

.....

# National Cancer II



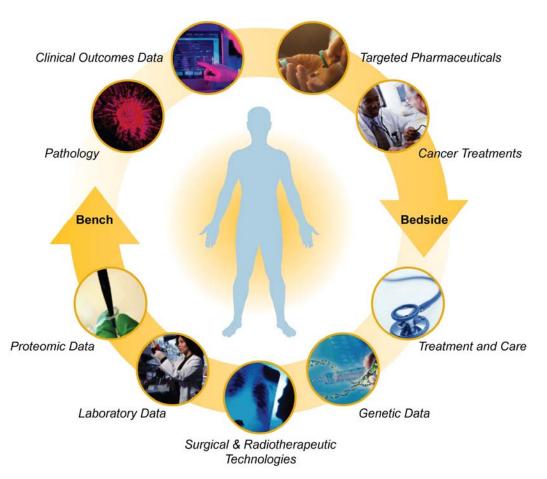
# Personalized Medicine and Digital Health Networks in Cancer Research and Clinical Care

Ken Buetow, Ph.D. Director, Center for Biomedical Informatics and Information Technology National Cancer Institute

> AMIA Joint Summits on Translational Science March 9, 2011

# 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 <u>Learning Health</u> System,



## **Redefining Cancer at a Molecular Level**







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. Cancer Bulletin Profile: Meet Dr. Raju Kucherlapati



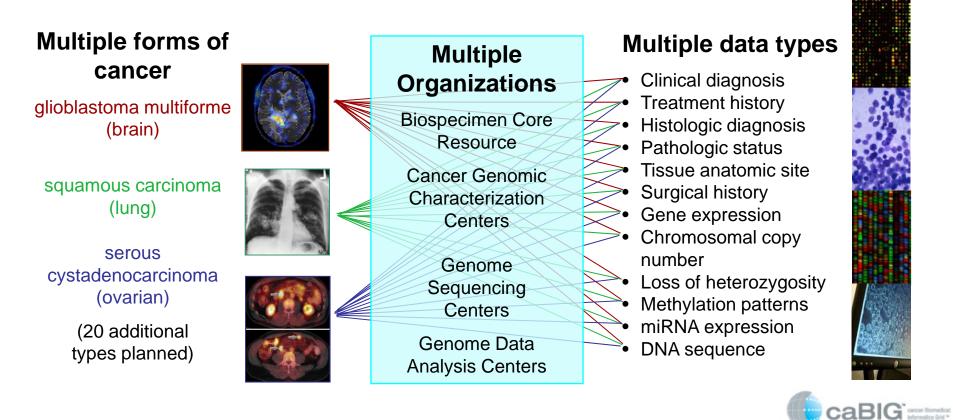


**NEW\* In Tough Economic Times, NIH Head Looks to Clinic** NIH Director, Francis Collins, discusses his plans for NIH and how programs like TCGA will bring different approaches to cancer treatments. <u>Read more</u>.





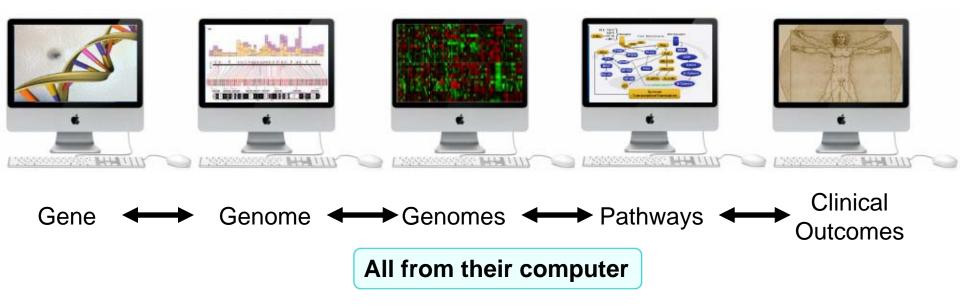
## Enabling a rich, molecular definition of Cancer





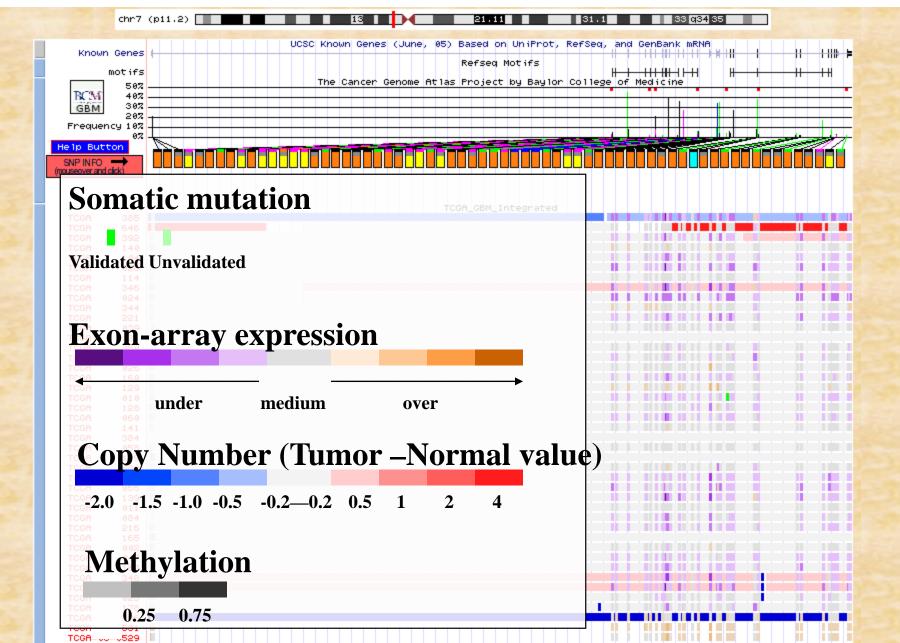


## Integrating complex, multidimensional molecular data

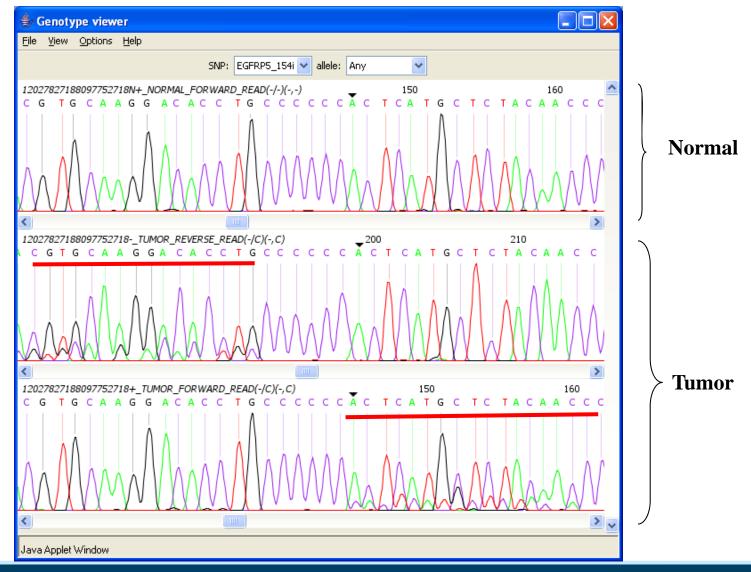




## **Comprehensive Genomic Summary**



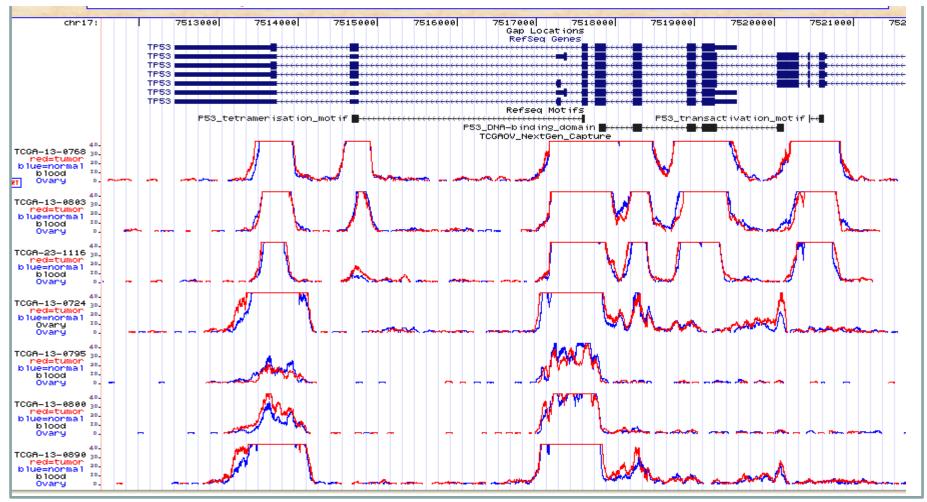
## Putative Somatic Mutations can be Manually Reviewed Eg: Frameshift Mutation in EGFR in Paired Tumor/Normal



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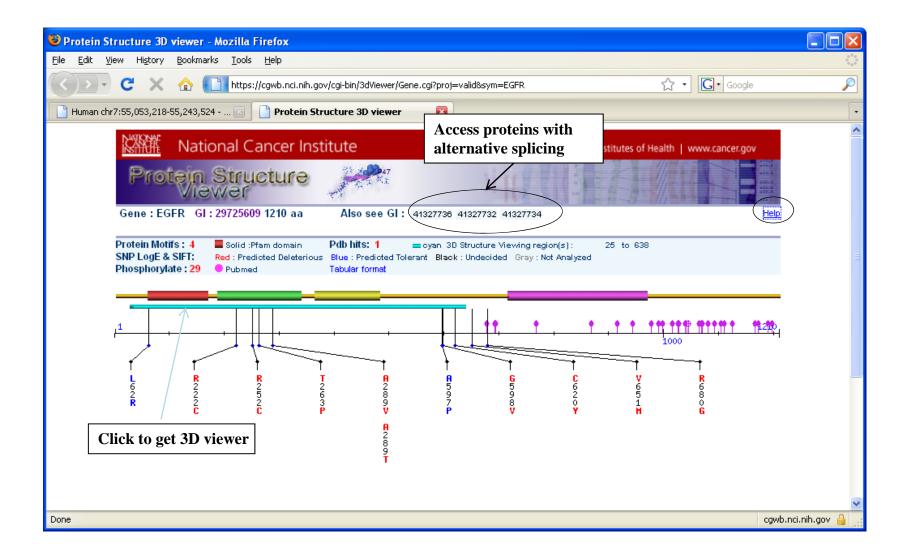
# Next-gen sequencing p53 analysis



Sample coverage maximized to 40x, height represents coverage Red line=coverage for a tumor sample Blue line=coverage for its matching normal

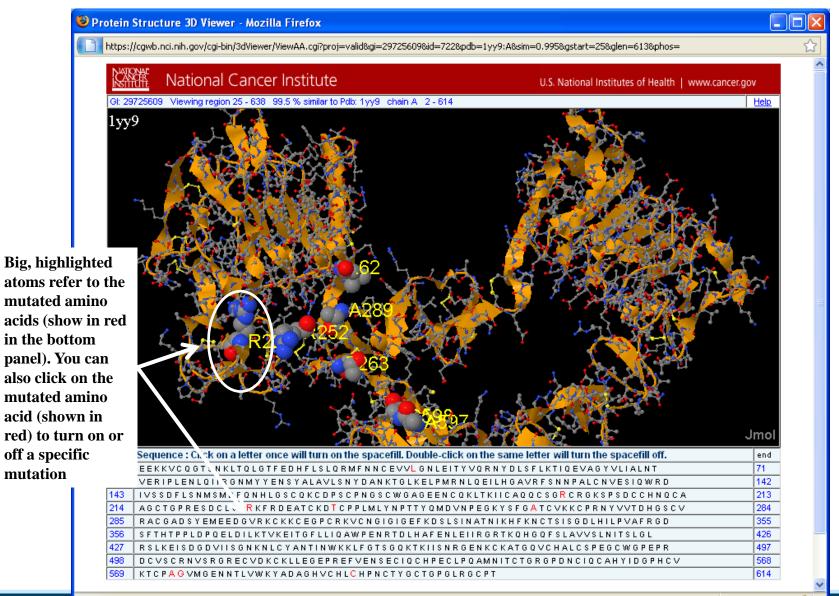
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## **Protein structure view of EGFR mutations**



