



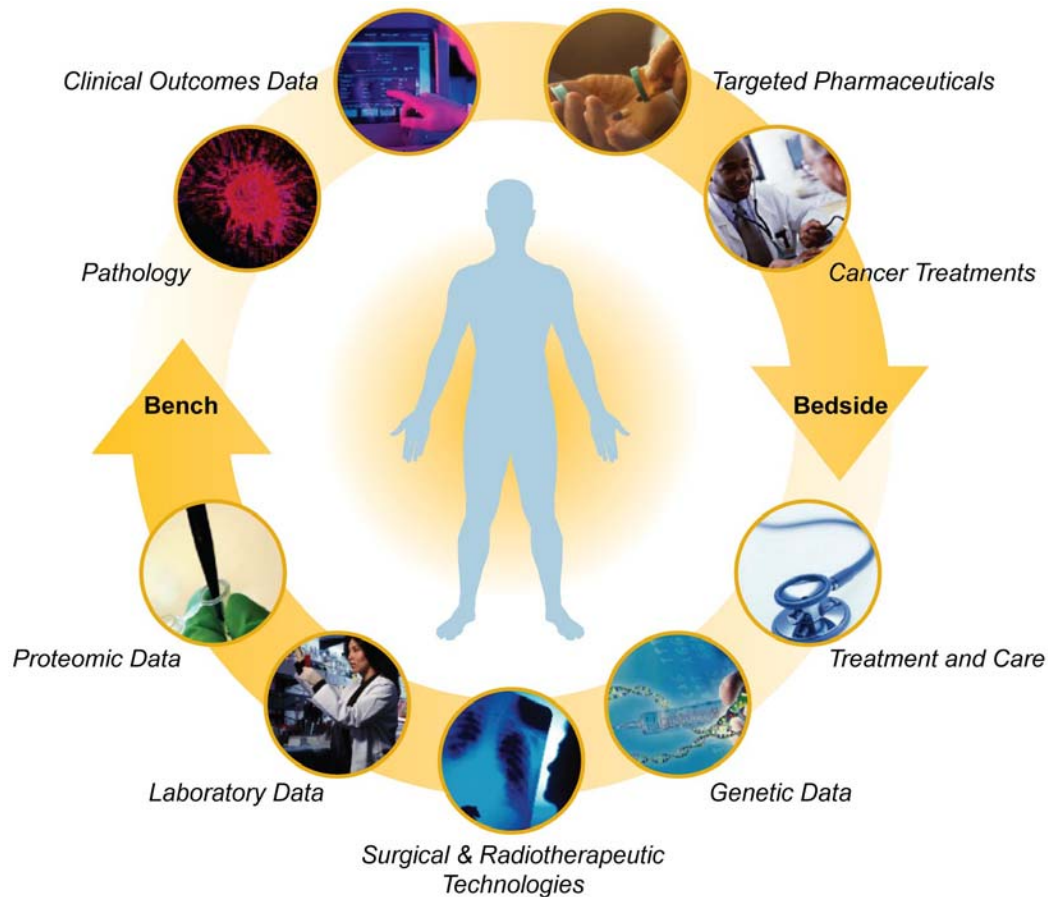
# The BIG Idea: Strategies to Achieve a Rapid-Learning Health System

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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**,

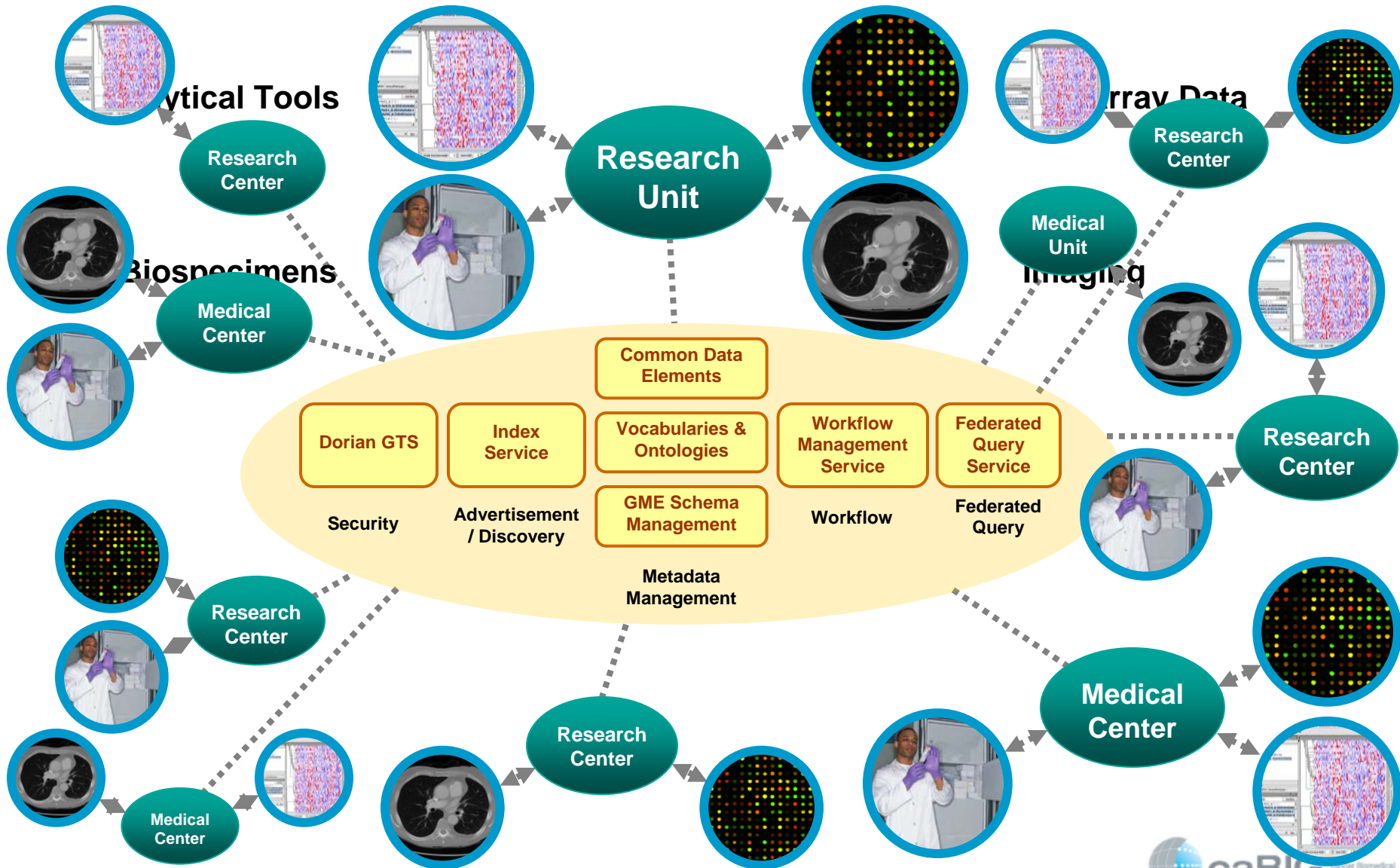
# caBIG<sup>®</sup>: Biomedical Information Highway



The cancer Biomedical Informatics Grid<sup>®</sup> (caBIG<sup>®</sup>) 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



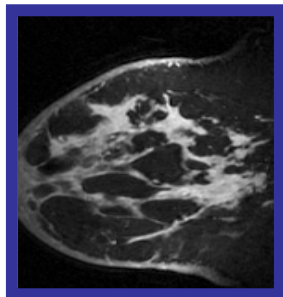
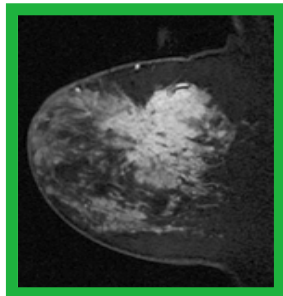
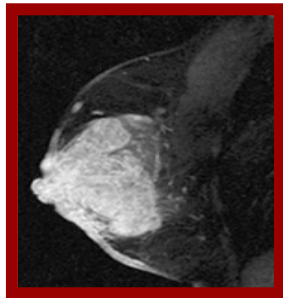
**The I-SPY trial (Investigation of  
Serial studies to Predict Your  
Therapeutic Response with  
Imaging And moLecular analysis):**

