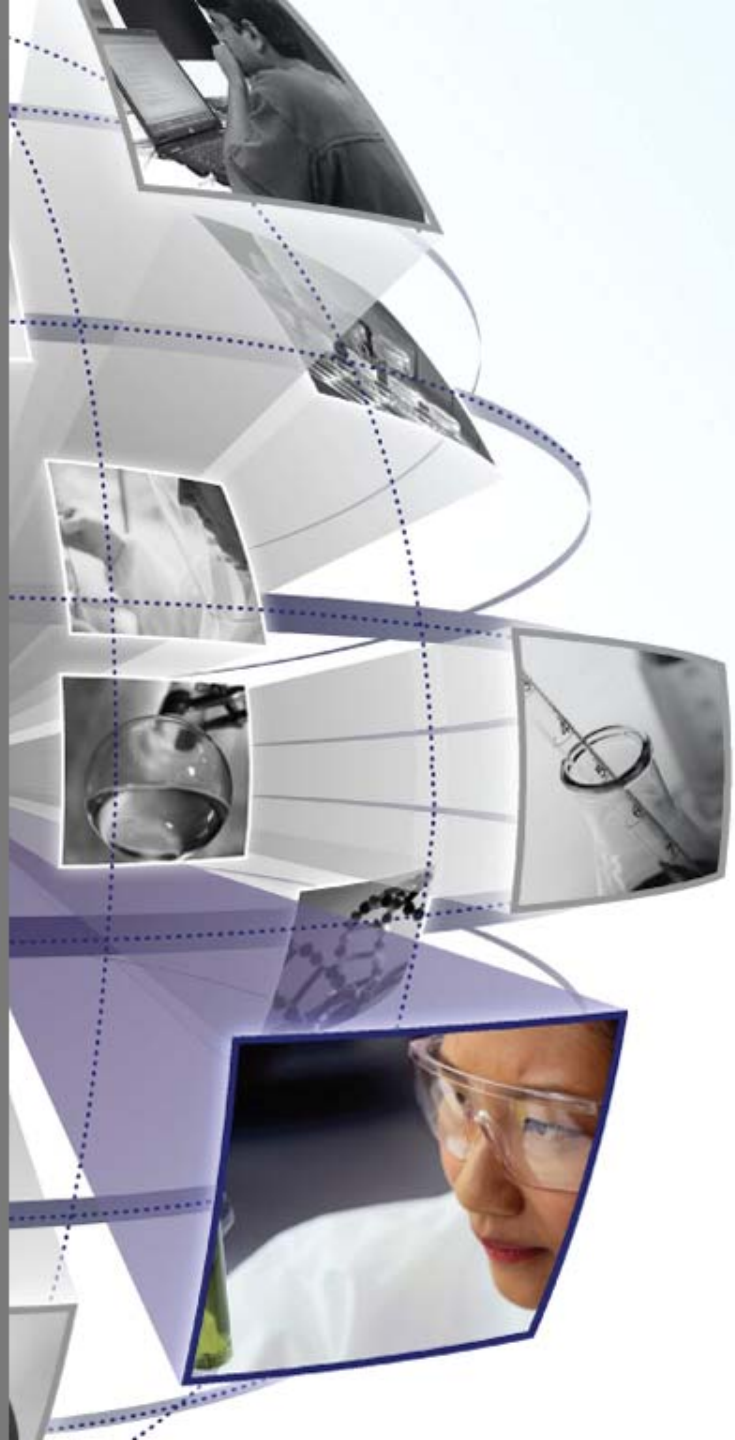
National Cancer Institute



caBIG®
cancer Biomedical Informatics Grid™

Powering Collaborations in Clinical Research

John Speakman
Associate Director, Clinical Sciences
Center for Biomedical Informatics and Information Technology
National Cancer Institute

Bill Dyer
Product Representative, Clinical Sciences
Center for Biomedical Informatics and Information Technology
National Cancer Institute

Umit Topaloglu, Ph.D.
IT Bioinformatics Manager
University of Arkansas for Medical Sciences