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## **3D Structure Viewer**

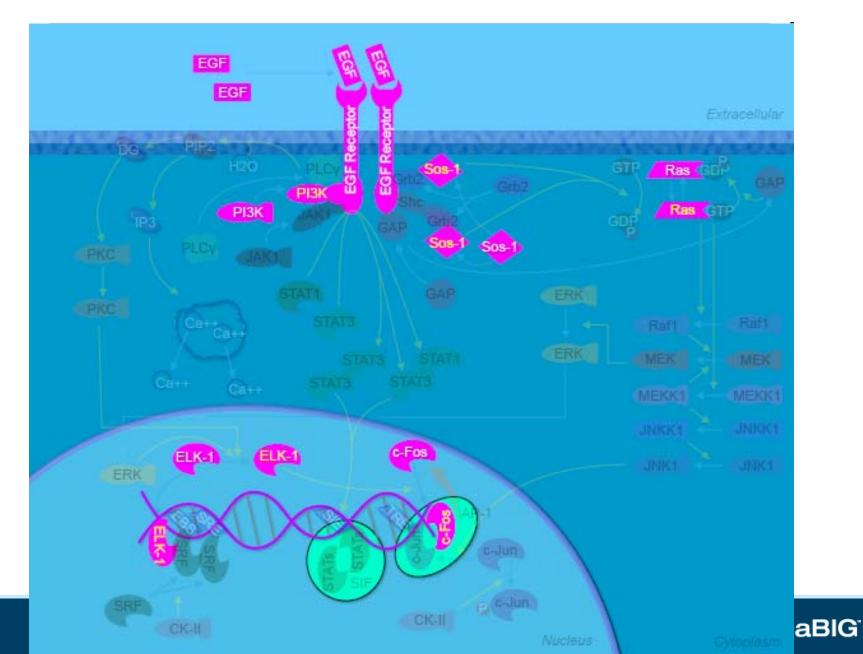


Jmol script completed

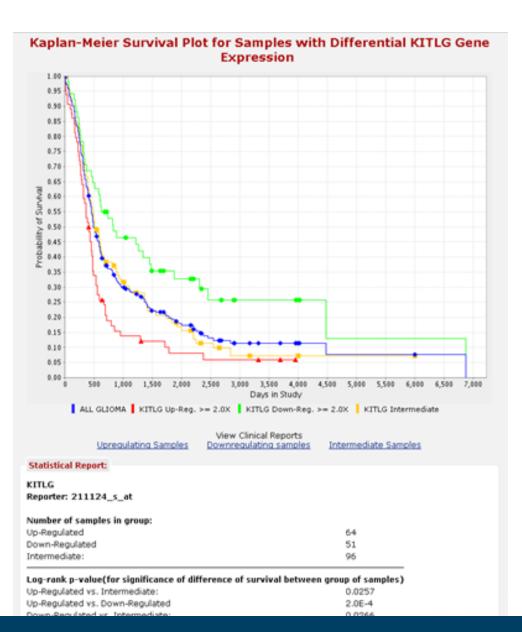
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\_cgwb.nci.nih.gov 🔒

## EGFR network mutation profile through CMA



## Gene expression analysis related to clinical outcome





#### Administration:

- View Results
- List Management
- Help

News:

- Data Version
- TCGA newsletter -March 2008
- Number of Patients -110
- Number of Expression Arrays - 985
- Number of Copy Number Arrays - 361

### PatientDID Lists:

- ALL\_PATIENTS
- Low\_Survival
- Med\_Survival
- High\_Survival
- TP53\_SomaticMu...
- EGFR\_SomaticMu...
- PTEN\_SomaticMu...
- RB1\_SomaticMut...
- DST\_SomaticMut...
- NF1\_SomaticMut...
- CDKN2A\_Somatic...
- PIK3R1\_Somatic...
- CENPF\_SomaticM...
- ITGB3\_SomaticM...

#### Gene Lists:

TCGA Target Se...

#### **Reporter Lists:**

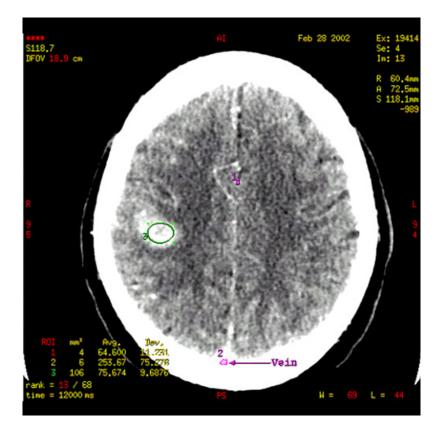
Embracing the complexity of cancer at the molecular level: in silico exploration of

An *in silico* exploration of Glioblastoma Multiforme



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# **Glioblastoma Multiforme (GBM)**



GBM is the most common type of brain tumor. High grade gliomas are incurable and tumors expressing a mesenchymal phenotype are the most aggressive form

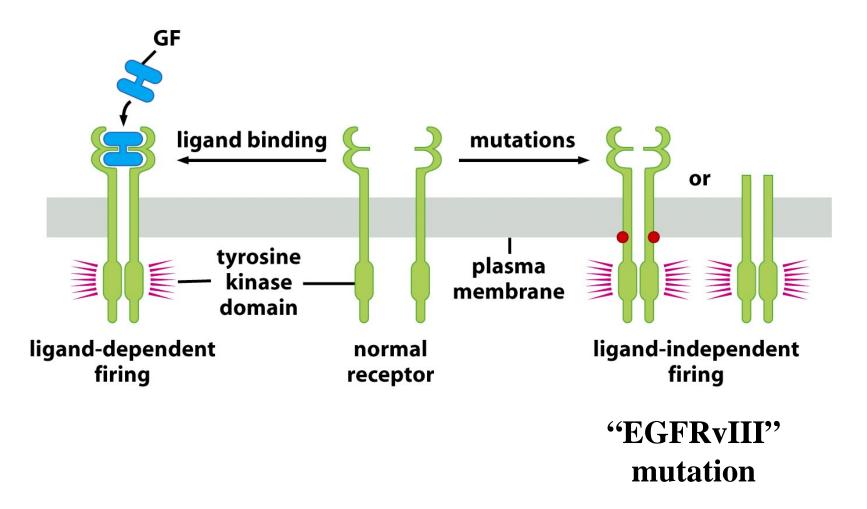
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# Chromosome 7 and EGFR seen as frequent targets of alteration in GBM



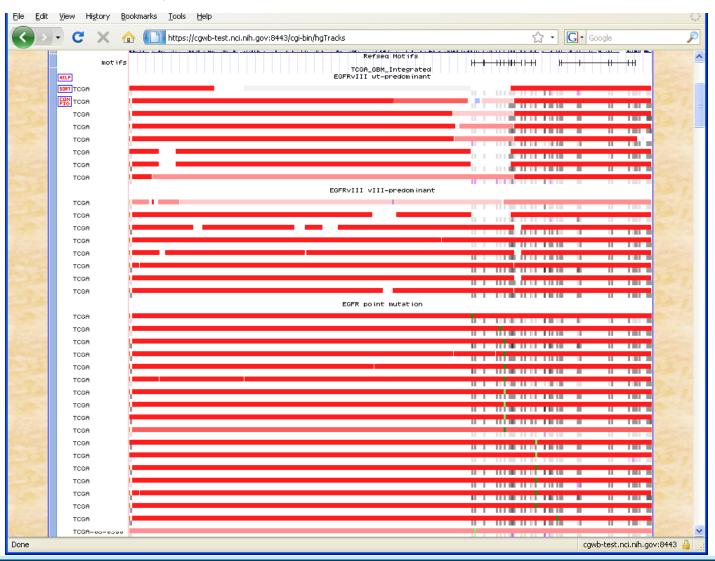
# Constitutive activation of EGFR leads to abnormal growth



Modified from The Biology of Cancer (© Garland Science 2007)

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## Add exon array to verify EGFRvIII expression correlates with CN Top row: Copy Number + Somatic mutation + Methylation Bottom row: Exon Array Expression

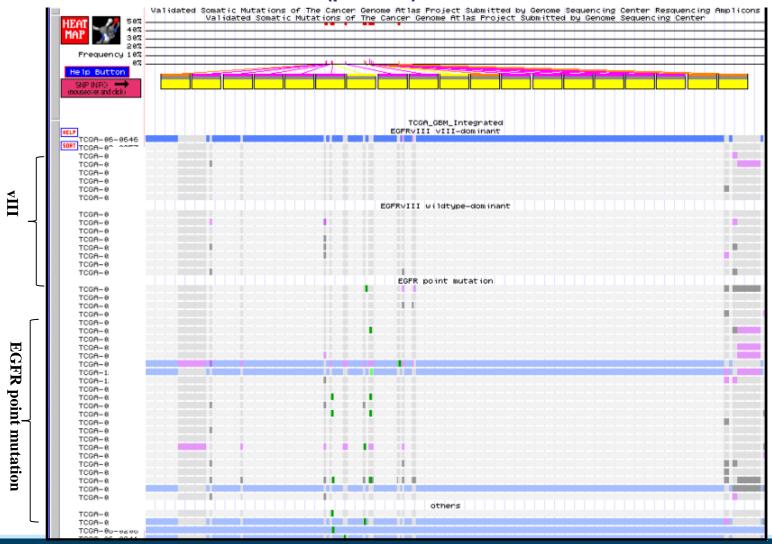


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## EGFR mutation subgroups viewed at the TP53 locus

# No mutation for EGFRvIII but 1/3 of EGFR point mutations have TP53 mutations (p=0.036)



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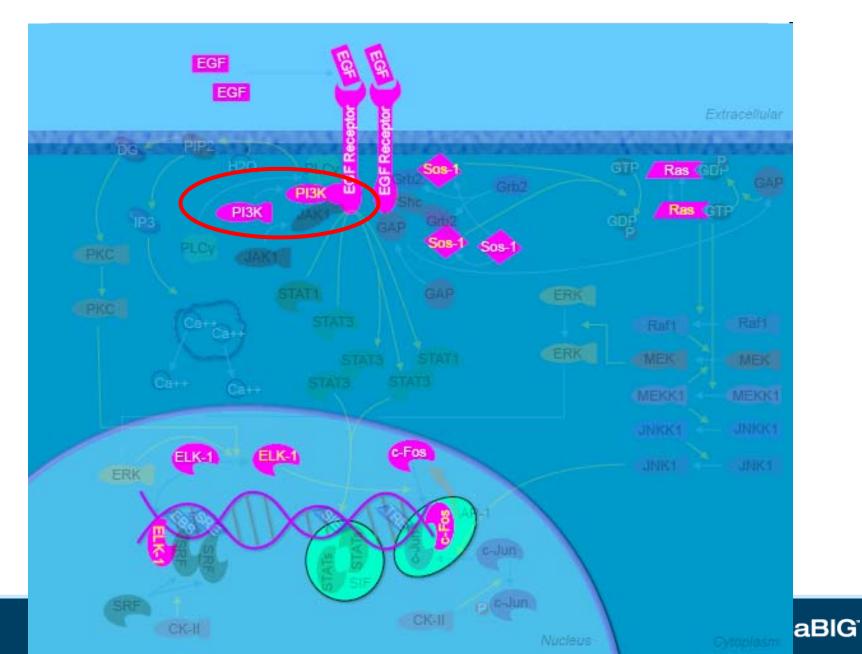
# Mutations in EGFR vIII and TP53 may be anti-correlated

|                   | EGFR amplification        |          |                     | No EGFR amplification     |          |                     |
|-------------------|---------------------------|----------|---------------------|---------------------------|----------|---------------------|
|                   | EGFR<br>point<br>mutation | EGFRvIII | No EGFR<br>mutation | EGFR<br>point<br>mutation | EGFRvill | No EGFR<br>mutation |
|                   | 18                        | 12       | 37                  | 7                         | 0        | 79                  |
| TP53<br>Fraction: | 5<br>28%                  | 0<br>0%  | 4<br>11%            | 3<br>43%                  | 0<br>N/A | 35<br>44%           |