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

Specialized Programs of Excellence (SPOREs)

Cancer and Leukemia Group B (CALGB)

American College of Radiology Imaging Network (ACRIN)

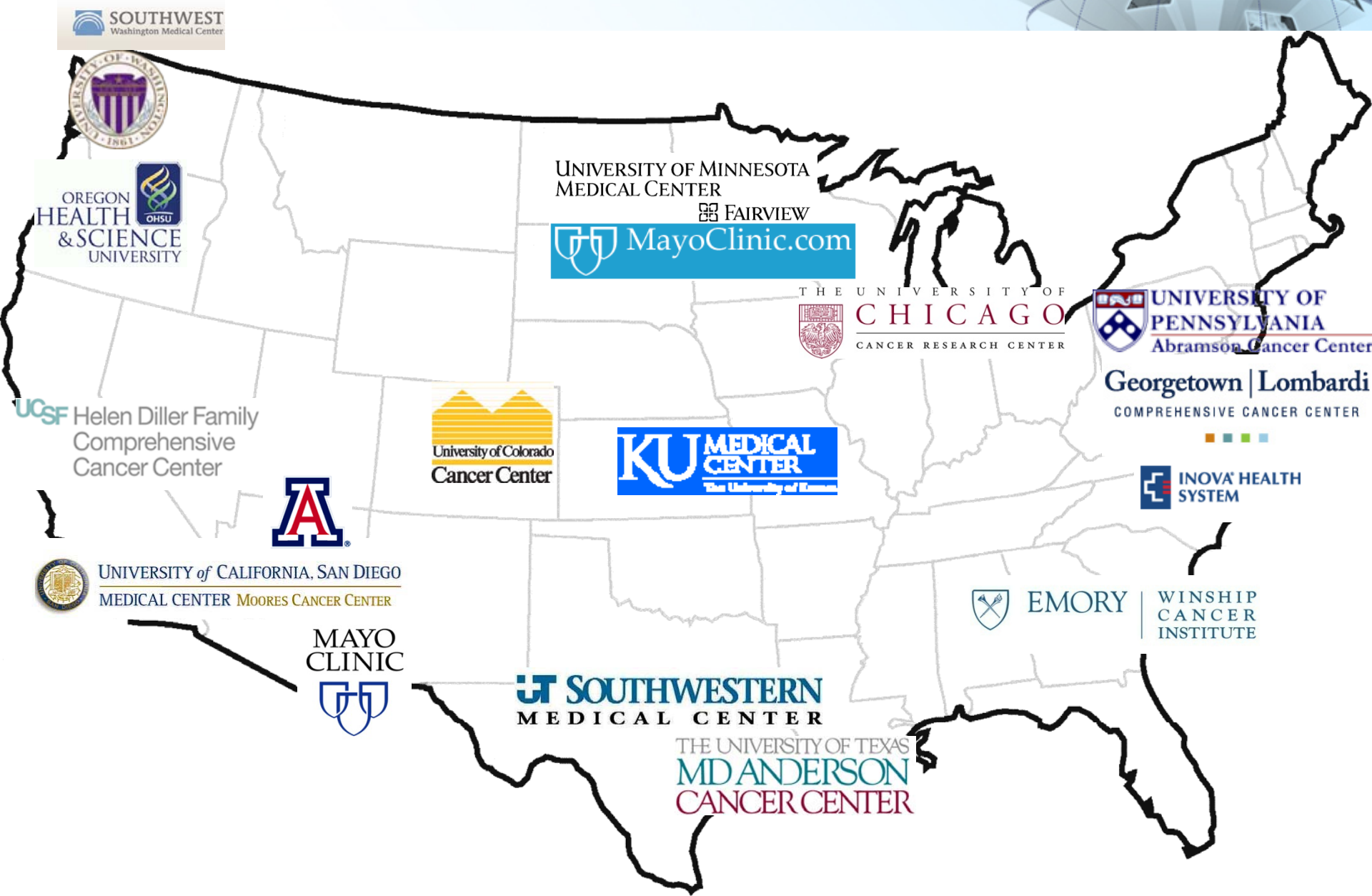
University of California at San Francisco (UCSF)

## Multiple Data Types

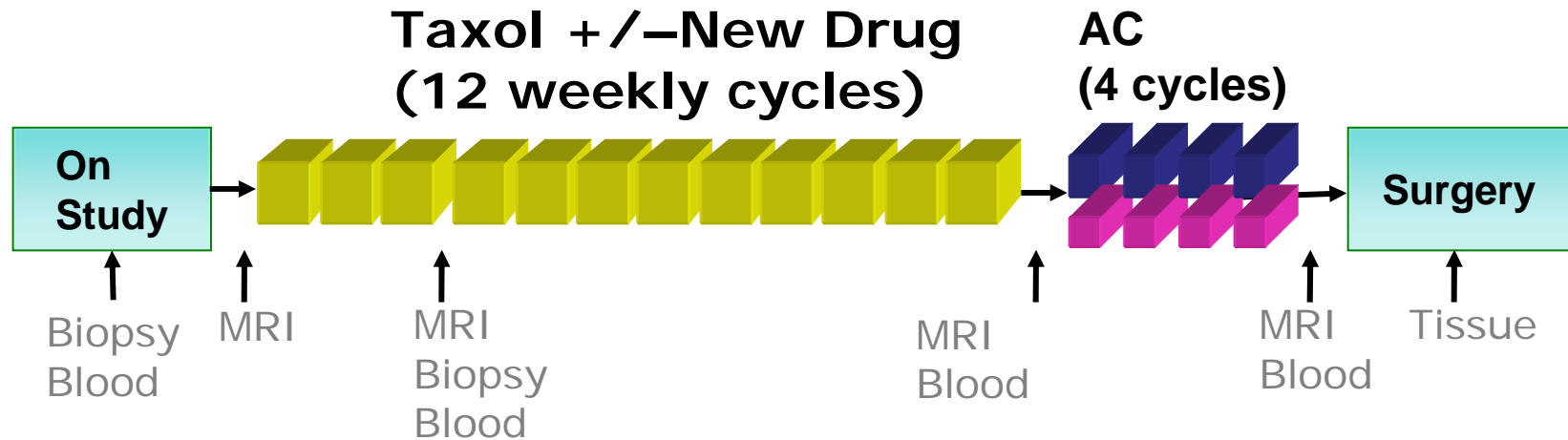
- Clinical diagnosis
- Treatment history
- Histologic diagnosis
- Pathologic status
- Tissue anatomic site
- Surgical history
- Gene expression
- Chromosomal copy number
- Loss of heterozygosity
- Methylation patterns
- miRNA expression
- DNA sequence



