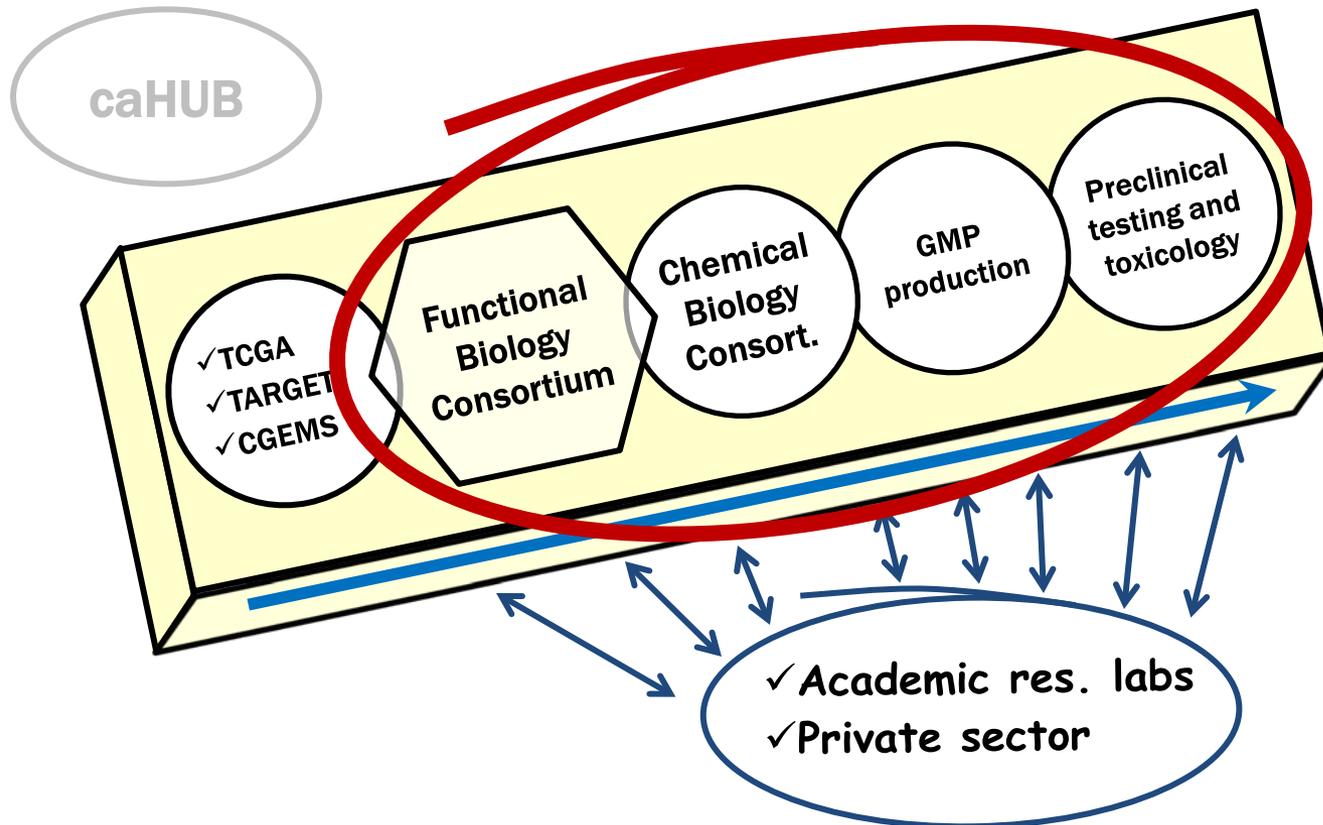
NCI Therapeutics Platform



NCI Therapeutics Platform



NCI Therapeutics Platform



NCI Therapeutics Platform

CLOUD COMPUTING

