



# Introduction and Principles of caBIG<sup>®</sup>

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*Workshop on Biomedical Data Sharing in the U.S. and China:  
Opportunities for Collaboration through  
the National Cancer Institute Cancer Bioinformatics Grid<sup>®</sup>*

Beijing, Peoples Republic of China

June 22, 2010

# The National Cancer Institute (NCI)

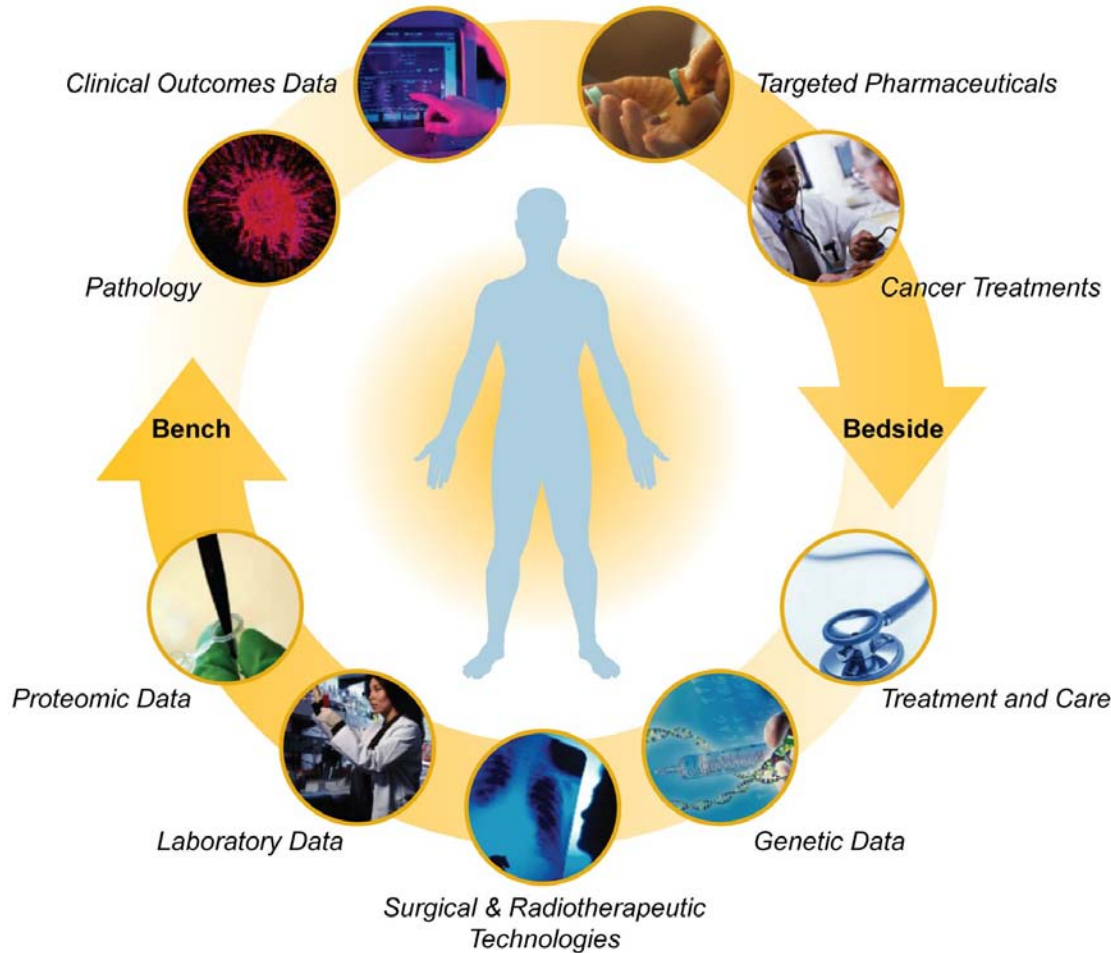
- U.S. Federal Government's principal agency for cancer research and training
- Part of the National Institutes of Health (NIH), one of 11 agencies that compose the Department of Health and Human Services (HHS)
- Established under National Cancer Institute Act of 1937, scope broadened by National Cancer Act of 1971
- Coordinates National Cancer Program, including:
  - NCI-designated Cancer Centers
  - Cooperative Groups
  - National Community Cancer Centers Program



## Defining Moment in Biomedicine...

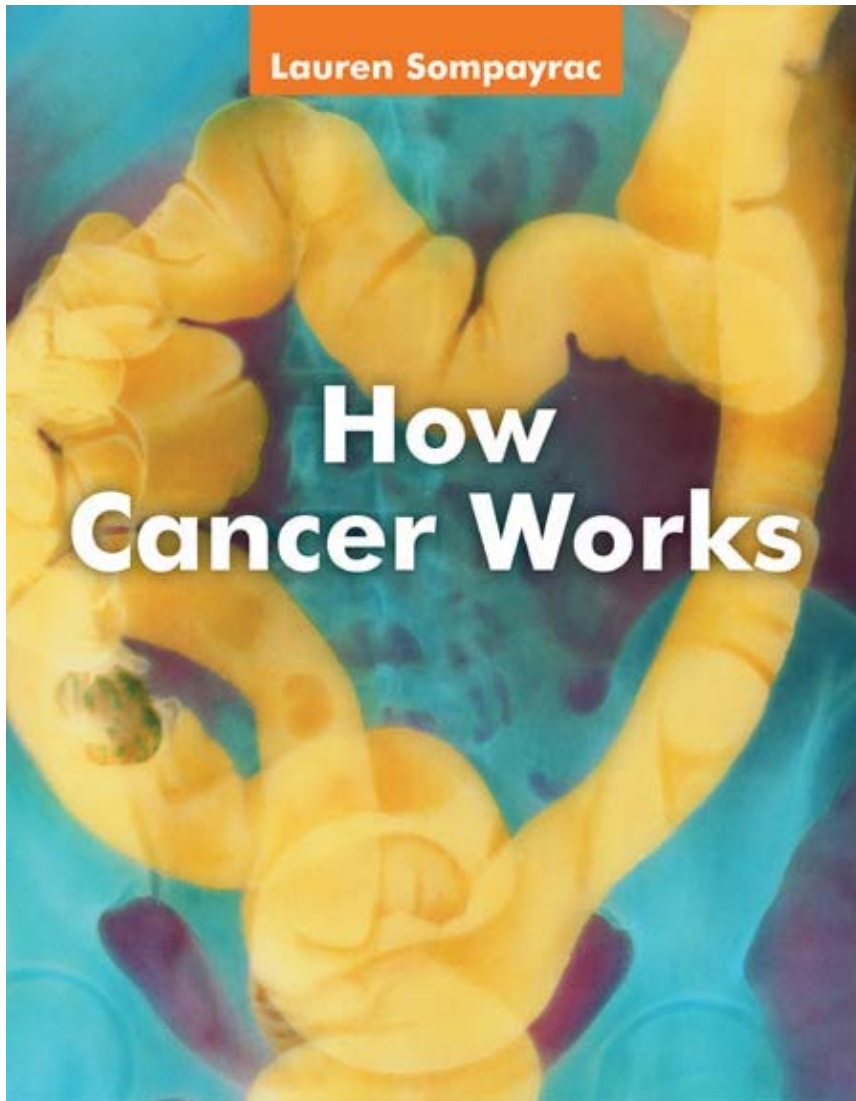
- **Several capabilities, needs and trends are converging:**
  - Vast and growing amount of molecular information
  - Ability to aggregate and process clinical information on an unprecedented scale
  - \$44+ Billion U.S. investment in Electronic Health Records
  - Unsustainable cost of new drug development

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



- **P**ersonalized, **P**redictive, **P**reemptive, **P**articipatory.....
- **U**nifies discovery, clinical research, and clinical care (bench-bedside-bench) into a seamless continuum
- **R**esults in improved clinical outcomes
- **A**ccelerates the time from discovery to patient benefit
- **E**nables a health care system, not a disparate “sector”
- **E**mpowers consumers in managing their health over a lifetime

# Still Fighting a War on Cancer



- We know “how cancer works”
- BUT:
- Estimated US cancer deaths 2009: 562,340  
*(American Cancer Society)*
- Estimated new US cancer cases 2009: 1,479,350  
*(American Cancer Society)*
- Cost of cancer deaths: \$960.7 billion in 2000, estimated \$1,472.5 billion in 2020  
*(Journal of the National Cancer Institute, Dec. 9, 2008)*

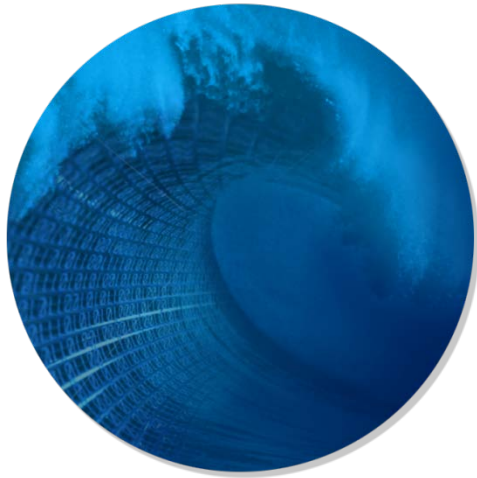
# Information and Community Fragmentation blocks the New Paradigm



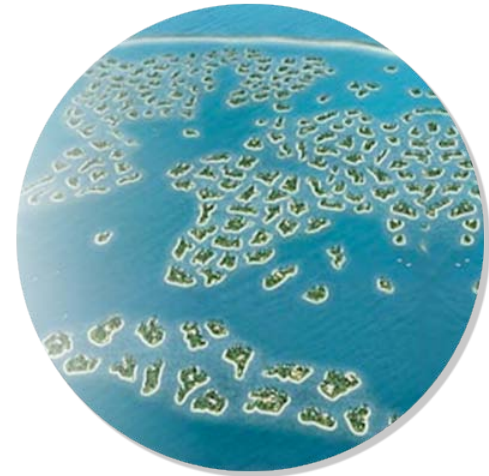
# Biomedicine is *Decades* Behind the “Knowledge Economy” Curve

- Translational research and personalized medicine require integration of multiple modalities and dimensions of data (clinical care / clinical trials / pathology / imaging / gene expression / population data, etc.)
- This integration is currently achieved by custom-built point solutions, if at all
- As a result, the data is often locked away in incompatible formats and systems
- Research studies are *artisanal*, handcrafted from one-of-a-kind components; clinical trials take too long to initiate, too long to accrue patients and too long to report outcomes
- Access to, and maturity of, informatics tools within the research community is inconsistent

# Obstacles to Integration



**Tsunami of Genomic  
and Clinical Data**



**Islands of Information**



**Standard Language**



**IT Systems Do Not Interoperate**



# The Cancer Biomedical Informatics Grid (caBIG®)

## caBIG® Vision:

A virtual web of interconnected data, individuals, and organizations that redefines how research is conducted, care is provided, and patients/participants interact with the biomedical enterprise.