# Projected I-SPY 2 study sites



# I-SPY Adaptive Trial Outline

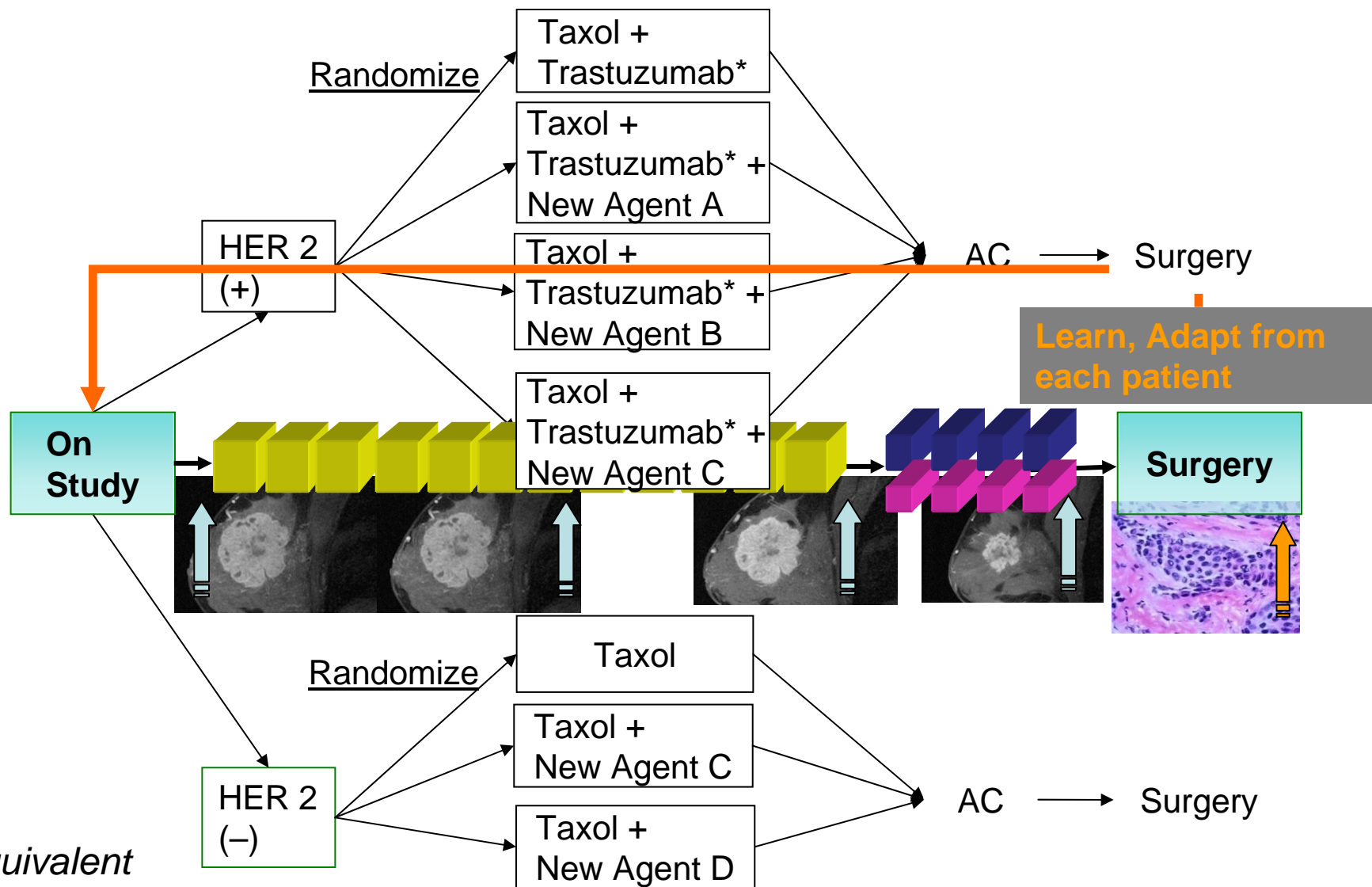


Accrual: Anticipate 800 patients over 3–4 years

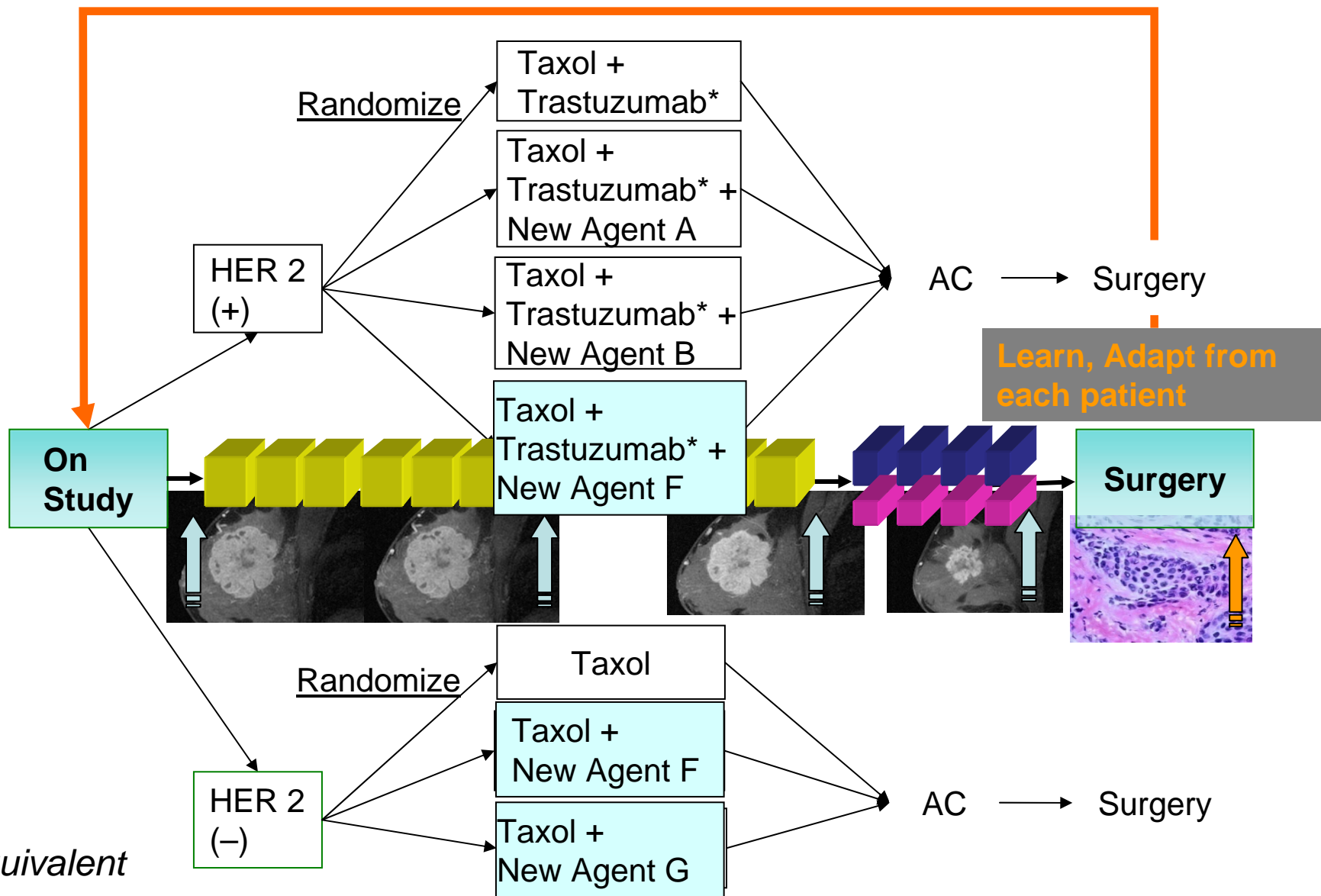
Enroll ~20 patients per month

Participating Sites: 15–20 across US and Canada

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

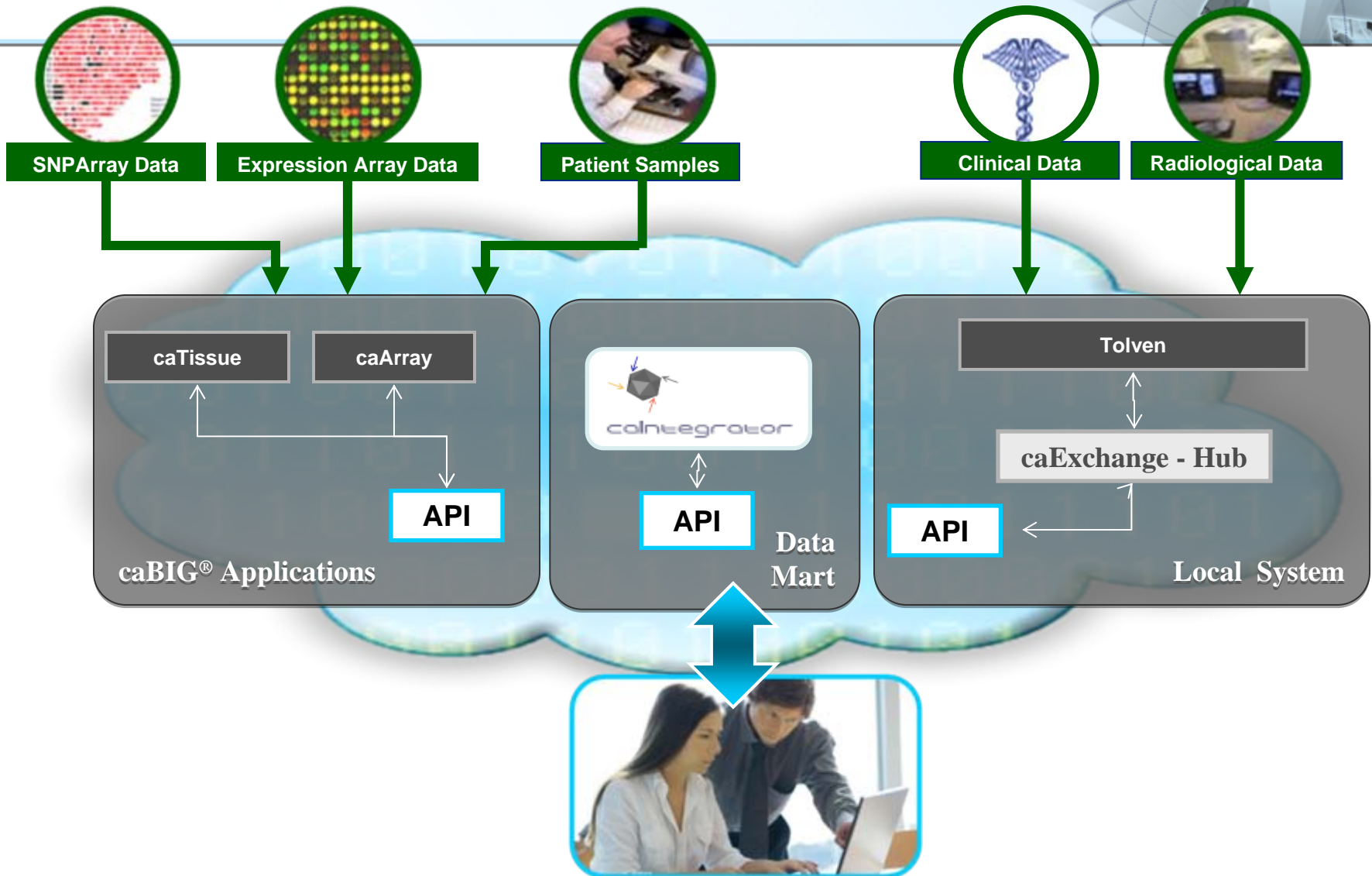


# I-SPY Adaptive Trial: Introduce several new agents for a given profile



\*Or Equivalent

