National Cancer Institute

caBIG™ cancer Biomedical Informatics Grid ™

# caBIG™, caTissue, and Achieving Silver-Level Compatibility


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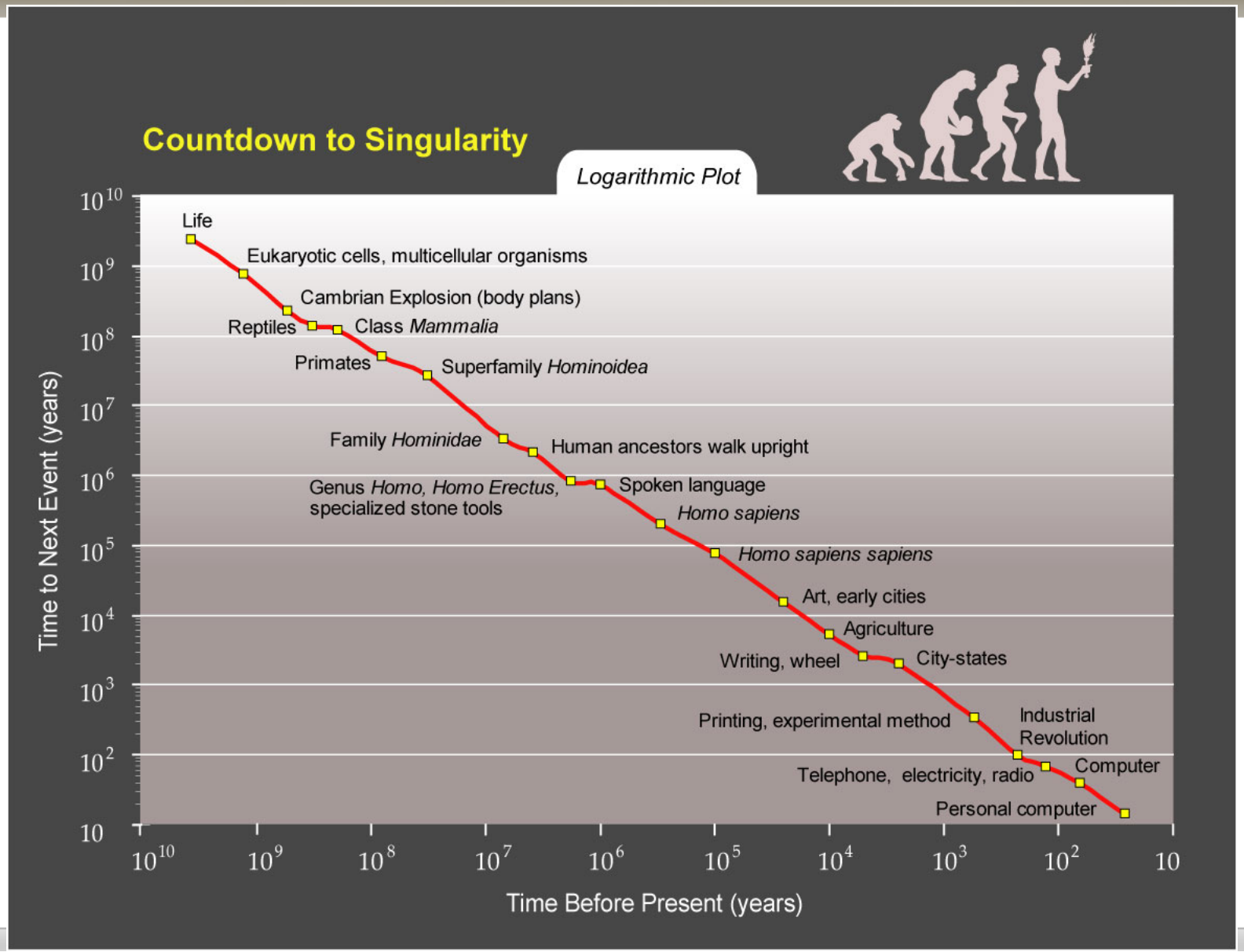
# Unprecedented Potential for Progress

- Technological change is exponential, not linear
  - "We won't experience 100 years of progress in the 21st century – it will be more like 20,000 years of progress (at today's rate)."
  - Ray Kurzweil, *The Law of Accelerating Returns*
- Scientific knowledge will double in the next 3 years
- Biologic knowledge will double in the next 5 years
- The sum of all human knowledge is just 1% of what it will be in the year 2050

