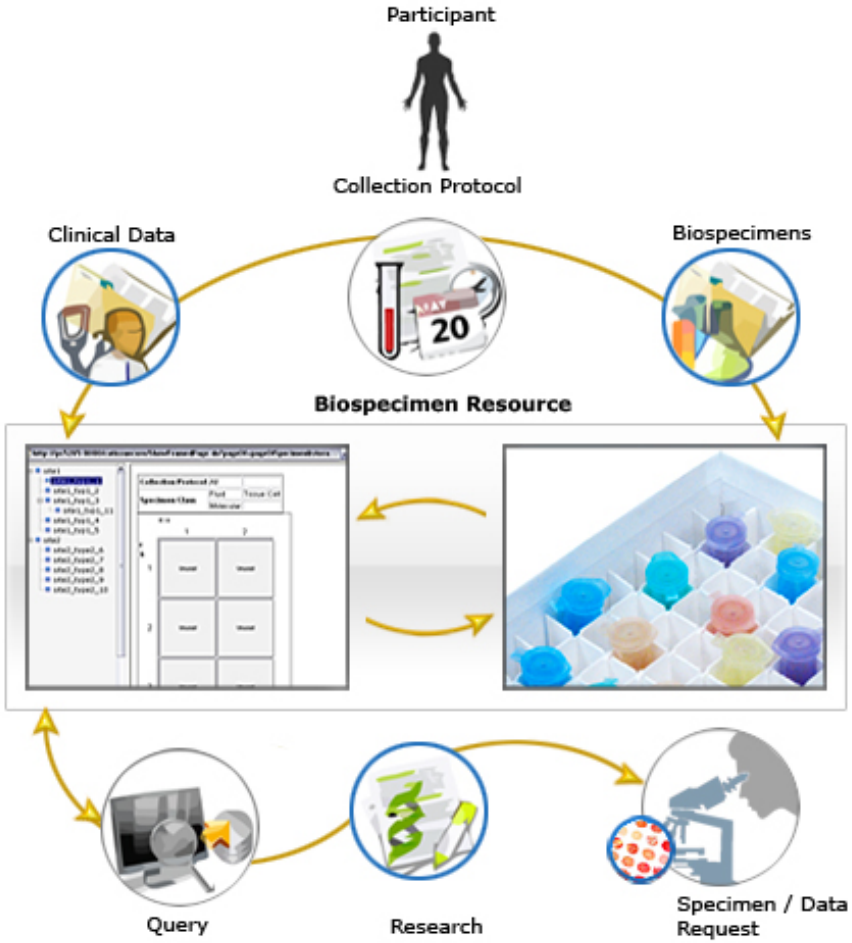
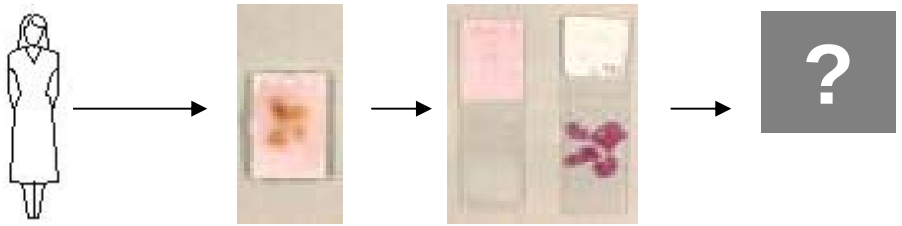
Development and Real-World Use of a System for Tracking Biospecimens and Biospecimen Data