# I-SPY Trial IT Infrastructure





# Redefining Cancer at a Molecular Level



National Cancer Institute National Human Genome Research Institute

THE CANCER GENOME ATLAS

Sign up for updates

Search  GO

About TCGA What We Do Publications News Center Launch Data Portal

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 >

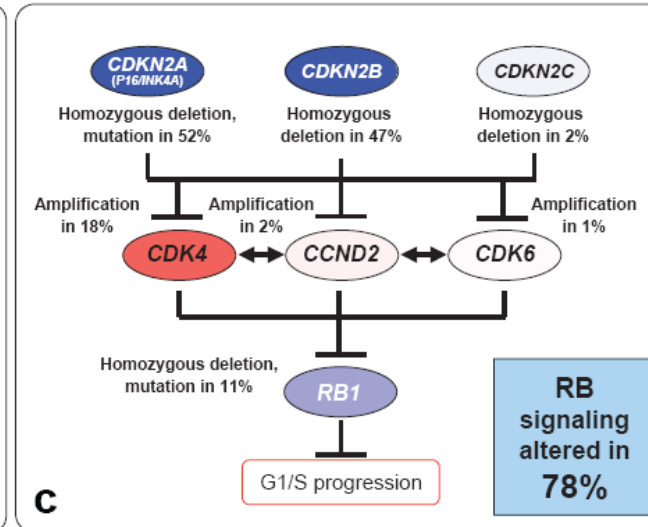
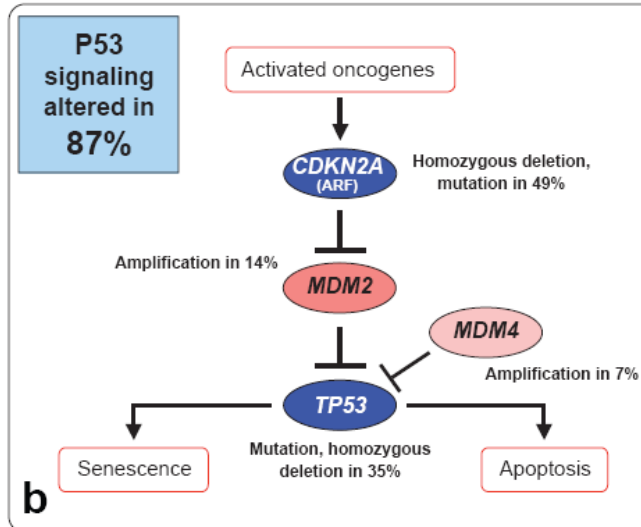
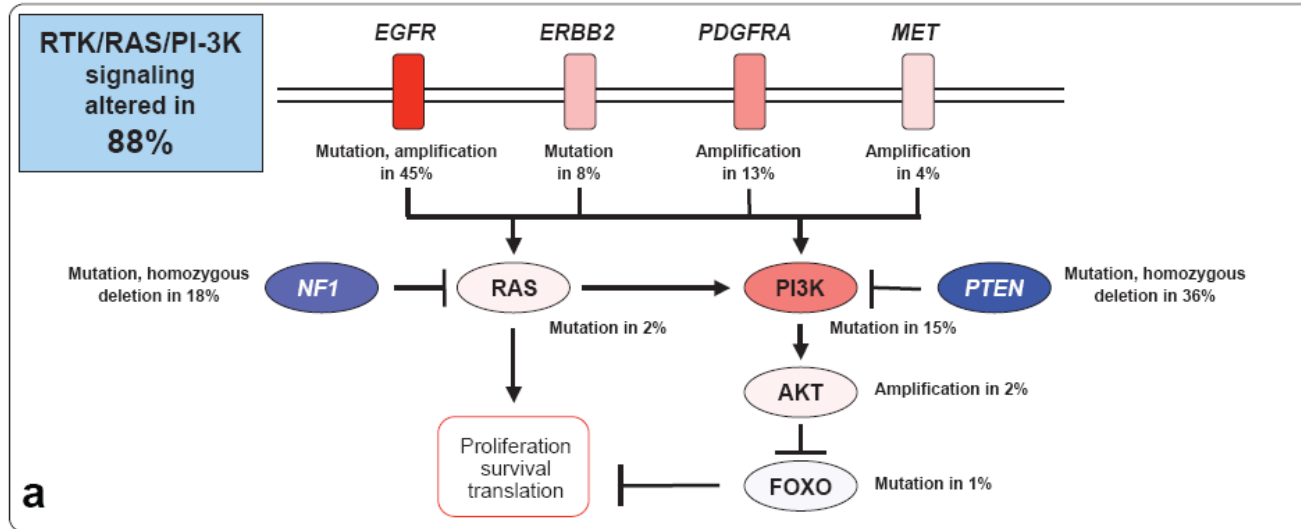
TCGA Expanding  
to Study 20 or  
More Cancers