## caBIG® Mission:

- **Connect** the cancer research community through a shareable, interoperable infrastructure
- **Deploy and extend** standard rules and a common language to more easily share information
- **Build** or adapt tools for collecting, analyzing, integrating and disseminating information associated with cancer research and care

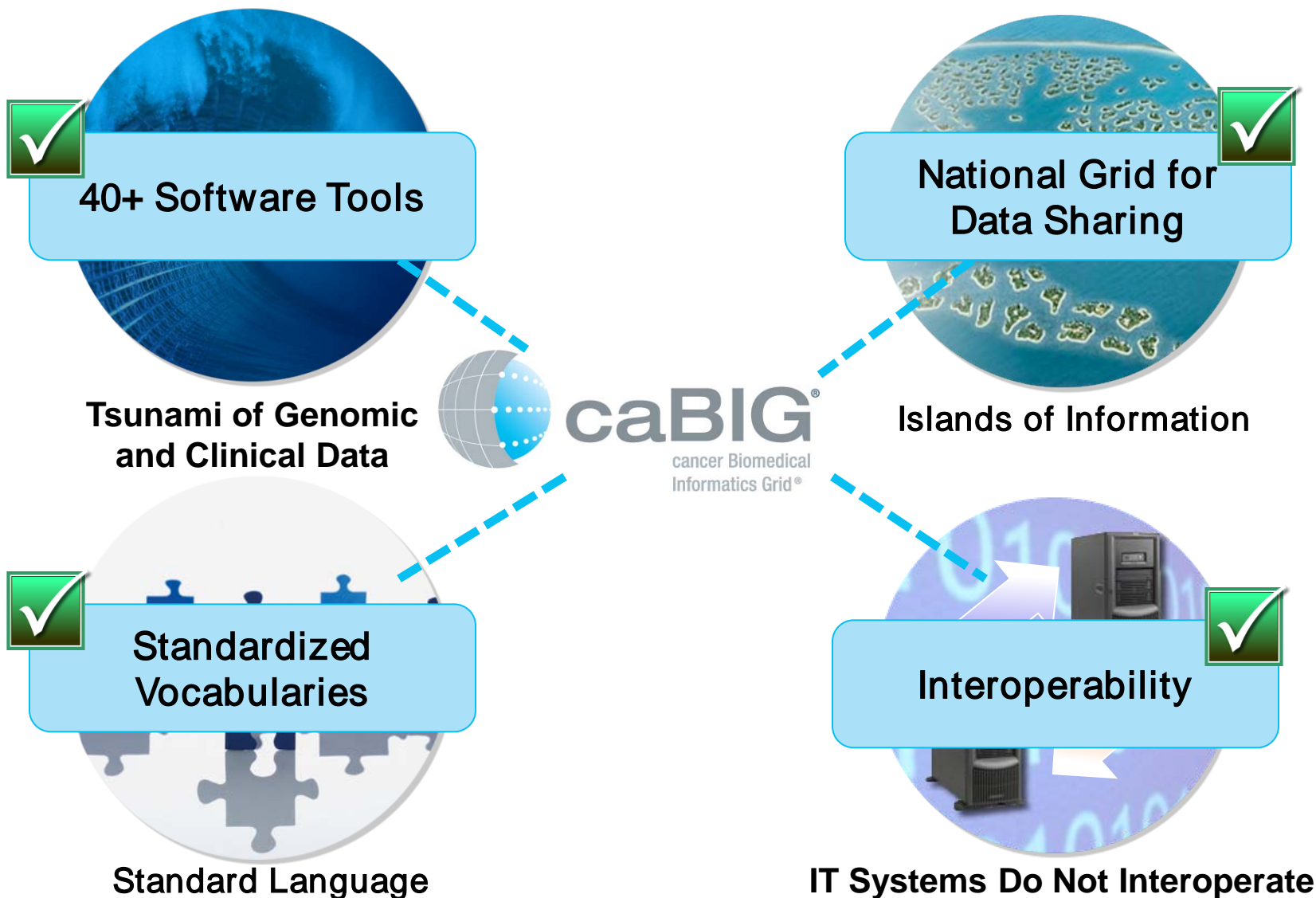
# caBIG<sup>®</sup> Core Principles

- Open Access
  - caBIG<sup>®</sup> is open to all, enabling wide-spread access to tools, data, and infrastructure
- Open Development
  - Planning, testing, validation, and deployment of caBIG<sup>®</sup> tools and infrastructure are open to the entire research community
- Open Source
  - The underlying software code of caBIG<sup>®</sup> tools is available for use and modification
- Federation
  - Resources can be controlled locally, or integrated across multiple sites



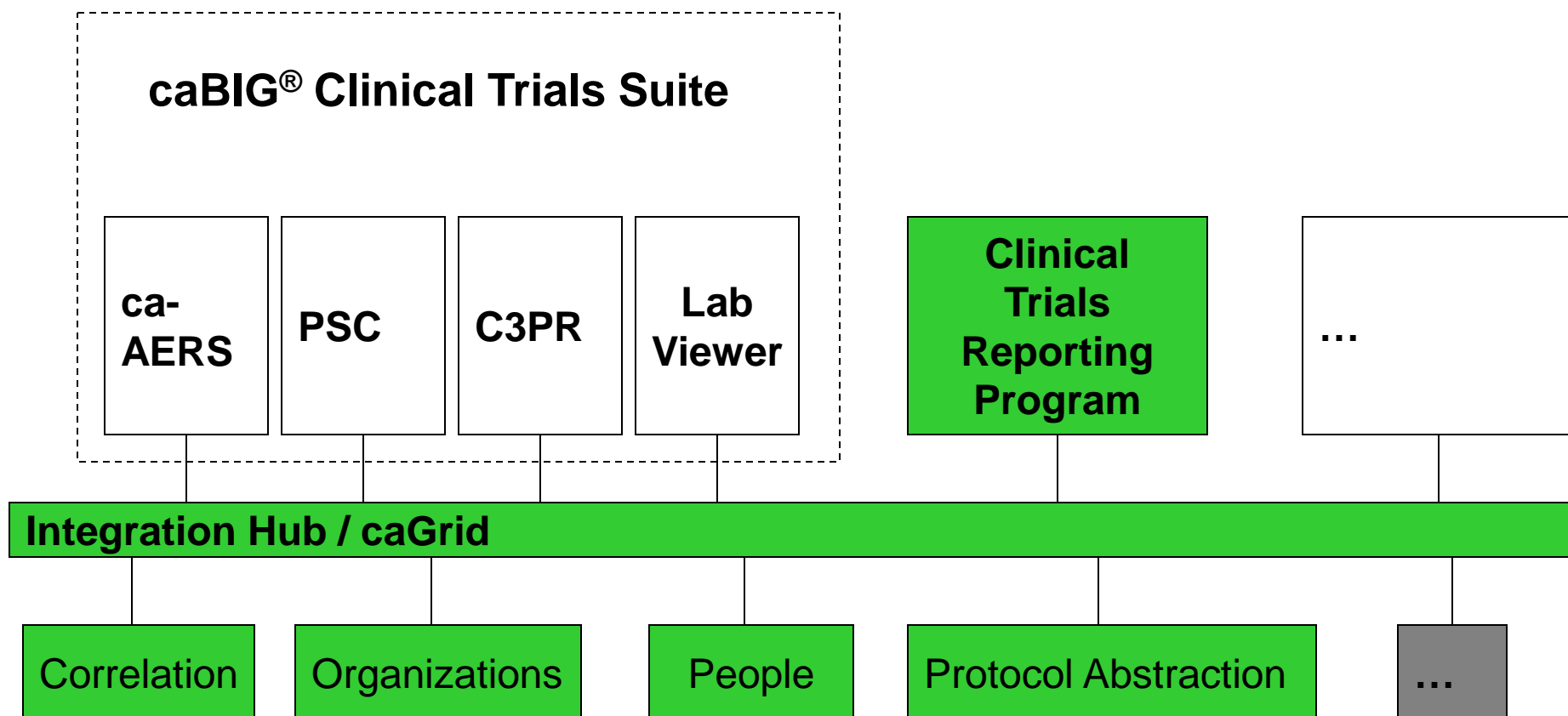


# caBIG<sup>®</sup> Overcomes the Obstacles to Integration



# A Semantic Services Oriented Architecture

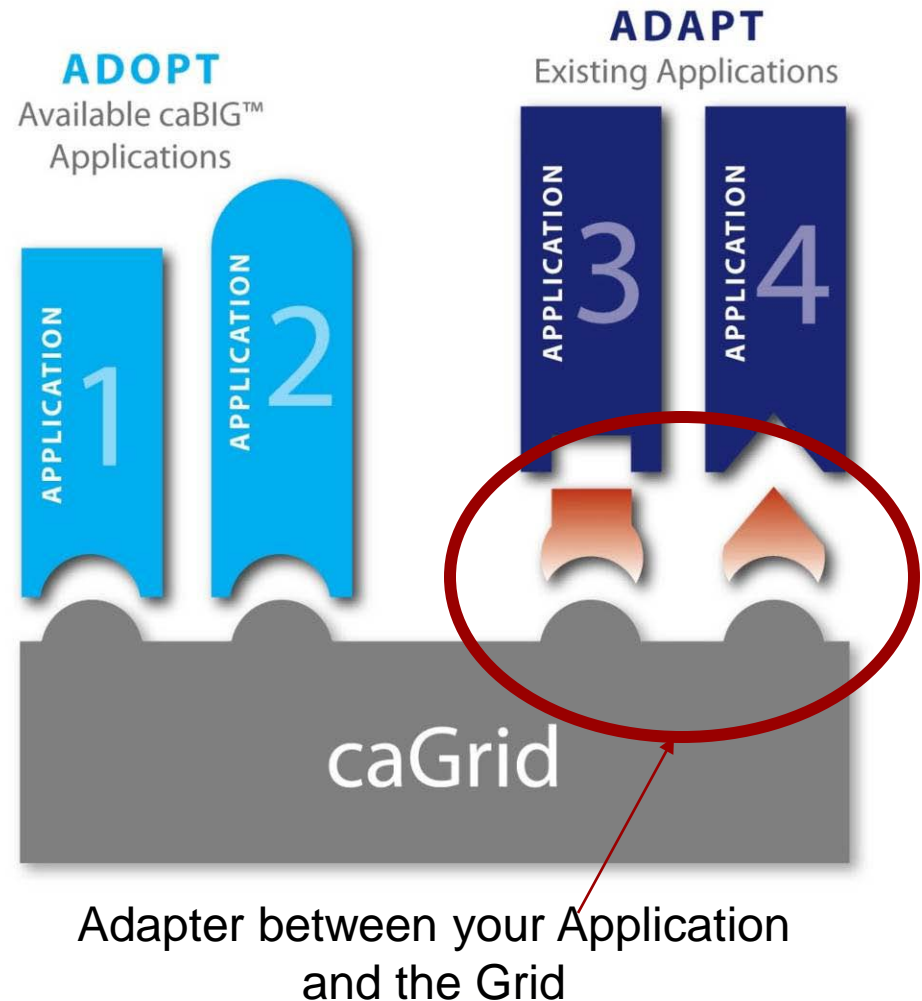
- Vendors, Cancer Centers also exploring service integration



# How do you use it?

**Adopting** involves installing software applications already made to caBIG<sup>®</sup> standards, integrating them into your workflow, and connecting to caGrid.

