

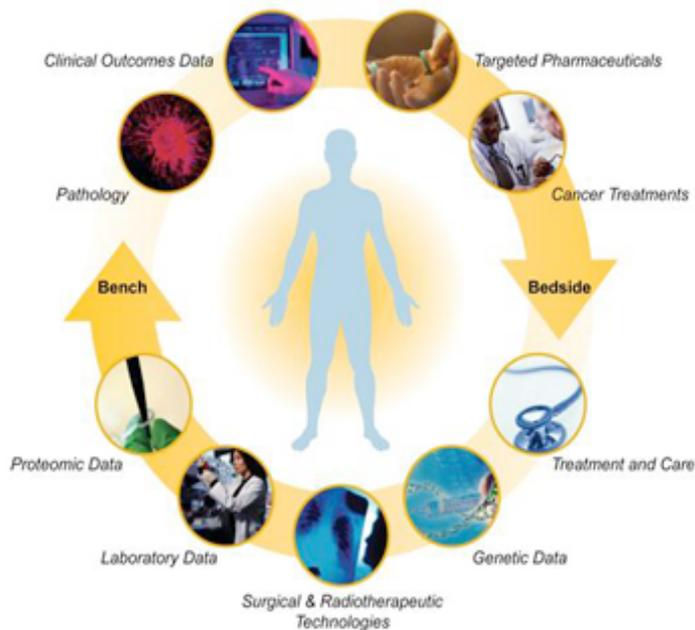
## The BIG Idea: Strategies to Achieve a Rapid-Learning Health System

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Associate Director for Biomedical Informatics and Information Technology  
National Cancer Institute

BIO IT World, April 21, 2010

### 21<sup>st</sup> Century Biomedicine

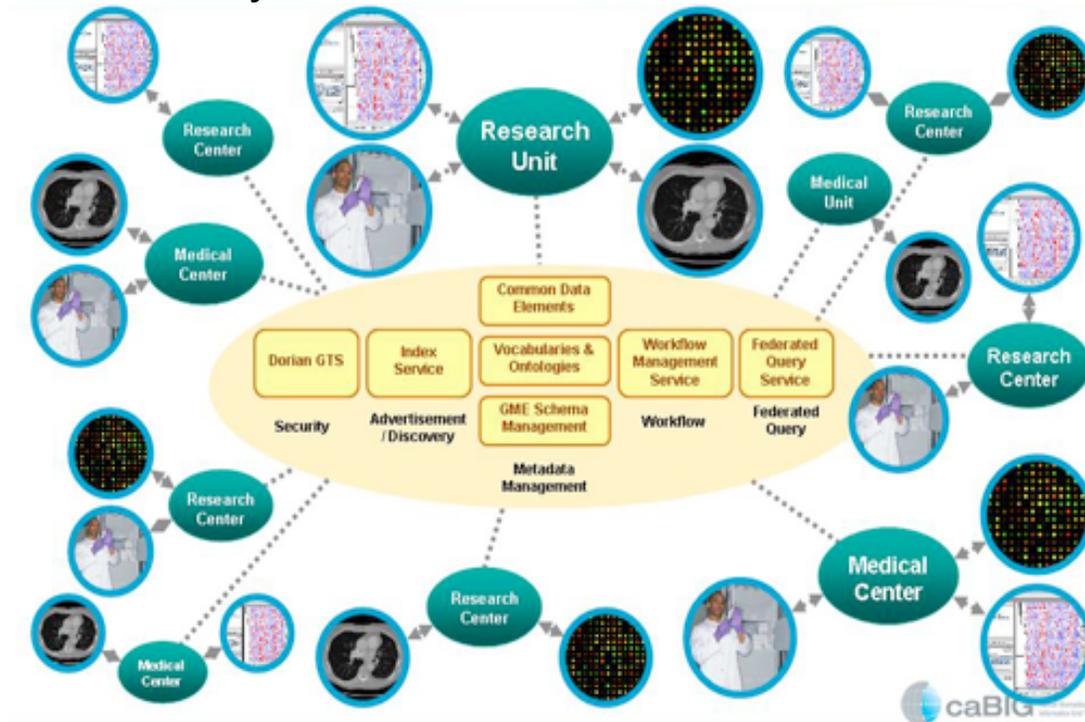


- Personalized, Predictive, Preemptive, Participatory.....
- Unifies discovery, clinical research, and clinical care (bench-bedside-bench) into a seamless continuum
- Results in improved clinical outcomes
- Accelerates the time from discovery to patient benefit
- Empowers consumers in managing their health over a lifetime
- Enables a Learning Health System.

### caBIG®: Biomedical Information Highway

The cancer Biomedical Informatics Grid® (caBIG®) is a virtual network of interconnected data, individuals, and organizations that redefines how research is conducted, care is provided, and patients/participants interact with the biomedical research enterprise.

## IT-enabled ecosystem



## Semantically-aware Services Oriented Architecture

- Semantically-aware Service Oriented Architecture (sSOA) supports the challenges of integrating diverse classes of information distributed across a distributed, heterogeneous cancer research and care community
- In addition to data integration, sSOA enables the coordination of functionality between the various information systems that reside within those organizations and enable collaborative data processing and work flow execution
- Services can be implemented in a largely standalone fashion to allow for the rapid creation of composite applications via service marshalling or integrated with existing applications
- Leverages and extends existing information models such HL7 RIM and the unified health care delivery/regulatory model BRIDG

## Services Aware Interoperability Framework (SAIF)

HL7 architectural approach and framework for the development and use of HL7 standards from a Services Oriented Architecture (SOA) perspective.

- Human-readable statement about APIs facilitating use and interconnection
- Machine-testable definitions expediting review and assuring uniformity

- Platform-independent specifications
- Expanded metadata infrastructure to support latest paradigms in biomedical informatics, including the semantic web
- Robust services framework to support integration

**The I-SPY trial (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis):**

A national study to identify biomarkers predictive of response to therapy throughout the treatment cycle for women with Stage 3 breast cancer.