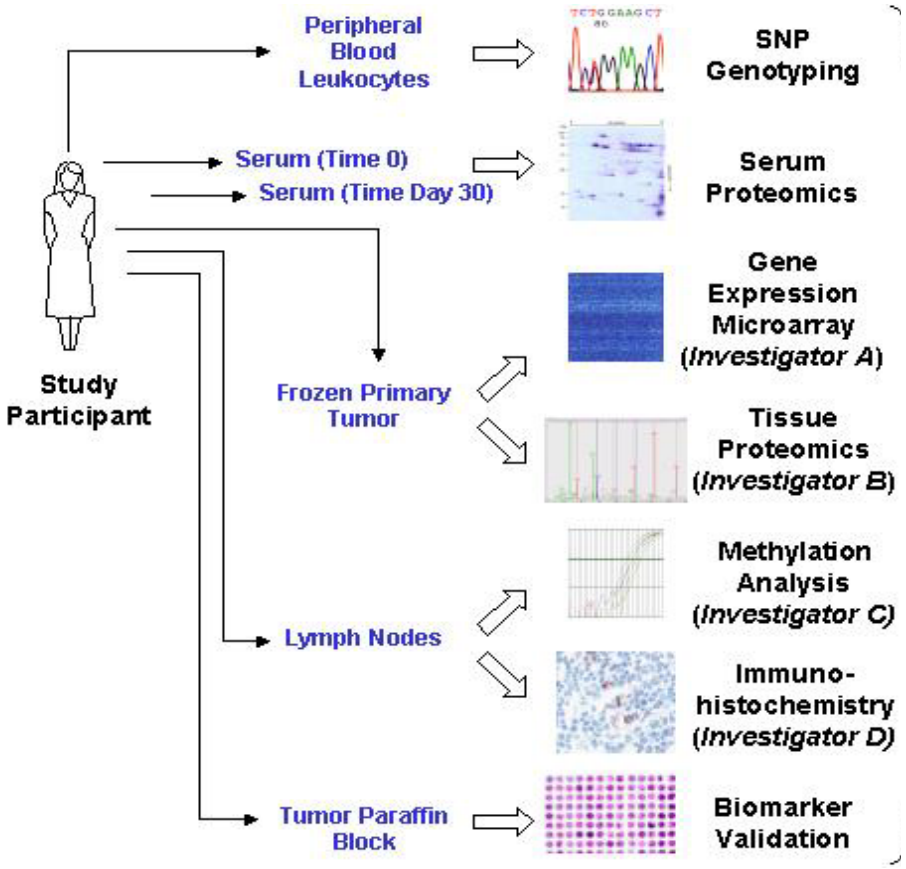
Mark A. Watson, M.D., Ph.D.
Rakesh Nagarajan, M.D., Ph.D
Dept. Pathology and Immunology

The Evolution of Biospecimen Banking

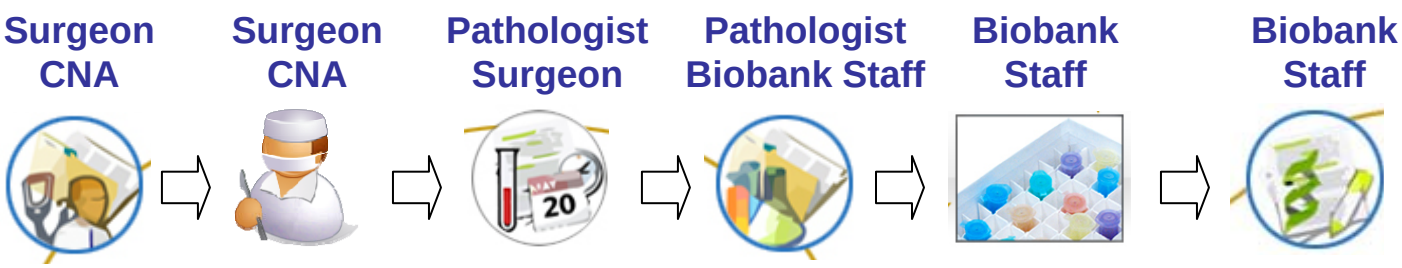
- 1988



- 2010



The Biospecimen Lifecycle



	Patient	Procedure	Acquisition	Processing	Storage	Distribution
Custodian	Surgeon CNA	Surgeon CNA	Pathologist Surgeon	Pathologist Biobank Staff	Biobank Staff	Biobank Staff
Location	Pre-OP	O.R.	O.R.	Pathology	Biobank	Biobank
Data	BMI HR	Clamp Time	Collection Time	Fixation Time	Storage Temp	Transfer Event