Agenda

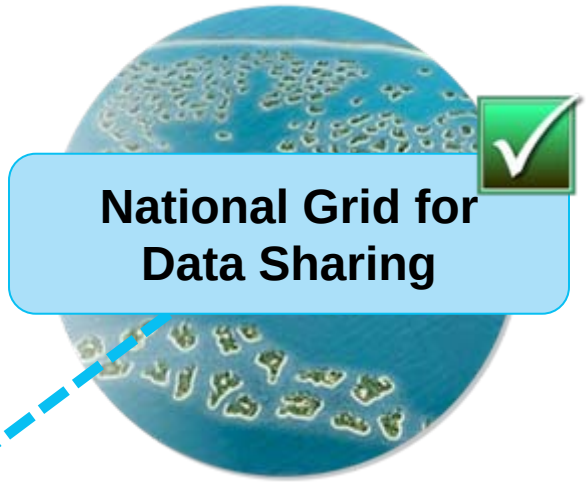
- **Setting the Scene (Speakman)**
  - caBIG® is enabling live, real world, collaborative, adaptive trials today
  - caBIG® provides a transformative architecture for clinical trials
- **caBIG® Clinical Trials Suite Demo (Dyer)**
  - Free, open source, stable, secure, supported reference implementations of the architecture – available today
- **Lessons Learned from Deployment (Topaloglu)**
  - Leveraging caBIG® enterprise-wide