**I-SPY Trial: Identify biomarkers predictive of therapeutic response in Stage 3 breast cancer**

- **Multiple Morphologic Patterns of Breast Cancer**
- **Multiple Sites/Organizations**
  - o Specialized Programs of Excellence (SPOREs)
  - o Cancer and Leukemia Group B (CALGB)
  - o American College of Radiology Imaging Network (ACRIN)
  - o University of California at San Francisco (UCSF)
- **Multiple Data Types**
  - o Clinical diagnosis
  - o Treatment history
  - o Histologic diagnosis
  - o Pathologic status
  - o Tissue anatomic site
  - o Surgical history
  - o Gene expression
  - o Chromosomal copy number
  - o Loss of heterozygosity
  - o Methylation patterns
  - o miRNA expression
  - o DNA sequence

## Projected I-SPY 2 study sites I-SPY Adaptive Trial Outline



## I-SPY Adaptive Trial Outline

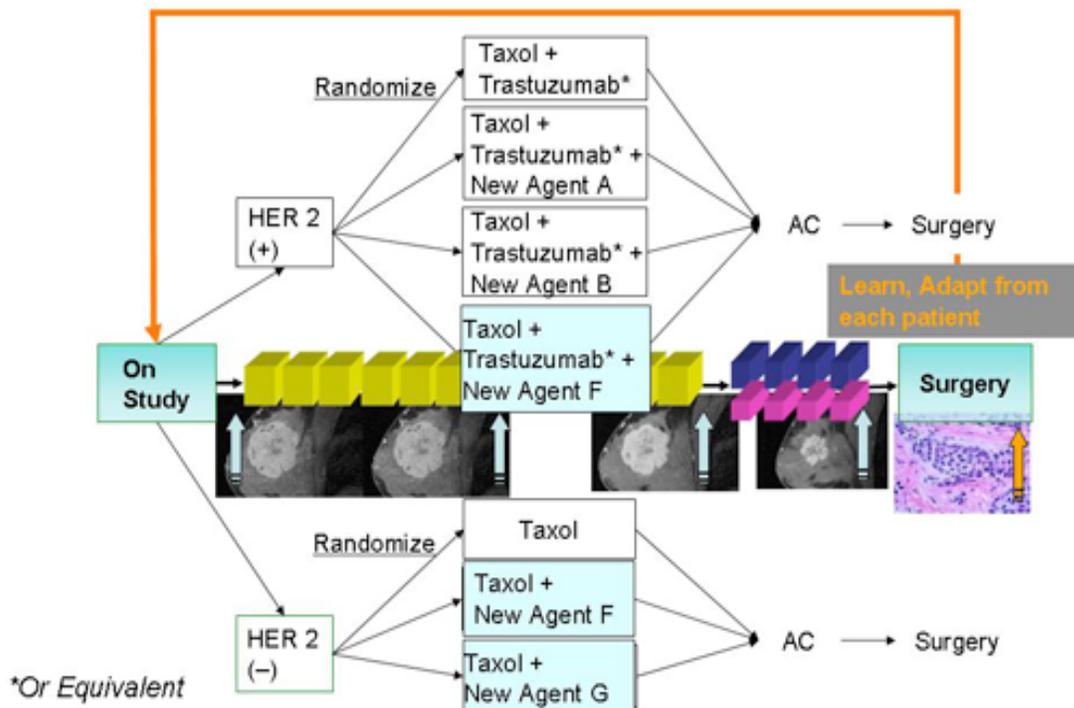


Accrual: Anticipate 800 patients over 3–4 years

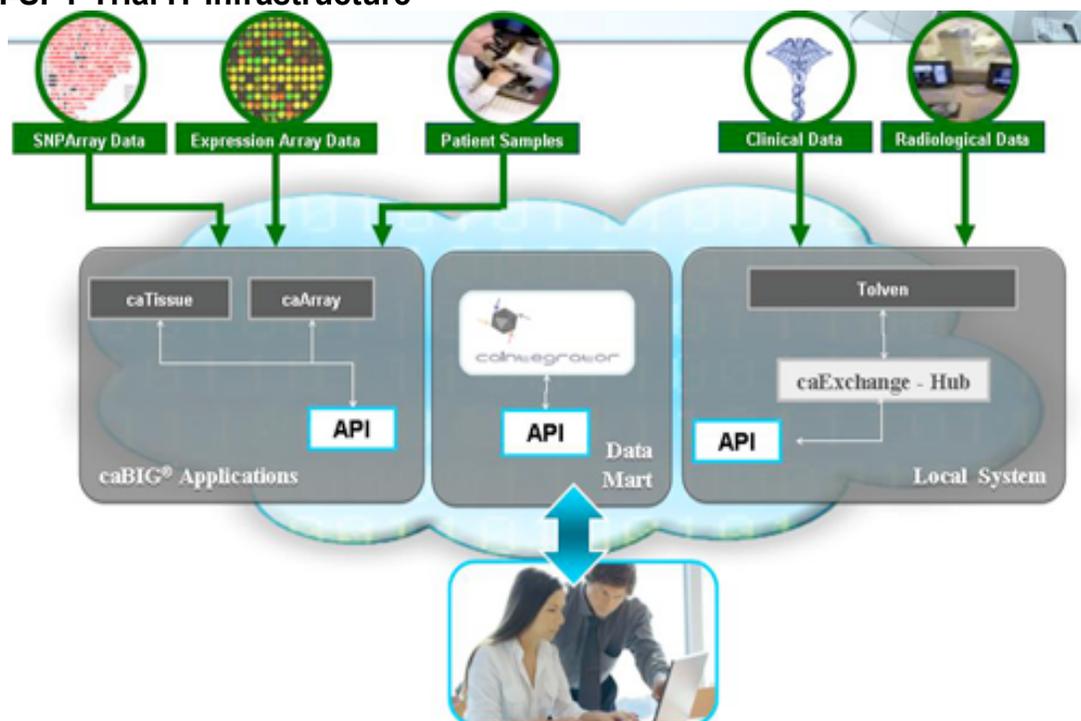
Enroll ~20 patients per month

Participating Sites: 15–20 across US and Canada

## I-SPY Adaptive Trial: Introduce several new agents for a given profile



## I-SPY Trial IT Infrastructure



## Redefining Cancer at a Molecular Level

 National Cancer Institute

National Human Genome Research Institute 

# THE CANCER GENOME ATLAS

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The Cancer Genome Atlas (TCGA) is a comprehensive and coordinated effort to accelerate our understanding of the genetics of cancer using innovative genome analysis technologies.