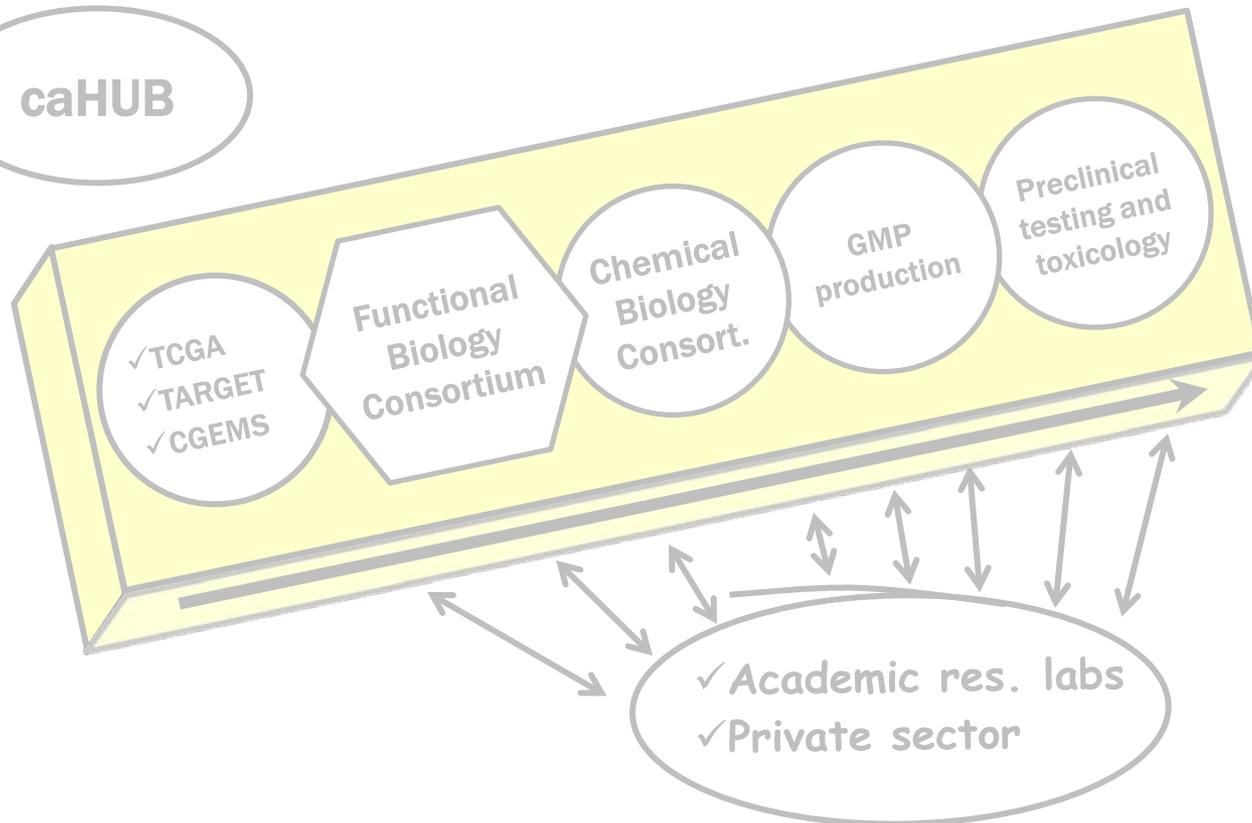
- ✓ Patient data
- ✓ Cancer electronic health record
- ✓ Data management, storage and analysis
- ✓ Science data (national cohort)