NCI's Mission Requires an Informatics Response to These Challenges

40+ Software Tools

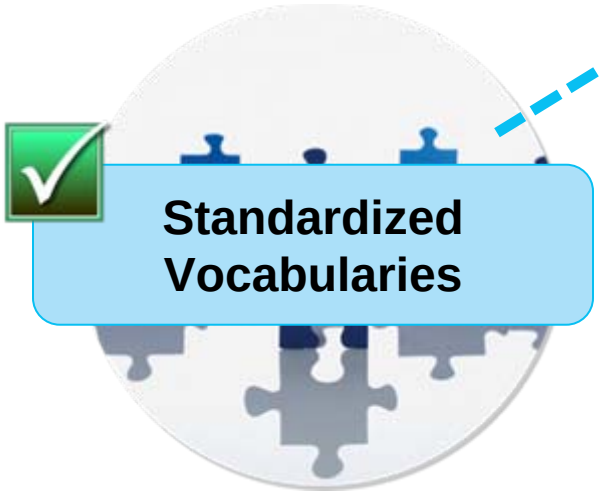
Tsunami of Genomic and Clinical Data

caBIG®
cancer Biomedical Informatics Grid®



National Grid for Data Sharing

Islands of Information



Standardized Vocabularies

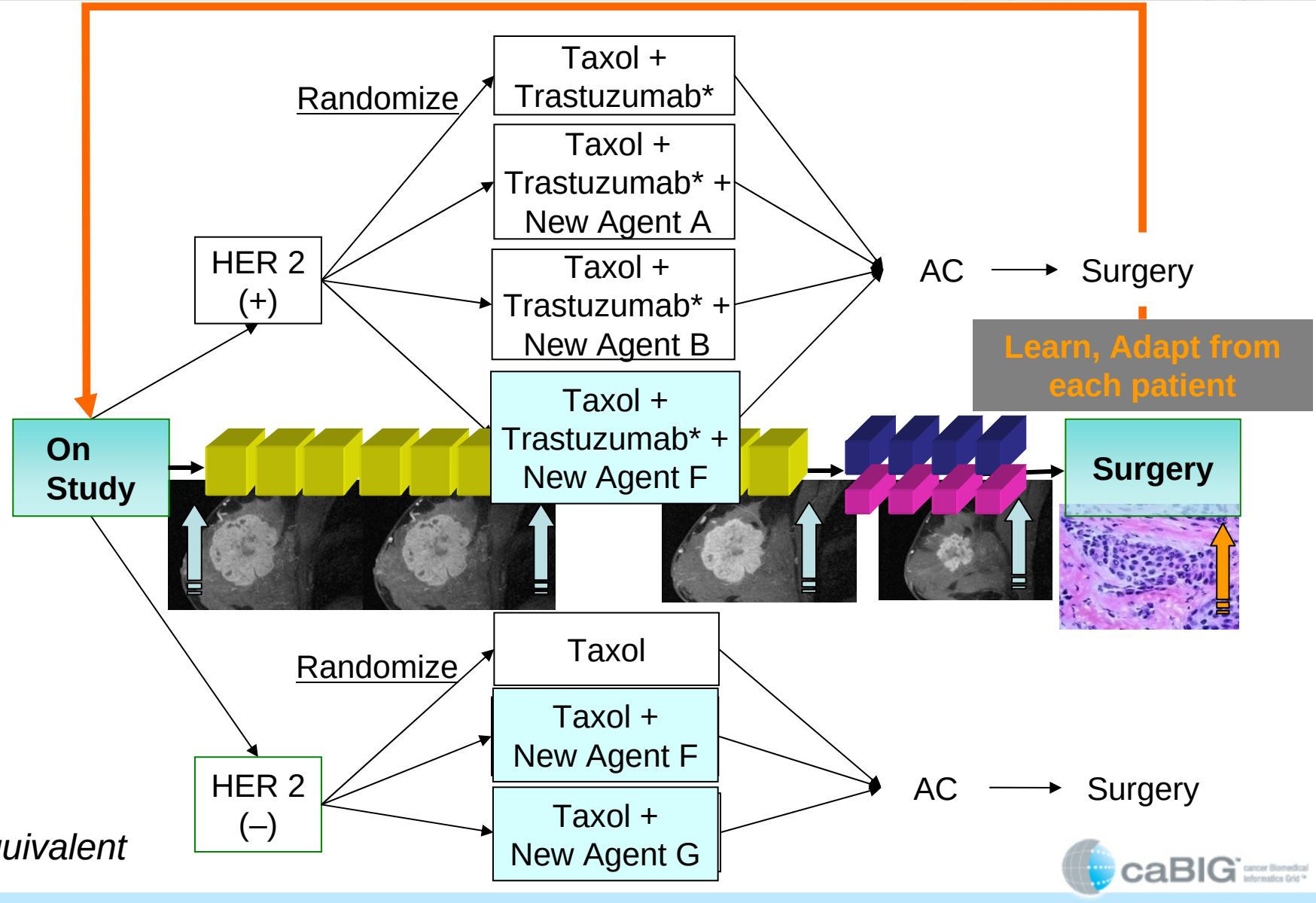
Standard Language

Interoperability

IT Systems Do Not Interoperate

caBIG cancer Biomedical Informatics Grid™

caBIG® Applications in Action Now: I-SPY 2 Adaptive Trial



**Or Equivalent*

caBIG cancer Biomedical Informatics Grid™

Interoperability: Eliminating Multiple Sources of Record

- Redundant data inevitably becomes redundant, inconsistent data
- Solution: a semantic services-oriented architecture
- Single source of record for each data type

"A man with a watch knows what time it is. A man with two watches is never sure."

