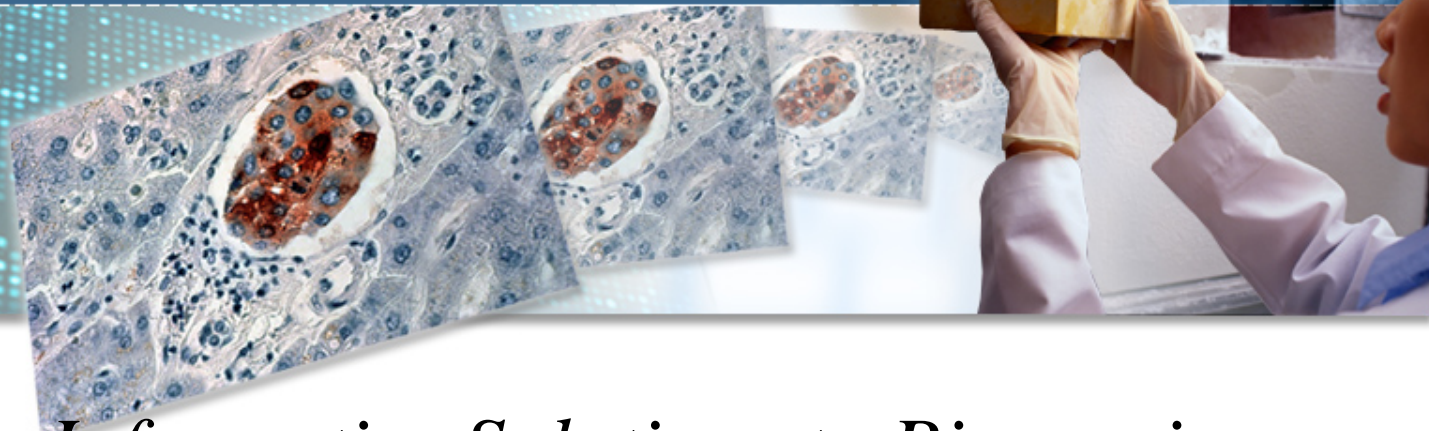


caBIG™, caTissue, and Achieving Silver-Level Compatibility

OBBR

Office of Biorepositories
and Biospecimen Research



*Informatics Solutions to Biospecimen
Management: Finding the Right Tools*

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Outline

- **Supporting Best Practices with Informatics**
 - Functions
 - Security
- **caBIG™**
 - caBIG™ compatibility
 - The value proposition of caBIG™
- **caBIG™ Biorepository-focused tools**
 - caTissue Core
 - Clinical Annotation Engine
 - caTIES
 - caTissue Suite



Supporting Best Practices

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- **Workflows that biorepository software should support**
- **Participant registration**
- **Consent tracking at a protocol/project level**
- **Biospecimen data and events:**
 - Collection
 - Barcoding and tracking
 - Processing
 - Storage
 - Distribution
- **Specimen QA & QC**
- **Security**
- **Reporting**



Specimen Tracking

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- **Treat each physically distinct entity as a different specimen**
- **Each with its own identifier**
- **Maintain parent-child relationship of specimens**
- **Support Aliquoting**
- **Support molecular extracts**
- **Linkage to physical labeling and synonyms**
- **Support barcoded containers and processes**



Integration

- **Enable integration with**
 - Clinical trials management systems
 - Protocol management systems
 - Patient and Participant annotation systems
 - Surgical and Anatomical Pathology Systems
 - Cancer Registries
 - Lab Systems



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C3D

C3PR

caTIES

CAE

caXchange /
LabViewer



To match the special nature of human biospecimens, systems should be protected by adequate security

- Physical access to systems
- Regular back up and archival of systems containing often irreplaceable resources
- Login protections
- Role- and attribute-based security that only allows access to authorized information
- **NIST**
 - Risk Management Guide for Information Technology Systems
 - Use to help determine level of risk for a particular system
 - Set security mechanisms to match the risk



Regulatory and Sharing Requirements

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- **Health Insurance Portability and Accountability Act (HIPAA)**
- **Human Subjects Research -CFR Title 45 Part 46**
- **FDA requirements -CFR Title 21 Part 11**
- **NIH Principles and Guidelines for Sharing of Biomedical Resources**
- **NIH Data Sharing Policy**