Learn More

TCGA Data Portal

Access TCGA Data Portal

# GBM Results: Pathways



# 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

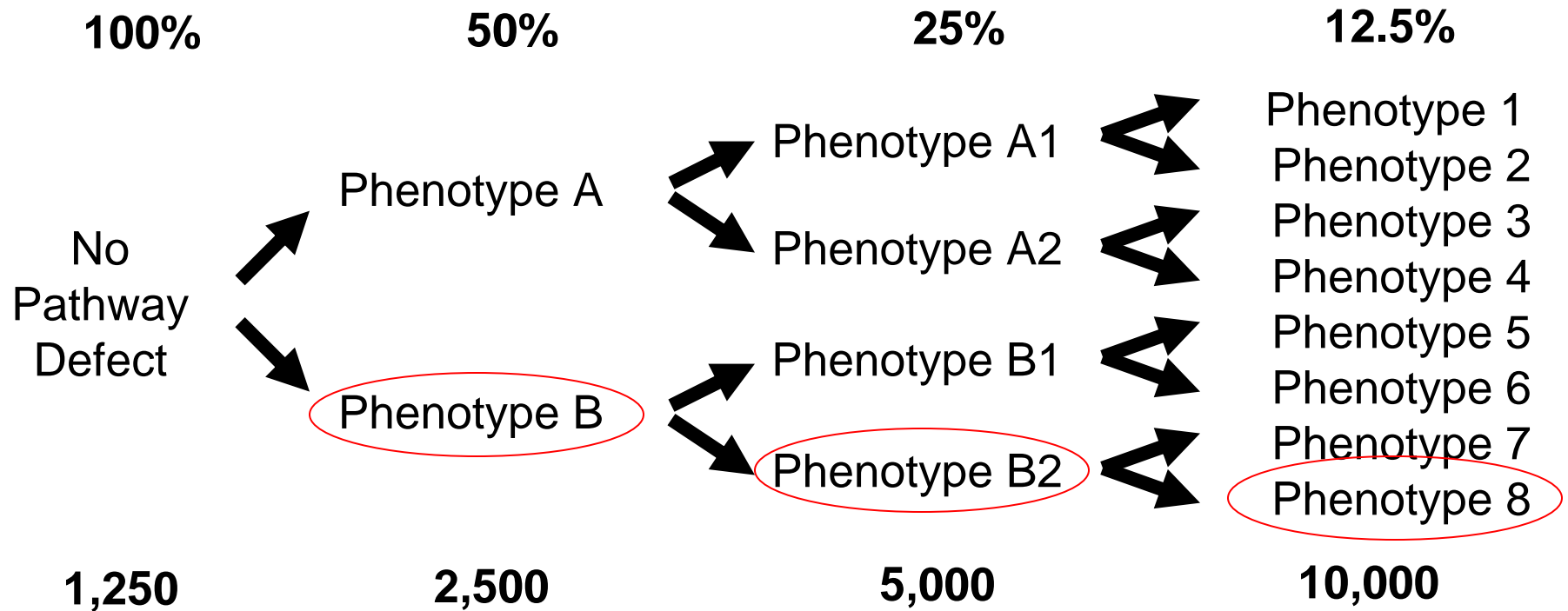
\* *Need a obtain a suitable specimen, wait for test results. (Results were obtained in days to weeks)*

\* *Need to screen many patients.*

# Size of Population with Pathway to Inhibit\*



## Population fraction containing signature



## Size of Population Needed To Screen

Courtesy H. Kim Lyerly, M.D., Director



**“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*<sup>™</sup>



## Vision:

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

## Mission:

The BIG Health Consortium<sup>™</sup> 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

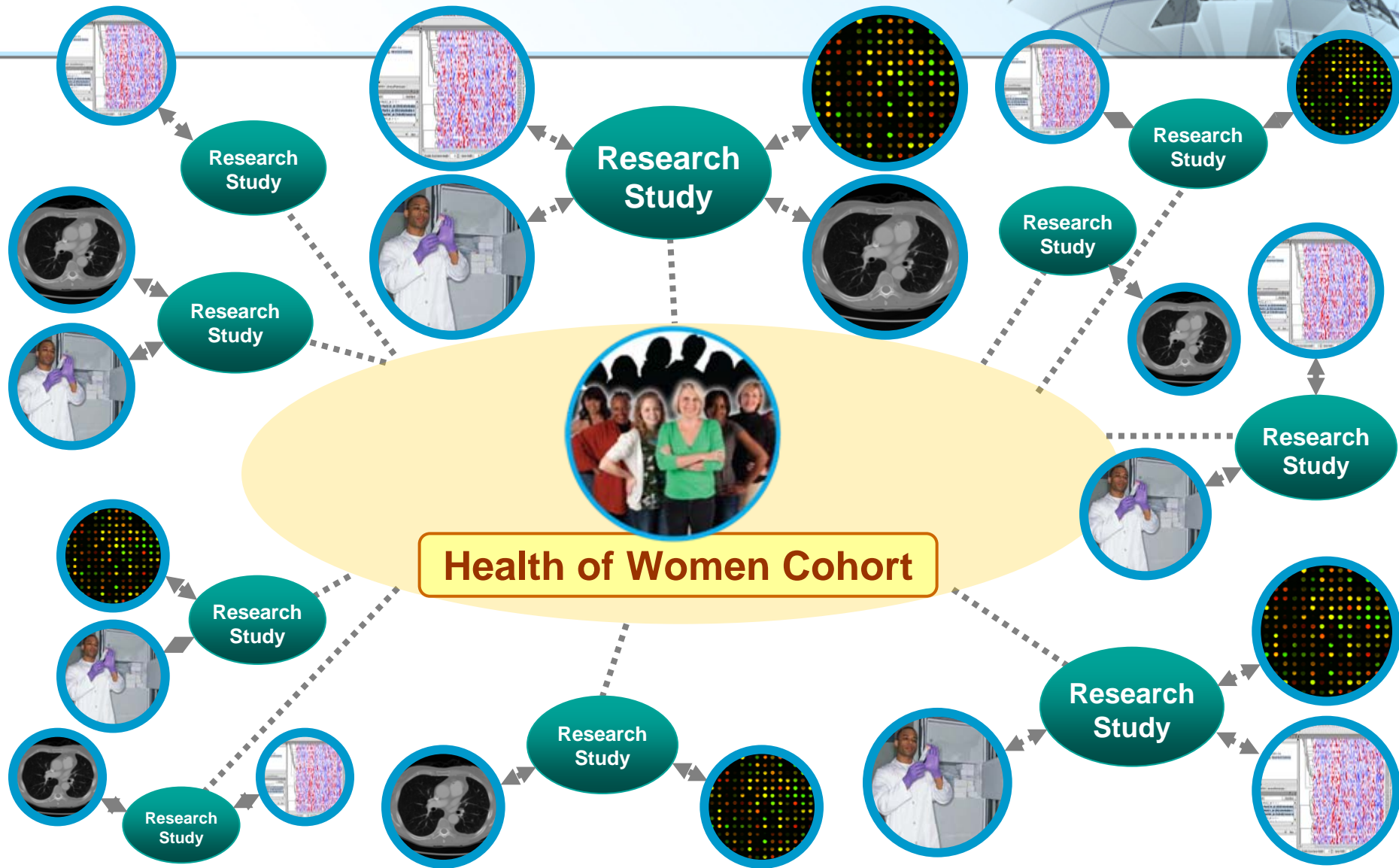
In response to this **single e-mail** invitation

- 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"