### News



**NEW\*** CBS Where America Stands: Cancer  
NIH Director, Dr. Francis Collins, is interviewed by Katie Couric on CBS Evening News, Jan. 28, drawing upon the discoveries being made by TCGA researchers to improve cancer treatments.

**NEW\*** In Tough Economic Times, NIH Head Looks to Clinic  
NIH Director, Francis Collins, discusses his plans for NIH and how programs like TCGA will bring different approaches to cancer treatments. [Read more.](#)

**Cancer Bulletin Profile: Meet Dr. Raju Kucherlapati**



[View Article >](#)

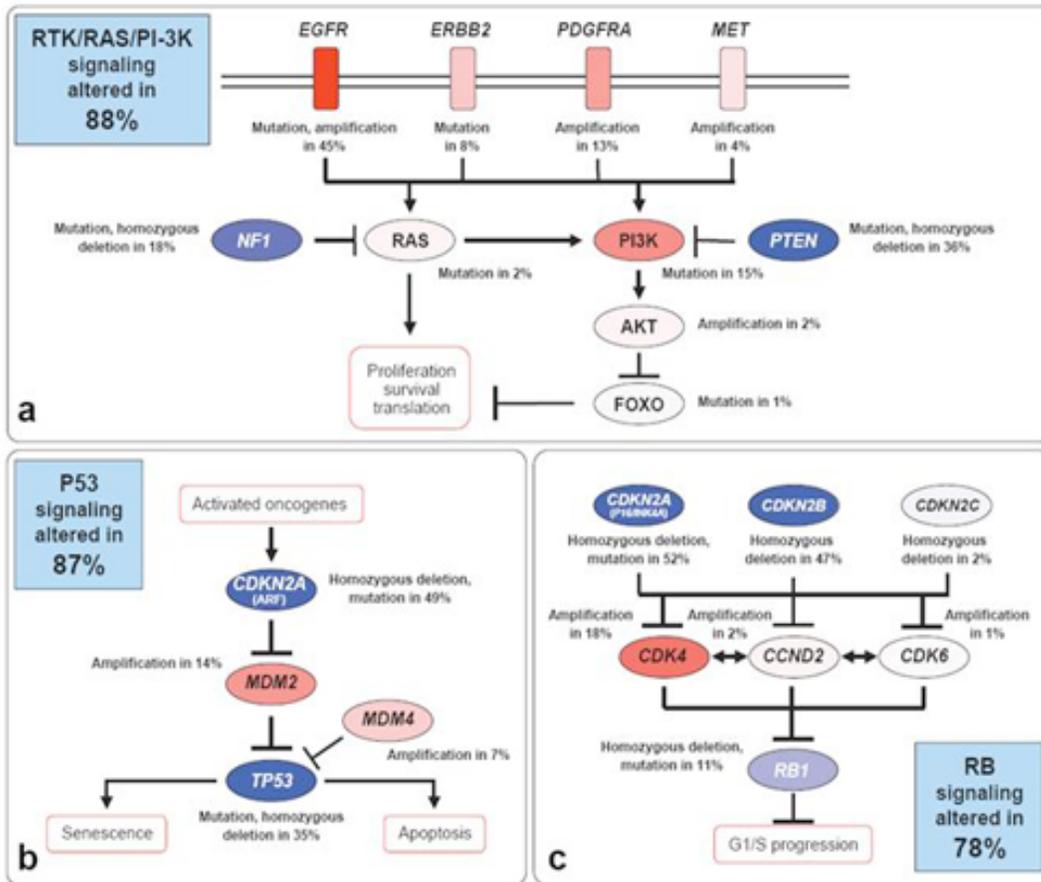
TCGA Expanding to Study 20 or More Cancers

[Learn More](#) 

TCGA Data Portal

[Access TCGA Data Portal](#) 

## GBM Results: Pathways



TCGA: *Nature* 2008

Patient selection for HER2 Tx required tissue screen and allowed only 1 of 4 women to participate

Calculated Sample Size And Study Duration	Hypothetical HER2+ Prevalence	Required "Screened" Population
1250 → 52 mos	100%	1250
	50%	2500
	25%	5000

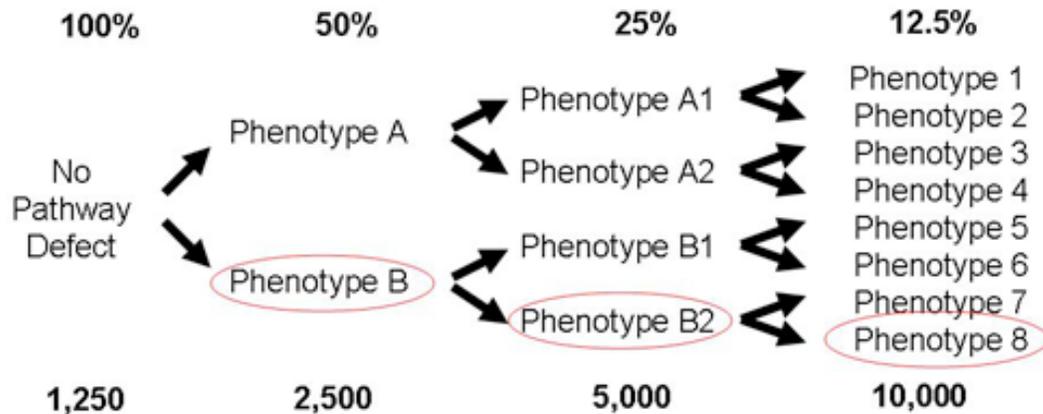
\* Need to obtain a suitable specimen, wait for test results. (Results were obtained in days to weeks)

\* Need to screen many patients.