# Kurzweil - *The Singularity is Near*



# 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 - within the repository

- 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

# Choosing a system

- **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

# Some Biospecimen Software Tools

caBIG cancer Biomedical Informatics Grid™

| Name | Organization | License | caBIG Compatibility |
|---|---|---|---|
| Sapphire R4 | LabVantage | Commercial | Bronze - under review |
| Freezerworks | Dataworks Development | Commercial | Bronze |
| LabMatrix | BioFortis | Commercial | Unknown |
| caTissue Core | caBIG | Open source | Silver |
| Waban LIMS | Waban | Commercial | Unknown |
| Biological Specimen Inventory System (BSI) | IMS | Commercial | Bronze |
| BIGR - Biomaterials and Information for Genomic Research | GulfStream Bioinformatics | Commercial | Unknown |
| Labrador | NCI | Unknown | Unknown |
| Biomaterial Tracking and Management - Research | Daedalus Software | Commercial | Unknown |
| TissueMetrix | Artificial Intelligence in Medicine Inc. | Commercial | Unknown |
| Oncore | PercipEnz | Commercial | Unknown |

# If you're going to build…

- End user involvement
- Use cases
- Follow a system development methodology
  - E.g. Unified Process
- Understand the true costs
  - *Brooks Law*
  - *"Adding manpower to a late software project makes it later."*
  - Costs of maintenance and support
  - The Mythical Man Month - Fred P Brooks, Jr.
- Strive for Capability Maturity Model Level 3

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# caBIG™ – NCI's Approach to the IT Infrastructure

# caBIG Community

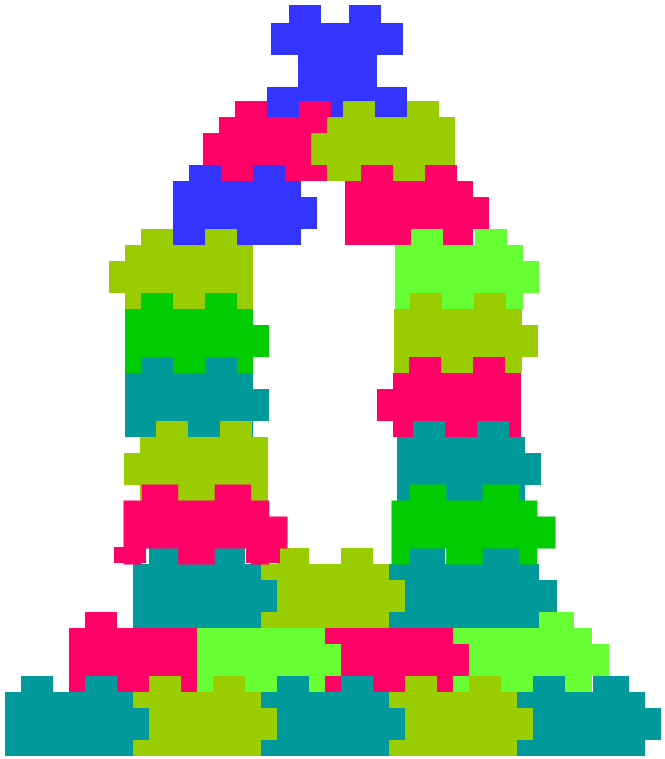
| | |
|---|---|
| Clinical Trial Management Systems | Addresses the need for consistent, open and comprehensive tools for clinical trials management. |
| Integrative Cancer Research | Provides tools and systems to enable integration and sharing of information. |
| Tissue Banks & Pathology Tools | Provides 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. |