# 20<sup>th</sup> 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

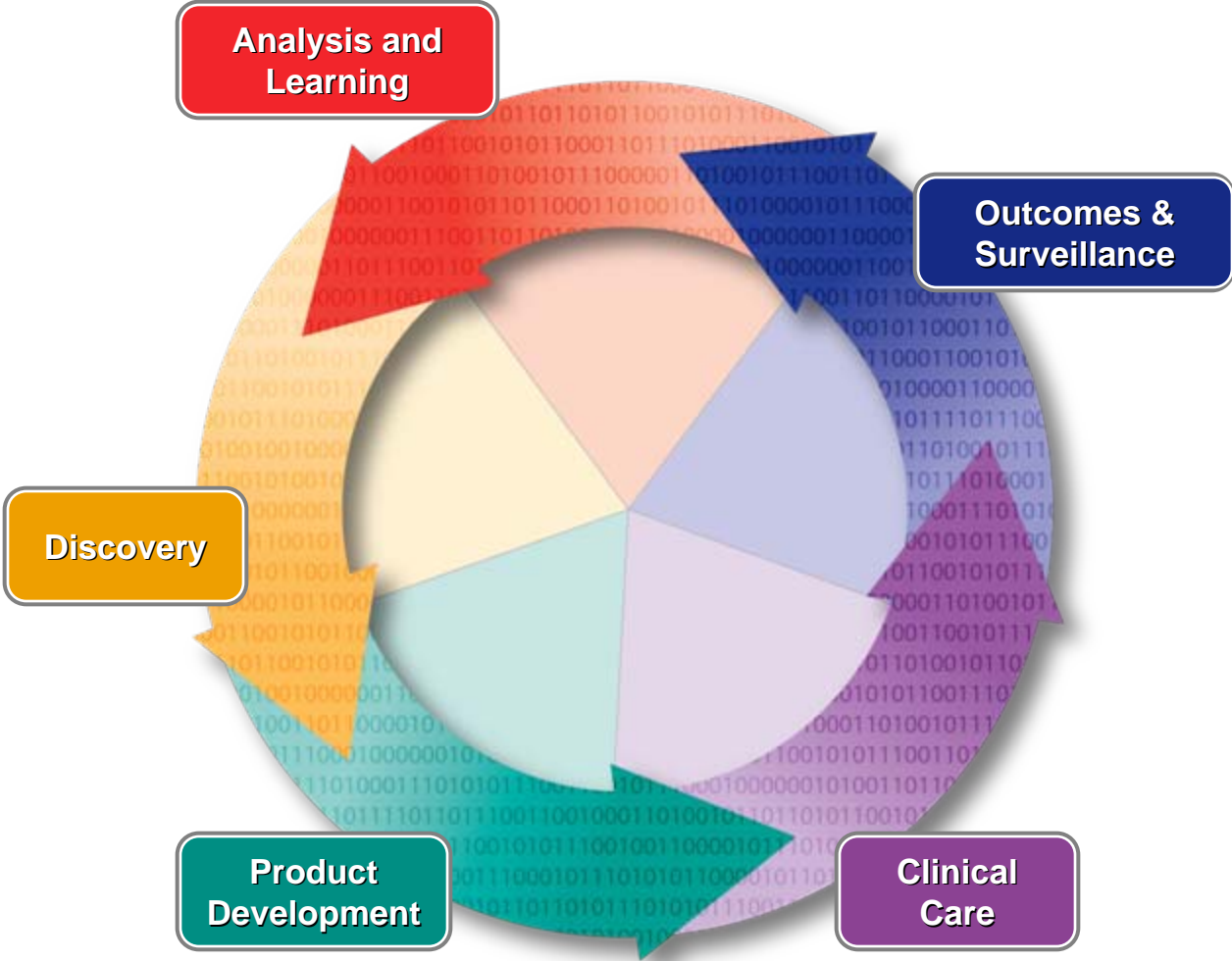
- Product launch
- Clinical adoption

## Outcomes & Surveillance

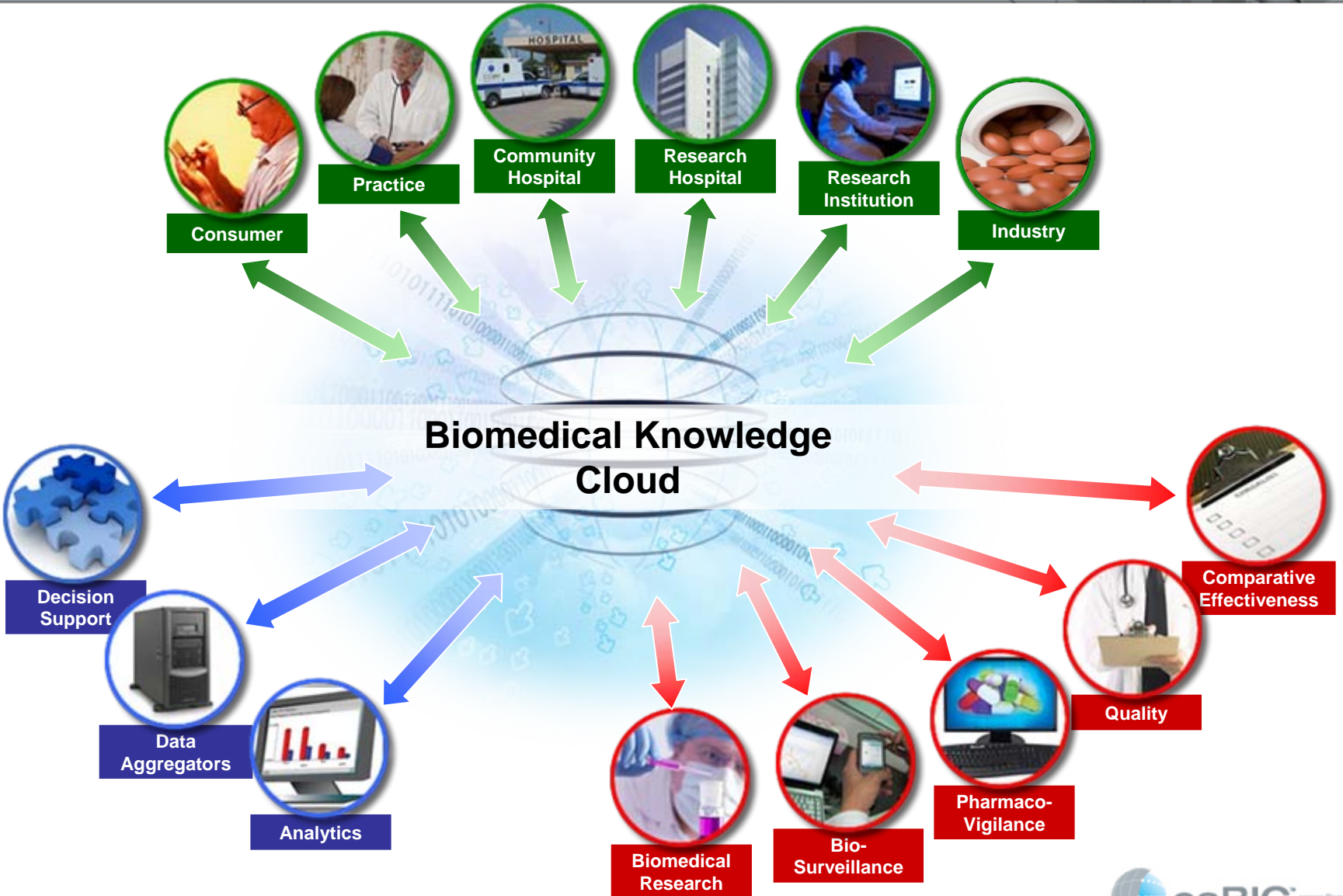
- Reporting of serious/fatal ADRs
- Re-labeling (or recall) as needed
- Additional indications as warranted