**Adapting** involves modifying your existing software applications to be caBIG<sup>®</sup> compatible, and then connecting to caGrid.



# Clinical Participant Registry (C3PR)

- Manages clinical trial subject data across multiple clinical trials
- Supports large-scale, geographically dispersed studies
- Provides enrollment statistics and a repository for participant information across studies, sites, systems, and organizations
- Role-based access by study personnel

**Frequently Used Shortcuts**

- [Search Participant](#)
- [Manage Study](#)
- [Manage Registration](#)

**Notifications** [My Inbox](#)

You don't have any notifications.

**C3PR Development Notes**

- [C3PR Wiki](#)
- [C3PR User Guide](#)

Build Number: c3pr v. 2.8

**Incomplete Registrations - Most Recent**

No incomplete registrations found.

**Pending Studies - Most Recent**

Short title	Primary identifier	Coordinating center	Phase
Test Study 3	Study3	National Cancer Institute	Phase I/II Trial

**Most Active Studies**

Short title	Primary identifier	Coordinating center	Accrual within last week
E1505	E1505	Eastern Cooperative Oncology Group	0
Test Study 2	TSt-2	National Cancer Institute	0
Test Study 1	Test-Study1	National Cancer Institute	0

# Patient Study Calendar (PSC)

- Create, edit, distribute study calendar templates, generate and view prospective calendars of patient activities, track activities as they occur, and manage study subject calendars
- Share calendar with subject either online or via calendar file
- Accommodates interventional, epidemiological / observational studies

The screenshot displays the Patient Study Calendar (PSC) interface. At the top, there is a navigation bar with tabs for Dashboard, Calendars, Activities, Administration, and Report. The main area shows a comprehensive schedule for a patient named Betty Ford, spanning from 2008 to 2012. A red vertical bar marks the current date as 'Today' on March 15, 2010. Below the calendar, there are two panels: 'Schedule details' and 'Modify schedule'. The 'Schedule details' panel lists various activities for the date 2010-03-11, such as 'E1505 / Treatment: Arm A, Regimen 1 / Vinorelbine 30 mg/m2 IV push over 10 minutes; Labels: pharma' and 'E1505 / Treatment: Arm A, Regimen 1 / Cisplatin 75 mg/m2 IV over 60 minutes, immediately following vinorelbine; Labels: pharma'. The 'Modify schedule' panel includes sections for 'Display', 'Notifications', 'Amendments', 'Delay or advance', and 'Select and modify'. It also features a 'Mark as occurred' button and a 'Next segment' field.



# Adverse Event Reporting System (caAERS)

- Used to collect, process and report adverse events
- Supports regulatory compliance and allows local collection, management, and querying of adverse event data, whether routine or serious
- Report in standard formats required by regulatory authorities
- Automated reporting to sponsor and (soon) FDA systems

The screenshot displays the caAERS (Cancer Adverse Event Reporting System) interface. At the top, there is a navigation bar with tabs for 'Adverse Events', 'Studies', 'Subjects', 'Rules', 'Administration', and 'Advanced Search'. Below this, there are three main action buttons: 'Report Adverse Events', 'Manage Reports', and 'Routing and Review'.

The main content area shows details for a specific study:
 

- Study:** (E1505) A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (> 4 cm) - IIIA Non-Small Cell Lung Cancer (NSCLC)
- Subject:** (10-02-04-1) Betty Ford
- Instructions:** The table below summarizes reporting screens.

There is a 'Labs' section with a table of laboratory results:

Lab	Date	Value	Unit	Status
RBC_SERUM	2009-03-04	3.9	Million/microL	✗
BILIRUBIN_TOTAL	2009-03-04	2.5	mg/dL	✗
LYMPHOCYTES_SERUM	2009-03-04	49.0	%	✗
SGOT_AST	2009-03-04	256.0	U/L	✗
WBC_SERUM	2009-03-04	12.7	K/U/L	✗
SGPT_ALT	2009-03-04	165.0	U/L	✗

Below the lab results, there is a 'Course' section with a table showing reporting details:

Report Type	Amendment #	# of AEs	Data Entry Status	Report Submission Status	Options
NCI SAE Report - for QA testing only	0	3	In-progress	Due in 3 days	Please select ▼

At the bottom of the course section, there is another table detailing adverse events:

AE Term	Grade	AE Start Date	Requires Expedited Reporting?
Vomiting	2	03/10/2010	Yes
Pain - Head/headache	1	03/10/2010	No
Nausea	1	03/10/2010	No

# caBIG<sup>®</sup> Integration Hub and Lab Viewer

- Configurable Hub for exchanging clinical trial information between applications and systems
- Can map and transfer laboratory data from non-standard clinical care systems into a standard format (suitable for receipt by clinical trials databases)

The screenshot displays the HL7 SDK Mapping Tool interface. On the left, a tree view shows the mapping structure for DRUGADMIN and DRUGNM. The main area shows search filters for Site, Lab Test, Numeric Result, and Date Range, all set to 'All'. Below the filters is a search button. The search results are displayed in a table titled 'Lab Activities - Search Results [23 record(s) found]'. The table has columns for Patient Id, Site, Date / Time, Lab Test, Text Result, Numeric Result, Unit Of Measure, Lower Limit, Upper Limit, Sent to CDMS, and Sent to caAERS. Several rows have red highlights in the Numeric Result column.

<input checked="" type="checkbox"/>	Patient Id	Site	Date / Time	Lab Test	Text Result	Numeric Result	Unit Of Measure	Lower Limit	Upper Limit	Sent to CDMS	Sent to caAERS
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	BANDS	Not Available	8.5	%	0.0	9.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	BASO	Not Available	3.0	%	0.0	4.0	2010-03-10 20:33:01	NOT SENT
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	BILRUBIN_TOTAL	Not Available	2.5	mg/dL	0.0	1.0	2010-03-10 20:33:01	2010-03-10 20:32:38
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	BUN	Not Available	19.0	mg/dL	7.0	21.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	CHLORIDE	Not Available	107.0	mEq/L	100.0	110.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	CREATININE	Not Available	1.5	mg/dL	0.0	14.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	CREATININE_CLEARANCE	Not Available	72.0	mL/min	52.0	146.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	EOSIN	Not Available	8.0	%	0.0	10.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	HEMATOCRIT	Not Available	48.0	%	40.0	52.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	HEMOGLOBIN	Not Available	14.0	g/dL	12.0	16.0	2010-03-10 20:33:01	NOT SENT
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	LYMPHOCYTES_SERUM	Not Available	49.0	%	15.0	45.0	2010-03-10 20:33:01	2010-03-10 20:32:38
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	MAGNESIUM	Not Available	1.9	mEq/L	1.0	2.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	MCH	Not Available	33.0	pg	27.0	34.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	MCHC	Not Available	35.0	g/dL	32.0	36.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	MONOCYTES_SERUM	Not Available	9.0	%	0.0	12.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	NEUT	Not Available	72.0	%	42.0	80.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	PLT	Not Available	322.0	KU/L	150.0	350.0	2010-03-10 20:33:01	NOT SENT
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	POTASSIUM	Not Available	4.4	mEq/L	3.0	5.0	2010-03-10 20:33:01	NOT SENT
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	RBC_SERUM	Not Available	5.9	Million/microL	4.0	6.0	2010-03-10 20:33:01	2010-03-10 20:32:38
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	SGOT_AST	Not Available	256.0	U/L	3.0	42.0	2010-03-10 20:33:01	2010-03-10 20:32:38
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	SGPT_ALT	Not Available	165.0	U/L	3.0	45.0	2010-03-10 20:33:01	2010-03-10 20:32:38
<input type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	SODIUM	Not Available	144.0	mEq/L	136.0	146.0	2010-03-10 20:33:01	NOT SENT
<input checked="" type="checkbox"/>	10-02-04-1	Not Available	3/4/09 10:28 PM	WBC_SERUM	Not Available	12.7	KU/L	3.0	11.0	2010-03-10 20:33:01	2010-03-10 20:32:38

Export options: [csv](#) | [Excel](#) | [XML](#)

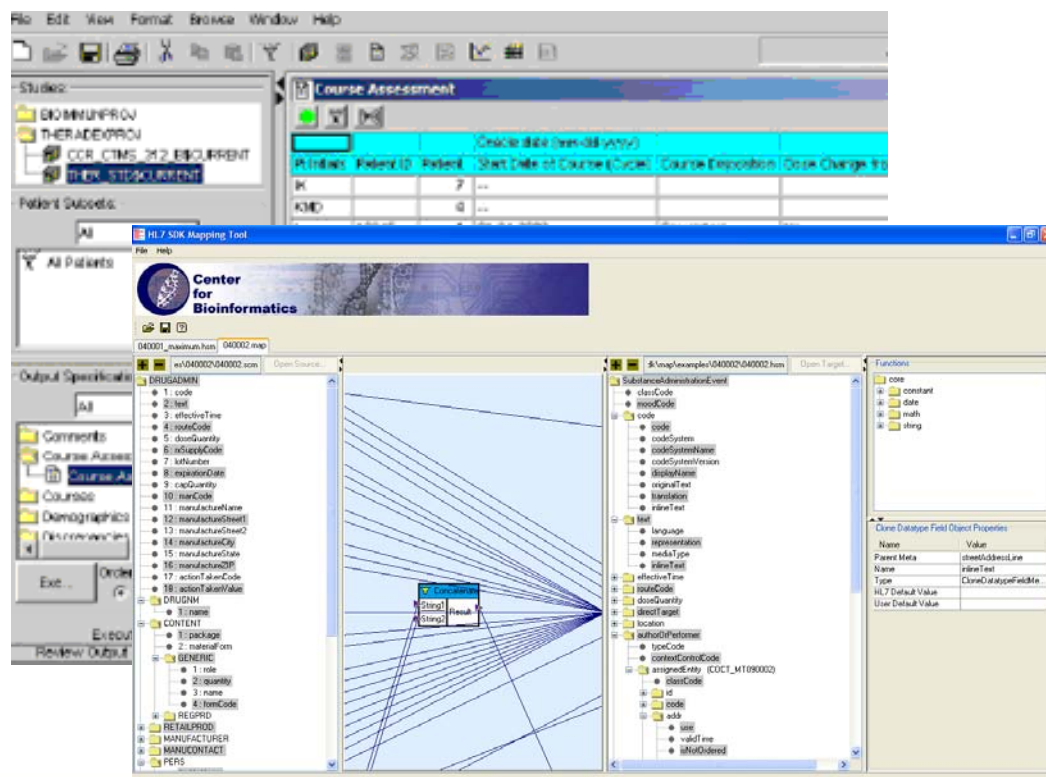
Buttons: Cancel | Load Labs to caAERS | Load Labs to CDMS