Deployment

- **Build vs Buy**
 - Understand the true costs
 - Plan for the future
 - A biorepository matures and achieves its value in years
 - Make sure the informatics can be sustained, extended, and think about a migration path
 - Open source
- **If you're going to build...**
 - End user involvement
 - Define your use cases!!
 - Follow a system development methodology
 - E.g. Unified Process
 - Follow a software development methodology
 - E.g. Agile
 - Strive for CMMI Level 3

- Items for distribution at meetings and through the OBBR Web site
 - NCI Best Practices for Biospecimen Resources
 - Biospecimen Basics: An Overview of the NCI Best Practices for Biospecimen Resources
 - Implementing caBIG™ for Biospecimen Resources: An Overview
 - Implementing caBIG™ for Biospecimen Resources: Next Steps
 - Providing Your Tissue for Research
 - Other biospecimen-related articles, publications, and news stories of interest



- **One-page document with broad overview of caBIG™ for Biospecimen Resources**
- **Target audiences include:**
 - Patients and Patient Advocates
 - NCI-designated Cancer Center Directors
 - Strategic Thinkers at Institutes and Biospecimen Resources
- **Topics Covered:**
 - What is caBIG™ and What does it offer Biospecimen Resources?
 - Strategic Considerations
 - Benefits to patients and advocates
 - Benefits to researchers and resource directors

- 9-page document highlighting "The Road to caBIG™ Compatibility"
- Designed for resources interested in the specific steps required for implementing caBIG™ compatibility
- Addresses public comments and frequently asked questions
- **Setting the Stage:**
 - Core Concepts
 - How does caBIG™ compatibility work
 - FAQs
- **Turning to Solutions:**
 - Available software tools
 - Overview of Alternatives
 - Skills, Technology, and Resources Required

Options for Implementing caBIG™ Biospecimen Resources

Option	Operating Scenario	Recommended Solution
1	Your resource has a paper-based system or a homegrown tool that would not be painful to abandon.	Adopt caTissue Core, and migrate existing electronic data to new tool.
2	Your resource has an existing basic tool that you want to keep. Examples: Access or MySQL database.	Become caBIG™ compatible by installing caTissue Core, and then mapping your tool to it. Connect from your tool to the outside world through caTissue Core.
3	Your resource has an existing informatics tool - more complex than a simple database, with separate modules for reporting and storage (e.g., standard reports are a small extract from a larger database system).	Make the existing tool caBIG™ compatible for your standard reports only. Data generated in required reports would be caBIG™ compatible; the underlying data need not be.
4	Your resource has an existing complex informatics tool (like Option 3), but your reporting needs vary greatly, and you would like to have the entire system caBIG™ compatible for maximum flexibility.	Make the full database compatible, by creating an interface that maps the existing tool's data structures to caBIG™ standards. This is the highest investment solution.

- Leveraging existing software tools available through caBIG™ reduces software development costs for biospecimen resources
- The shared standards governing caBIG™ allows even small repositories to advertise their presence and specimen/data availability -AND- learn what others have to offer
- Your own research comes first -you can select the data to share · caBIG™ tools already have built-in security and privacy considerations - enhancing patient confidence
- Increased data sharing increases the effectiveness and efficiency of cancer research -helping individual scientists, the cancer research community, and ultimately the cancer patient

The willingness of cancer patients to share tissue is fundamental to cancer research. Our willingness to share biospecimen-related data is critical to maintaining public trust.



What's Required: Skills and Technology Needed

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- Some specialized IT skills are required to adopt caBIG™ tools, and to make an existing tool caBIG™ compatible.
- Required skills: Intermediate Java and/or .NET development skills, with experience installing dependent software sets (e.g., Java, JBOSS, MySQL), administering systems, configuring line code, and similar tasks of moderate technical complexity.
- Options 1, 2 or 3 described above will take a few weeks - or less.
- Full system conversion (Option 4) is likely to take more investment on the order of months rather than weeks.

You do not have to hire full time staff, or invest in an IT lab, to fulfill bioinformatics best practices.

You may need to “borrow personnel at your institution with specialized IT skills for initial installation and routine maintenance.

The technical environment will include application and database servers; likely to be available at your institution without heavy investment by your lab if you don't already have them.