Generic Biospecimen (Tumor) Bank

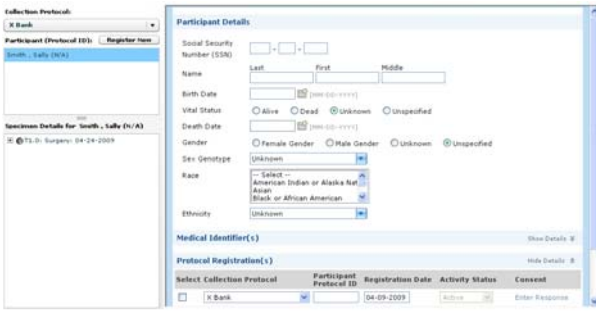
- *Pre-operative consent is obtained and operative frozen tissue specimens (tumor and non-malignant) are collected from surgical discards.*

Consent Patient
Register to Protocol
Provide Diagnosis
Provide Operative Date

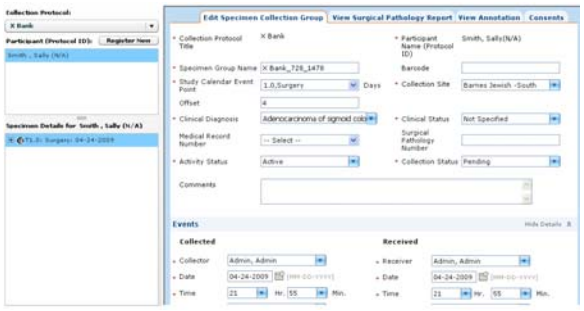
Collect Specimen

Receive Specimen
Store Specimen