↕ Patient selection

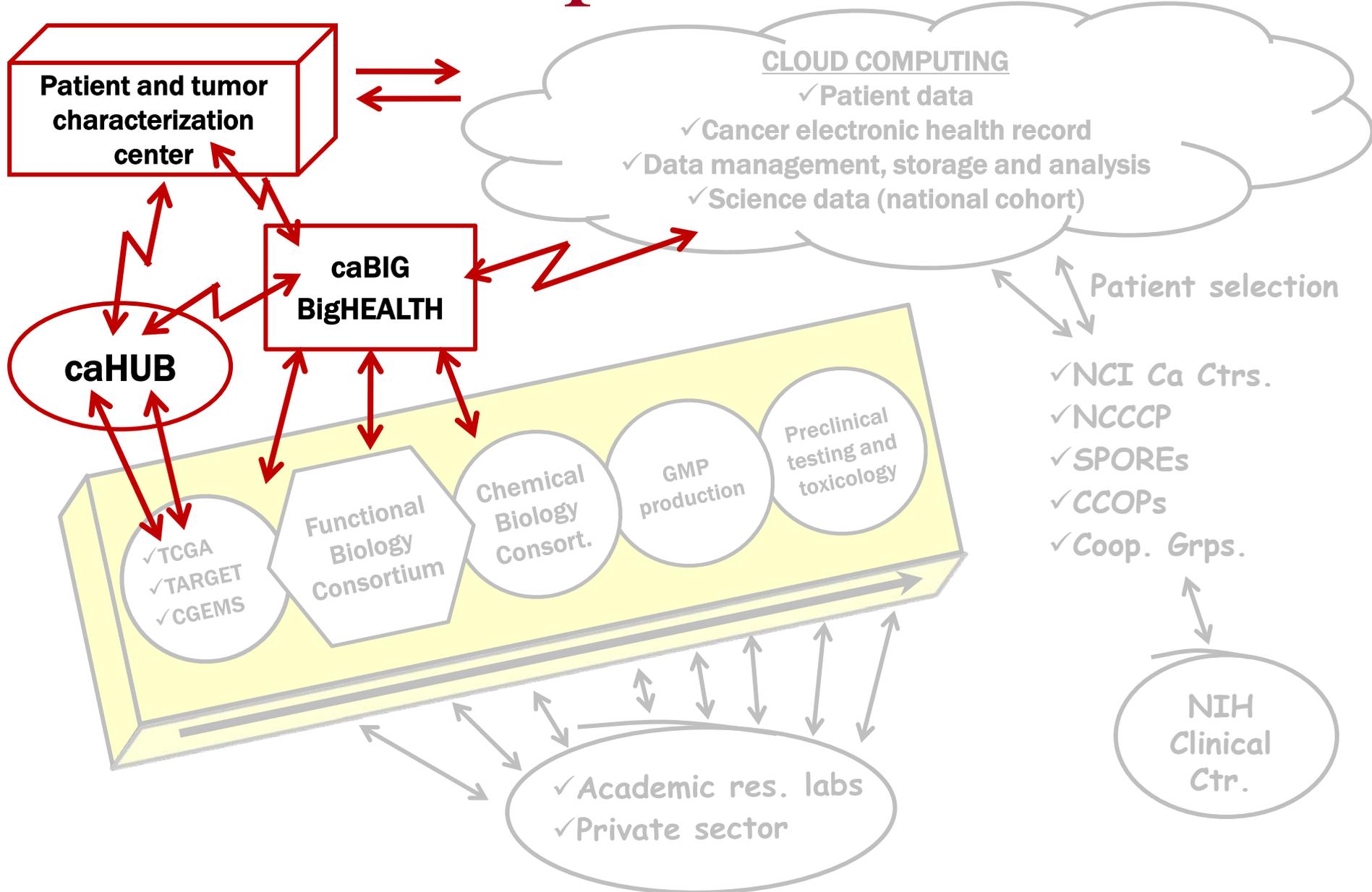
- ✓ NCI Ca Ctrs.
- ✓ NCCCP
- ✓ SPOREs
- ✓ CCOPs
- ✓ Coop. Grps.