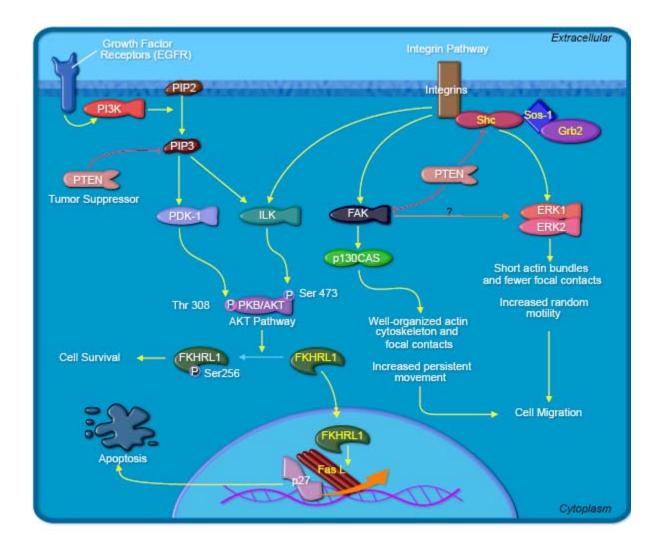
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caBIG<sup>\*</sup>

## **EGFR** network mutation profile through CMA



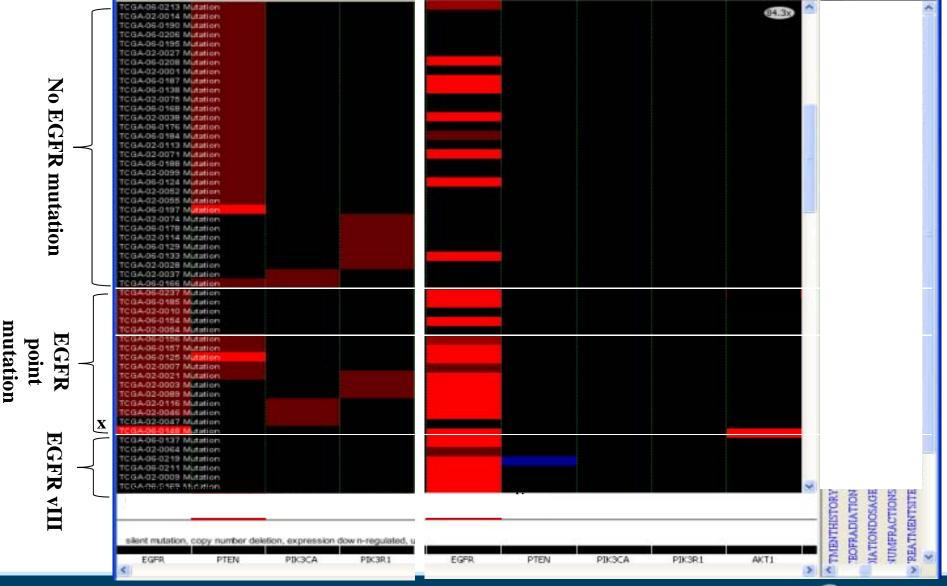
## Alterations in PI3K pathway through CMA



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somatic mutations (left) and copy number (right) shows frequent co-occurrence of EGFR point mutations with other genes in PI-3K pathway but not the EGFR vIII mutations



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## Summary

 No P53 mutations were found in amplified samples with EGFRvIII while significant levels of P53 mutation were found in amplified samples with EGFR point mutations. Suggests alternative molecular etiologies

2) EGFR point mutations co-exist with additional mutations in other genes involved in PI-3K pathway while EGFRvIII rarely have additional mutations in PI-3K pathway. This suggests the possibility of oncogene addiction in EGFRvIII tumors but not in tumors with EGFR point mutations even though both types of mutations target EGFR extracellular domains.

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## For Affiliates » Total Cancer Care » Overview

| Total Cancer Care   | Overview   |  |
|---|--|--|
| <ul> <li>» Overview</li> <li>» <u>Contact Information</u></li> <li>» <u>How Do I Participate?</u></li> <li>» <u>How Does Total Cancer</u><br/><u>Care Work?</u></li> <li>» <u>Why Participate in Total</u><br/><u>Cancer Care?</u></li> </ul> | What is Tota<br>Total Cancer<br>that enables<br>patient and I<br>generations.                    |  |
| <ul> <li><u>Participating Institutions</u></li> <li><u>Research Partnerships</u></li> <li><u>Leadership &amp; Governance</u></li> <li><u>Evidence-Based Oncology</u></li> <li><u>Program</u></li> </ul>                                       | In 2003, Moff<br>holistic plan<br>individualize<br>integration o<br>outcomes. Th<br>care and out |  |
| Share This Page   | beyond. Tota<br>holistic appr<br>preventive m  |  |
|   | preventive n   |  |

## What is Total Cancer Care?

Total Cancer Care is Moffitt Cancer Center's comprehensive approach to cancer that enables researchers and caregivers to identify and meet all the needs of a patient and his or her family during the patient's lifetime and for future generations.

In 2003, Moffitt Cancer Center began developing Total Cancer Care, which is a holistic plan to improve the standard of cancer care by providing individualized, evidence-based treatment decisions based on the large-scale integration of information technology, scientific discovery and health outcomes. This approach will provide evidence-based guidelines to improve care and outcomes for cancer patients throughout the state of Florida and beyond. Total Cancer Care addresses cancer as a public health issue and takes a holistic approach by encompassing all aspects of the disease, including preventive measures such as the study of genetic predispositions, impact of

#### Moffitt News

3/3/2011 <u>Moffitt Cancer</u> <u>Center Appoints</u> <u>Vice President/Chief</u> <u>Nursing Officer And</u> <u>Vice President/Chief</u> <u>Health Informatics</u> <u>Officer</u>

3/2/2011 <u>Moffitt Cancer</u> <u>Center Recognizes</u> <u>Colorectal Cancer</u> Awareness Month

# The Washington Post

We are using a patient's genome to protect against heart attacks and stroke.

Each person responds differently to medicine. Using DNA, our doctors match heart patients with the right blood thinner. It's one of the many ways we are tailoring medicine to the unique characteristics of each patient.

VanderbiltHealth.com/breakthroughs

VANDERBILT WUNIVERSITY

MEDICAL CENTER

The promise of discovery

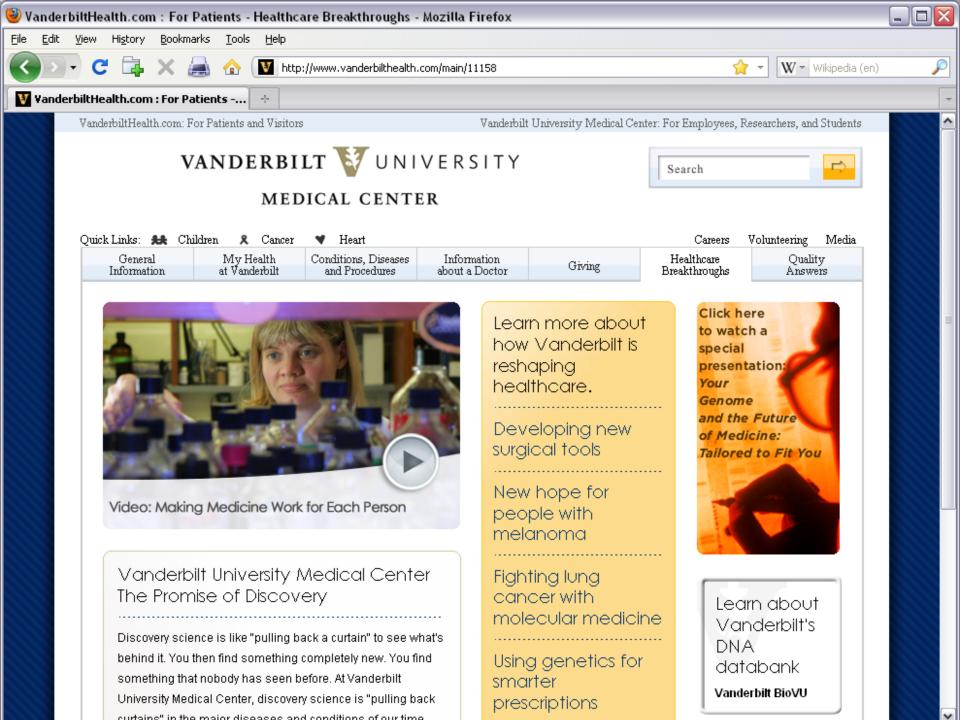




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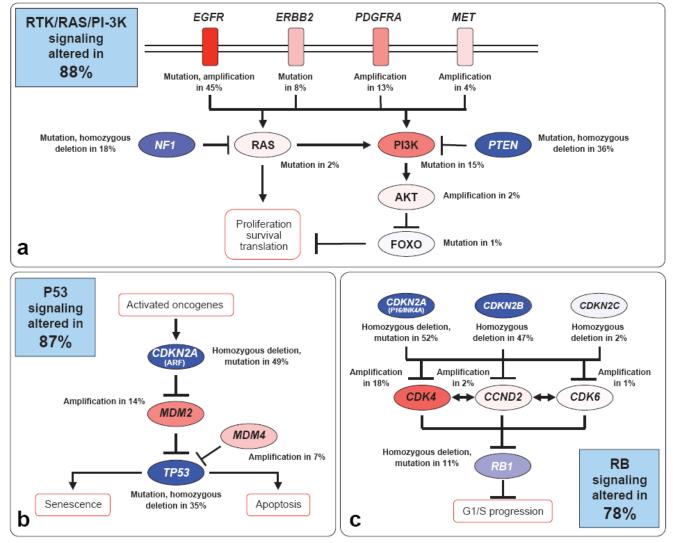
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## **GBM Results: Pathways**

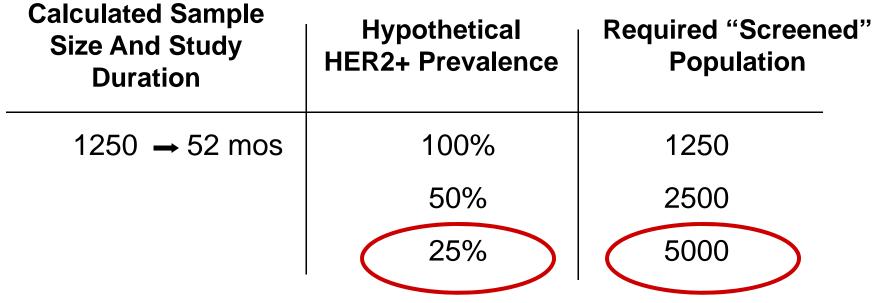




TCGA: Nature 2008



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



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

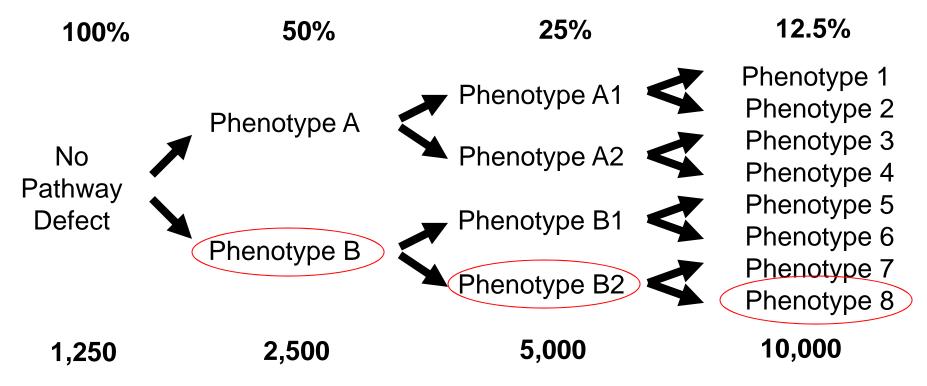
**Duke** Comprehensive Cancer Center

\* Need to screen many patients.