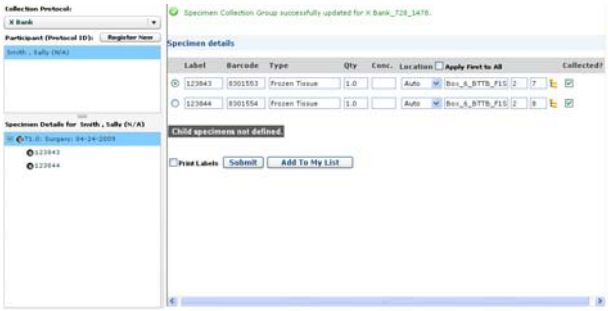
CRA



Pathologist



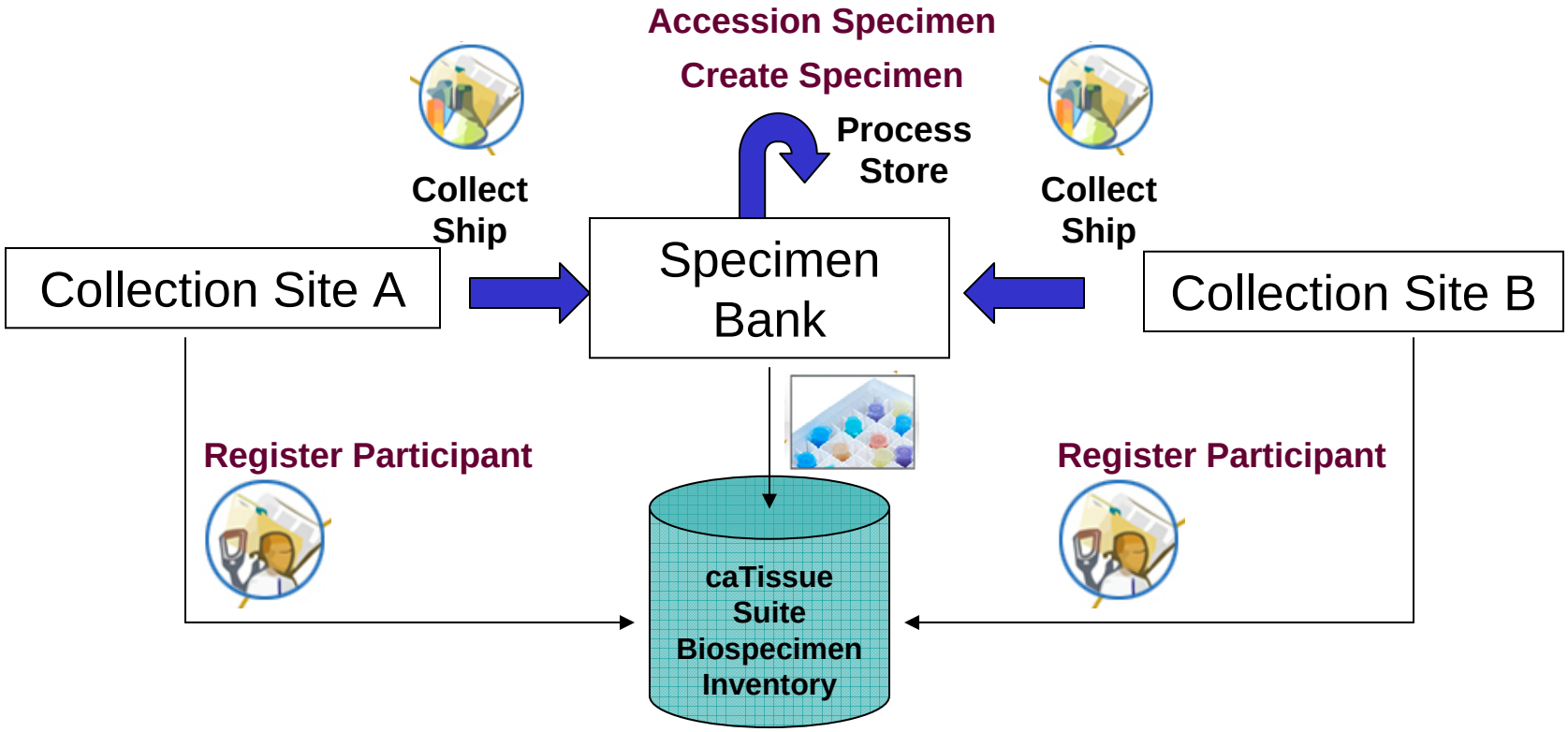
Biobank



TIME

Multisite Trial

- *Participants are registered, specimens collected, and then processed at independent sites by different users over time.*



Multiple Time Point Clinical Trial

- *Specimens are collected at multiple time points from a participant who is independently registered to a clinical trial.*