- *Lee Segall*

Getting There from Here: Eliminating Inconsistency, then Redundancy

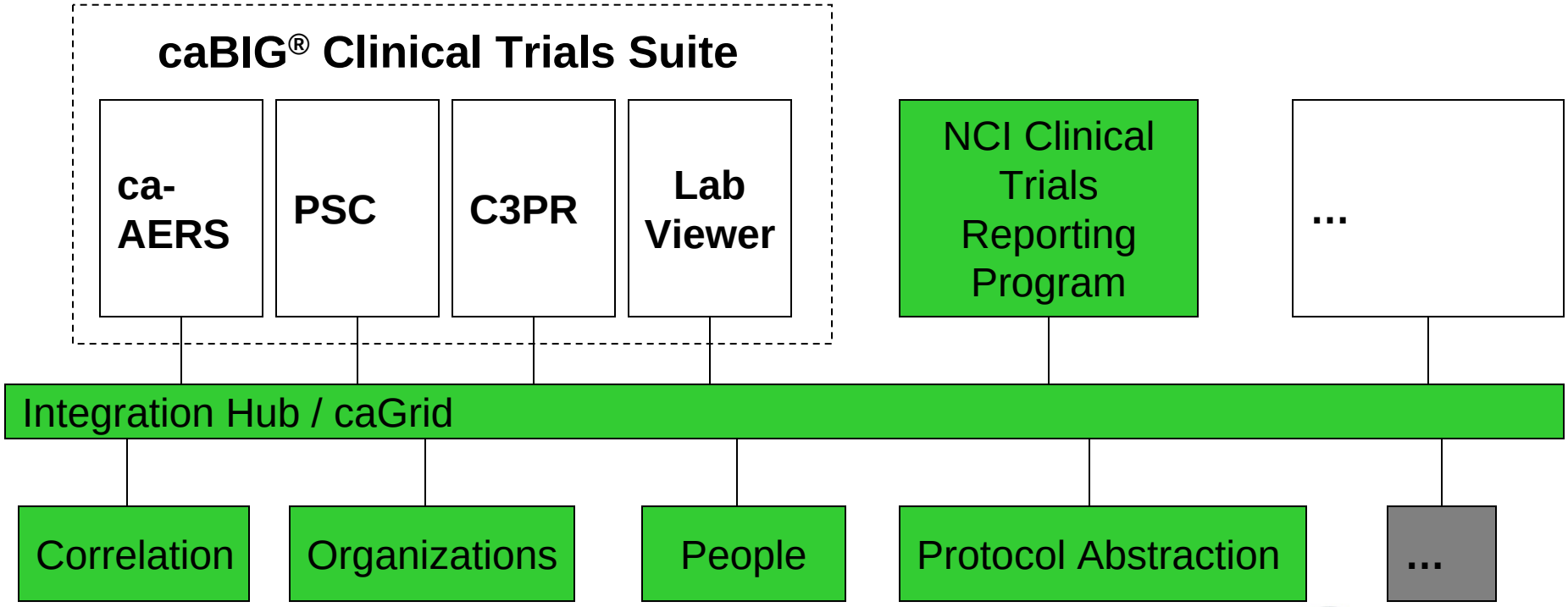
Application 1

Application 2

Service A

Leveraging NCI Enterprise Services

- NCI is committed to this architecture for its own operations
- For-profit and non-profit developers have already demonstrated apps that leverage NCI services
- Alignment with standards bodies, public/private groups



Roadmap: caBIG® "Periodic Table" of Services

"CAPABILITY"/"BUSINESS"

R Registration	**Pt** Protocol	**Oc** Study Outcomes	**Po** Patient Outcomes	**E** Eligibility	**Ae** Adverse Event	**Hx** Hx and Physical	**Dx** Discharge Note	**Ds** Decision Support	**Ra** Referral and Authorization

	Cr Credentialing		**S** Specimen		**Tp** Treatment Plan	**I** Image	**L** Lab	**Rx** Pharmacy	**Sc** Scheduling

"CORE"

Sd SDTM	**Qr** Data Query	**C** Correlation	**O** Organization	**P** Person	**Pa** Protocol Abstraction	**D** Disease	**A** Agent	**Mp** Master Problem List	**Ay** Allergy

"Infra / UTILITY"