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



## Population fraction containing signature



Size of Population Needed To Screen

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

**Duke** Comprehensive Cancer Center

## **20<sup>th</sup> Century Research > Care Paradigm**

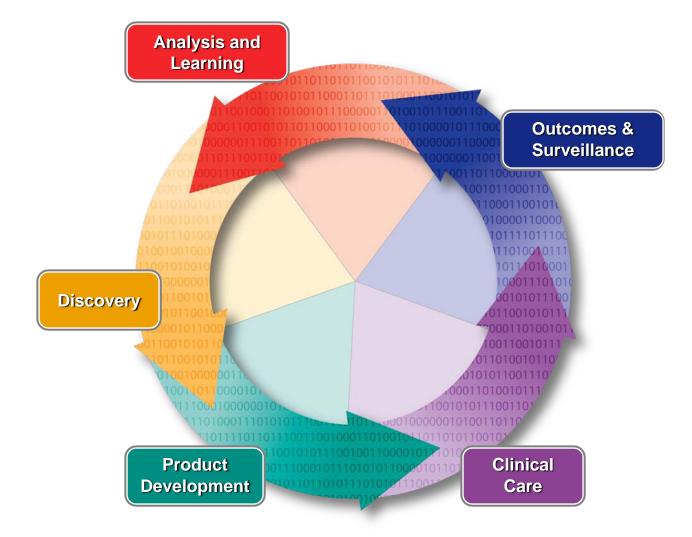
Approval





## **21th Century Learning Health System**







"We are now poised for the third big transformation, which will come from behavioral changes, as all participants in the ecosystem – patients, physicians, payers, companies and more – revisit and realign their practices in order to improve health outcomes."

# Ernst & Young, Progressions 2011





- Pharma 1.0: The "Blockbuster" model
- Pharma 2.0: Cost-efficient, diversified product/market model – portfolios of more-targeted drugs in strategic therapeutic areas (chronic conditions, cancer)
- Pharma 3.0: The health outcomes ecosystem supplementing the 2.0 model, companies will shift focus from solely on units sold to include ability to improve outcome. Trend driven by:
  - Health care systems lack of sustainability
  - New technology

Ernst & Young, Progressions 2011



## "This growing pool of data will be generated across the ecosystem through multiple new channels, such as

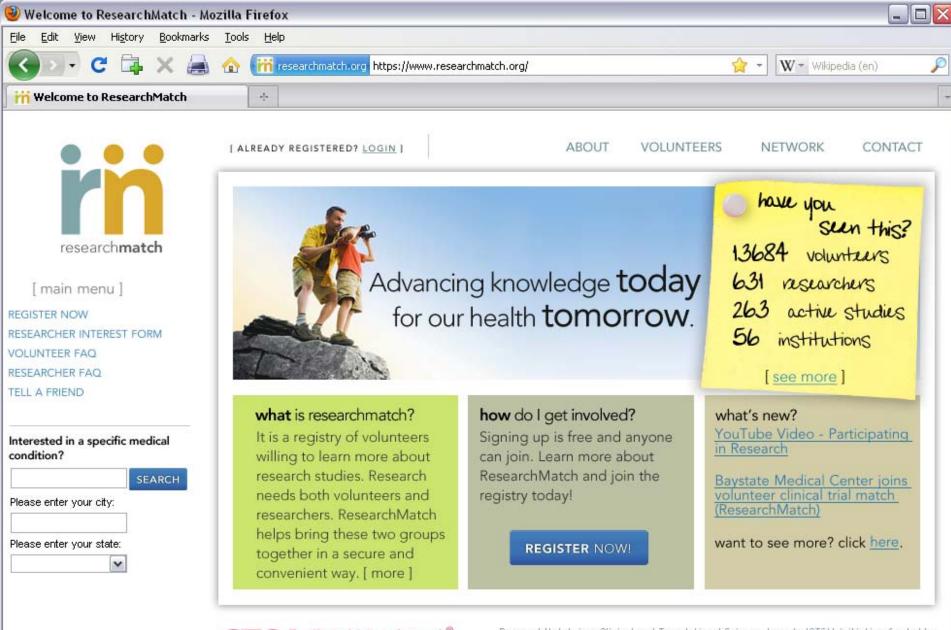
- electronic health records,
- social media,
- online communities,
- wireless devices and
- smartphones,

meaning that no single entity will own or control all of the data about any company, product, disease state or patient behavior."

"While value in the future will be determined by data, data alone is not the answer. Instead, value will come from developing insightful solutions with the data."

Ernst & Young, Progressions 2011





CTSA Clinical & Translational <sup>®</sup> Science Awards

The Clinical and Translational Science Awards (CTSA) is a registered trademark of DHHS. ResearchMatch is a Clinical and Translational Science Awards (<u>CTSA</u>) initiative funded by the <u>National Center for Research Resources</u>, part of the <u>National Institutes of Health</u>. Powered by UMLS through the National Library of Medicine (<u>see more</u>)





caBIG<sup>®</sup> 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



LOVE/AVON Going Beyond a Cure



#### AOW is Speeding National Research Investigations...



- Sister Study: NIH/NIEH study to determine how environment and genes affect breast cancer risk
  - 5,000 women needed...54,411 total responses from AOW
    - 1600 recruited in 48 hours
    - 2300 recruited in 2 weeks
- Variations in Health Needs of Breast Cancer Survivors: NIH-funded study to reduce disparity in cancer burden due to sexual orientation
  - 100 lesbian, bisexual women required...**15,412 responses from AOW** 
    - 158 recruited



#### And Local Studies...



- BEAM Study: Breast Estrogen and Methylation investigation at Northwestern University and Johns Hopkins University
  - 300 women required...10,617 responses from the AOW
    - 23 at NU in 16 months
    - 34 at JHU in 5 months
- Obesity Study: Controlled diet and exercise study at UCLA monitoring markers of risk for breast cancer
  - 20 participants needed...16,466 total responses from the AOW
    - 125 recruited
    - Fully enrolled in <u>12 hours</u>



#### With Targeted Populations



- Milk Study: Biomarker study recruiting lactating women scheduled for a breast biopsy; conducted at UMass, funded by Avon
  - 250 women needed...62,826 total responses from AOW
    - 31 recruited in 24 hours...<u>representing a 6 month acceleration in</u> <u>recruitment</u>
    - 324 recruited to date
    - Study enlarged to 1000 based on response

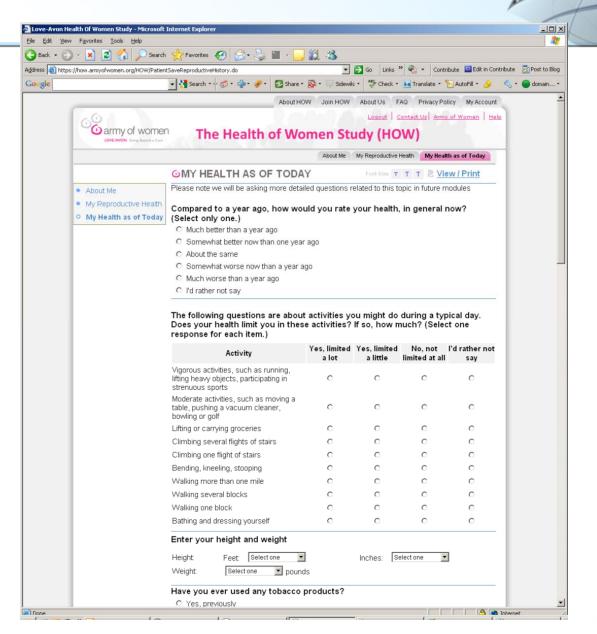


#### AOW/caBIG<sup>®</sup> Collaboration: Health of Women Study (HOW)



- Members of AOW are invited to join the HOW study and respond to periodic secure online questionnaires concerning health history
- Authorized researchers access data and design study protocols based on profiles and data of potential research participants
- Database enables "interactive" and "dynamic" process as researchers conceive new projects and women add more health information, new theories can be generated and additional opportunities for participation arise







## 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

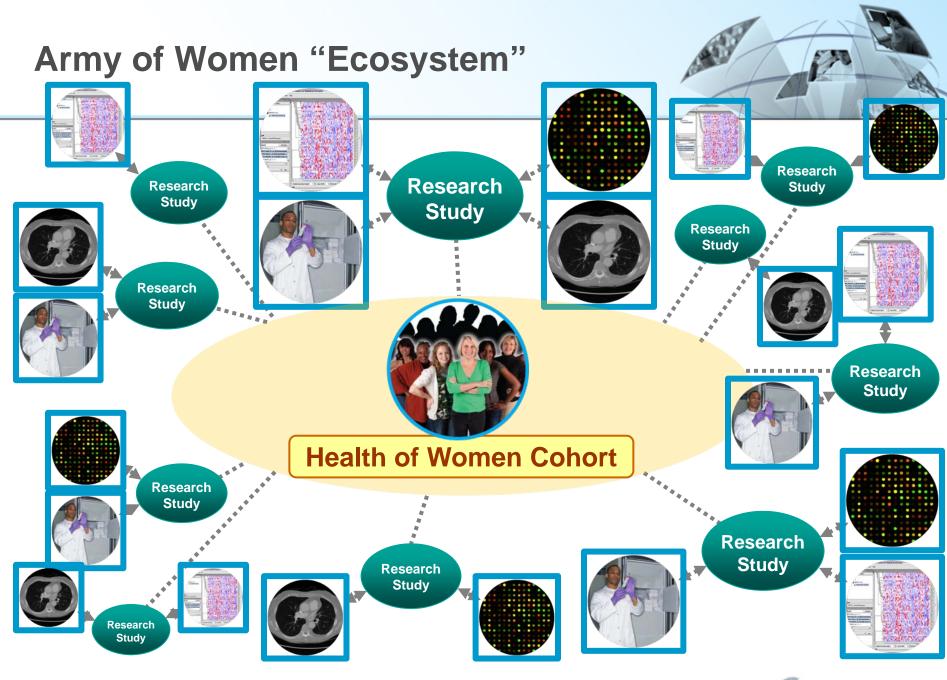
#### In response to this single e-mail invitation

- 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







# Panacea Biotec – "a research-based health management company"





#### 21<sup>st</sup> Century Biomedical Research Still Faces Huge Data/Knowledge Challenge

- 21<sup>st</sup> Century research is based on a continuum from bench to bedside and back, and makes use of digital "data" of all kinds – biological, molecular, clinical, laboratory, pharmacy, etc. – to drive knowledge.
- But.... at present, these data are still:
  - Of varying quality;
  - Non-conformant to standard vocabularies;
  - Frequently incomprehensible or prohibitively laborious to translate from one discipline to another.
- Unlike almost all sectors in today's knowledge economy, biomedicine has no means for efficient collection, aggregation, integration, analysis, interpretation, and transmittal of data so that it can be converted into practical, useful knowledge by anyone other than the original author.