Courtesy H. Kim Lyerly, M.D., Director, Duke Comprehensive Cancer Center

## Size of Population with Pathway to Inhibit\*

Population fraction containing signature



Size of Population Needed To Screen

Courtesy H. Kim Lyerly, M.D., Director, Duke Comprehensive Cancer Center

“The world we have created today has problems which cannot be solved by thinking the way we thought when we created them.”

- *Albert Einstein*

## Forming a 21<sup>st</sup> Biomedical Ecosystem: *The BIG Health Consortium™*

### Vision:

A biomedical system that synergizes the capabilities of the entire community to realize the promise of personalized medicine

### Mission:

The BIG Health Consortium™ is a collaboration among stakeholders in biomedicine, including **government, academe, industry, non-profit, and consumers**, who come together in a novel organizational framework **to demonstrate the feasibility and benefits of the personalized medicine paradigm.**

### Strategy:

Through a series of personalized medicine **Projects**, with an expanding number of collaborators, BIG Health is **bootstrapping** a new approach in which clinical care, clinical research, and scientific discovery are linked.

## The Love Army of Women

NCI is partnering with the Love/Avon Army of Women to build a consumer-controlled online cohort of one million women, called the Health of Women (HOW) Study

## Army of Women Health of Woman Study

Invitation sent out in escalating batches to current AOW population (262,047) between 12/8/09 and 12/28/09

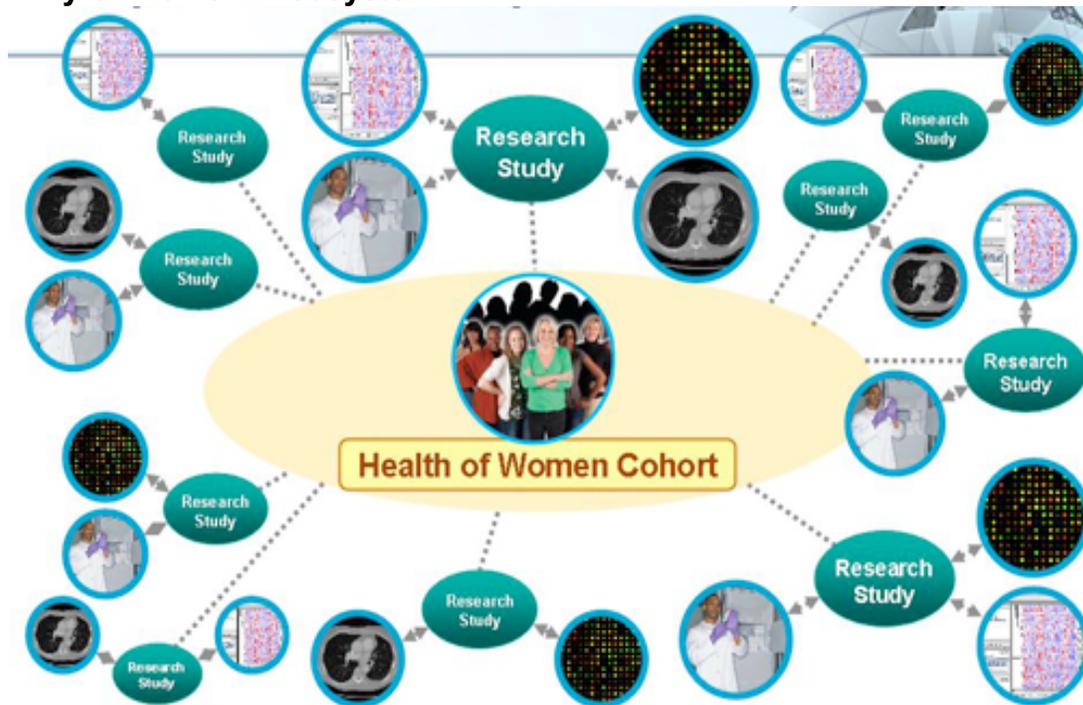
In response to this single e-mail invitation

- 30% viewed the invitation
- 57% who viewed the invitation clicked yes they were interested

By 2/11/10

- 28,032 users (62% of those who clicked yes)
- 25,162 have completed and submitted first module

## Army of Women “Ecosystem”



## **20th Century Research > Care Paradigm**

### **Discovery:**

- Biological pathways
- Target identification and validation

### **Product Development:**

- Candidate selection and Optimization
- Pre-clinical testing
- Phase I, II, III
- New Drug application and Approval