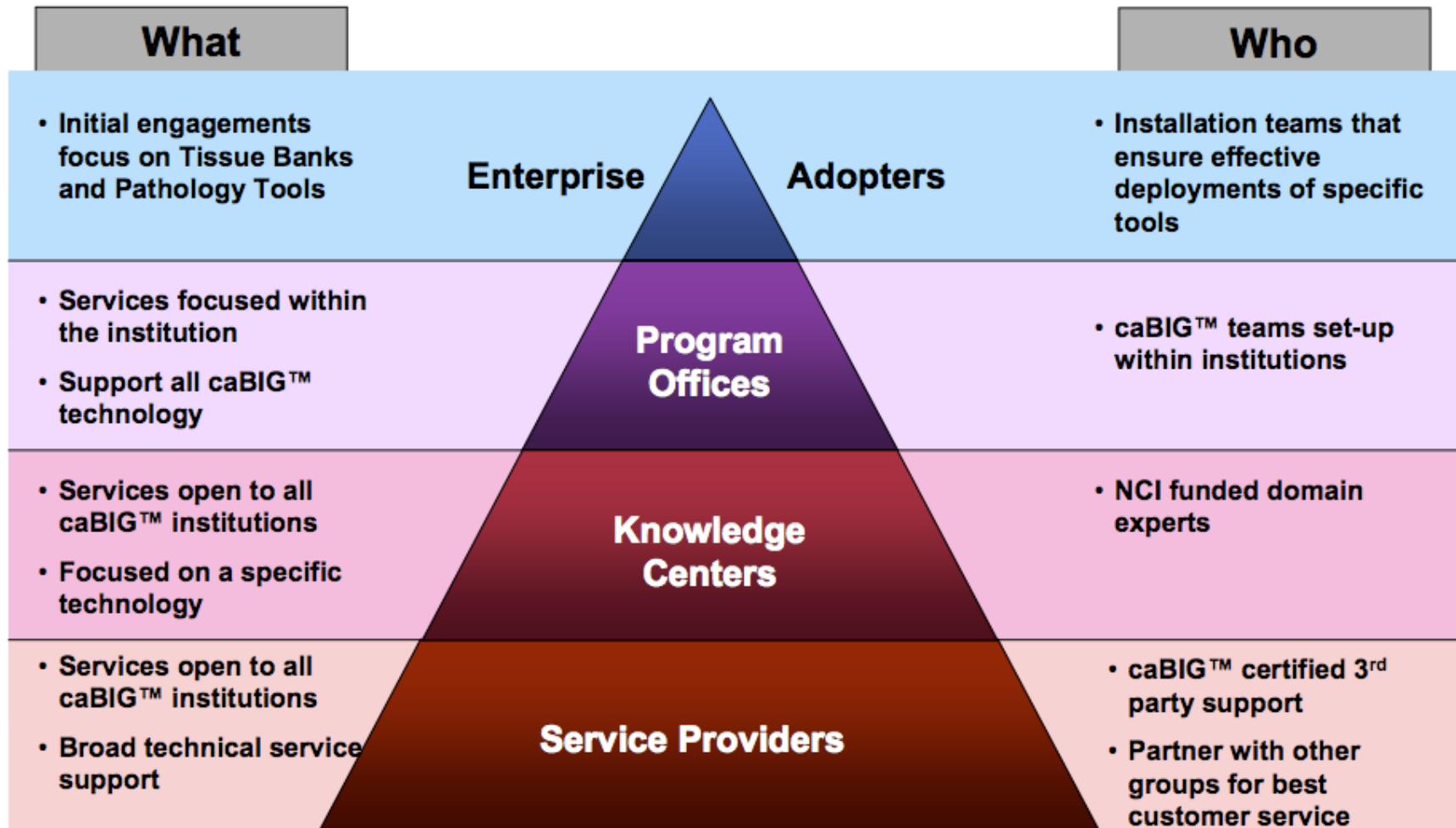


caBIG[™] cancer Biomedical
Informatics Grid [™]

**Enterprise
Support Network**



Facilitating Adoption



Ongoing Tool Development, Adoption and Participation

Staying Connected

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For more background visit:

<http://caBIG.cancer.gov>

To join the caBIG™ technical effort visit:

<http://caBIG.nci.nih.gov>

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

caBIG™ cancer Biomedical Informatics Grid™ Search

Cancer and Molecular Medicine caBIG: A New Network caBIG and You Media Center

caBIG™: power of connection™

How can information technology help fight cancer?

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. [Read More](#)

caBIG In Action

How caBIG will link together cancer research, drug development and patient care. [Watch Video](#)

News Center

The first few sentences of the Press Release will go here. Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed. Tempor incididunt ut labore et dolore magna aliqua. Ut enim. Veniam, quis nostrud exercitation... [Read More](#)

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