# caBIG<sup>®</sup> Clinical Connector

## Clinical Data Management System (CDMS/EDC) Integration

The Clinical Connector enables the exchange of data between the caBIG<sup>®</sup> Clinical Trials Suite and any caBIG<sup>®</sup> compatible Clinical Data Management System (CDMS)

- Supports the Cancer Central Clinical Database (C3D) and other conforming CDMS products
- Reduces duplicate data entry and streamlines clinical trials workflow



# Integration of caBIG<sup>®</sup> Clinical Trials Suite

## caBIG<sup>®</sup> Central Clinical Participant Registry (C3PR)

**Summary**

Full Name: John Smith  
 Subject Primary Identifier: 123-45-6  
 Gender: Male  
 About Value: 123-45-6  
 Current Epoch: Treatment A  
 Study Status: Active  
 Study Site: Central Cancer Institute  
 Site ID: ABC123  
 Registration Date: 11/28/2008  
 Registration Status: Registered  
 Data Entry Status: Incomplete  
 Registration Status: Incomplete

**Enrollment Details**

Informed Consent Signed Date: (mm/dd/yyyy)  
 Consent Version: 1.0  
 Registration Start Date: 02/12/2009  
 Primary Disease: Phase 1  
 Payment Method: (dropdown)

Eligibility is verified and patient is registered to a study

## Patient Study Calendar (PSC)

Calendar view for patient: John Smith  
 Study: ABC123  
 Schedule view: Study schedule  
 Study events: (calendar view)  
 Study site: (dropdown)  
 Study site location: (dropdown)  
 Study site address: (text area)  
 Study site phone: (text area)  
 Study site fax: (text area)  
 Study site email: (text area)  
 Study site website: (text area)  
 Study site contact: (text area)  
 Study site notes: (text area)

Tracks the patient schedule throughout the study

## Lab Viewer

Lab ID	Lab Name	Lab Type	Lab Status	Lab Date	Lab Time	Lab Location	Lab Operator	Lab Result	Lab Unit	Lab Reference
1	Complete Blood Count	Chemistry	Completed	11/28/08	08:00	Lab A	John Doe	12.3	g/dL	12.3-15.0
2	Urea Nitrogen	Chemistry	Completed	11/28/08	08:00	Lab A	John Doe	10.0	mg/dL	8.0-12.0
3	Serum Creatinine	Chemistry	Completed	11/28/08	08:00	Lab A	John Doe	1.2	mg/dL	0.8-1.2

Identifies labs, loads them into the CDMS and AE system



## Clinical Data Management System

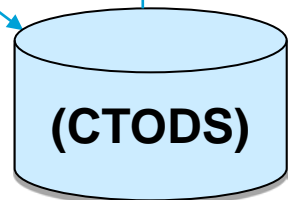
Study ID	Site ID	Applicant	Product	Phase	Study Status	Study Start	Study End
12345	67890	ABC	XYZ	Phase 1	Active	11/28/08	11/28/08
12345	67890	ABC	XYZ	Phase 1	Completed	11/28/08	11/28/08

Clinical data is captured

## caBIG<sup>®</sup> Adverse Event Reporting System (caAERS)

caAERS Adverse Event Reporting System  
 Manage reports | Enter AEs  
 Subject: John Smith  
 Study: ABC123  
 Evaluation Period: 12/15/08 - 12/31/08  
 # of Reports: 0  
 # of AEs: 2  
 Data Entry Status: In Progress  
 Report Status: No Reports

Identifies and tracks adverse events and any associated schedule changes

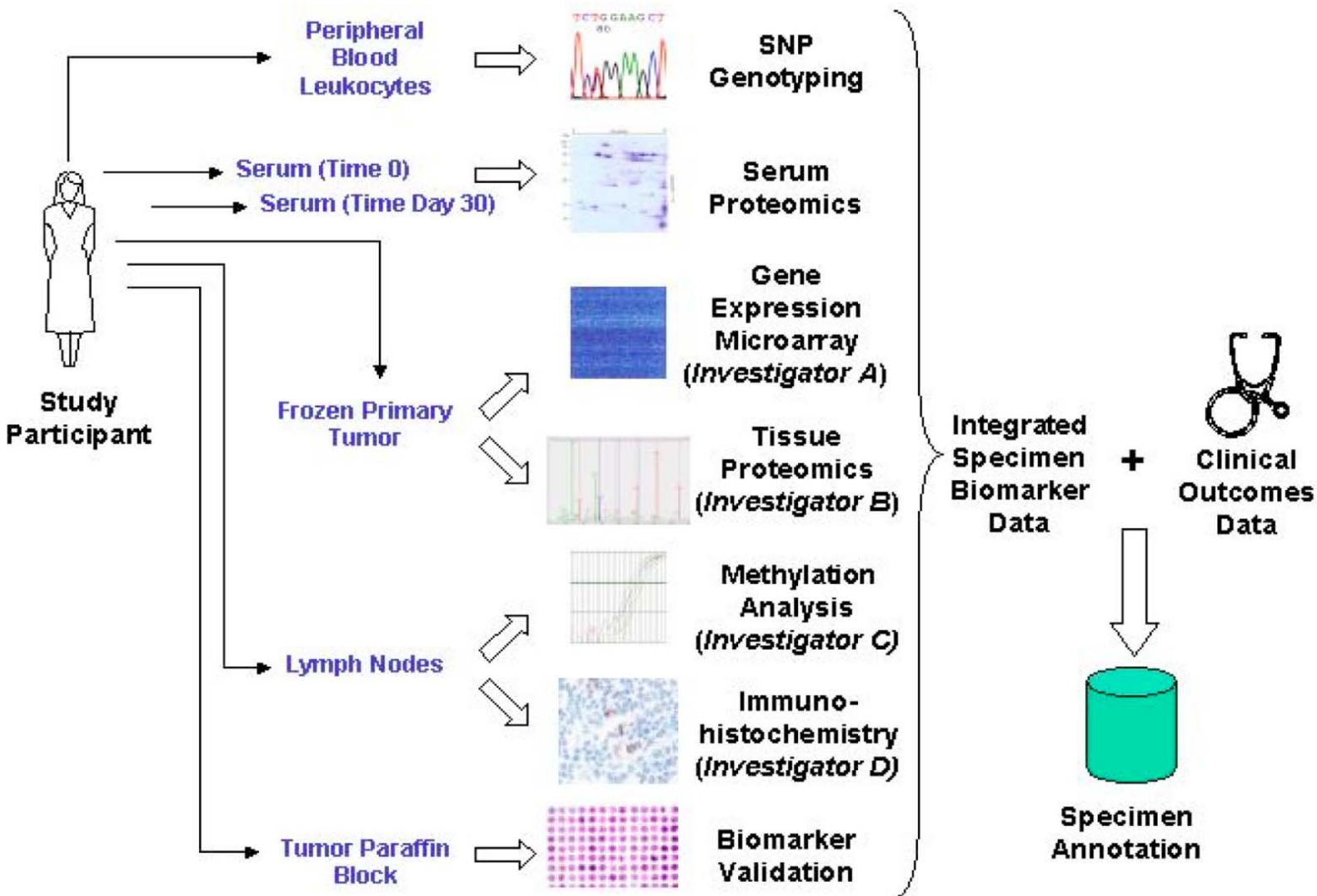


Clinical Trial Object Database System



Patient visits the Physician

# Biospecimen Banking: caTissue



# Biospecimen Banking: caTissue

Web-based application for tracking the acquisition, storage and distribution of biospecimens

- Specimen history
- Basic annotation
- Simple and Advanced Query
- Integration with existing systems - via API
- Role based security
- Temporal Queries (e.g., querying by patient age, time between events)

The screenshot shows the caTissue application interface. On the left is a hierarchical tree view of the biospecimen storage structure, including levels like 'Persistent test lab', 'warehouse', and 'MC-80 Freezer #1'. On the right is a grid view showing specimen information and container status. The grid has 4 columns and 4 rows. The first row, first column cell contains the text 'Specimen : Tissue D1\_11235712'. The other cells in the grid are labeled 'Unused'. Above the grid is a selection box for 'Collection Protocol' (set to 'All') and 'Specimen Class' (with options 'Molecular', 'Fluid', 'Cell', and 'Tissue'). A red bracket on the right side of the grid points to the grid cells with the text: 'This selection depicts the dimensions and contents of the container.'

Collection Protocol	All			
Specimen Class	Molecular	Fluid	Cell	
	Tissue			
Columns →	1	2	3	4
Rows ↓	1	2	3	4
1	Specimen : Tissue D1_11235712	Unused	Unused	Unused
2	Unused	Unused	Unused	Unused
3	Unused	Unused	Unused	Unused
4	Unused	Unused	Unused	Unused

Home

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[home](#) » [workspaces](#) » [tissue banks and pathology tools](#) » shared biospecimen data directory

## Shared Biospecimen Data Directory



This directory contains a list of known sites that share biospecimen data using caTissue or some other caBIG™ compatible product. Sites can be accessed by following the provided links, though in some cases access is restricted to known IP addresses. Each site offers additional summary data and the ability to request a username/password in order to conduct a detailed search for biospecimen data.