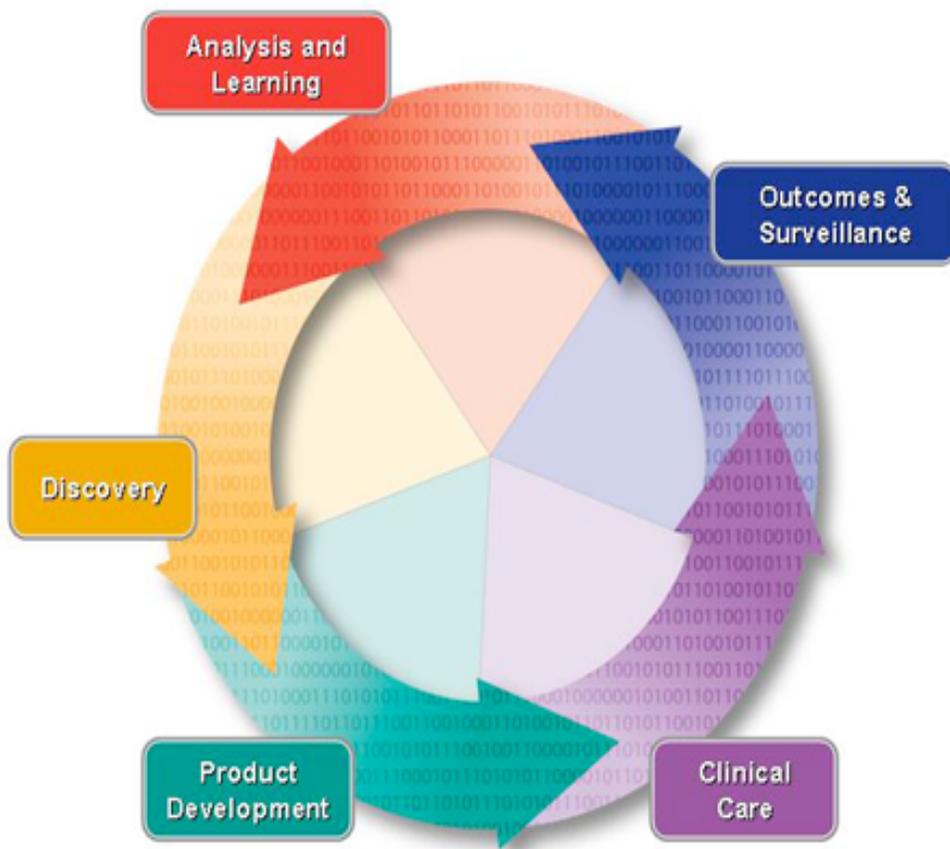
### **Clinical Care:**

- Product launch
- Clinical adoption

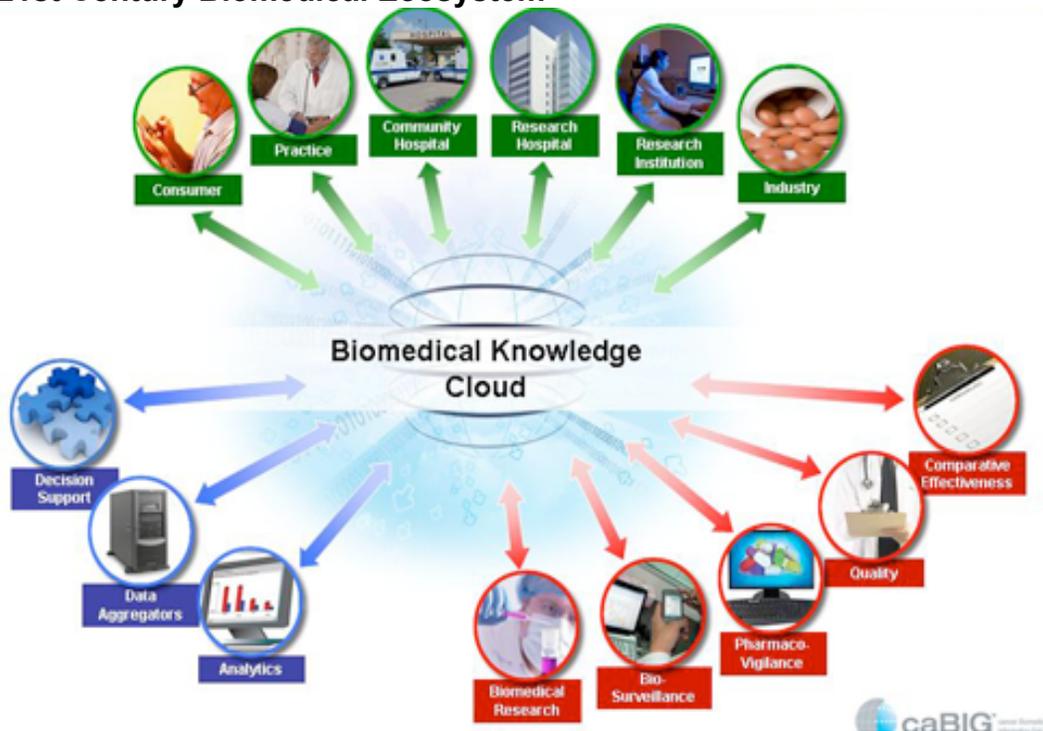
### **Outcomes and Surveillance:**

- Reporting of serious/fatal ADRs
- Re-labeling (or recall) as needed
- Additional indications as warranted

## 21<sup>st</sup> Century Learning Health System



## A 21st Century Biomedical Ecosystem



## Creating “Smart” Electronic Health Records

- NCI has partnered with **ASCO** and the **Cancer Community** to create Oncology-extended EHRs
- These EHRs will enable collection of cancer diagnostic and staging information, treatment plans, and patient outcomes in the care setting

## caEHR Wiki

The screenshot shows the 'caEHR Project Wiki Home Page' on the National Cancer Institute website. The page features a navigation bar with 'Home', 'About', 'Attachments (2)', 'Info', and 'Site Support'. Below the navigation bar, there is a 'Project Overview' section, a 'Core Working Group and Industry Inputs' section, and an 'EHR Vendor and Community Meetings' section. The 'Project Overview' section provides an overview of the NCI Cancer Electronic Health Record (caEHR) Project, detailing project deliverables, release schedules, and project milestones. The 'Core Working Group and Industry Inputs' section describes the Clinical Oncology Requirements for an EHR (CORE) project, which was undertaken by the American Society of Clinical Oncology (ASCO), the National Cancer Institute (NCI) Center for Biomedical Informatics and Information Technology, and the National Community Cancer Center Program (NCCCP) to specify the informatics needs of practicing oncologists. The 'EHR Vendor and Community Meetings' section lists several meetings, including the September 9, 2009 EHR Vendor teleconference meeting slides and the October 7, 2009 EHR Vendor meeting slides.