#### **Ecosystem to create "Translatable Informatics" Framework**

- an open information technology framework comprised of standards, specifications, vocabularies, and code bases – that enables users to capture, aggregate, integrate, analyze, interpret, and transmit data through open interfaces between different repositories, institutions, or other sources of data.
- facilitates the translation of data into information at all points of the biomedical life cycle (discovery science, translational science, clinical development, clinical care, population science.)

Translatable Informatics generates the flow of information necessary to sustain all participants in the biomedical ecosystem.



#### **Translatable Informatics Ecosystem "interests"**

- Pharmaceutical companies need a reusable clinical trials infrastructure to avoid "re-creating" every clinical trial de novo, especially for molecularly targeted drugs in which patient subgroups must be identified early in the process.
- Research institutions need a common framework to use data trapped within their own different departments and laboratories, to fuel collaborations and accelerate time to discovery.
- Individual researchers need "liquid data' at their fingertips that can be used to form or validate research hypotheses, empowering them to leverage more diverse and/or larger datasets than those they have themselves generated.
- Clinical care providers need to mobilize the clinical data already in their systems to measure the efficacy of their current care, to improve clinical outcomes, and to fuel research by correlating clinical profiles with molecular data.
- Patient advocacy organizations need cost-effective platforms to gather clinical information from their patient population as well as accompanying research data generated from those populations, to help physicians determine most effective care and to help drive therapy-focused research by academics and pharmaceutical companies.



#### The Role of the Commercial IT Sector

- Software developers and systems integrators need to provide products and services customized to the biomedical market.
- Since the use of TI requires only open, defined interfaces between systems, it does not disrupt the development and commercialization of proprietary information technology products and services.
- Such IT companies will benefit from:
  - The creation of a "common market" evolved from the fragmented components of the different sectors;
  - The reduction of risk that results from having a core collection of nonviral, open source code that can be reused



#### **Requisites for Translatable Informatics**

- Data Standards: Shared data standards ensure that data generated at different locations and by different applications is accessible/meaningful.
- Grid or network: A grid that provides the "backbone" to which applications and data sources can connect, and allows researchers to access shared data via the use of web-query tools.
- Policies for Data Sharing: Numerous legal, ethical, security, and cultural constraints must be addressed to enable the requisite collection, aggregation, integration, analysis, interpretation and transmission of data for collaborative research. Policies that promote broad-based information sharing under appropriate access terms are needed for compliance with HIPAA (Health Insurance Portability and Accountability Act), government regulations, and institutional policies.

caBIG<sup>®</sup> has prototyped the requisites



#### **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

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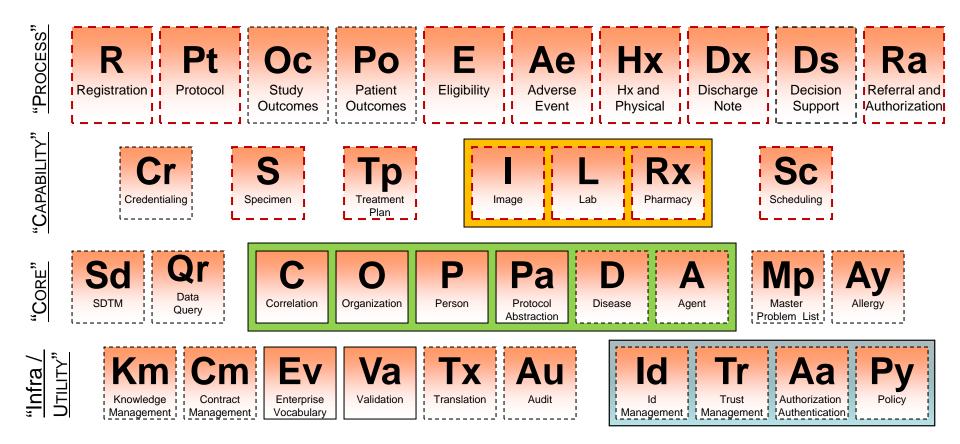
#### Services Aware Interoperability Framework (SAIF)

# 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



#### **NCI Enterprise sSOA** *Periodic Table of Services*





## **Usage Patterns for NCI Services**

- Service Specifications: NCI services layered service specifications (conceptual model, platform independent model and platform specific model) for organizations wishing to build or adapt products that can interoperate with NCI services
- Reference Implementations: NCI provides reference implementations of these services that provide Application Programming Interfaces implemented in many technologies

All NCI specifications and reference implementations are made available via a non-viral Open Source license that explicitly allows for commercial, closed source reuse and derivative works



#### **Technology Bindings Utilized by NCI Services**

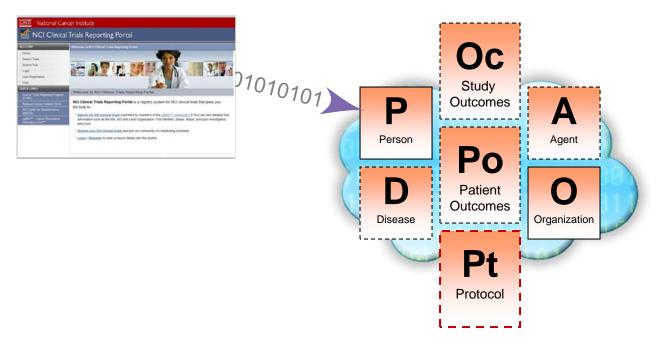
# NCI Services are designed to be readily accessed using a variety of technologies. These include:

- Application Programming Interfaces: Commonly implemented as Remote Enterprise Java Beans (EJB's), but increasingly including API's that utilize .NET frameworks
- Grid Services: Access via the NCI's semantically-aware SOA infrastructure, caGrid
- Web Services: Access via WS-I compliant web services
- REST APIs: Simple APIs that allow for easy connection to services but can't utilize the advanced semantic capabilities of caGrid
- Accessible via CONNECT Gateway





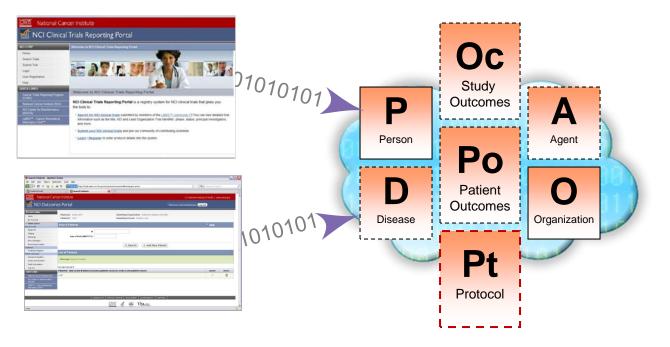
NCI Enterprise Services were created to support the systematic collection of the NCI's Clinical Research Portfolio through the Clinical Trials Reporting Program



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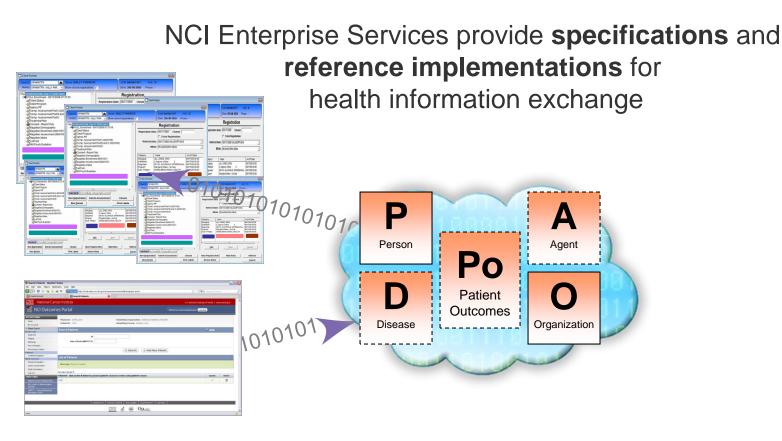


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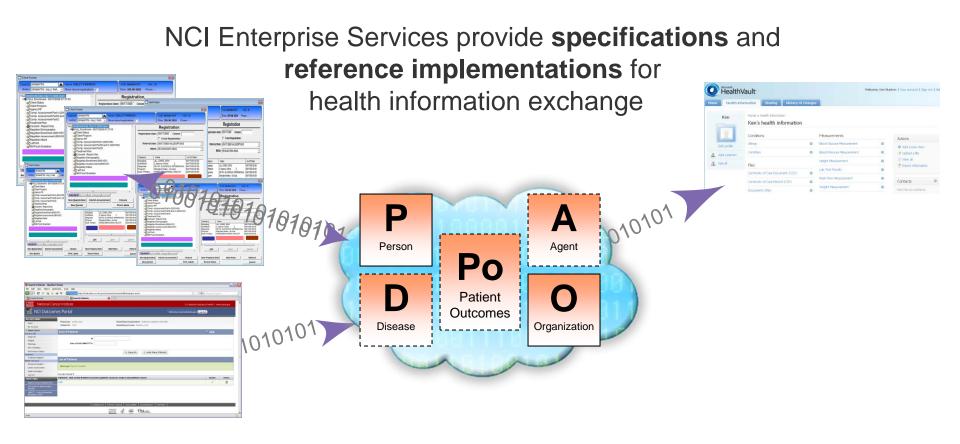
The core of the **Clinical Trials Reporting Program** services represent the information need for a modular, **Ultra-light Electronic Health Record** 

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The core of the **Clinical Trials Reporting Program** services represent the information need for a modular, **Ultra-light Electronic Health Record** 

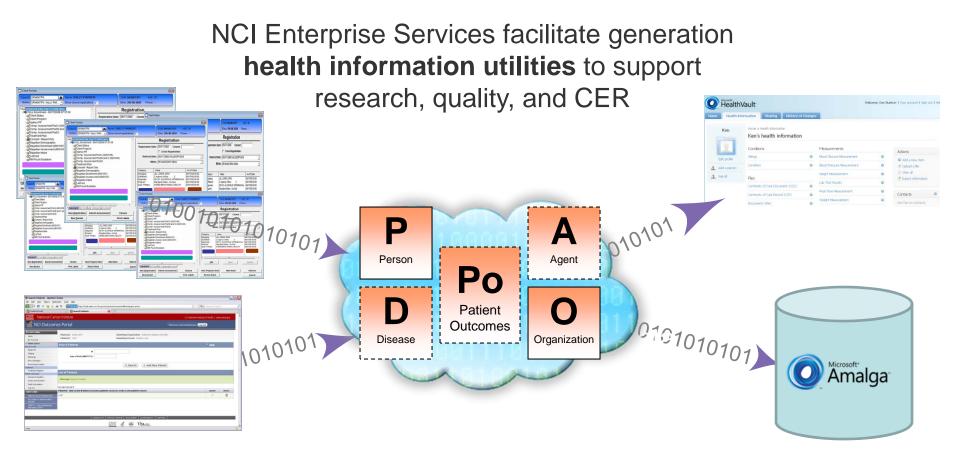




Services support the electronic transmission health information to **patient-controlled health records** 

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#### NCI/SAIC/Microsoft e-Health for All Prototype