Site Name	Version	Biobank Use
<a href="#">Indiana University</a>	caTissue Core 1.2.0.1	Production
<a href="#">Louisiana Cancer Research Consortium</a>	caTissue Core 1.2.0.1	Production
<a href="#">Thomas Jefferson University</a>	caTissue Core 1.2.0.1	Production
<a href="#">University of Pennsylvania</a>	caTissue Core 1.2.0.1	Production
<a href="#">University of Pittsburgh</a>	caTissue Core 1.2.0.1	Production
Washington University in St. Louis	?	?
Yale University	?	?
<a href="#">Baylor College of Medicine</a>	caTissue Suite 1.0 (RC2)	Production
Dana Farber Cancer Institute	?	?
<a href="#">Fred Hutchinson Cancer Research Center</a>	caTissue Suite 1.0 (RC1)	Testing
<a href="#">Johns Hopkins</a>	caTissue Suite 1.0 (RC2)	Testing
Mayo Clinic	?	?
MD Anderson	?	?
<a href="#">Memorial Sloan Kettering Cancer Center</a>	caTissue Suite 1.0 (RC2)	Testing
<a href="#">Northwestern University</a>	caTissue Suite 1.0 (RC2)	Testing
<a href="#">University of California - San Francisco</a>	caTissue Core 1.2.0.1	Testing
<a href="#">University of California - Los Angeles</a>	caTissue Core 1.2.0.1	Testing
<a href="#">University of Michigan</a>	>caTissue Core 1.2.0.1	Production

To publish or update your institution's information, please contact Miguel Buddle ([✉buddle\\_miguel@bah.com](mailto:buddle_miguel@bah.com)).

last modified 05-13-2008 09:42 PM

# Array Data Management: caArray

- Store array data
- Parse popular expression/SNP array formats (Affymetrix, Illumina and GenePix) - store native files for other providers
- MAGE-TAB compatible import
- MIAME-compatible annotation
- Browse and Search



The screenshot shows the caArray Data Portal homepage. At the top left is the caArray logo, which consists of a cluster of colored dots (red, blue, grey) and the text "caArray Array Data Management System". To the right of the logo is the URL "https://array.nci.nih.gov" in teal. Below the logo and URL is a grey banner with the text "Welcome to the caArray Data Portal" and links for "Help" and "Print". Below the banner is a paragraph of text: "caArray is an open-source, web and programmatically accessible array data management system. caArray guides the annotation and exchange of array data using a federated model of local installations whose results are shareable across the cancer Biomedical Informatics Grid (caBIG®). caArray furthers translational cancer research through acquisition, dissemination and aggregation of semantically interoperable array data to support subsequent analysis by tools and services on and of the Grid. As array technology advances and matures, caArray will extend its logical library of assay management."

**Browse caArray**

Location	
(All Locations)	▼
<a href="#">Experiments</a>	100
<a href="#">Organisms</a>	7
<a href="#">Array Providers</a>	4
<a href="#">Unique Array Designs</a>	36
Hybridizations	9573
Registered Users	229

**Search caArray**

Keyword:

Category:

Location:



# NBIA: *in vivo* Imaging Repository

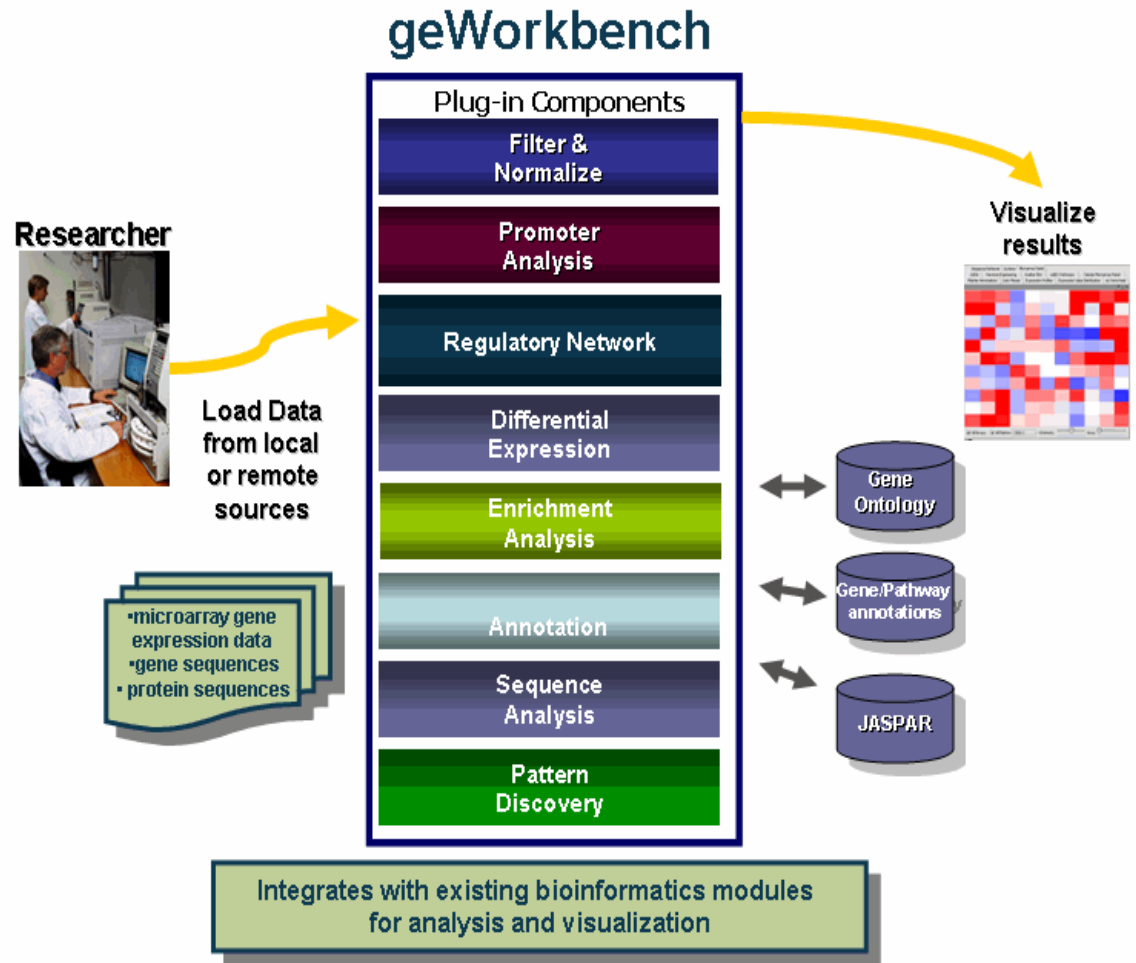
- Searchable, web-based repository of *in vivo* images
- Popular image formats supported including CT, MRI, and digital x-rays (DICOM standard)
- Also contains annotation files (PDF, image markup) and annotation data provided by curators

The screenshot shows the NCIA website interface. At the top, there is a red header with the National Cancer Institute logo and the text "National Cancer Institute" and "U.S. National". Below this is a blue header with the NCIA logo and the text "National Cancer Imaging Archive". A navigation bar contains links for "TOOLS", "HOME", "SEARCH IMAGES", "MANAGE DATA BASKET", and "HELP". The main content area is divided into several sections:

- Left Sidebar:** Contains "DICOM Image Viewers", "QUICK LINKS" (NCIA NEWS, NCIA USER'S GUIDE, NCI HOME, NCICB HOME), and logos for "caBIG™", "CANCER IMAGING PROGRAM", "Center for Bioinformatics", "RSNA", and "NIBIB".
- Main Content:** Features a "WELCOME TO NATIONAL CANCER IMAGING ARCHIVE" section with a "New!" announcement: "NCIA now offering web-based image visualization and markup of archived image data." with a link to "more information". Below this is a welcome message and a list of supported tools: "Lesion detection and classification", "Accelerated diagnostic imaging decision", and "Quantitative imaging assessment of drug response".
- Right Sidebar:** Contains a "USER LOGIN" section with fields for "EMAIL" (jaffec1@mail.nih.g) and "PASSWORD", and buttons for "Login" and "Register". Below this is a "NEW USER REGISTRATION" section with a message: "New users are asked to complete a one-time registration form. Please make note of your username and password for future visits. Registration will ensure that we can inform you about important changes and new data."

# Molecular Profiling Platform: geWorkbench

Comprehensive and extensible collection of tools for the management, analysis, visualization and annotation of biomedical data



# 20th Century Biomedical 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

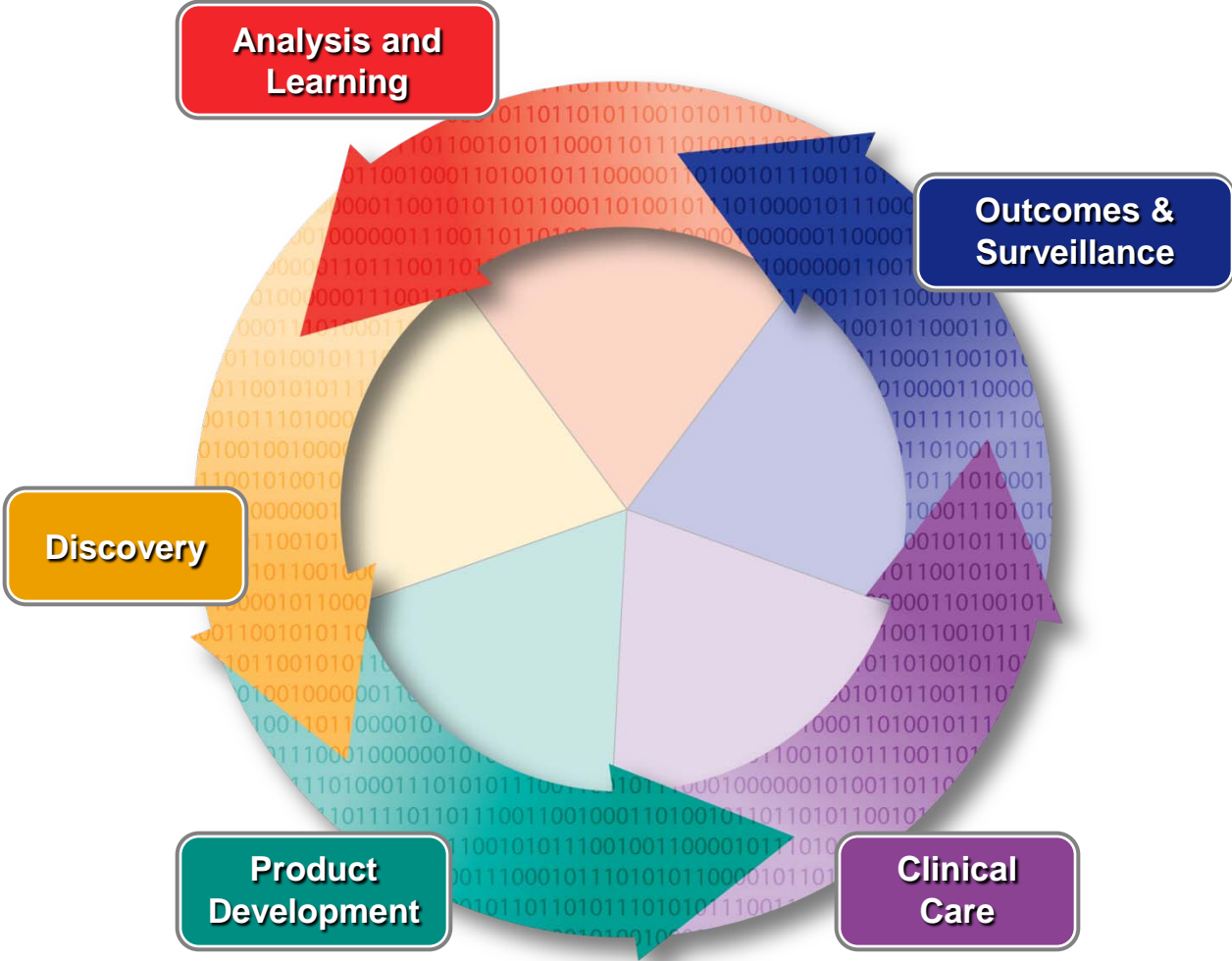
## Clinical Care

- Product launch
- Clinical adoption

## Outcomes & Surveillance

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

# 21th Century Biomedical Paradigm: a Learning Health System



# Software-Enabled Bridging of Research and Care

RESEARCH

SOFTWARE



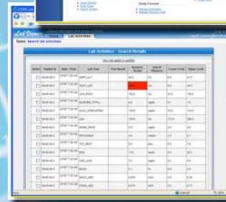
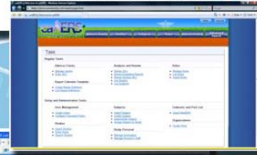
Clinical Trial