↕
**NIH
Clinical
Ctr.**

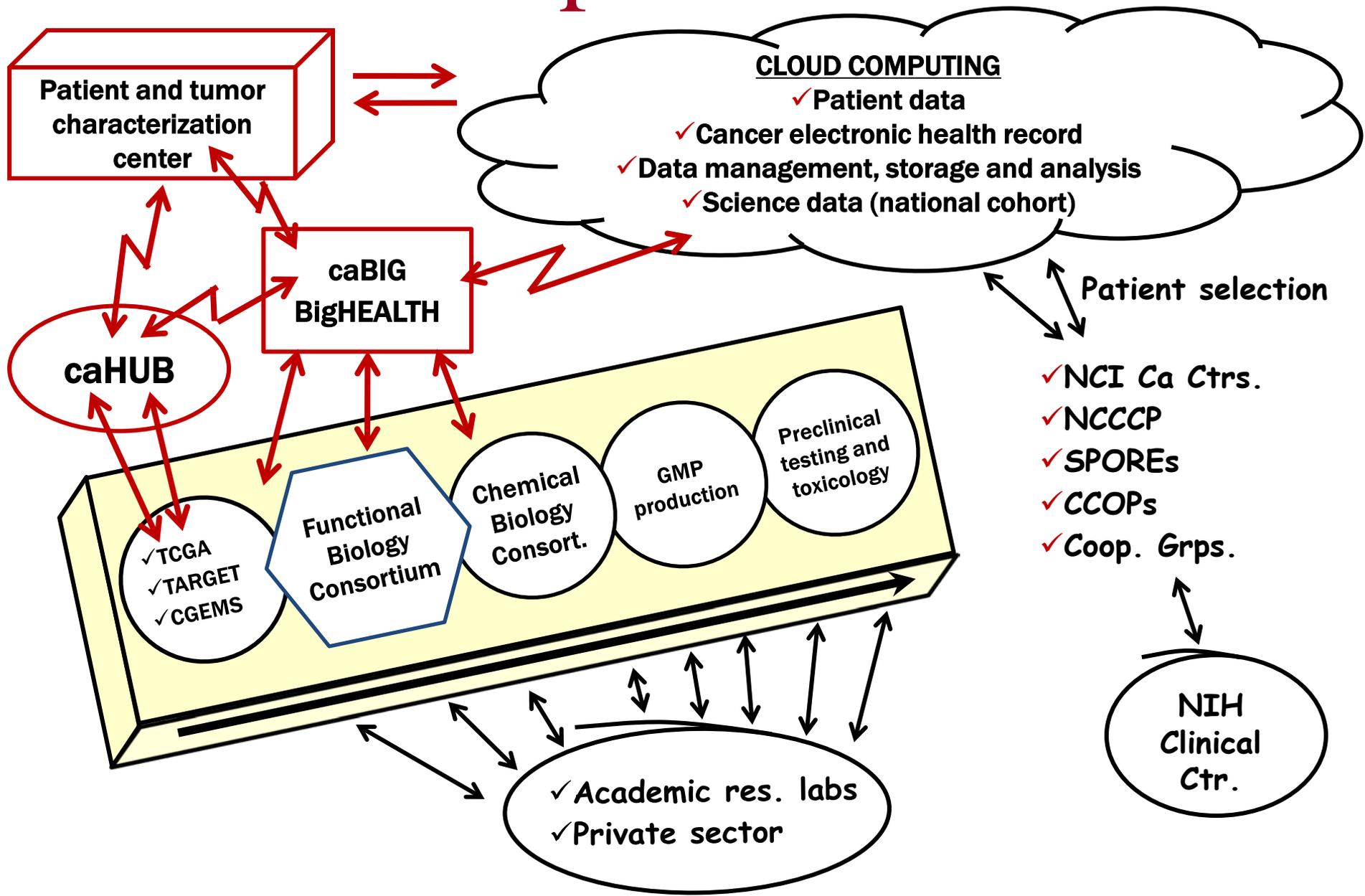
caHUB



NCI Therapeutics Platform

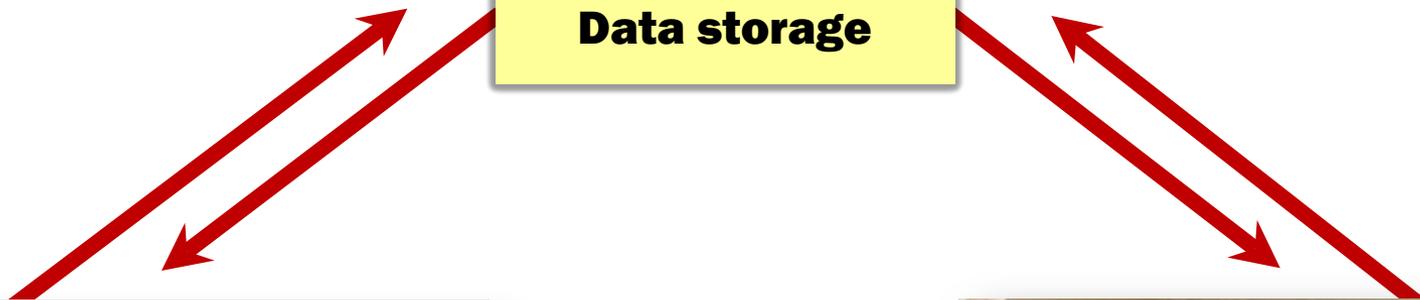
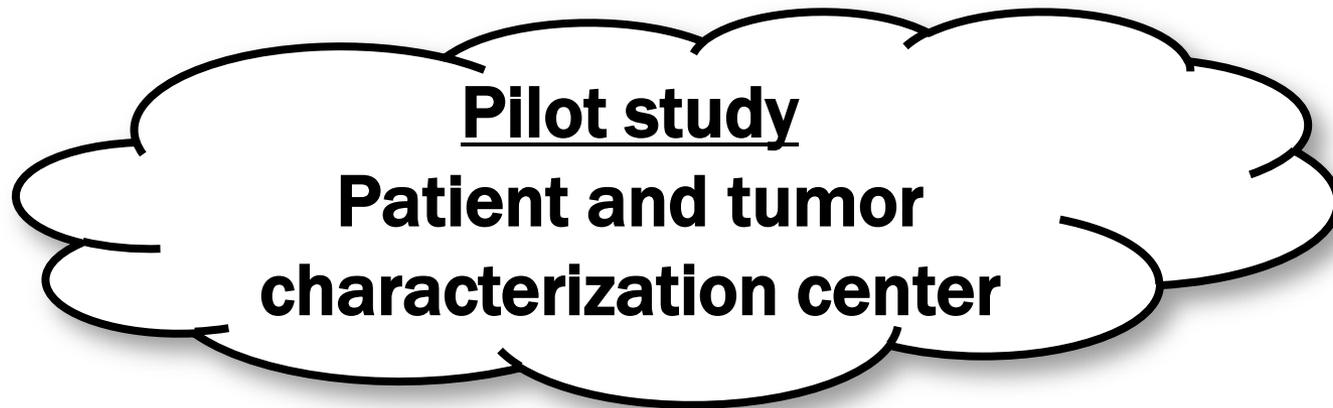


NCI Therapeutics Platform



Personalized Cancer Medicine Hypothesis

- Documentation of drug target's expression/activity increases the likelihood of efficacy for a drug designed to extinguish the target
 - e.g., HER2/herceptin in breast cancer
- **Knowledge of the target's signaling circuitry can further inform the deployment of drugs**
 - e.g., K-RAS status for EGFR inhibitors



Work and Projects Underway

- **Physical sciences and cancer**
- **TCGA scale up**
- **CaHUB — value of community program**
- **Tumor/Patient characterization center(s)**
- **Functional and chemical biology**
- **Infectious etiology of cancer**
- **NCI as the enabler — academia, private, and public sectors**
- **Clinical trials reengineering**

Summary

- NCI must develop the therapeutics development platform for personalized cancer medicine
- ARRA funding will continue to require monitoring and adjustment
- **We must continue to model for – and plan a soft landing in – the out years after ARRA**
- Doubling of NIH cancer budget will present unique challenges



www.cancer.gov



Federal Coordinating Council for CER

- June 29 report to the HHS Secretary by 15 member council recommends:
 - **Invest in the dissemination of CER information**
