National Cancer Institute

caBIG™ cancer Biomedical Informatics Grid ™

caBIG™, caTissue, and Achieving Silver-Level Compatibility

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National Institutes of Health

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Outline

- Informatics in the Best Practices
  - Functions
  - Development
  - Security
- caBIG
  - Why caBIG compatibility?
  - What does it take?
  - Support programs
- caBIG and Tissue Banks
  - caTissue Core
  - caTIES
  - caTissue Suite

Informatics and the Best Practices

Functionality

- Aim to identify the major areas that biorepository software should support
  - Participant registration
  - Consent tracking
  - Biospecimen collection
  - Processing
  - Storage
  - Distribution
  - Specimen QA & QC
  - Security
    - Who can see/access/order which specimens
  - Reporting
    - Help biorepository managers to manage their collection…
    - What's past its "use by" date

Specimen tracking

- Treat each physically distinct entity as a different specimen
  - … with its own identifier
- Maintain parent-child relationship of specimens
  - Aliquoting
  - Molecular extracts
- Linkage to physical labelling
  - Barcodes

Integration

- Seek to integrate with those clinical data systems that provide useful clinical annotation of stored biospecimens
  - Pathology systems
    - Anatomic pathology
    - Clinical pathology
  - Cancer registries
  - Operating room systems
    - Anesthesia records

Security

- To match the special nature of human biospecimens systems should be protected by adequate security
  - Physical access to systems
  - Back up of systems containing often irreplaceable resources
  - Login protections
  - Role based security that only allows access to authorized information

- National Institute of Standards and Technology (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

- 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

Development

- **Use of structured information**
  - **Databases instead of free text**
- **Build vs Buy**
  - Understand the true costs
  - Plan for the future
    - Establishing a resource that will realize its value in years
    - Make sure the informatics will still be around then
  - Open source
- **If you're going to build…**
  - End user involvement
  - Use cases
  - Follow a system development methodology
    - E.g. Unified Process
  - Strive for CMMI Level 3

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caBIG™ – NCI's Approach to the IT Infrastructure

caBIG Community

Clinical Trial Management Systems	**Addresses the need for consistent, open and comprehensive tools for clinical trials management.**
Integrative Cancer Research	**Provides tools and systems to enable integration and sharing of information.**
Tissue Banks & Pathology Tools	**Provides for the integration, development, and implementation of tissue and pathology tools.**
***In vivo* Imaging**	**Provides for the sharing and analysis of in vivo imaging data.**

Responsible for evaluating, developing, and integrating systems for vocabulary and ontology content, standards, and software systems for content delivery.	**Vocabularies & Common Data Elements**
Developing architectural standards and architecture necessary for other workspaces.	**Architecture**

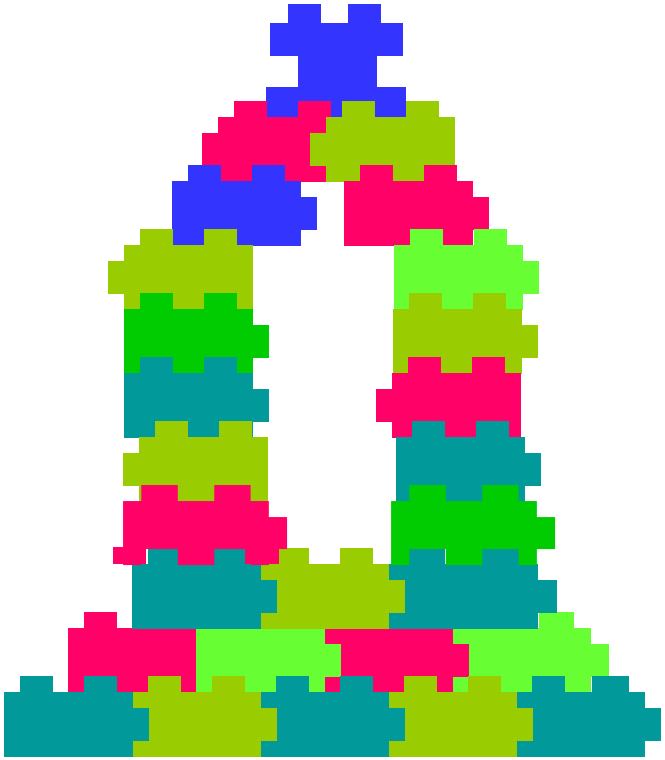
Data Sharing and Intellectual Capital	**sharing of data, applications and infrastructure within the cancer community.**
Training	**training in the use of the caBIG™ resources including on-line turtorials, workshops, training programs.**
Strategic Planning	**Assists in identifying strategic priorities for the development and evolution of the caBIG™ effort.**