Group A (10mg)

Group B (30mg)

Group C (control)

CTMS



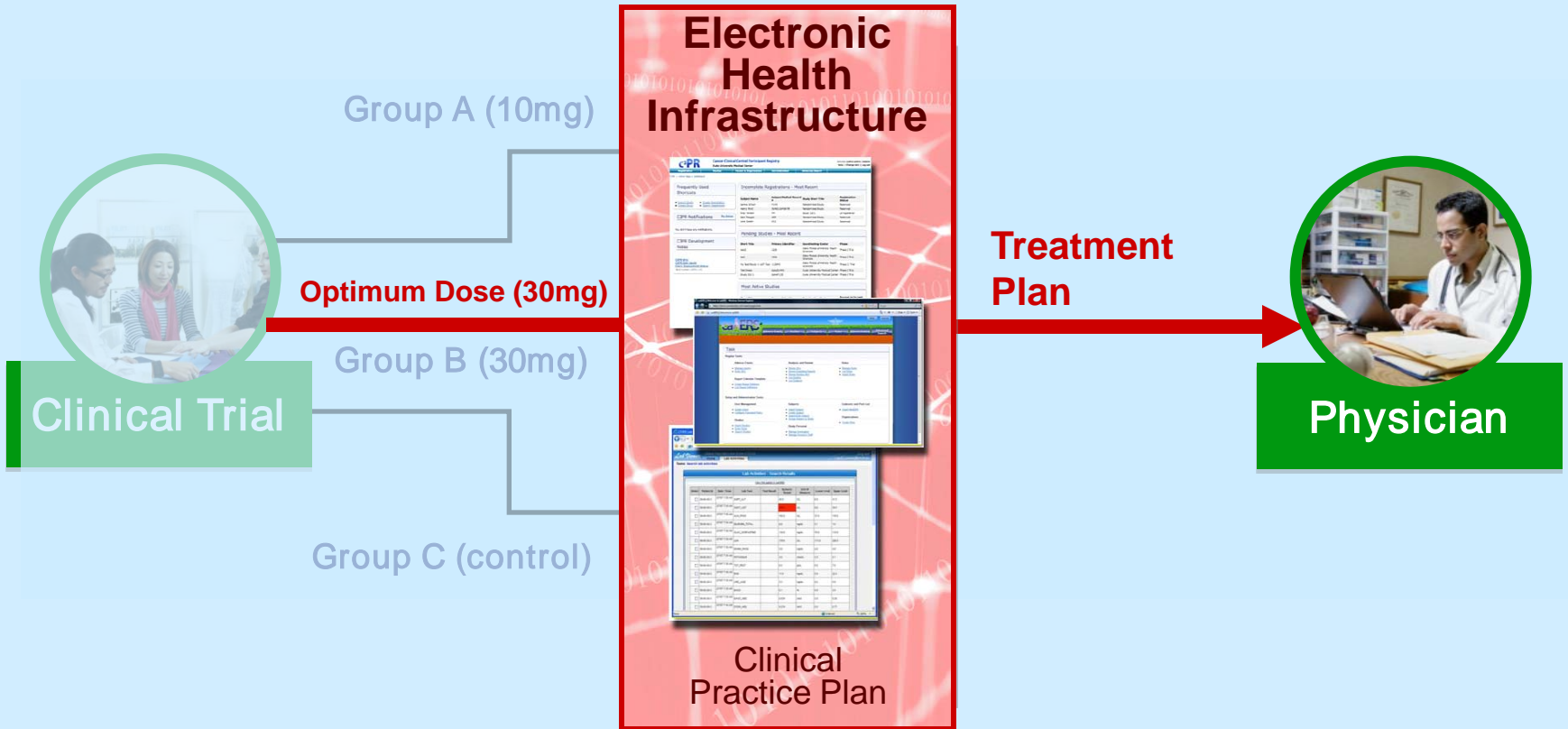
Electronically Executed Protocol

# Software-Enabled Bridging of Research and Care

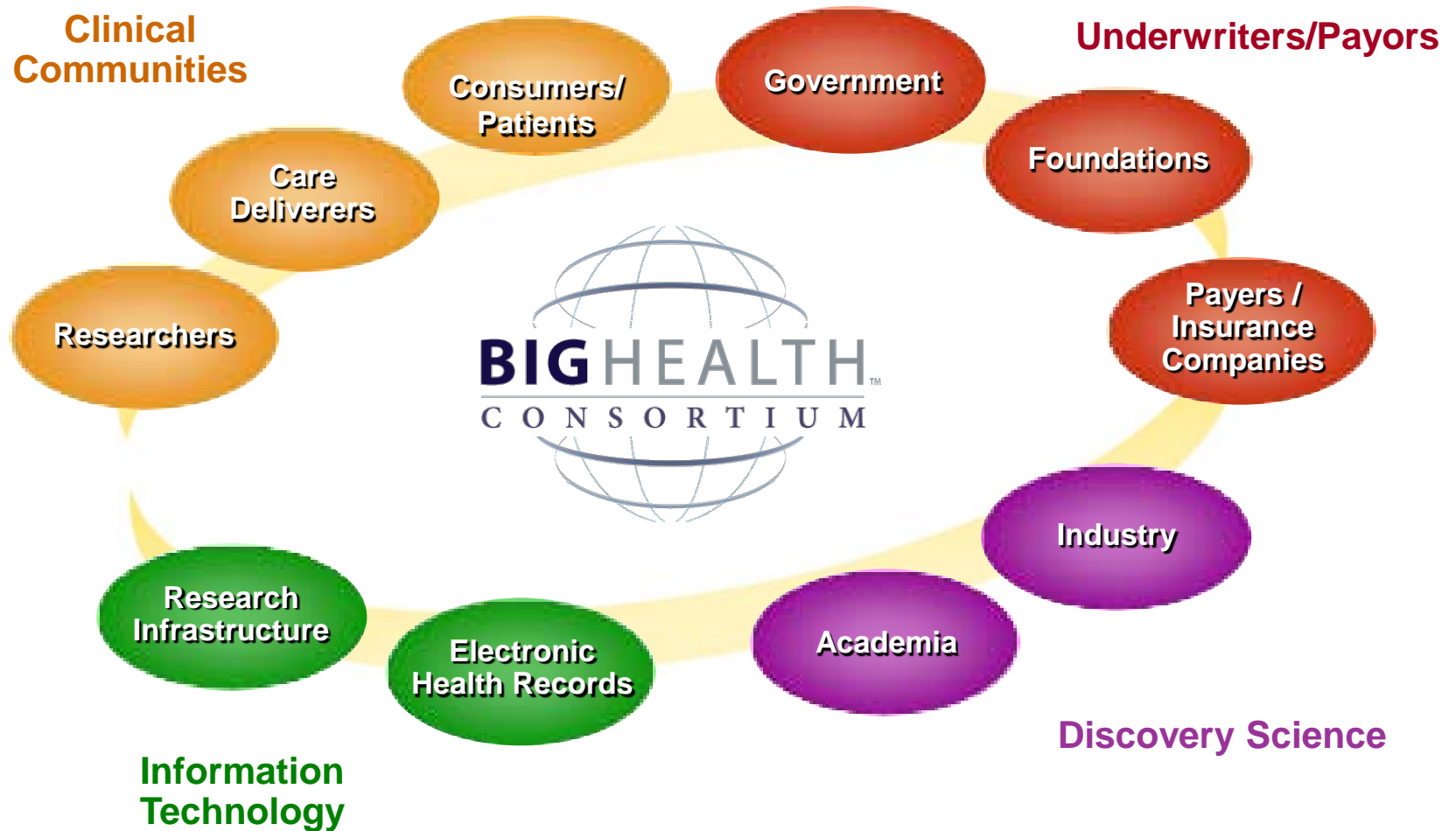
RESEARCH

SOFTWARE

CARE



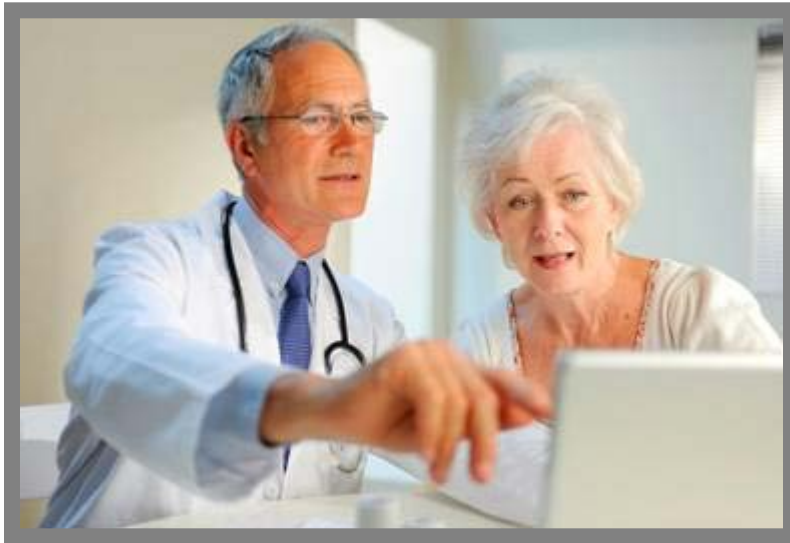
# A Diverse NCI-Fostered Biomedical Ecosystem



# Defining Electronic Health Records for Oncology

NCI has worked with ASCO to obtain requirements for an “Oncology-extended EHR”, now working with HL7 to define a structured specification, will subsequently develop a reference implementation

Oncology-extended EHR



The screenshot displays a software interface for an oncology-extended EHR. The main window is titled "Client Packets" and shows patient information for Sally Parker. The interface includes a navigation tree on the left, a registration form on the right, and a table of assessment results at the bottom.