<http://wiki.nci.nih.gov/display/caEHR>

### Using EHRs to Facilitate Clinical Trials

Clinical Information from EHRs can be fed electronically into the electronic Clinical Report Form...

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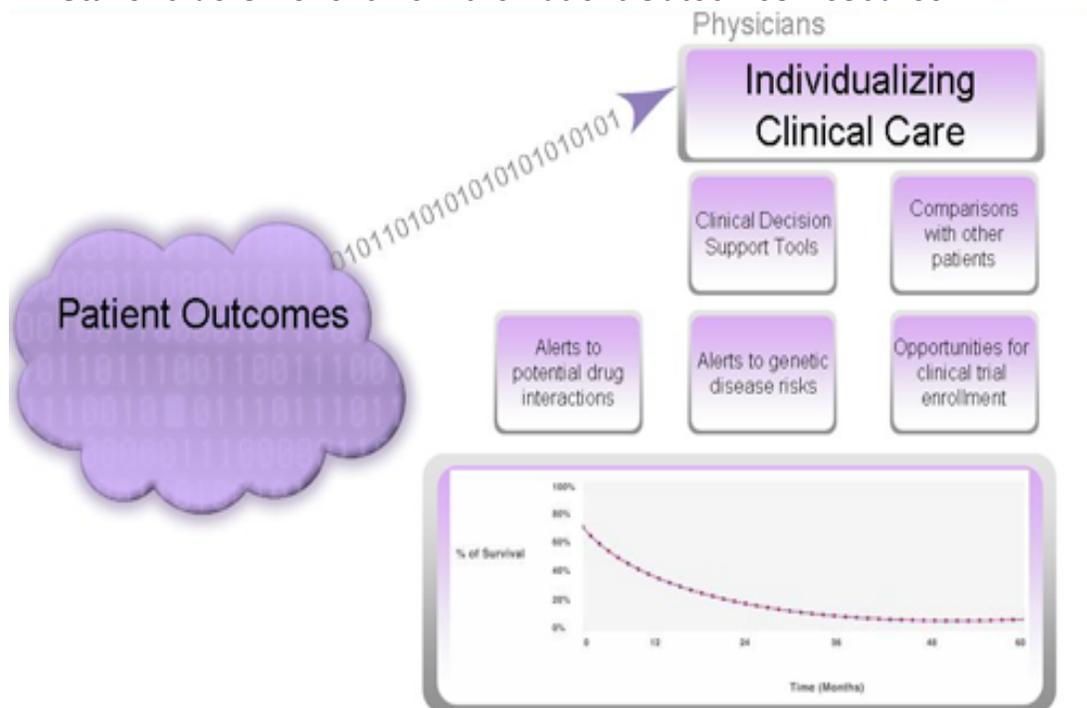
### Using EHRs to Empower Survivors

Clinical Information from EHRs can be fed electronically into the Personal Health Records

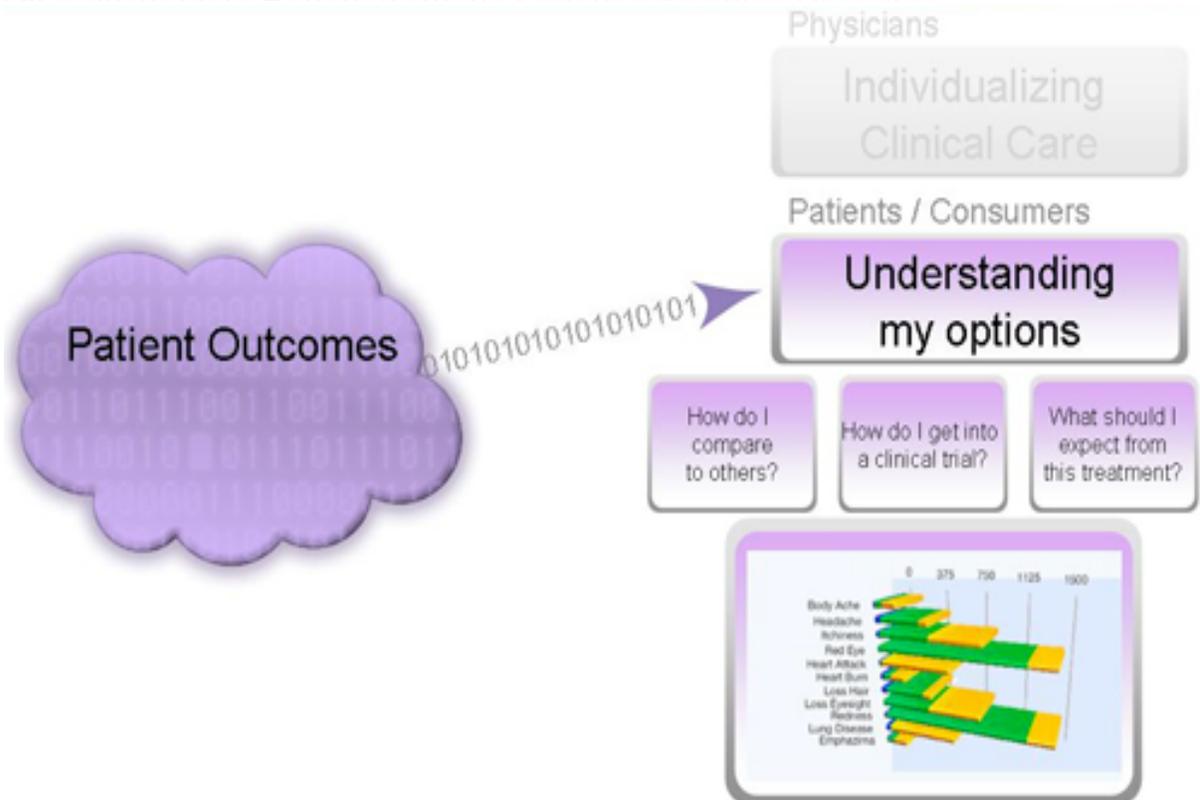
### Utilizing “Smart” EHRs to Create a Learning Health System