Cancer Research Landscape

- Integrated Systems
  - Homegrown/ Commercial
  - Smooth navigation between applications
  - Difficult to expand/extend
  - Large IT staff
  - $10M's invested
- Heterogeneous Systems
  - Complex mix of commercial and homegrown components (may be composed of dozens of components)
  - No common interfaces
  - Medium size IT staff
  - $1M's invested
- Informal/ no systems
  - Use of productivity applications (e.g. Excel, Access)
  - Complex manual processes
  - Small or no IT staff
  - $100K's invested

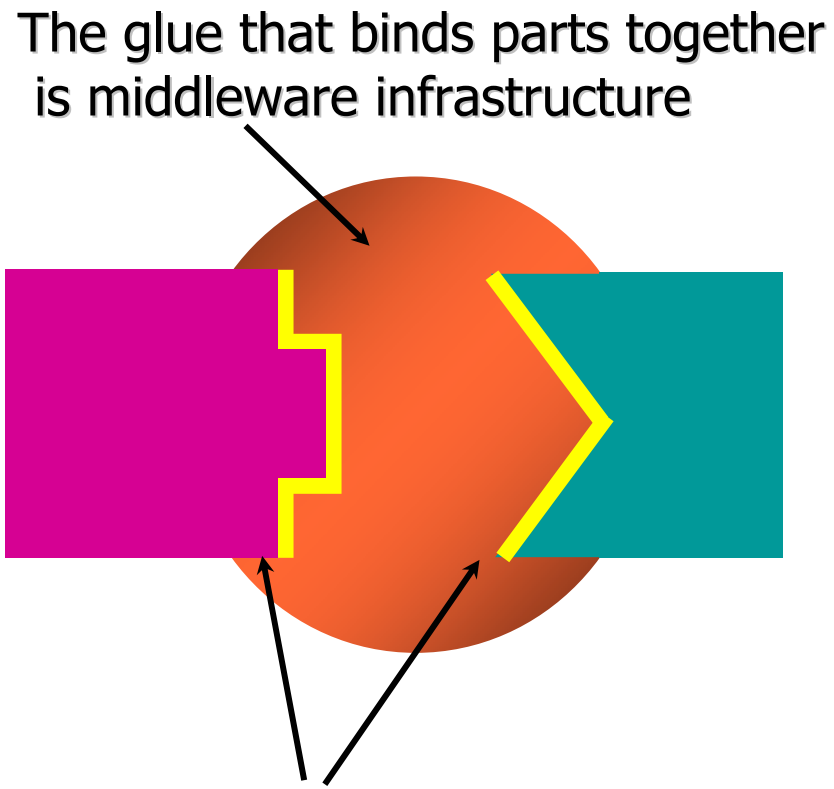
caBIG Approach

- **Modules that address specific needs**
- **Connect through defined Electronic interfaces**
- **Use of international data standards**



Boundaries and Interfaces

- **focus on boundaries of how how things fit together, not on the internal details**
- **once they're built: assume that will be diverse & changing**



caBIG Biospecimen Objectives

- Virtual biorepositories
  - The ability to search networked biospecimen databases
- Support for multi site studies
  - Specimens collected at multiple locations
  - E.g. Prostate SPORE Biomarker study
- Rare diseases
  - Statistical power only reached through pooling resources
- Biospecimens are the raw material for molecular analysis platforms
  - Need to exchange data with their informatics systems
- Linkage to clinical data on biospecimens
  - Key data on specimens and patients exists in other systems
- Development of common practices for biospecimen handling
  - Establishing commmon data elements will support this

Biospecimen Best Practices Toolkit: Written Background Materials

- 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

Implementing caBIG™ for Biospecimen Resources: An Overview

- 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

Implementing caBIG™ for Biospecimen Resources: Next Steps

- **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 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.**