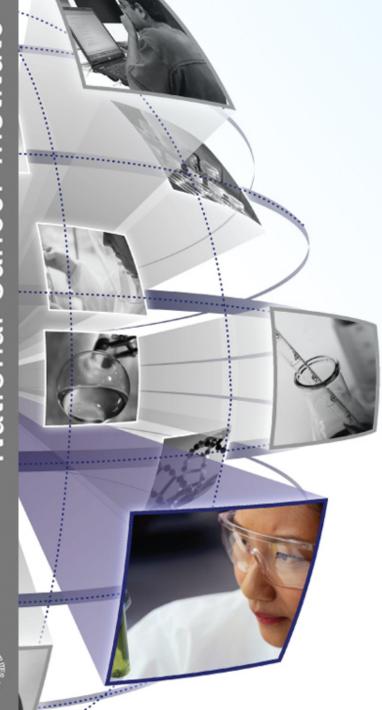


Services support the electronic transmission health information to **patient-controlled health records** 

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# National Cancer II





Prototyping a Rapid Learning Healthcare System:

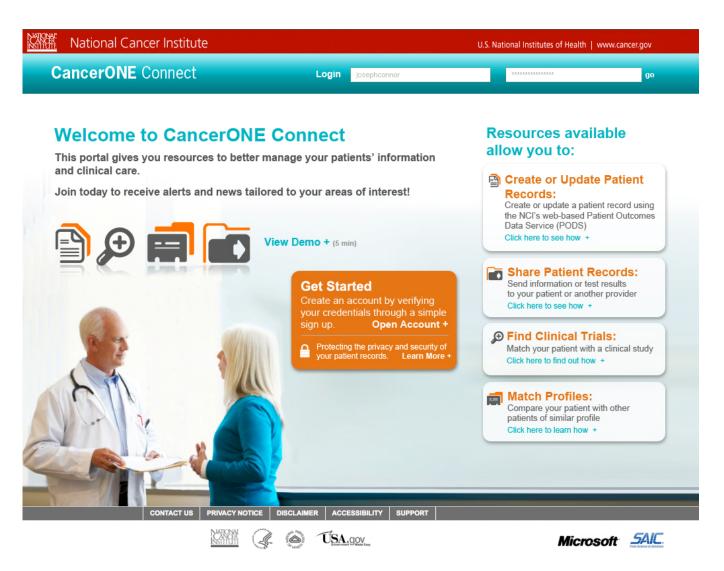
The Cancer e-Life Collaboration







#### **CancerONE Provider Portal**



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#### **Provider Capture of Information**

| Welcome Back, Joseph Connor, M.D.<br>ALERT: GnRH Agonists: Safety Review of Drug Class Used to Treat<br>Prostate Cancer (5/03/2010) +<br>ALERT: Velcade (bortezomib): Starting Dose Adjustments for Patients<br>Hepatic Impairment (1/26/2010) +<br>ALERT: Tarceva (erlotinib) May 2009 (5/8/2009) + |   | C th D      | Create or Update Patien<br>Records:<br>Create or update a patient record u<br>the NCI's web-based Patient Outco<br>Data Service (PODS)<br>Launch + |  |  |
|--|---|-------------|--|--|--|
| View Past Alerts+<br>Current News:   | Publications:   | _           | to your patient or another provider<br>Launch +  |  |  |
| Panel looks at Environmental<br>Cancer Risks Read More +<br>MRI scans accurately spot spread   | NCI's Cancer Information Service (CIS): G<br>latest and most accurate cancer information<br>patients, their families, the public, and healt<br>professionals online or speak to an informa  | n for<br>th | Find Clinical Trials:<br>Match your patient with a clinical study<br>Launch +  |  |  |
| of cancer: study Read More +<br>Substance Found to Kill Cancer<br>Stem Cells Read More +   | specialist (1-800-4-CANCER)       Read More +         NCI Publications Online:       Order comprehensive research-based information for patients and their families, health professionals, cancer research-ers, advocates, and the public. Read More +         PubMed:       Access 20 million citations for biomedical literature from MEDLINE, life science journals, and online books maintained by the U.S. National Library of Medicine. Read More + |             | Match Profiles:<br>Compare your patient with other<br>patients of similar profile<br>Launch +  |  |  |
| Protecting the privacy and security of<br>your patient records. Learn More +   |   |             |  |  |  |
|  | NCI Cancer Bulletin: Read the NCI's biwee<br>online newsletter designed to provide usefu<br>timely information about cancer research to<br>cancer community. Read More +  | ıl,         |  |  |  |

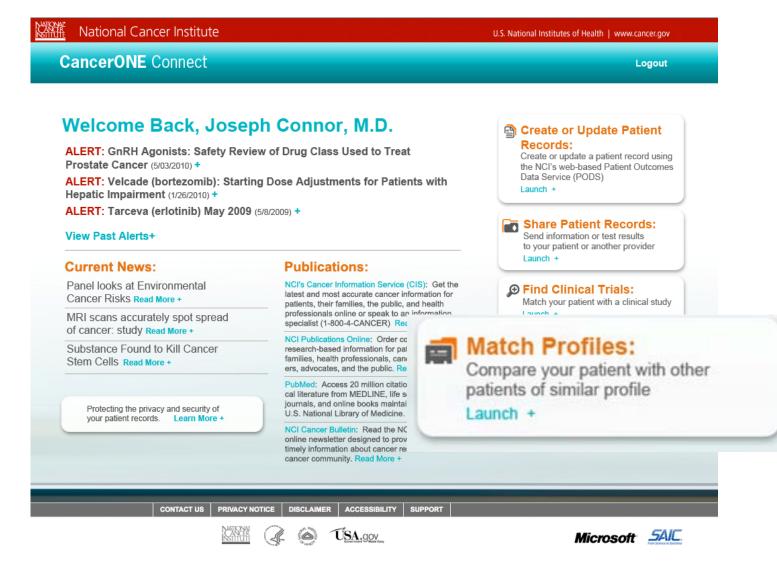
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#### "ultra-light" oncology EHR: an on-ramp to electronic health for community practices

| 000   |   | Diagnosis   |   | $\bigcirc$ |  |
|---|---|---|---|------------|--|
|   | (♠) ↓ 1P) (☐ nih.gov (https://trials-demo.nci.nih.gov/outcomes/outcomes/executeDiagnosis.action |   |   |            |  |
| Diagnosis   | +   |   |   | च          |  |
| A 10TCA IAP   | sos lostituto   |   |   | -          |  |
| National Can  | cerinstitute  |   | U.S. National Institutes of Health   www.cancer.gov |            |  |
| MCI Outcom  | es Portal   |   | Welcome, mulairee@mail.nih.gov   Log Out.           |            |  |
| NCI OUTCOMES  | Physiology, Lines CDUT  | Publishe Organization Organization builtari   |   |            |  |
| Home  | Physician: User, CBIIT<br>Patient ID: TestPt00002   | Submitting Organization: Organization by Hari<br>Submitting Person: Mulaire, Edmond |   |            |  |
| My Account  | F 4101( 10. 1031 100002   | Submitting Forders molaire, Lamona  |   |            |  |
| Patient Search  | Diagnosis   |   | () Help   | - 1        |  |
| Baseline Data<br>u Diagnosis  |   |   |   |            |  |
| Staging   | Diagnosis:*   |   |   |            |  |
| Pathology   |   | S (antiduce)  |   |            |  |
| Prior Therapies   | Diagnosis Date:*  | 📰 (mm/dd/yyyy)  |   | - 1        |  |
| Performance Status  |   |   |   | - 1        |  |
| Treatment   |   | 🔚 Save 🛛 🙆 Cancel   |   | - 1        |  |
| Treatment Regimen   |   |   |   | - 1        |  |
| Patient Outcomes<br>Disease Evaluation                                  |   |   |   | - 1        |  |
| Lesion Assessment   |   |   |   | - 1        |  |
| Death Information   |   |   |   |            |  |
| Log Out   |   |   |   |            |  |
| QUICK LINKS   |   |   |   | - 1        |  |
| National Cancer Institute (NCI)   |   |   |   | - 1        |  |
| NCI Center for Bioinformatics<br>(NCICB)                                |   |   |   |            |  |
| caBIG <sup>™</sup> - Cancer Biomedical<br>Informatics Grid <sup>™</sup> |   |   |   |            |  |
|   |   |   |   |            |  |
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|   |   | TSA.gov   |   |            |  |
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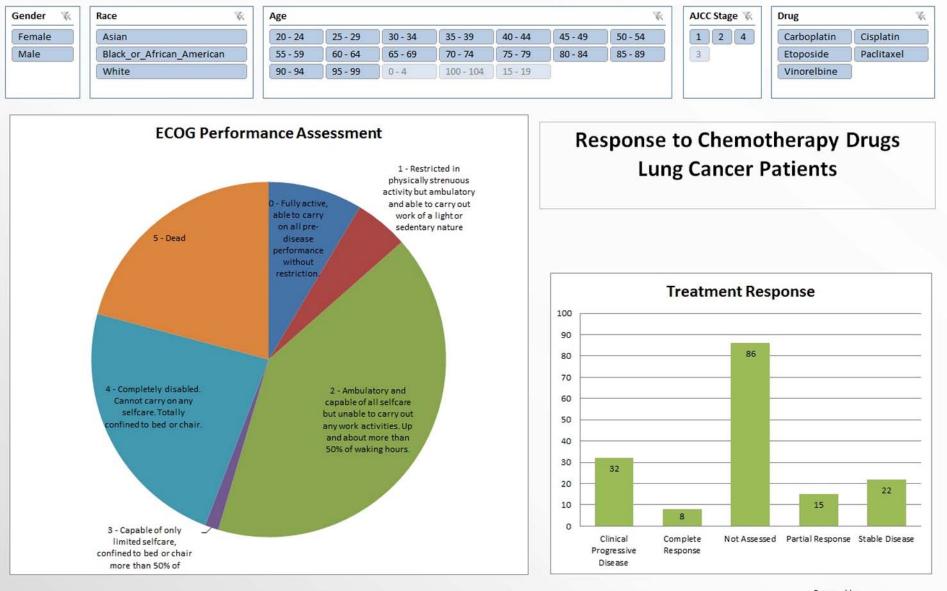


#### **Information-driven Care**



cancer Biomedical Informatics Grid<sup>®</sup>

#### National Cancer Institute



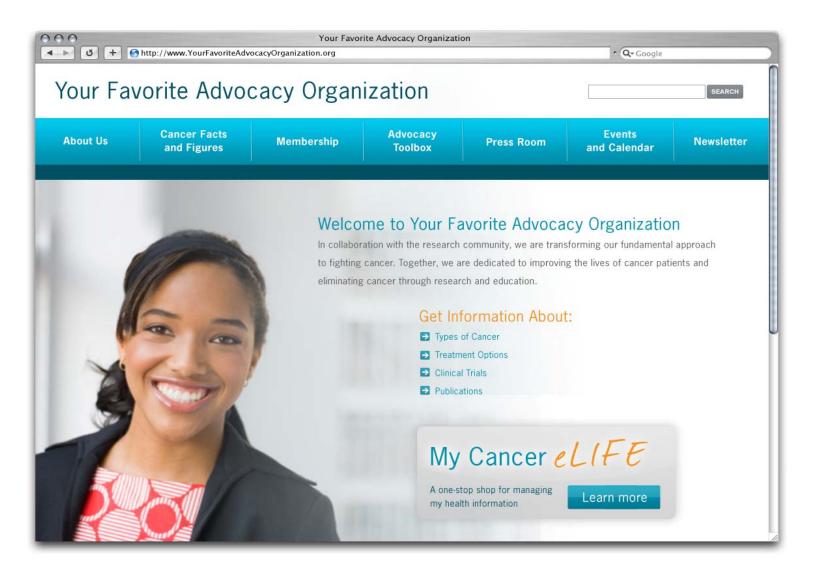






Amalga

#### My Cancer e-LIFE: supporting a new model of Advocacy





#### Contribute your knowledge to help conquer cancer

#### ABOUT US

NETWORKS NETWORKS 📑 📘 🚟

#### Join today and Contribute to help conquer cancer

- Share your information (if you wish) with cancer researchers and other cancer survivors
- Access information, tools, and communities to help you live with cancer
- Track day-to-day experiences such as side effects, etc
- Share information with your doctor(s)



#### TOOLS & COMMUNITY TRACK SHARE SIGN IN Get Started Access information, Track day-to-day Share information with All health records you create through the tools, and communities experiences such as side cancer researchers and community are stored in Microsoft HealthVault, a to help you live with effects, etc. wellness, other cancer survivors security-enhanced service that lets you gather your cancer learning and more and with your doctors. health records online.