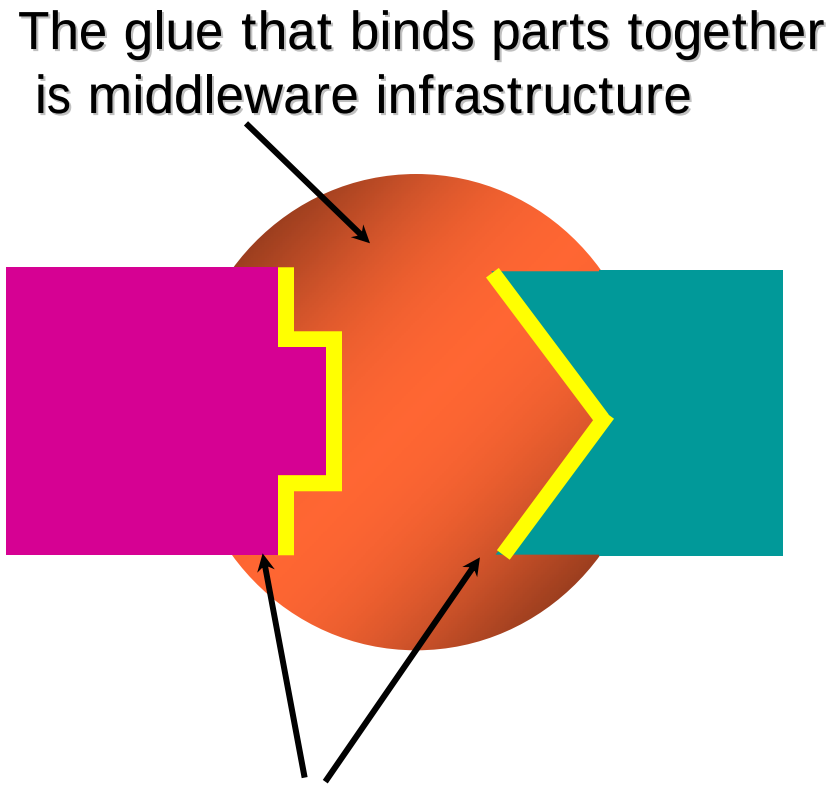
# caBIG Approach

- **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**



# Interoperability benefits for Biospecimens

- 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 common 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

# 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.** |

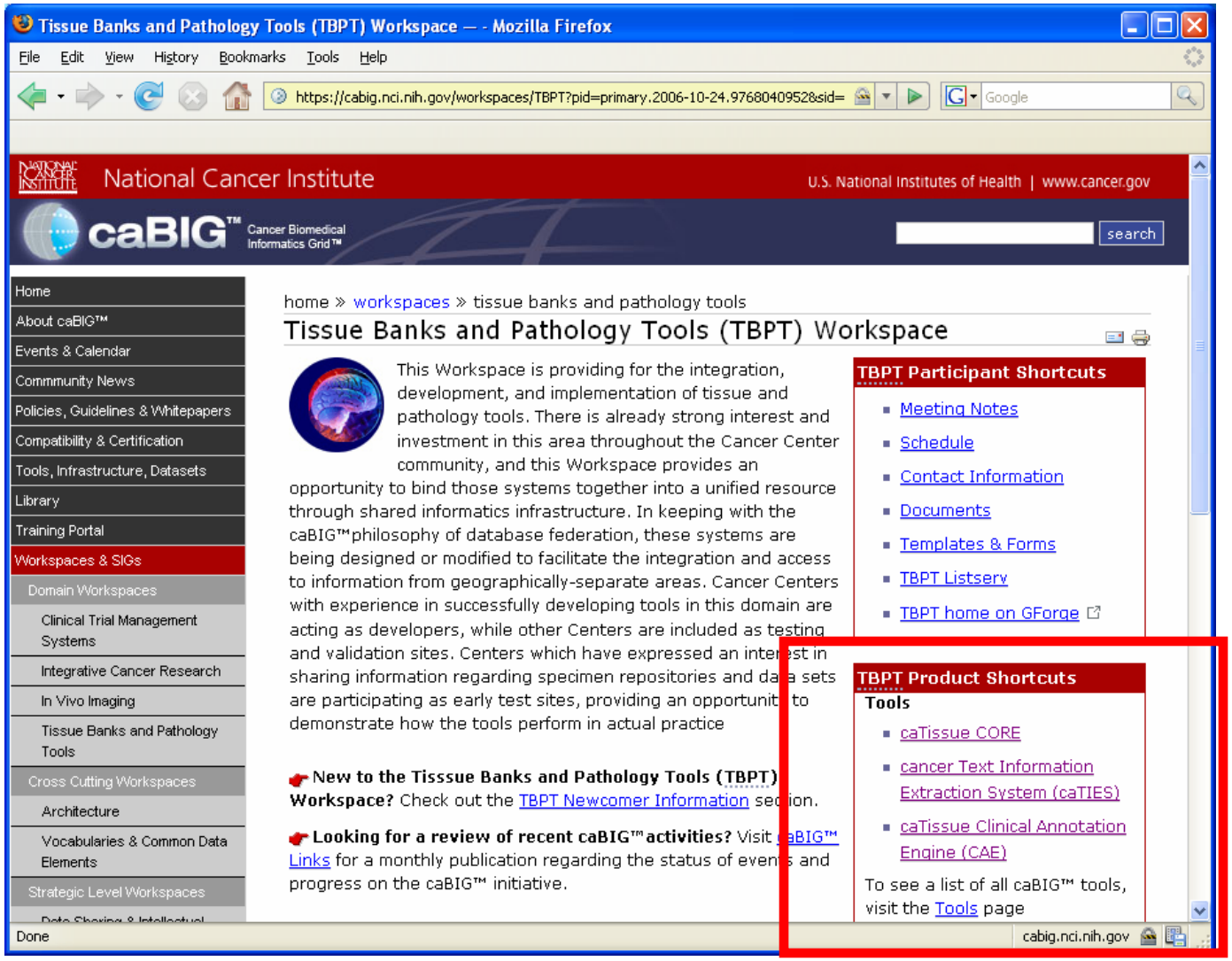
# caBIG Biorepository and Pathology Tools