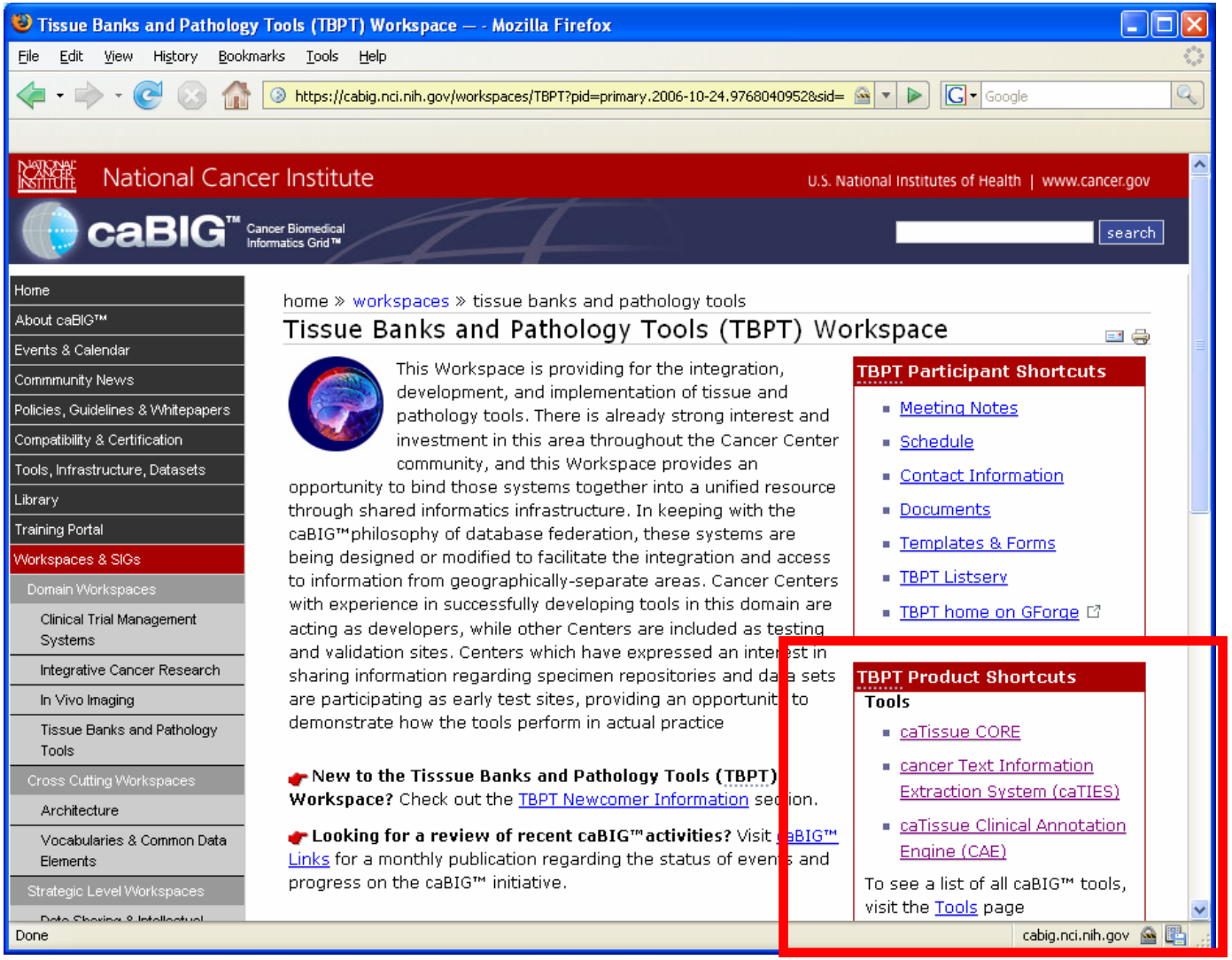
caBIG Biorepository and Pathology Tools

caBIG™ Benefits Biospecimen Resource Leaders, Researchers and Advocates

- 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.

caBIG Portal: http://caBIG.nci.nih.gov



caTissue Core

caTissue Core — - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://cabig.nci.nih.gov/tools/catissuecore

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caBIG™ Cancer Biomedical Informatics Grid™ search

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  - Domain Workspaces
    - Clinical Trial Management Systems
    - Integrative Cancer Research
    - In Vivo Imaging
    - Tissue Banks and Pathology Tools

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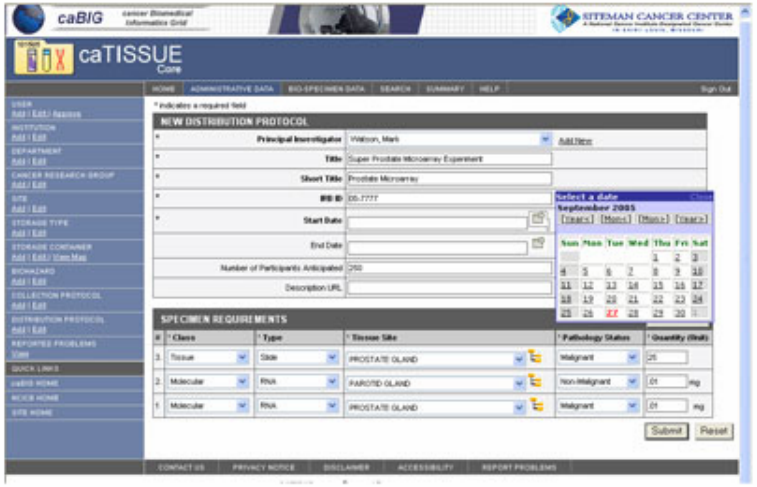
caTissue Core