**Client Packets**

Client ID: SP043477F0 Name: SALLY PARKER DOB: 04/04/1977 AGE: 31  
History: SP043477F0 - SALLY PAR... Show closed registrations:   
SSNs: 395 99 3659 Phone: -

Registration

Registration Date: 09/17/2008 Closed:   
 Crisis Registration:

Referral Date: 09/17/2008 VALUEOPTIONDHS  
RBHA: 05 MARICOPA RBHA

Category	Value	As Of Date
Managing:	JLL JONES, MSW	09/17/08 00:00
OutPatient:	2 Agency office: 2	09/17/08 00:00
Diagnosis:	291.81 ALCOHOLIC WITHDRAWAL	09/17/08 00:00
Program:	Standard Intake - No Sub	09/17/08 00:00
Quar. Priority:	UNITED BEHAVIORAL HEALTH	02/01/09 00:00

Chemotherapy drugs

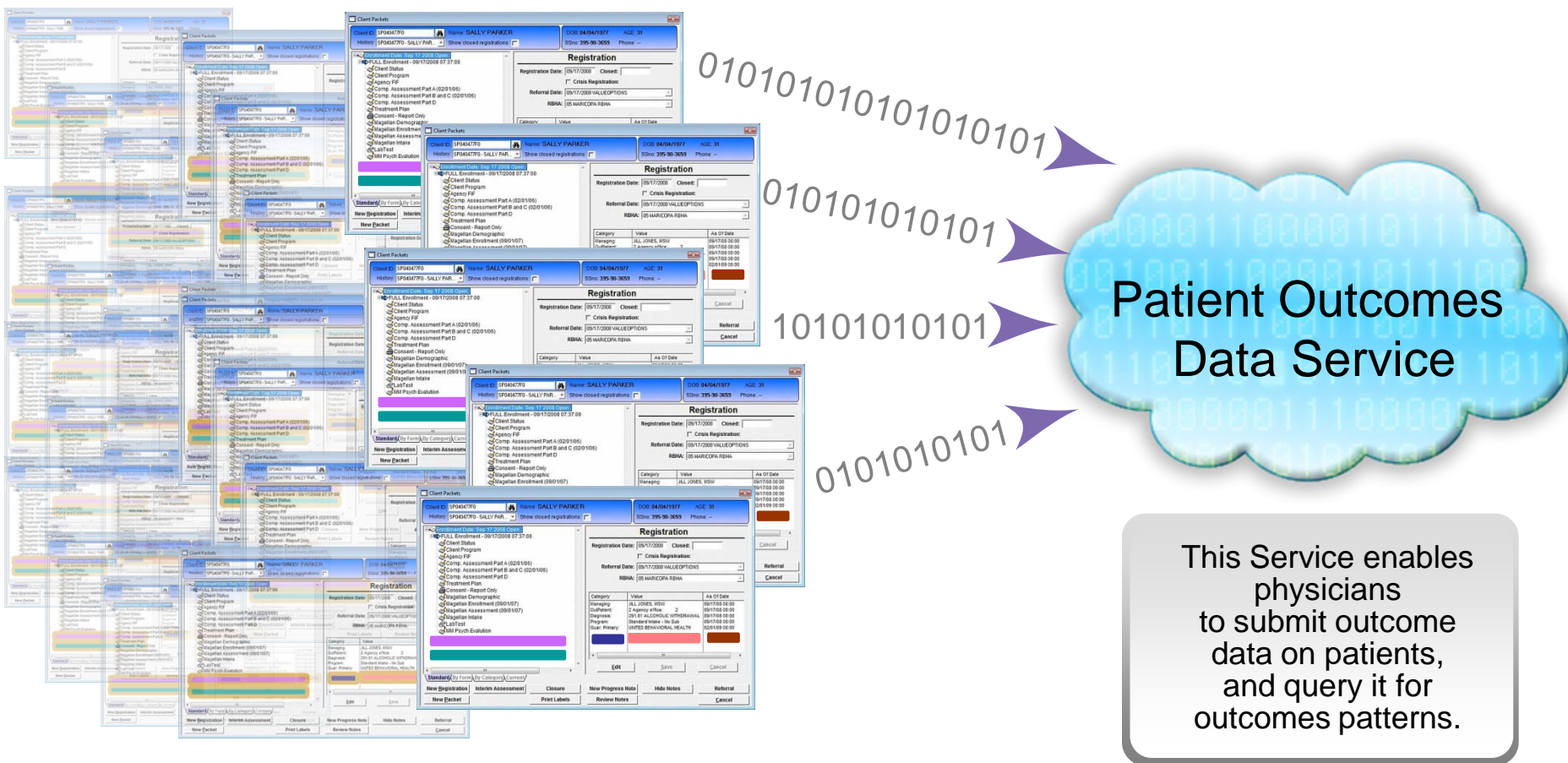
Standard (By Form) (By Category) (Current)

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



# Utilizing “Smart” Electronic Health Records to Accelerate Research

Data on hundreds of thousands of patient encounters can be fed into the Patient Outcomes Data Service electronically

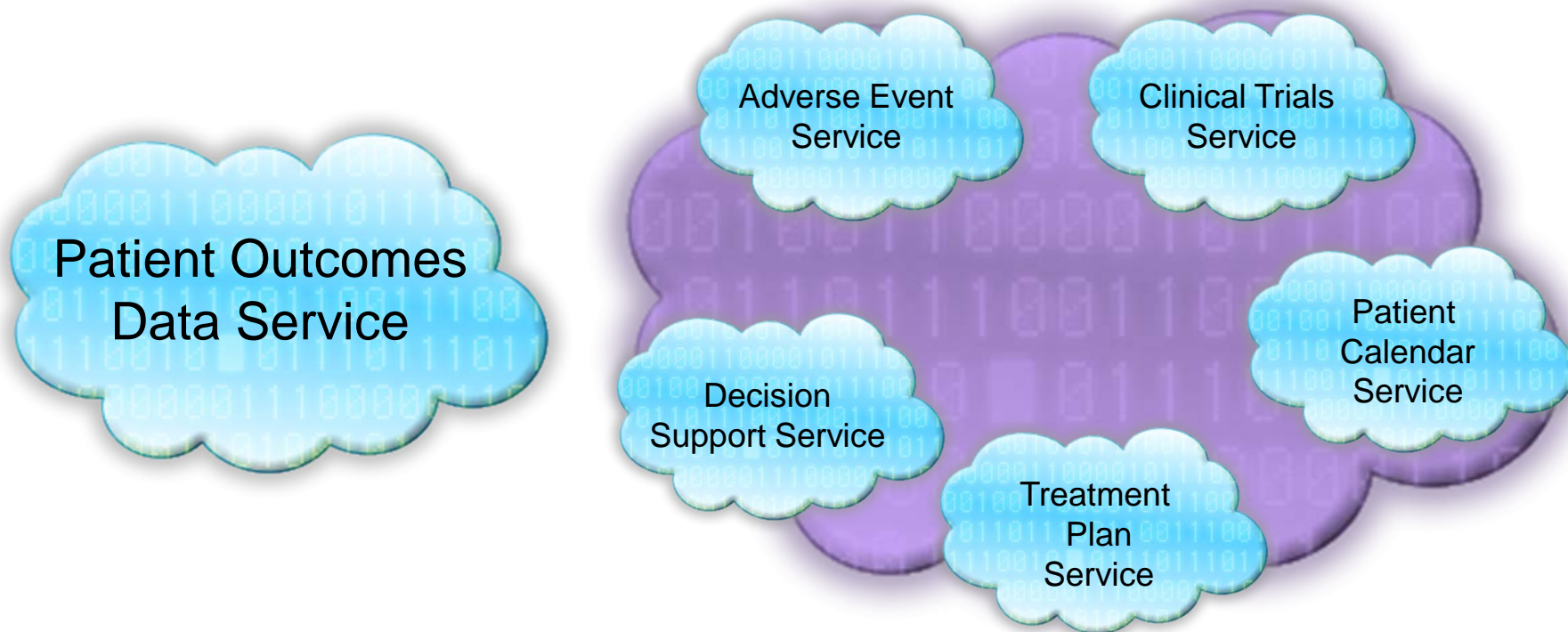


# Outcomes Portal

The screenshot shows a web browser window displaying the NCI Outcomes Portal. The browser's address bar shows the URL <https://trials-demo.nci.nih.gov/outcomes/home.action>. The page header includes the National Cancer Institute logo and the text "National Cancer Institute" and "U.S. National Institutes of Health | www.cancer.gov". Below the header is a navigation bar with the "NCI Outcomes Portal" title and a "Log In" button. A sidebar on the left contains a menu with "Home", "Create Account", and "Log In" under "NCI OUTCOMES", and "National Cancer Institute (NCI)", "NCI Center for Bioinformatics (NCICB)", and "caBIG™ - Cancer Biomedical Informatics Grid™" under "QUICK LINKS". The main content area features a banner image of a doctor and a section titled "Outcomes Home" with a "Help" link. Below this, a paragraph states: "This Site enables you to submit and manage clinical outcomes data for your patients. You can:" followed by a list of actions: "Create an account" to submit data, "Log In" to your account and then "Create a patient" or "Update and/or add data to an existing patient". A footer section contains links for "CONTACT US", "PRIVACY NOTICE", "DISCLAIMER", "ACCESSIBILITY", and "SUPPORT", along with logos for the National Cancer Institute, the Department of Health and Human Services, and USA.gov.