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



# A 21<sup>st</sup> 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

Oncology-extended EHR



Client Pockets

Client ID: SP043477F0 Name: SALLY PARKER DOB: 04/04/1977 AGE: 31  
History: SP043477F0 - SALLY PAR... Show closed registrations:   
SSNs: 395-98-3659 Phone: -

Enrollment Date: Sep 17, 2008 Open

- Full Enrollment - 09/17/2008 07:37:00
- Client Status
- Client Program
- Agency PIP
- Comp. Assessment Part A (02/01/05)
- Comp. Assessment Part B and C (02/01/05)
- Comp. Assessment Part D
- Treatment Plan
- Consent - Report Grid
- Magellan Demographic
- Magellan Assessment (09/01/07)
- Magellan Assessment (09/01/07)
- Magellan Intake
- UJSTest
- UJL Psych Evaluation

Chemotherapy drugs

### Registration

Registration Date: 09/17/2008 Closed:   
 Crisis Registration:  
Referral Date: 09/17/2008 VALUEOPTIONS  
RBHA: 05 MARICOPA RBHA

Category	Value	As Of Date
Managing	JLL JONES, MSW	09/17/08 08:00
Outpatient	2 Agency office - 2	09/17/08 08:00
Diagnosis	295.01 ALCOHOLIC WITHDRAWAL	09/17/08 08:00
Program	Standard Intake - In Sub	09/17/08 08:00
Over Primary	UNITED BEHAVIORAL HEALTH	02/01/09 08:00

Edit Save Cancel

Standard (By Form) (By Category) Current

New Registration Interim Assessment Closure New Progress Note Hide Notes Referral  
New Packet Print Labels Review Notes Cancel





Added by [Ann Wiley](#), last edited by [Ann Wiley](#) on Feb 09, 2010 ([view change](#))  
Labels: [EDIT](#)

#### Contents

- [EHR Vendor and Community Meetings](#)
- [Project Overview](#)
- [Core Working Group and Industry Inputs](#)
- [Architecture Work Stream](#)
- [Analysis Work Stream](#)
- [Information Modeling Work Stream](#)

## EHR Vendor and Community Meetings

The September 9, 2009 EHR Vendor teleconference meeting slides can be found [here](#).

The October 7, 2009 EHR Vendor meeting slides are posted [here](#).

## Project Overview

This site provides an overview of the National Cancer Institute's (NCI) Cancer Electronic Health Record (caEHR) Project. The site will detail project deliverables as they evolve, release schedules and project milestones throughout the life-cycle of this project. Currently the site details specific work stream artifacts as well as engagements with the EHR vendor communities and the critical role the Clinical Oncology Requirements for an EHR (CORE) working group has played in the development and refinement of Ambulatory Oncology EHR requirements.

The project will utilize an iterative development of releases of services-based, modular EHR capabilities for the oncology sector that may be implemented directly or adapted by vendors into existing products. The project will demonstrate appropriate software engineering practices and position for effective integration of oncology sites into the broader oncology eco-system in an attempt to move us closer to effective bench-to-bedside-and-back cancer care.

Please provide any comments concerning the artifacts or items as presented on this site to the following mail address: [NCIcaEHR@mail.nih.gov](mailto:NCIcaEHR@mail.nih.gov)

## Core Working Group and Industry Inputs

The Clinical Oncology Requirements for the EHR (CORE) project 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.

### Clinical Oncology Requirements for an EHR (CORE)

The functional requirements work group considered the information collection, decision support, and reporting needs of the oncologist providing patient-focused care in a clinical setting. Using an iterative, consensus-based process, the group outlined the key types of data and functions oncologists need to support four categories of functionality

CORE high level specifications can be found [here](#).

<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...

Smart EHR

Category	Value	As Of Date
Managing	JILL JONES, MSW	09/17/08 00:00
Outpatient	2 Agency office: 2	09/17/08 00:00
Degrees	2W1 B1 ALCOHOLIC WITHDRAWAL Program	09/17/08 00:00
Qual: Primary	UNITED BEHAVIORAL HEALTH	02/01/09 00:00

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eCRF

Original Form	Field/Question/Section	Data Element/Code Value Domain	Action	Status	Comments
PLAS CONTACT	What is the source of the site contact information?	Medical Record, Participant, Family, Site Physician, CRA, Cancer Register, Outcome Physician/Outpatient	Optional (optional)	Completed	This has an enumerated list of values (SDV) to be included in the value domain of the CDE.
AC/RNAGE F1	Date of last contact	Optional (optional)	Optional (optional)	Completed	
CONSENSU F1	Site has an enumerated list of values (SDV) to be included in the value domain of the CDE.	Optional (optional)	Optional (optional)	Completed	
TOPIC Status	What is the topic status?	Participant's vital Status	Optional (optional)	Completed	Should be reviewed by "Participant's vital Status"
VITAL Status	What is the vital status?	Participant's vital Status	Optional (optional)	Completed	



# Using EHRs to Empower Survivors



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

Smart EHR

Personal Health Record

Category	Value	All Dates
Management	ALL JONES, VISA	08/11/08 00:00
Staffwork	2 Agency other	08/11/08 00:00
Progress	291.81 ALCOHOL WITHDRAWAL	08/11/08 00:00
Program	Standard Intake - No Sub	08/11/08 00:00
Star Priority	UNITED BEHAVIORAL HEALTH	08/11/08 00:00

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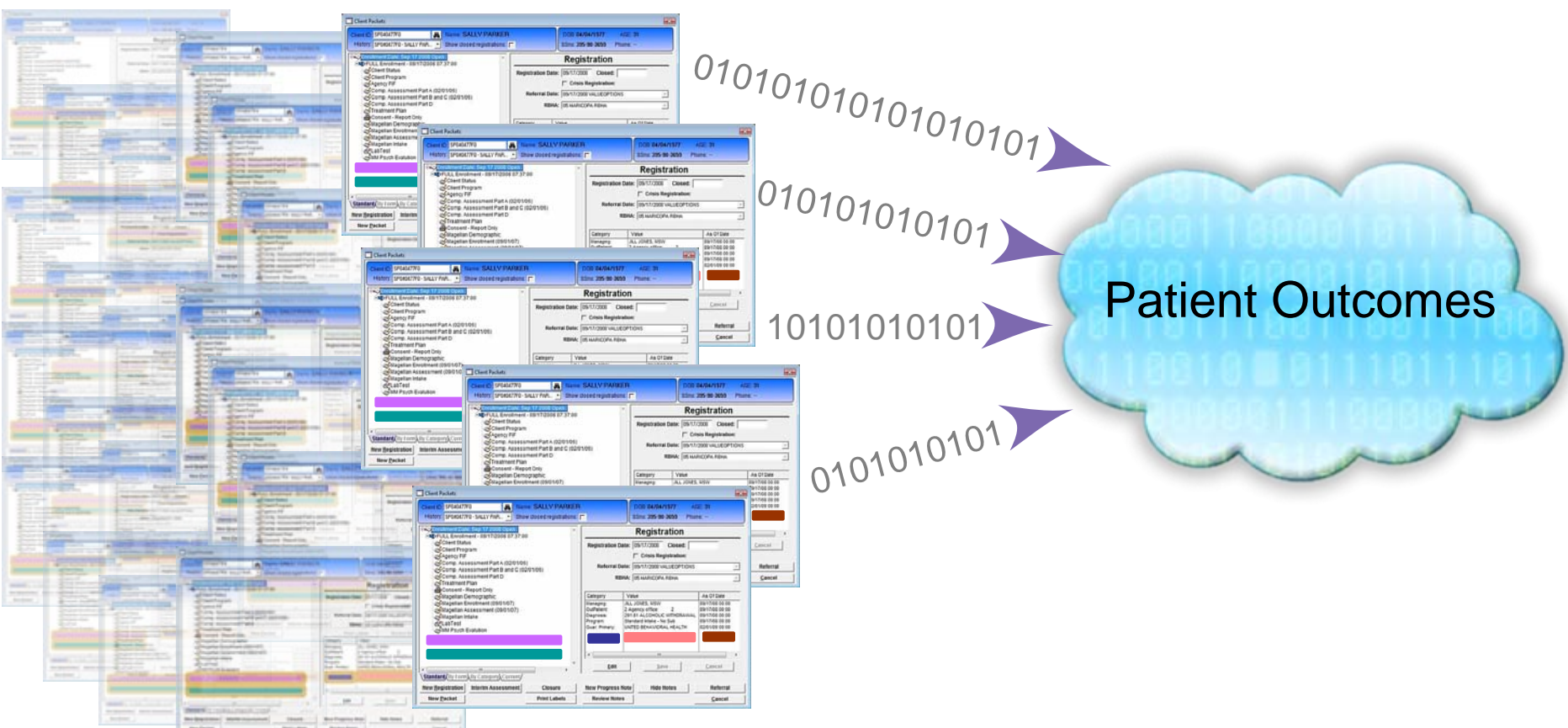
Ken's health information