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- Tool Download Files
- End User Support Resources
- Related caBIG™ Tools
- Developer Institution(s)
- Adopter Institution(s)
- Related Articles

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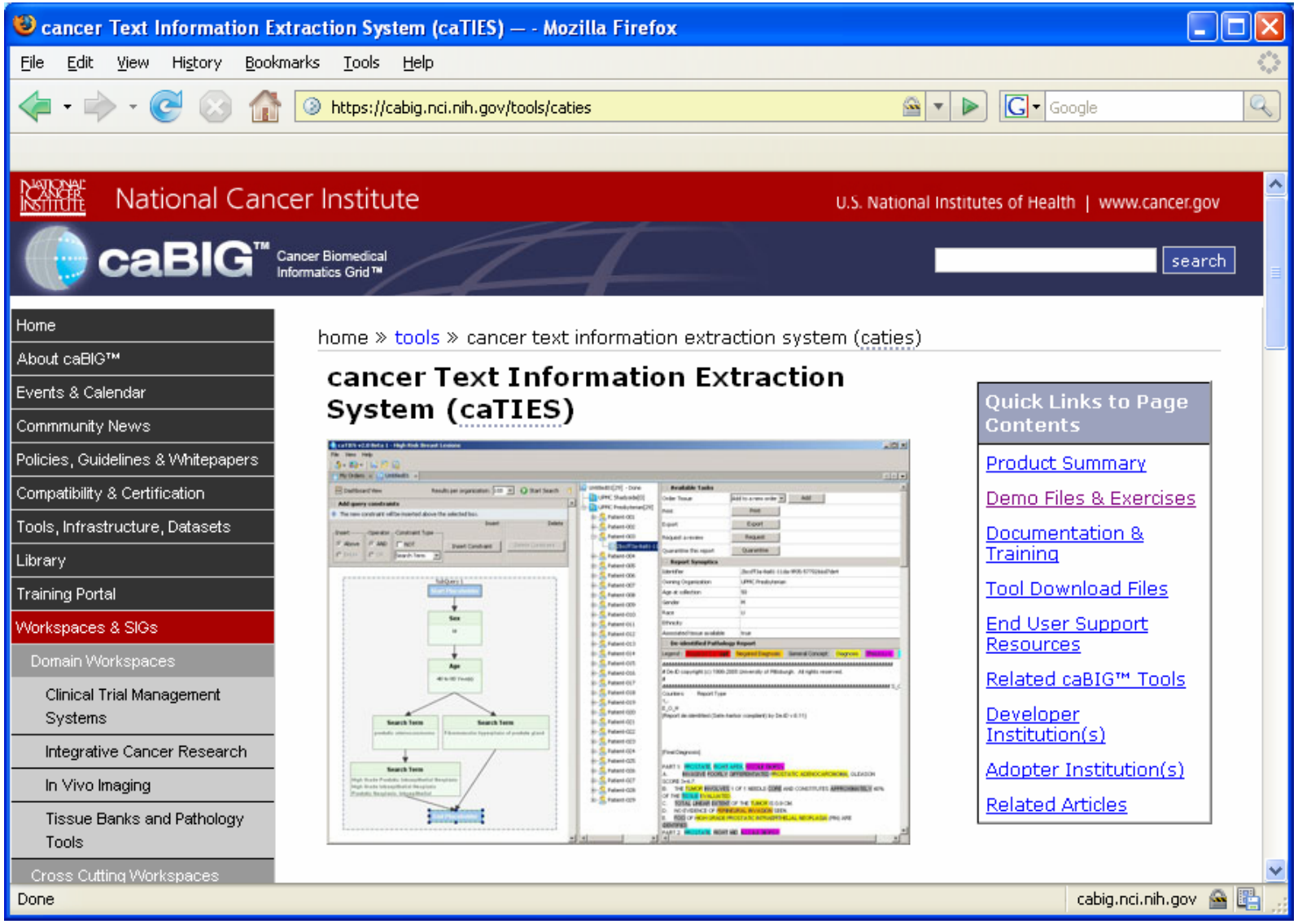
cancer Text Information Extraction System



What's Required: Skills and Technology Needed

- 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.
  - ✓ We don't have precise cost estimates for recommended options at this time.