# caBIG™ Benefits Biospecimen Resource Leaders, Researchers and Advocates

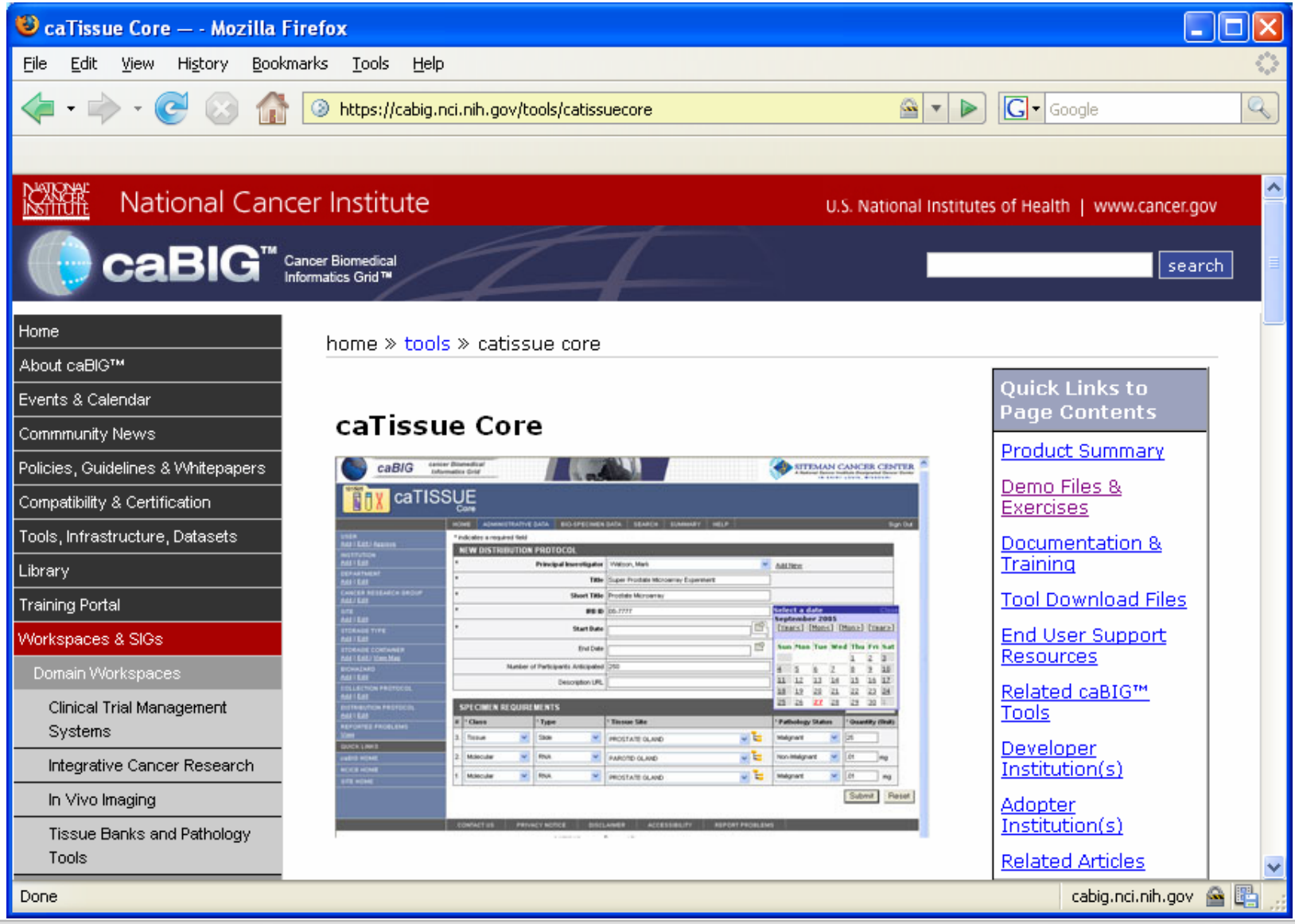
- Leveraging existing software tools available through caBIG™ reduces software development costs for biospecimen resources
- The shared standards governing caBIG™ allows even small repositories to advertise their presence and specimen/data availability – AND – learn what others have to offer
- Your own 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.**