With **appropriate authorization**, data on patient encounters can be electronically fed into a Patient Outcomes Resource

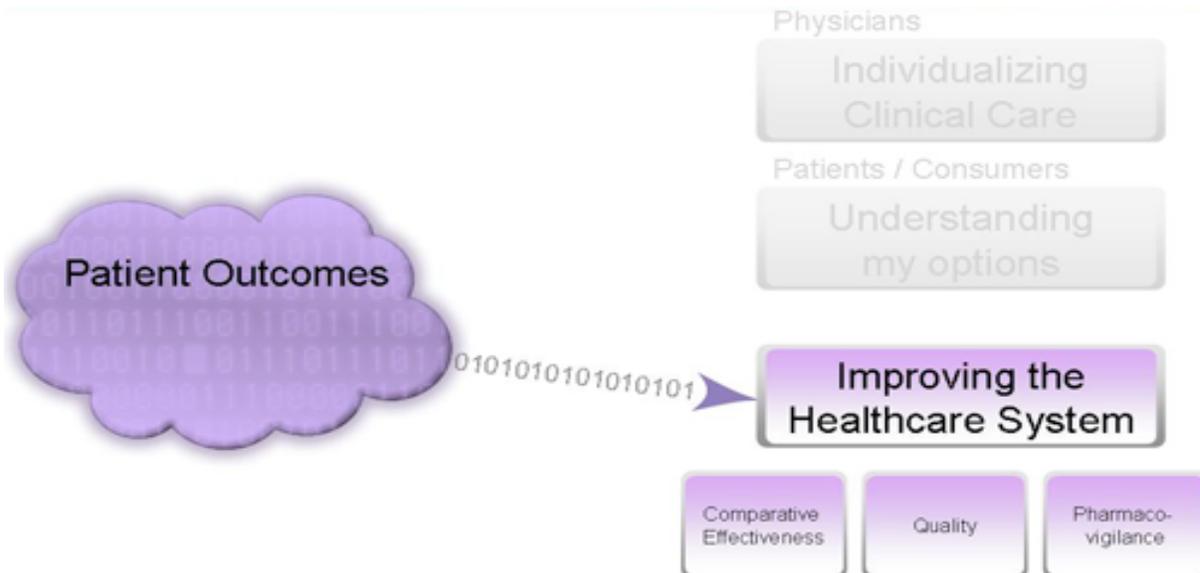
### All Stakeholders Benefit from the Patient Outcomes Resource