- Conditions: Allergy, Condition
- Measurements: Blood Glucose Measurement, Blood Pressure Measurement, Height Measurement, Lab Test Results, Peak Flow Measurement, Weight Measurement
- Files: Continuity of Care Document (CCD), Continuity of Care Record (CCR), Documents (File)
- Actions: Add a new item, Upload a file, View all, Export information
- Contacts: Ken has no contacts.

# 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



Patient Outcomes

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Physicians

Individualizing Clinical Care

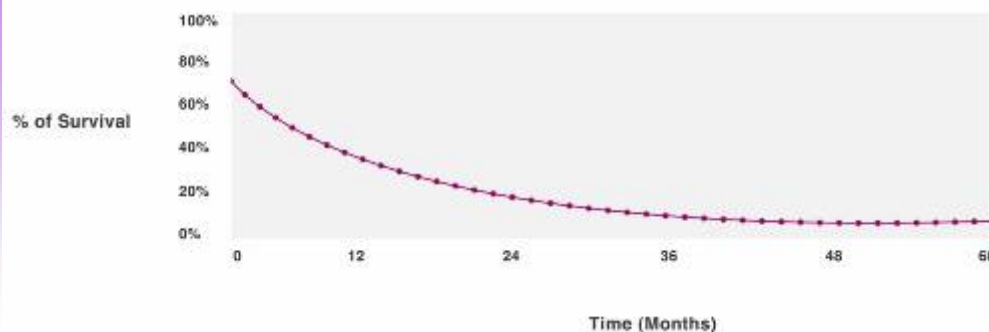
Clinical Decision Support Tools

Comparisons with other patients

Alerts to potential drug interactions

Alerts to genetic disease risks

Opportunities for clinical trial enrollment



# All Stakeholders Benefit from the Patient Outcomes Resource



Patient Outcomes

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Physicians

Individualizing  
Clinical Care

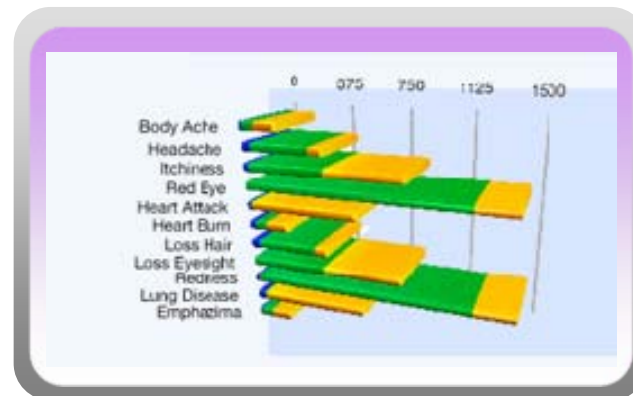
Patients / Consumers

Understanding  
my options

How do I  
compare  
to others?

How do I get into  
a clinical trial?

What should I  
expect from  
this treatment?



# All Stakeholders Benefit from the Patient Outcomes Resource



Patient Outcomes

Physicians

Individualizing  
Clinical Care

Patients / Consumers

Understanding  
my options

Improving the  
Healthcare System

Comparative  
Effectiveness

Quality

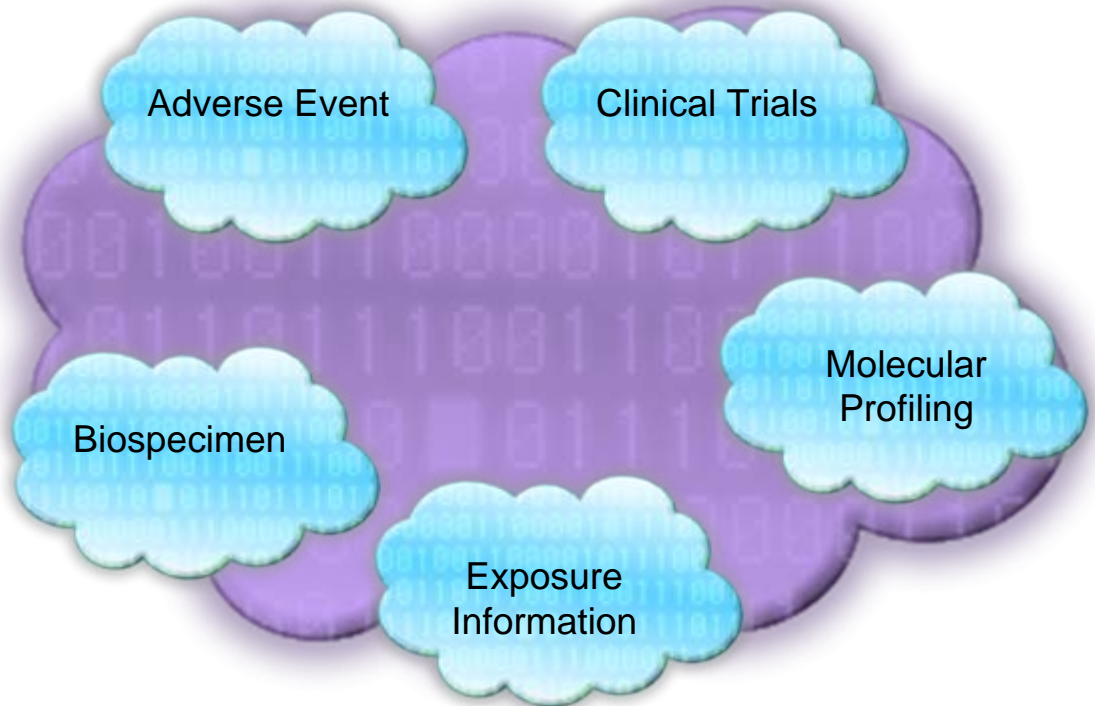
Pharmaco-  
vigilance



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



## Cancer Knowledge Cloud



# Researchers Can Query the Data in the Cancer Knowledge Cloud



Cancer  
Knowledge  
Cloud

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## Epidemiologists

- Query data to seek correlations among genes, environment, outcome
- Develop standing online cohorts of volunteers

## Basic Researchers

- Generate new hypotheses
- Identify biomarker-outcome correlations
- Validate biomarkers *in silico*

## Clinical Researchers

- Seek clinical trial participants
- Enrich clinical studies with appropriate sub-groups
- Identify new indications

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



Cancer  
Knowledge  
Cloud

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## Epidemiologists

New links to behaviors and exposures that increase / decrease risk of disease or disease reoccurrence

## Basic Researchers

New drug targets

## Clinical Researchers

Targeted drugs for molecularly-defined sub-groups

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



“Smart” EHRs



Cancer  
Knowledge  
Cloud



Researchers

# 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.





**caBIG™**  
cancer Biomedical  
Informatics Grid™

**For more information,  
please visit:**

<http://caBIG.cancer.gov>

<http://www.bighealthconsortium.org>