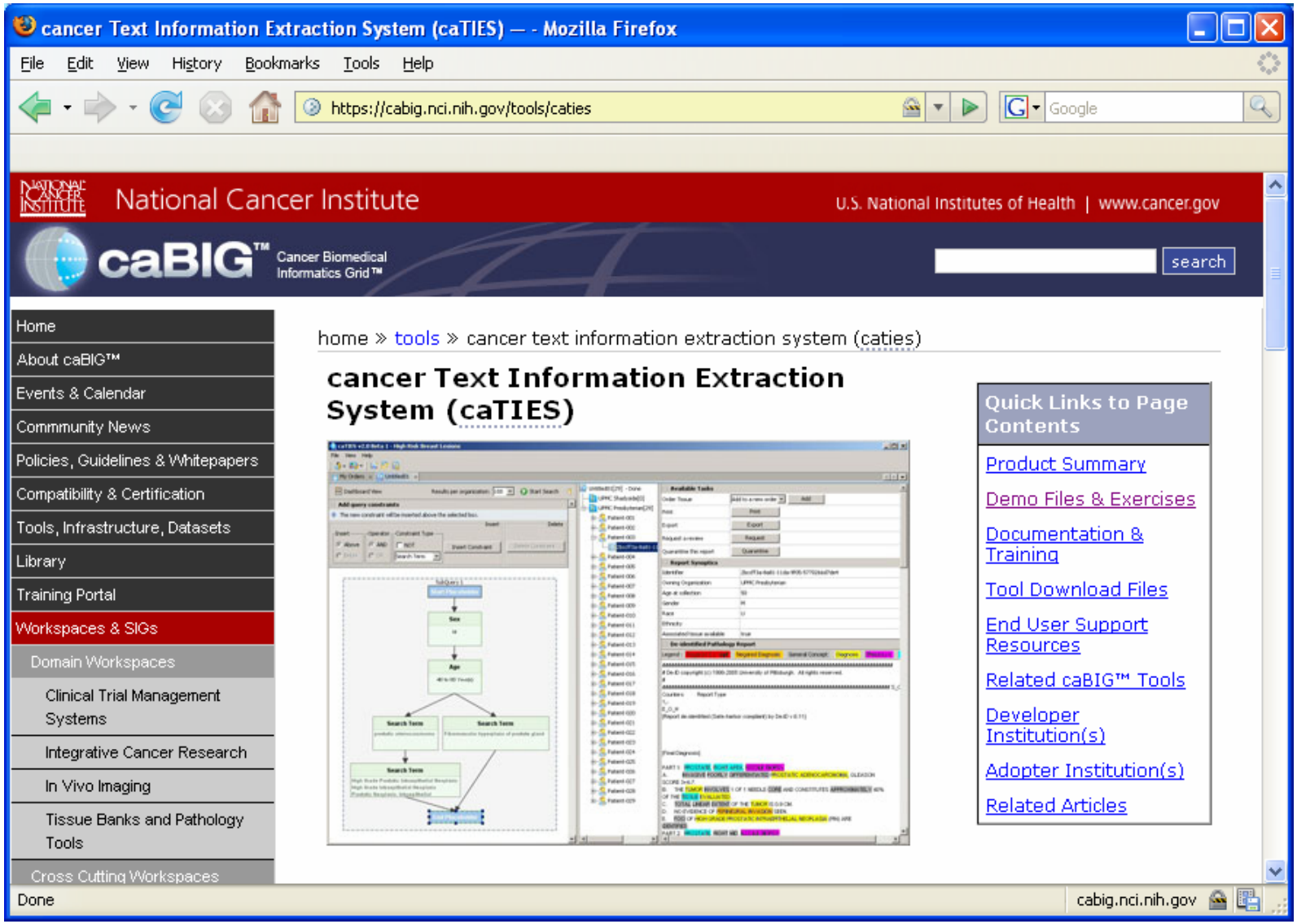
# caBIG Portal: http://caBIG.nci.nih.gov