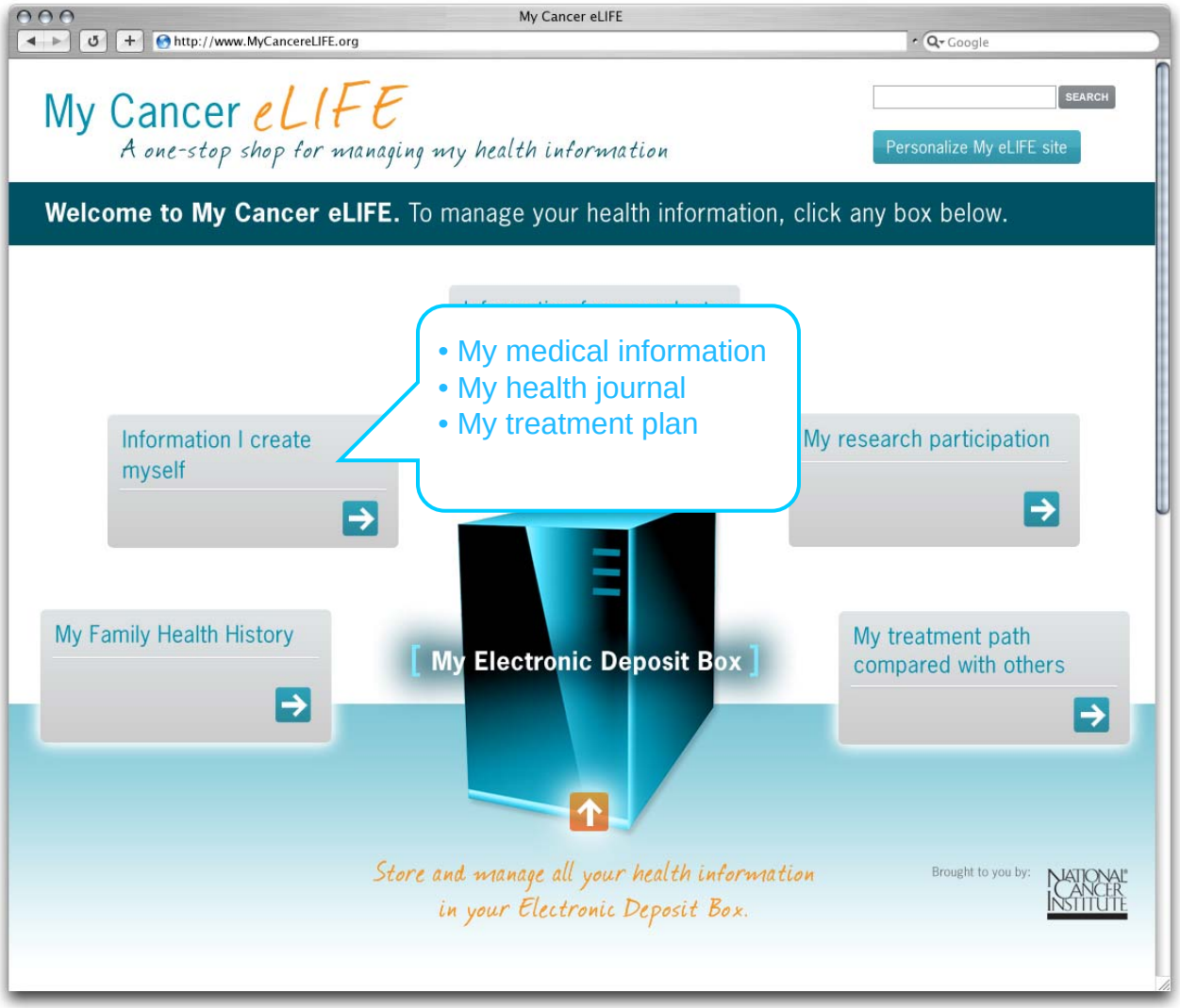
Km Knowledge Management	**Cm** Contract Management	**Ev** Enterprise Vocabulary	**Va** Validation	**Tx** Translation	**Au** Audit	**Id** Id Management	**Tr** Trust Management	**Aa** Authorization Authentication	**Py** Policy