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.

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Enterprise Support Network

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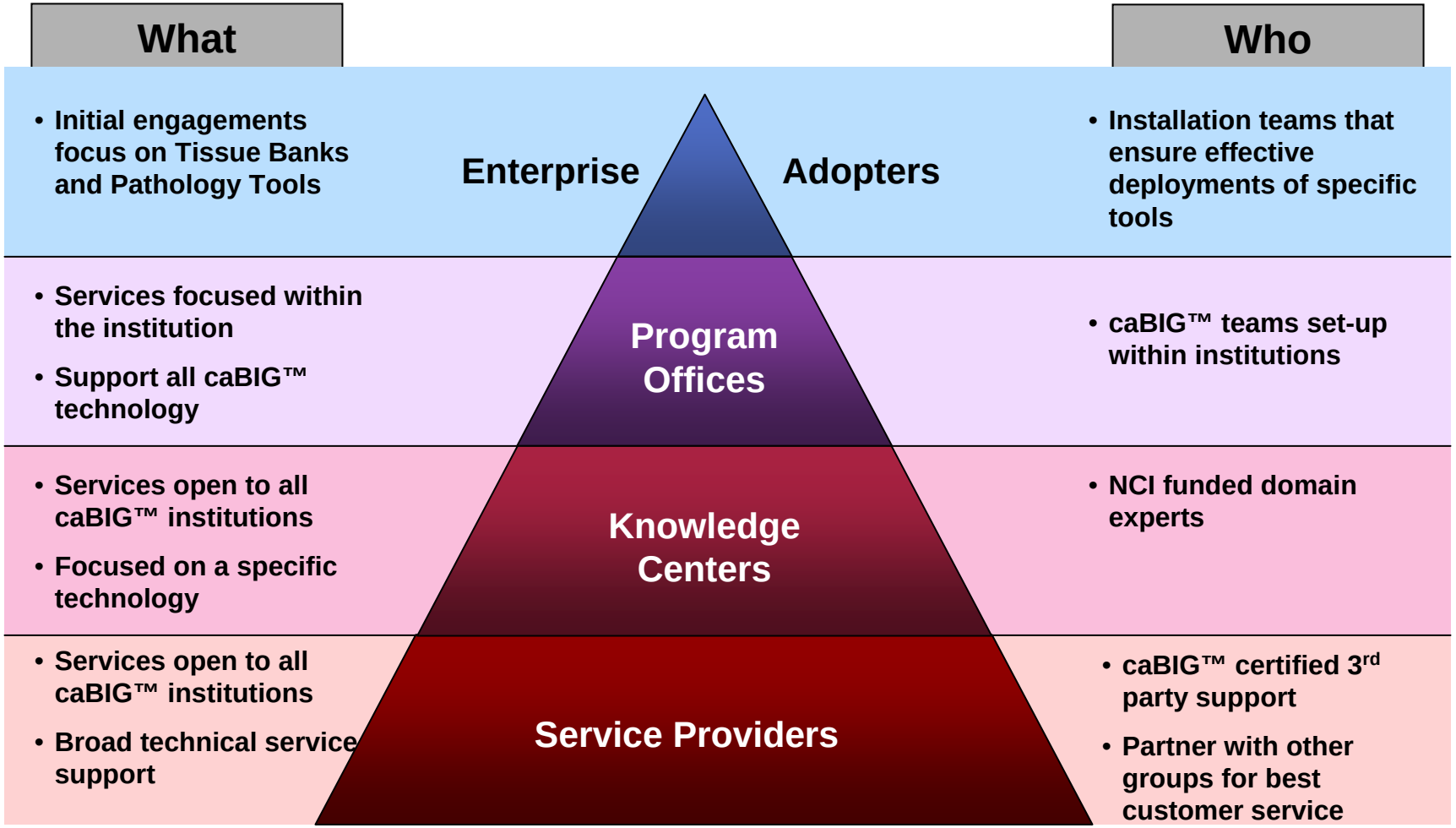
Facilitating Next Generation Adoption



Ongoing Tool Development, Adoption and Participation

Stay Connected to the caBIG™ Community

For more background visit:

caBIG.cancer.gov

To join the caBIG™ technical effort visit:

caBIG.nci.nih.gov