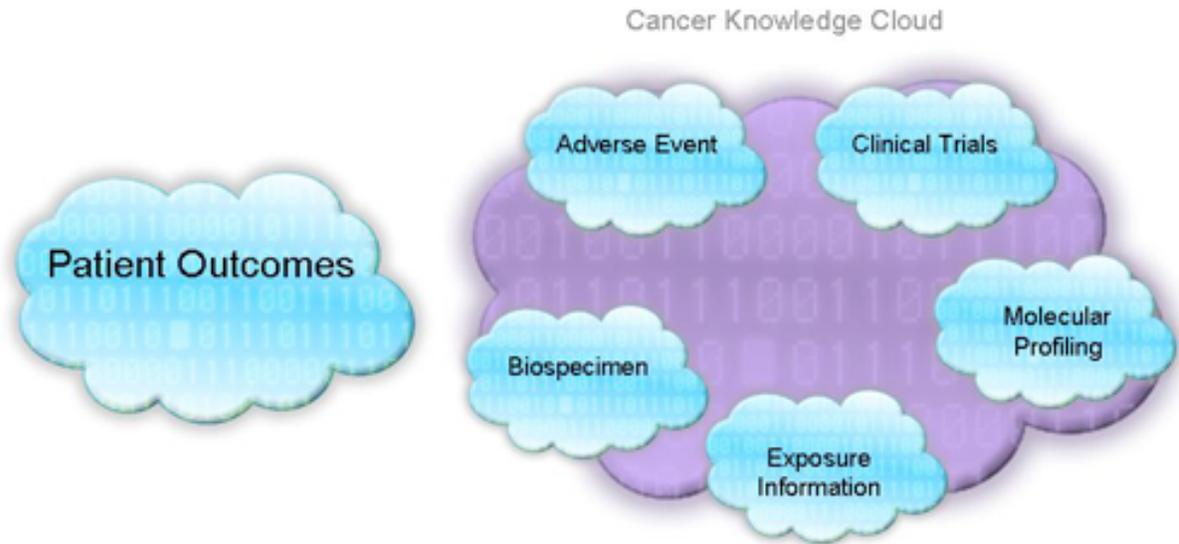
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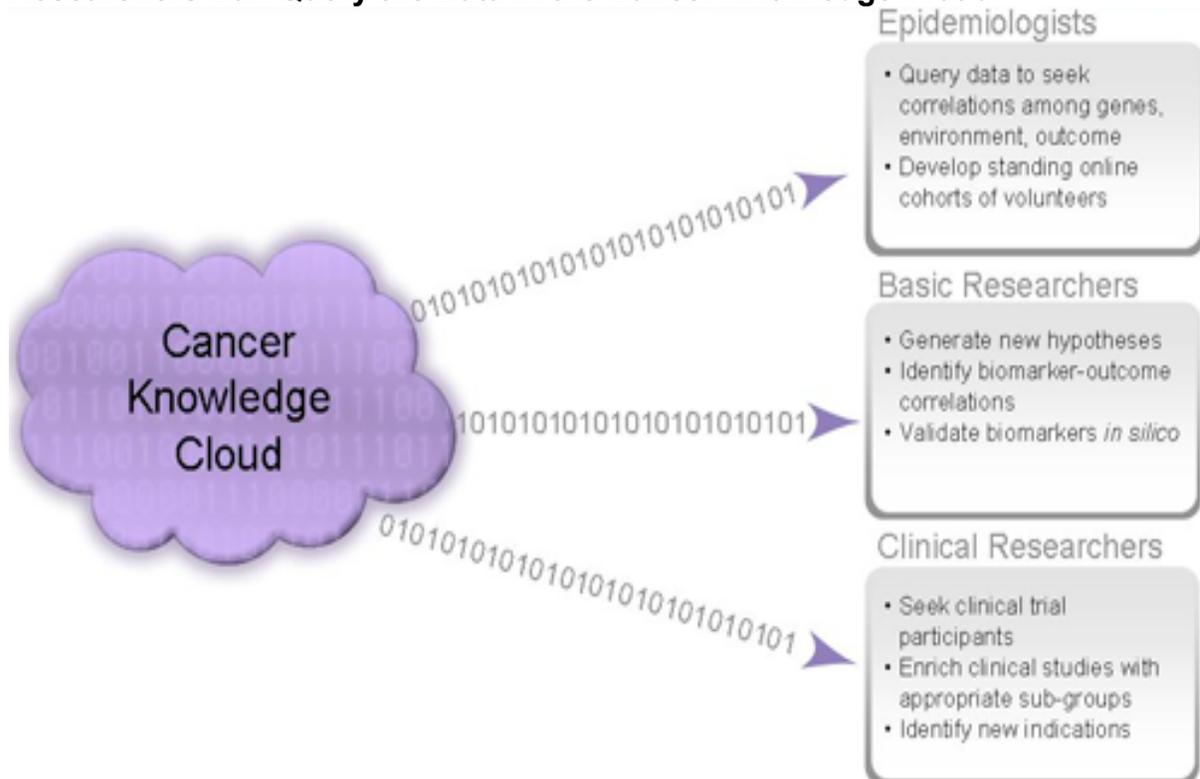
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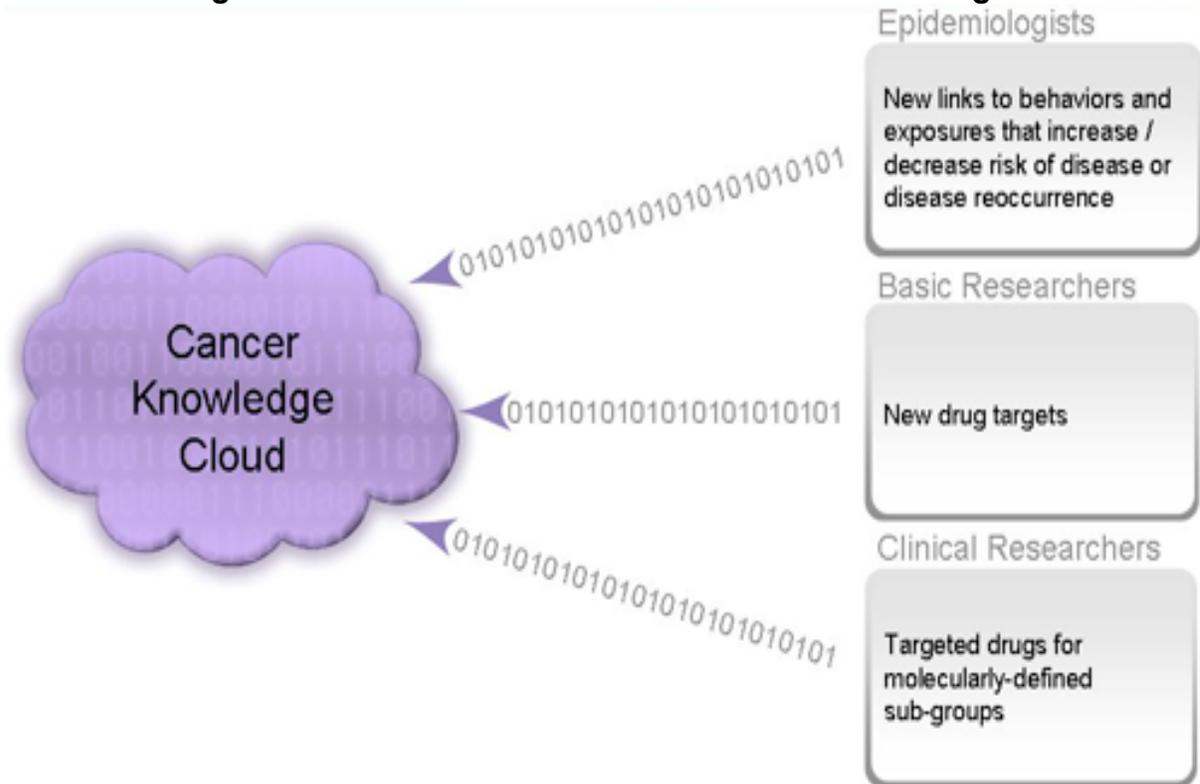
## The Patient Outcomes Resource is one of Many within the Biomedical Community



## Researchers Can Query the Data in the Cancer Knowledge Cloud



## New Knowledge From Research is Fed into the Cancer Knowledge Cloud



## Virtuous Circle From Smart EHRs Through Research and Back to Clinical Care (Rapid Learning Health System)



### **In Summary...**

- We're at a special moment when numerous trends in science, technology, demographics and sociology are converging.
- The digitalization of medicine is a national priority.
- The opportunity to attain personalized medicine – a natural outcome of the learning health care system – is currently slowed by the continued use of outmoded models for product development
- National Cancer Institute is pioneering a new ecosystem – enabled by its data interoperability platform – to drive collaborations and ensure the requisite information liquidity.

**For more information, please visit:**

<http://caBIG.cancer.gov>

<http://www.bighealthconsortium.org>