caBIG cancer Biomedical Informatics Grid™

My Cancer eLIFE

caBIG cancer Biomedical Informatics Grid™

My Cancer eLIFE



caBIG cancer Biomedical Informatics Grid™

My Cancer eLIFE

caBIG cancer Biomedical Informatics Grid™

My Cancer eLIFE

caBIG cancer Biomedical Informatics Grid™

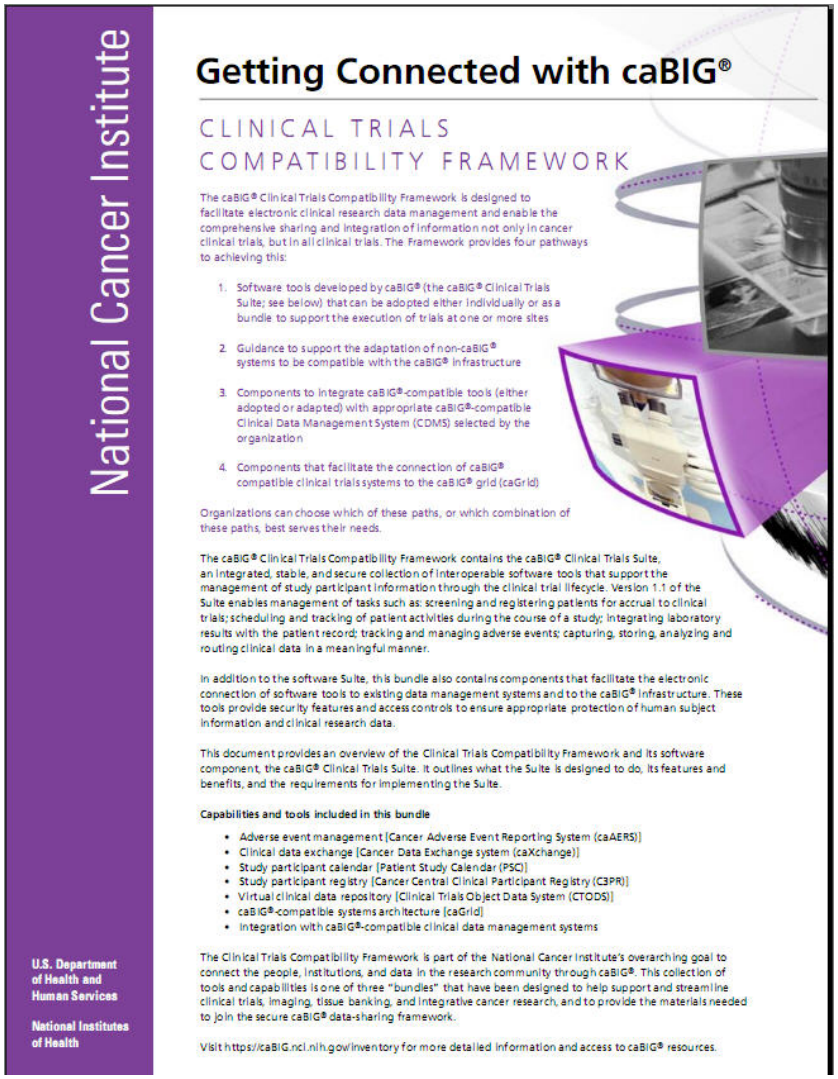
My Cancer eLIFE

My Cancer eLIFE

caBIG cancer Biomedical Informatics Grid™

caBIG® Clinical Trials Suite

- Production software, ability to leverage services: “NCI content inside”
- Free, open source, non-viral license
- Installable as an interoperable Suite or as components
- Adverse event management (caAERS)
- Clinical data exchange (Integration Hub)
- Study participant calendar (PSC)
- Study participant registry (C3PR)
- Integration with CDMSes via Clinical Connector



National Cancer Institute

U.S. Department of Health and Human Services

National Institutes of Health

Getting Connected with caBIG®

CLINICAL TRIALS COMPATIBILITY FRAMEWORK

The caBIG® Clinical Trials Compatibility Framework is designed to facilitate electronic clinical research data management and enable the comprehensive sharing and integration of information not only in cancer clinical trials, but in all clinical trials. The Framework provides four pathways to achieving this:

1. Software tools developed by caBIG® (the caBIG® Clinical Trials Suite; see below) that can be adopted either individually or as a bundle to support the execution of trials at one or more sites
2. Guidance to support the adaptation of non-caBIG® systems to be compatible with the caBIG® infrastructure
3. Components to integrate caBIG®-compatible tools (either adopted or adapted) with appropriate caBIG®-compatible Clinical Data Management System (CDMS) selected by the organization
4. Components that facilitate the connection of caBIG® compatible clinical trials systems to the caBIG® grid (caGrid)

Organizations can choose which of these paths, or which combination of these paths, best serves their needs.