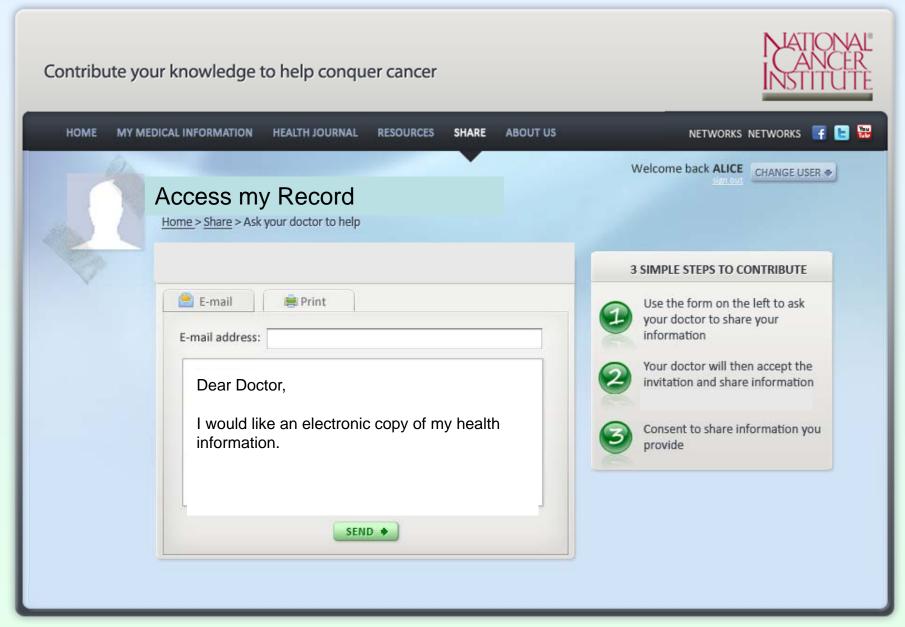


Join now to connect with cancer survivors and help cancer researchers

FOLLOW US 🔶



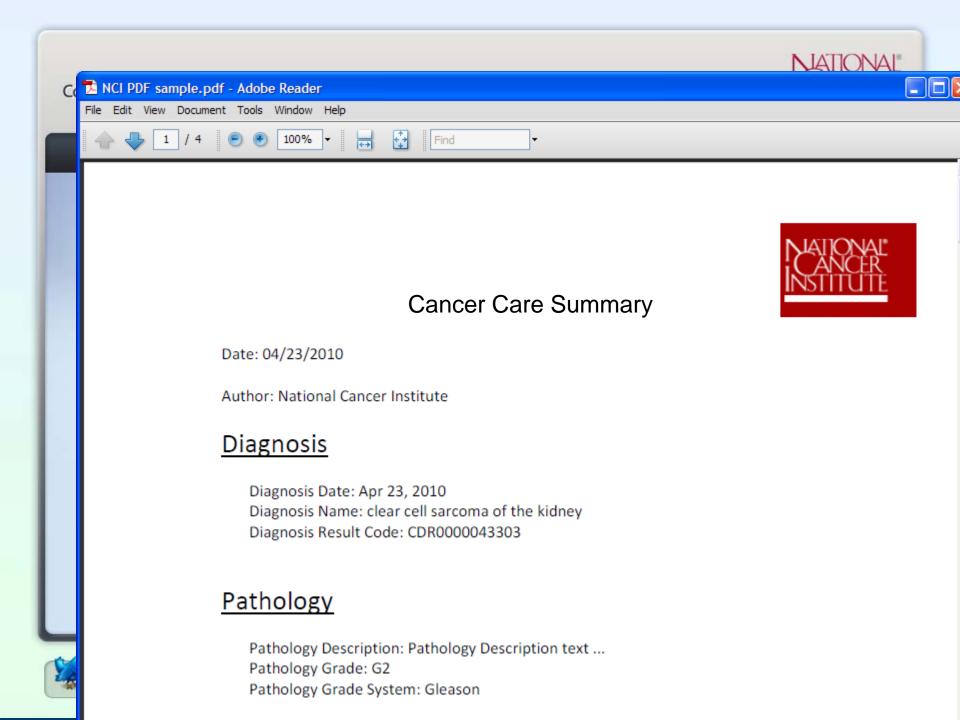
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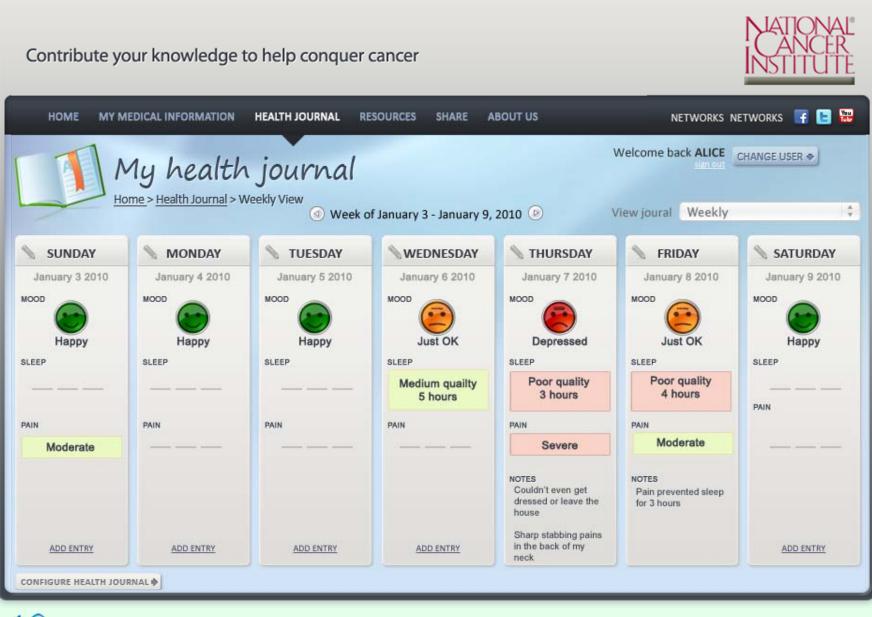




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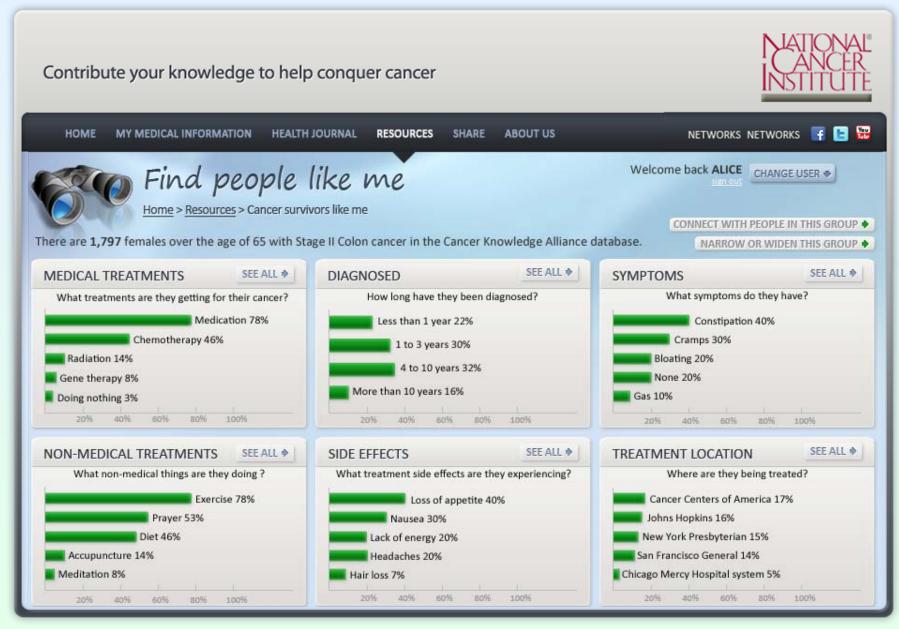






Connects with O HealthVault

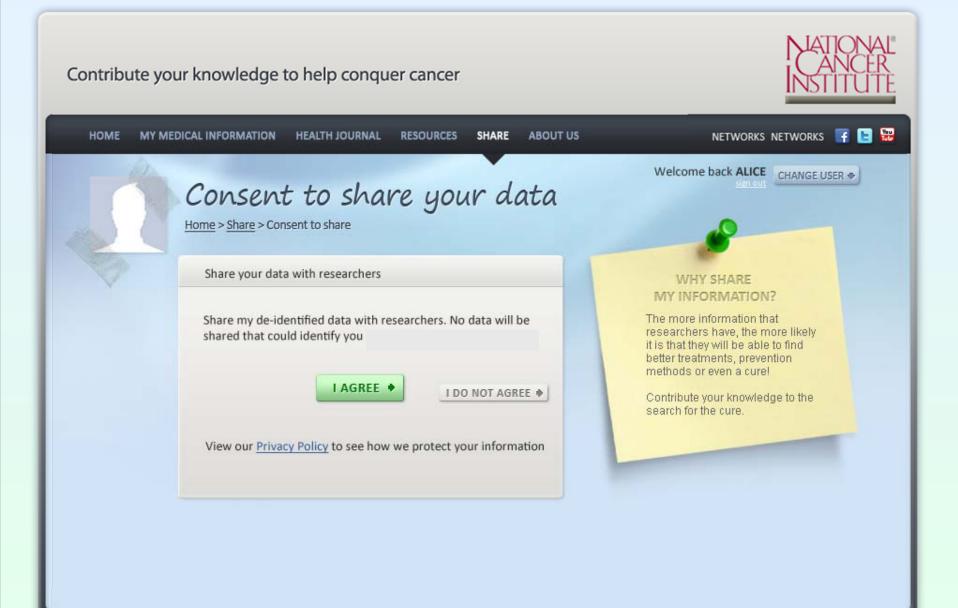
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Connects with





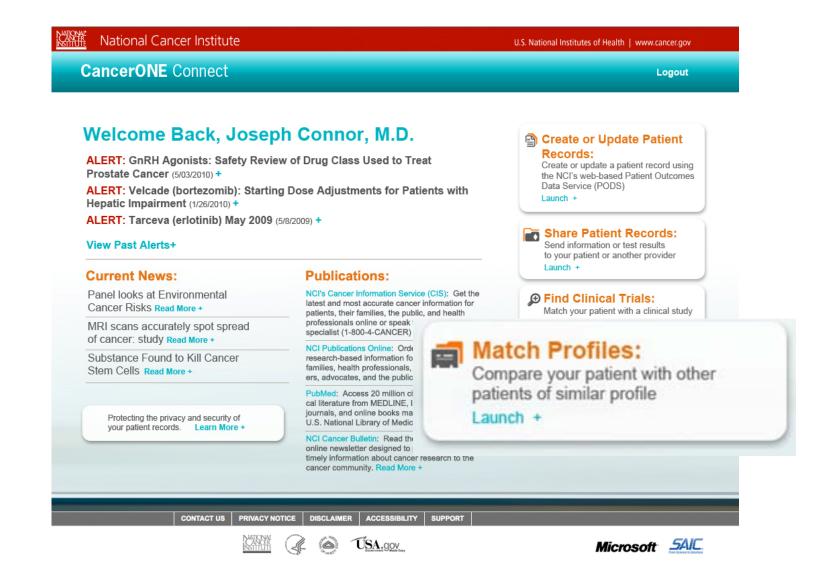


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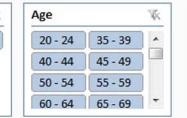
#### **Joining Provider and Patient Information**