 - **Focus CER on priority populations** (racial and ethnic minorities; persons with disabilities or multiple chronic conditions; the elderly; children)
 - **Emphasize high-impact health arenas** (medical and assistive devices; surgical procedures; behavioral interventions; prevention)
 - **Invest in data infrastructure** (link current data sources to answer CER questions; develop distributed electronic data networks and partnerships with the private sector)

ARRA Process

- Nearly 50 ARRA funding announcements have been posted and made available to the community to apply for NCI support
- **Grants ready to award are submitted weekly through NIH to the White House**
 - After inclusion on the weekly list, generally about 2 weeks until the grant is officially awarded

NCI FY 2009 Operating Budget: NCI Operating Policies

- **NCI operating policies**
 - 3% inflationary adjustments on non-competing grants
 - Award at full commitments of record for categorical (non-modular) grants
 - No cut to modular non-competing RPGs
 - **NCI to award more competing RPGs than FY 2008 (1,284 to 1,412)**
 - Will hit NIH target for competing new investigator R01s

NCI FY 2009 Operating Budget: NCI RPG Policies

- **NCI RPG policies**

- **3% above current levels for Type-2** (last year's grant award, in most cases) for competing continuing grants
 - Unless PI requested less than 3% or peer review recommended less than 3%
- **5% above current levels** for grants recommended for 7 modules or fewer
- **~17% cut from Type-1 level requested** (or approved by peer review)