# The Patient Outcomes Data Service is one of Many Services, Planned and Existing, for the Biomedical Community

Cancer Knowledge Cloud



# Researchers will be able to Query the Data in the Cancer Knowledge Cloud



Cancer  
Knowledge  
Cloud

## Epidemiologists

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

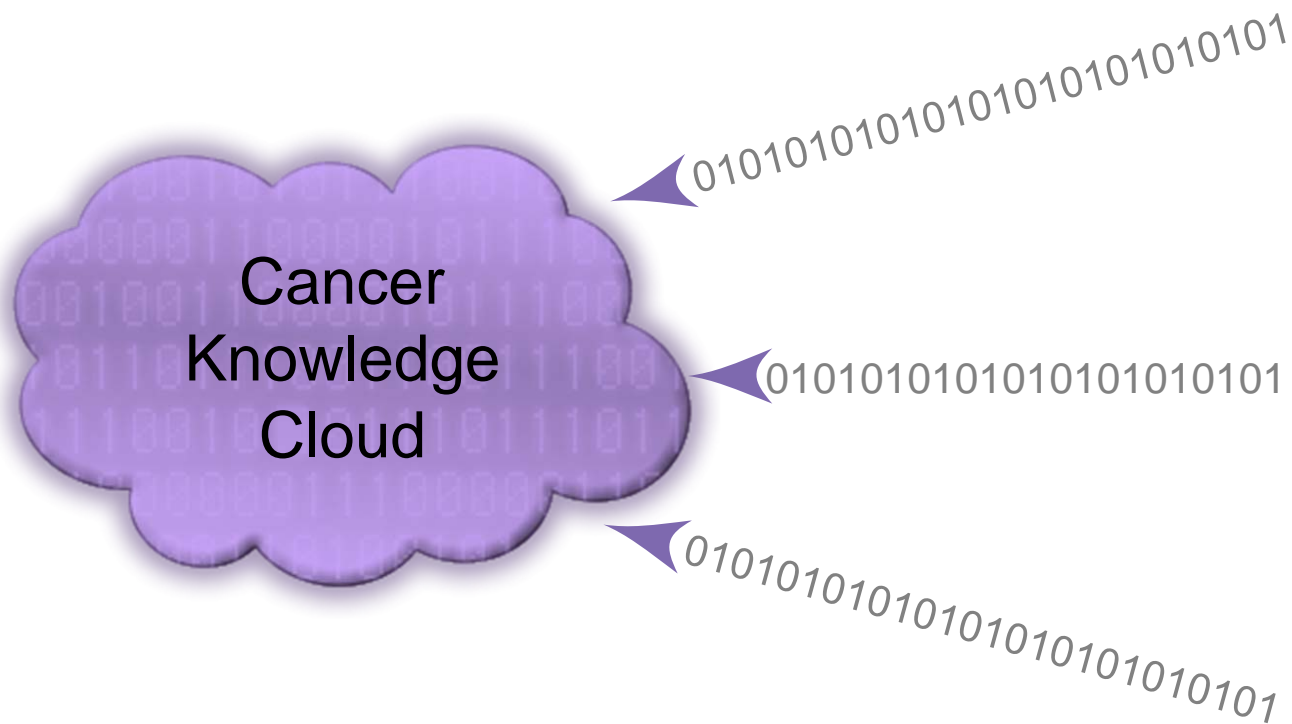
## Basic Researchers

- 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



## Epidemiologists

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

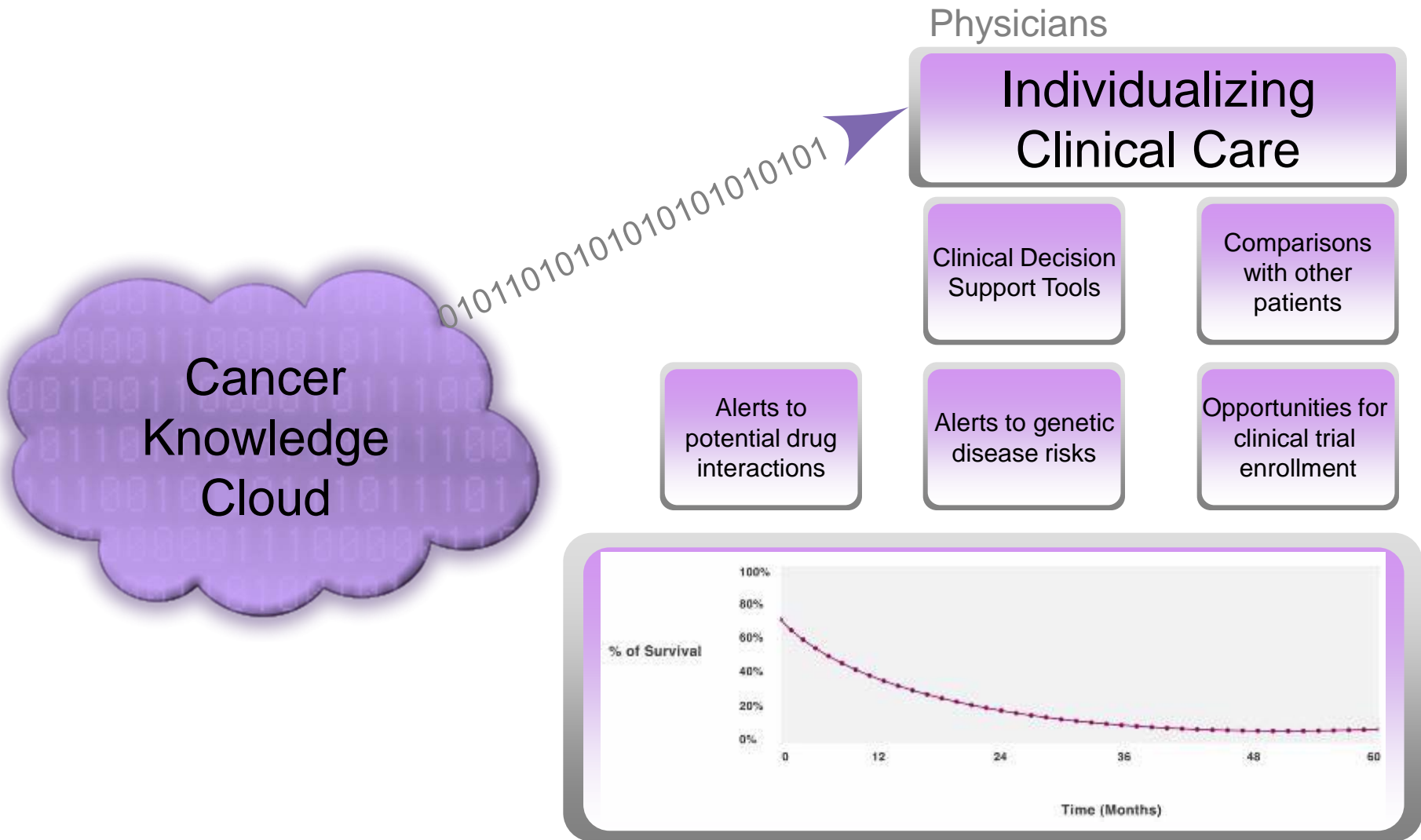
## Basic Researchers

New drug targets

## Clinical Researchers

Targeted drugs for molecularly-defined sub-groups

# All Stakeholders Benefit from the Cancer Knowledge Cloud



# All Stakeholders Benefit from the Cancer Knowledge Cloud

Cancer Knowledge Cloud

010101010101010101

Physicians

Individualizing Clinical Care

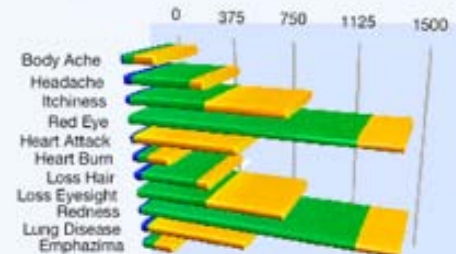
Patients / Consumers

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 Cancer Knowledge Cloud



Cancer  
Knowledge  
Cloud

0101010101010101

Physicians

Individualizing  
Clinical Care

Patients / Consumers

Understanding  
my options

Improving the  
Healthcare System

Comparative  
Effectiveness

Quality

Pharmaco-  
vigilance



# Take-Home Messages

- caBIG<sup>®</sup> provides standards-based infrastructure and tools to facilitate and accelerate critical functions in research and, increasingly, healthcare processes
- The Cancer Community writ large is moving towards large-scale data sharing, and those who are caBIG<sup>®</sup>-connected have an advantage
- caBIG<sup>®</sup> web-based services will soon enable organizations to partake of a-la-carte or comprehensive capabilities across the discovery-development-care continuum
- As the U.S. moves towards EHRs and full digitalization of health care, the caBIG<sup>®</sup> standards-based data interoperability will enable organizations to move data between regulators, health care providers, *etc.*
- Since caBIG<sup>®</sup> has been developed by NCI, all capabilities are freely available and open to all

# Finding What You Need...

- **If you want additional general information about caBIG<sup>®</sup>**
  - <http://cabig.cancer.gov/>
- **If you want to receive our monthly e-newsletter**
  - <http://cabig.cancer.gov/resources/newsletter/>
- **If you want a complete overview of the caBIG<sup>®</sup> program**
  - <https://cabig.nci.nih.gov/training/cabigessentials/player.html>
- **If you want a complete list of caBIG<sup>®</sup> tools**
  - <https://cabig.nci.nih.gov/adopt/>
- **If you want a demo-for-the-perplexed**
  - Call (301) 594-3602

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Training Portal
<b>Workspaces &amp; SIGs</b>
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Integrative Cancer Research
In Vivo Imaging
Tissue Banks and Pathology Tools
Cross Cutting Workspaces
Architecture
Vocabularies & Common Data Elements
Strategic Level Workspaces
Data Sharing & Intellectual Capital
Documentation & Training

## Welcome to the caBIG™ Community Website!

The National Cancer Institute is launching a 21st century information initiative that will transform the way we do cancer research. We are creating a network that will freely connect the entire cancer community. In doing so, we are leveraging valuable resources and saving precious time toward new discoveries.

New visitors are encouraged to visit [About caBIG™](#). If you are already familiar with caBIG™ but looking for a synopsis of recent activities by the [workspaces](#) and [SIGs](#) look at [What's BIG This Week](#) and the monthly newsletter [caBIG™ Links](#).

<b>Get Started</b> <ul style="list-style-type: none"><li>• About caBIG™</li><li>• caBIG™ FAQs</li><li>• How It Works</li><li>• "caBIG™ Essentials" Self-Paced Training Program</li><li>• Getting Connected with caBIG™</li><li>• Glossary</li></ul>	<b>Products</b> <ul style="list-style-type: none"><li>• Tools, Infrastructure, Data Resources</li><li>• Compatibility Guidelines &amp; Certification</li><li>• Data Standards</li><li>• Policies, Guidelines &amp; Whitepapers</li><li>• caGrid (the "grid")</li></ul>	<b>Participant Shortcuts</b> <ul style="list-style-type: none"><li>• What's BIG This Week</li><li>• Events &amp; Calendar</li><li>• caBIG™ Links (newsletter)</li><li>• Materials for Speakers</li><li>• Workspaces &amp; SIGs</li></ul>
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*The content of this website is intended for caBIG™ participants and others needing specific information about caBIG activities and products. General audiences are invited to learn more about the caBIG™ initiative by visiting <http://cabig.cancer.gov>.*

### caBIG™ Spotlight

**Biomedical Informatics Without Borders**  
Presentations now available from the joint NCRI-NCI conference. [Learn More](#)

**caBIG™ Enterprise Support Network Knowledge Center Sites Launched.**  
[Learn More](#)

**caBIG™ Wins Best Practices Editors' Choice Award**  
Awarded by Bio-It World. [Learn More](#)

### caBIG™ News

[10-20-2008](#)  
Requesting Applications for caBIG® Support Service Providers

[10-17-2008](#)  
What's BIG This Week - 10/17/08

[10-16-2008](#)  
caBIG® Support Service Providers

john.speakman@nih.gov

National Cancer Institute

U.S. DEPARTMENT  
OF HEALTH AND  
HUMAN SERVICES

National Institutes  
of Health

2010 caBIG® Annual Meeting:

Building a Collaborative Biomedical Network

September 13-15, 2010

Marriott Wardman Park Hotel  
Washington, D.C.

For more information visit <https://cabig.nci.nih.gov/2010AnnualMeeting>

cancer Biomedical Informatics Grid®