The caBIG® Clinical Trials Compatibility Framework contains the caBIG® Clinical Trials Suite, an integrated, stable, and secure collection of interoperable software tools that support the management of study participant information through the clinical trial lifecycle. Version 1.1 of the Suite enables management of tasks such as: screening and registering patients for accrual to clinical trials; scheduling and tracking of patient activities during the course of a study; integrating laboratory results with the patient record; tracking and managing adverse events; capturing, storing, analyzing and routing clinical data in a meaningful manner.

In addition to the software Suite, this bundle also contains components that facilitate the electronic connection of software tools to existing data management systems and to the caBIG® infrastructure. These tools provide security features and access controls to ensure appropriate protection of human subject information and clinical research data.

This document provides an overview of the Clinical Trials Compatibility Framework and its software component, the caBIG® Clinical Trials Suite. It outlines what the Suite is designed to do, its features and benefits, and the requirements for implementing the Suite.

Capabilities and tools included in this bundle

- Adverse event management [Cancer Adverse Event Reporting System (caAERS)]
- Clinical data exchange [Cancer Data Exchange system (caXchange)]
- Study participant calendar [Patient Study Calendar (PSC)]
- Study participant registry [Cancer Central Clinical Participant Registry (C3PR)]
- Virtual clinical data repository [Clinical Trials Object Data System (CTODS)]
- caBIG®-compatible systems architecture [caGrid]
- Integration with caBIG®-compatible clinical data management systems

The Clinical Trials Compatibility Framework is part of the National Cancer Institute’s overarching goal to connect the people, institutions, and data in the research community through caBIG®. This collection of tools and capabilities is one of three “bundles” that have been designed to help support and streamline clinical trials, imaging, tissue banking, and integrative cancer research, and to provide the materials needed to join the secure caBIG® data-sharing framework.

Visit https://caBIG.ncl.nih.gov/inventory for more detailed information and access to caBIG® resources.

caBIG cancer Biomedical Informatics Grid™

Online Resources

Clinical Trials Management Systems (CTMS) Workspace	https://cabig.nci.nih.gov/workspaces/CTMS
caBIG® Tool Landing Page	https://cabig.nci.nih.gov/tools
CTMS Knowledge Center	https://cabig-kc.nci.nih.gov/CTMS/KC
Access to CTMS Tools: • Recorded Demos • Presentations • Documentation and Training Materials • Live Demo Environment	https://cabig.nci.nih.gov/workspaces/CTMS Product shortcuts for each tool provide access to: • Recorded Demos • Presentations • Documentation and Training Materials • Live Demo Environment
NCI Center for Bioinformatics (NCICB) Open Source Project Site	http://gforge.nci.nih.gov
caBIG® Product Representative	cabigproductrep@nih.gov

Up Next…

- **caBIG® Clinical Trials Suite Demo (Dyer)**
  - Free, open source, stable, secure, supported reference implementations of the architecture – available today
- **Lessons Learned from Deployment (Topaloglu)**
  - Leveraging caBIG® enterprise-wide

caBIG® at Bio-IT World 2010

- **The BIG Idea: Strategies to Achieve a Rapid-Learning Health System – Ken Buetow, Ph.D.**
  - Wednesday, April 21, 2:45 pm - Amphitheater
  - Plenary, Tracks 2,3,4,6,7
- **caBIG® in the Trenches: Deploying an Infrastructure that Enables Collaboration – R. Mark Adams, Ph.D.**
  - Wednesday, April 21, 12:00 noon – City View 2
  - Track 2: IT Infrastructure – Software
- **Developing and Implementing caBIG® Enterprise Services – George Komatsoulis, Ph.D.**
  - Thursday, April 22, 12:00 noon – City View 2
  - Track 2: IT Infrastructure – Software

Visit caBIG® at Booth #200-202

caBIG cancer Biomedical Informatics Grid™