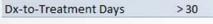
cancer Biomedical Informatics Grid<sup>®</sup>

#### National Cancer Institute

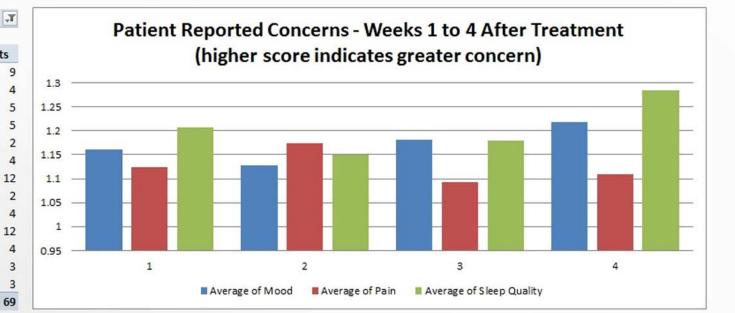




#### **Patient Reported Outcomes Treatment Delay > 30 Days**



| Diagnosis                  | ٣   | Patients |
|----------------------------|-----|----------|
| breast cancer              |     | 9        |
| colon cancer               |     | 4        |
| colorectal cancer          |     | 5        |
| hematopoietic/lymphoid car | nce | 5        |
| kidney/urinary cancer      |     | 2        |
| lip and oral cavity cancer |     | 4        |
| lung cancer                |     | 12       |
| ovarian epithelial cancer  |     | 2        |
| pancreatic cancer          |     | 4        |
| prostate cancer            |     | 12       |
| skin cancer                |     | 4        |
| thyroid cancer             |     | 3        |
| uterine corpus cancer      |     | 3        |
| Grand Total                |     | 69       |



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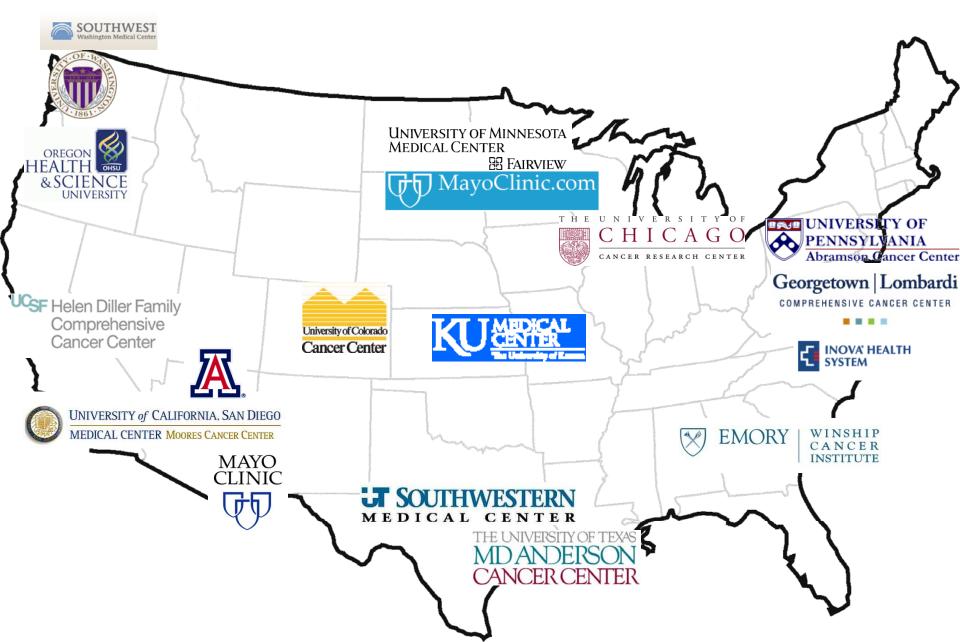


### The I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis):

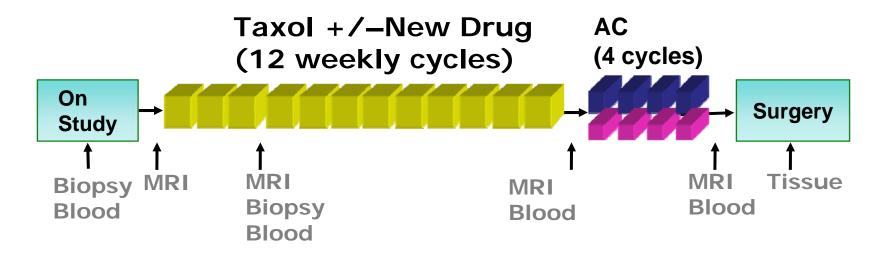
A national study to leverage biomarkers in predicting response to combinatorial therapy for women with Stage 3 breast cancer. (PI Laura Esserman, UCSF )



#### **Projected I-SPY 2 study sites**



#### **I-SPY Adaptive Trial Outline**



Accrual: Anticipate 800 patients over 3–4 years

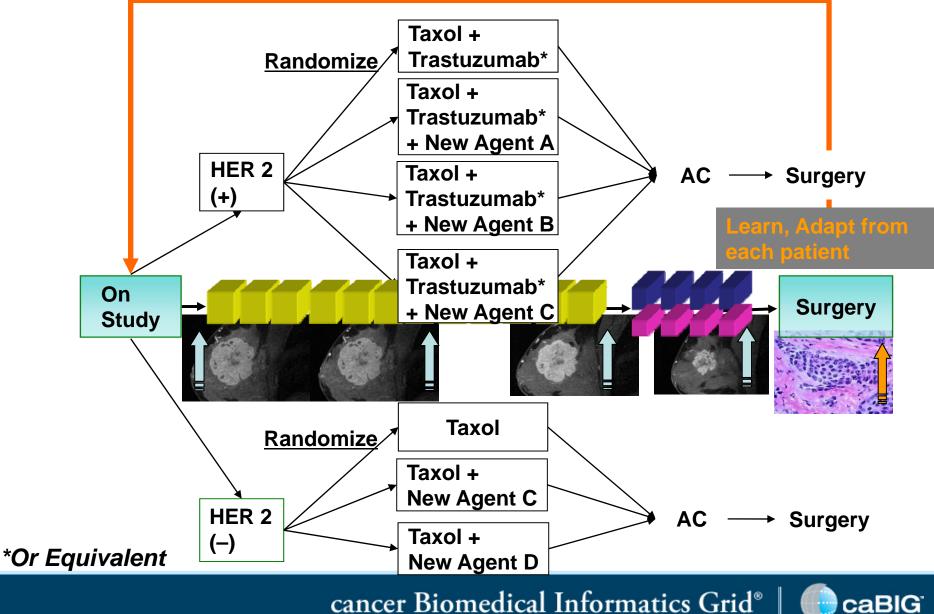
Enroll ~20 patients per month

Participating Sites: 15–20 across US and Canada

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#### **I-SPY** Adaptive Trial:

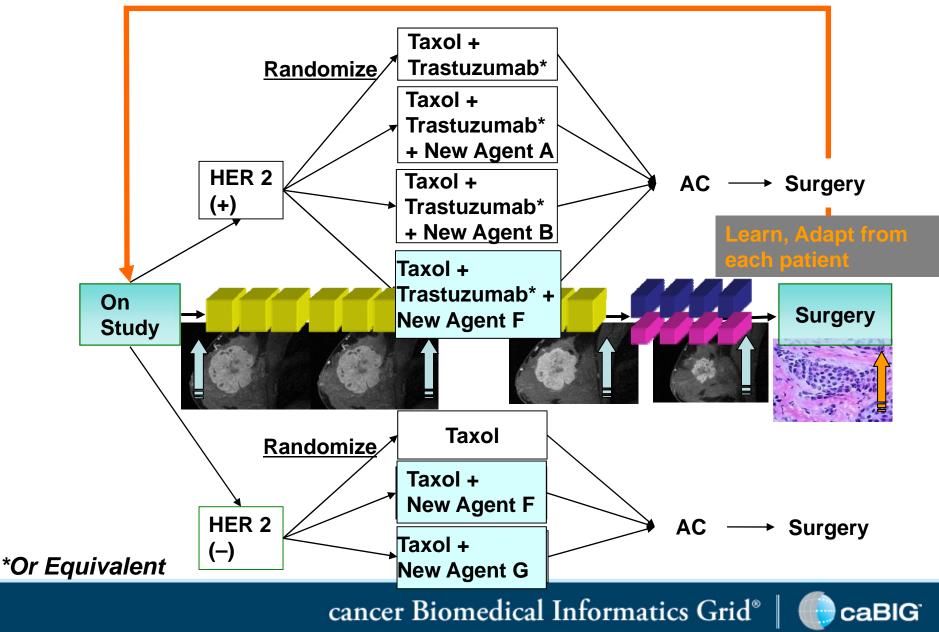
Introduce several new agents for a given profile



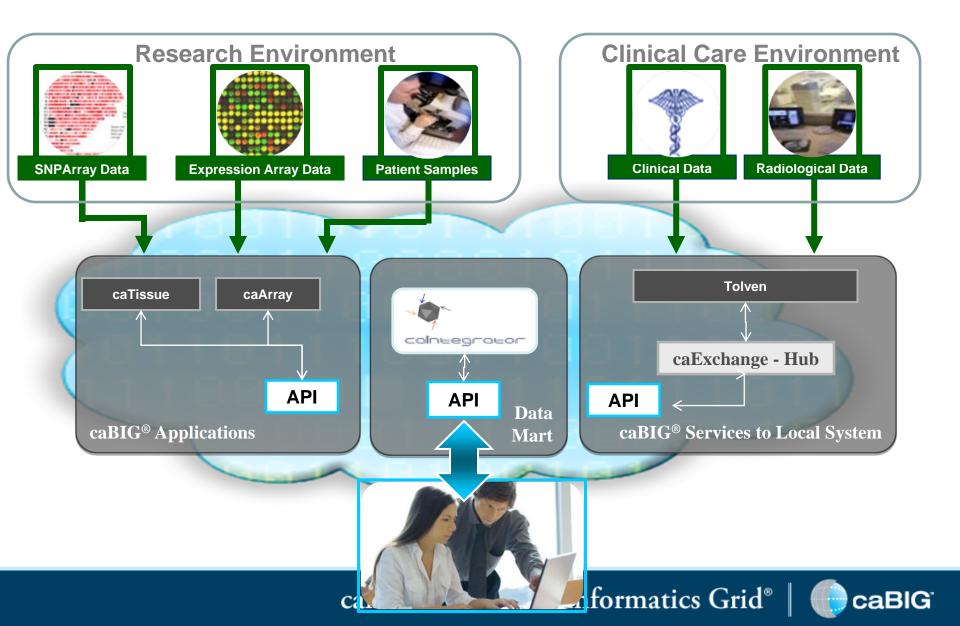
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#### **I-SPY Adaptive Trial:**

Introduce several new agents for a given profile



#### **I-SPY TRIAL IT Infrastructure**







- Opportunities exist right now to use data in new ways to transform research and clinical care
  - It's a unique moment many trends are converging
  - Technology now offers possibilities not feasible ever before
  - We can work differently using information technology and seamless flow of data – to accelerate research AND improve clinical care
- Participants from every sector have a contribution to make – consumers, providers, industry, government, academe – to conquer cancer