# caTissue Core



# cancer Text Information Extraction System



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# Enterprise Support Network

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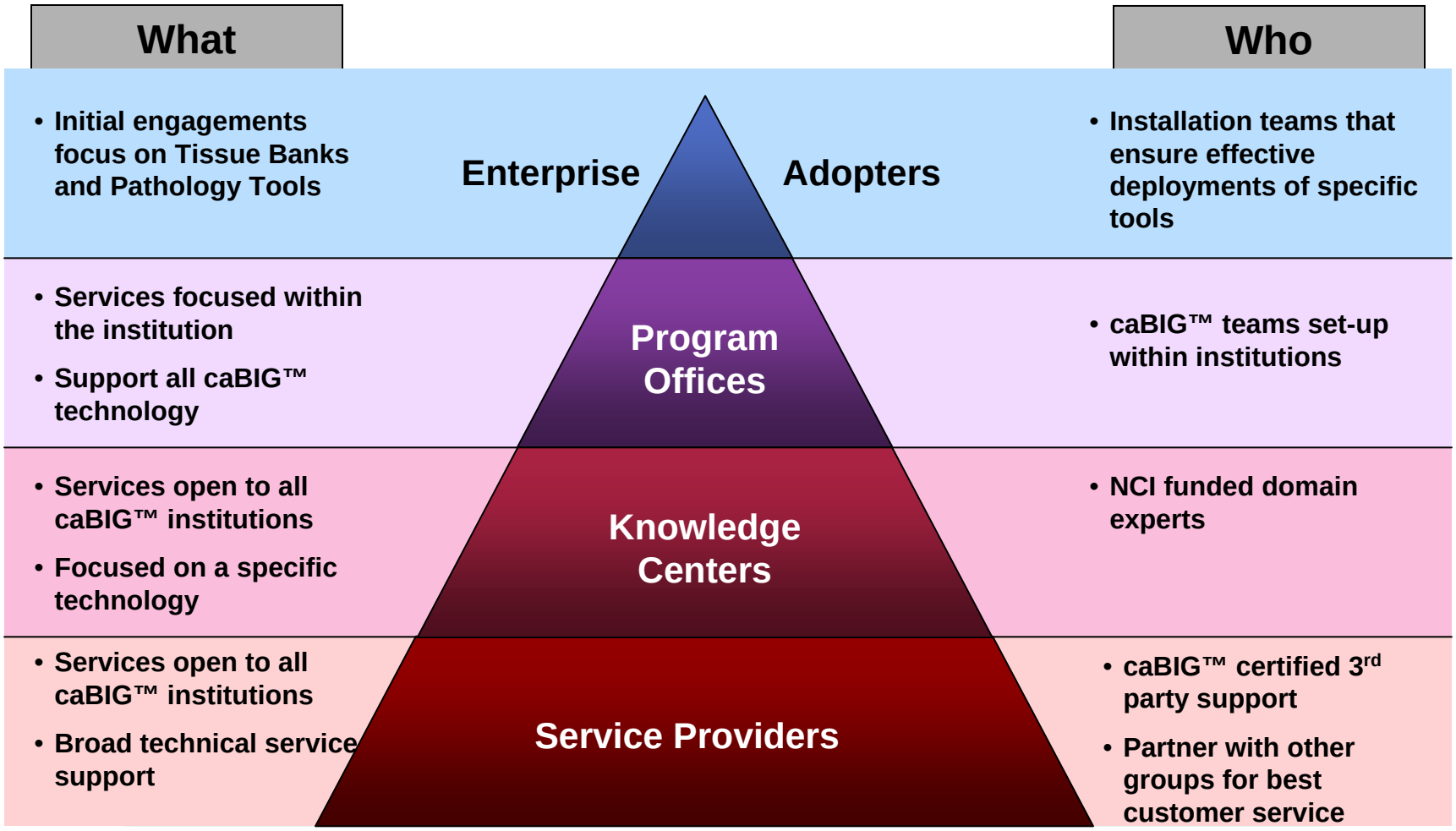
# Facilitating Next Generation Adoption




**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