Consent Patient A
Register to Protocol

Collect Specimen 1

Collect Specimen 2

Collect Specimen 3

Consent Patient B
Register to Protocol

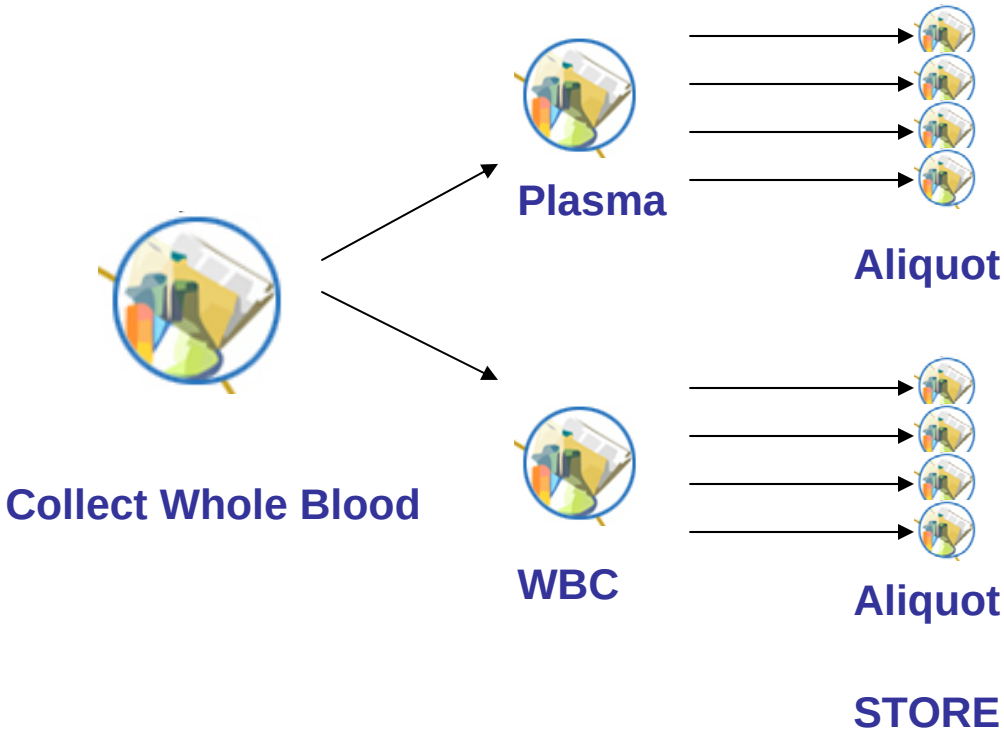
Collect Specimen 1

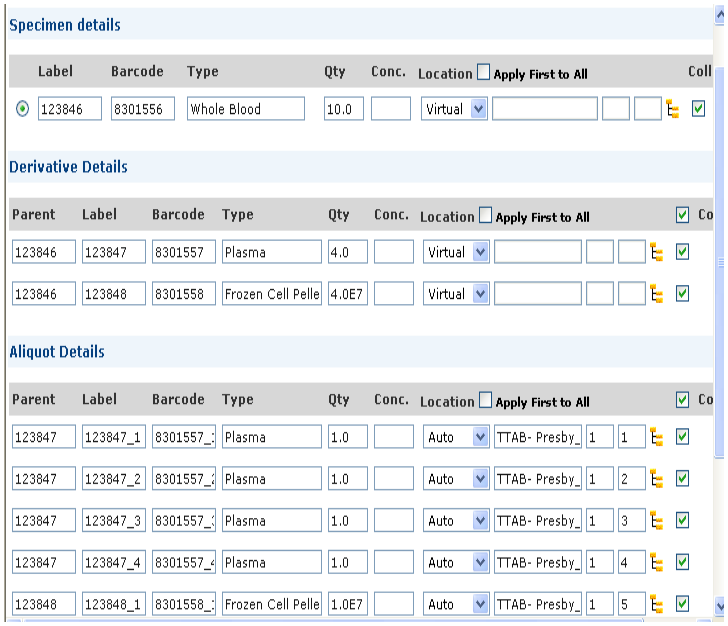
Collect Specimen 2

TIME

Multi-Component Blood Protocol

- *A tube of whole blood is collected which is then processed and aliquoted into individual components, as per a unique SOP for that protocol.*

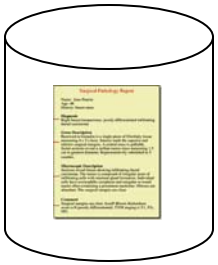




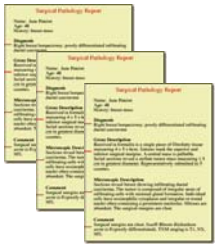
Surgical Pathology Block Archive

- *Pathology report texts that are loaded into the system are the basis for a search and block request. Blocks are requested, deidentified, sectioned, and distributed for a study.*

caTissue Suite

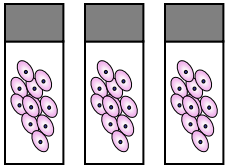


Path Report Loading

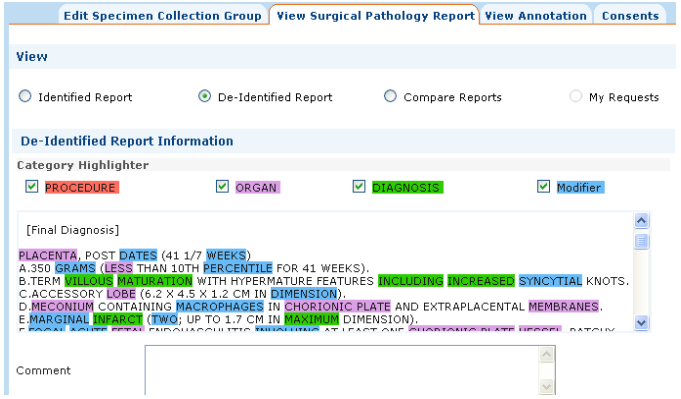


Search for cases based on path report

Retrieve requested blocks from pathology and accession as new specimens



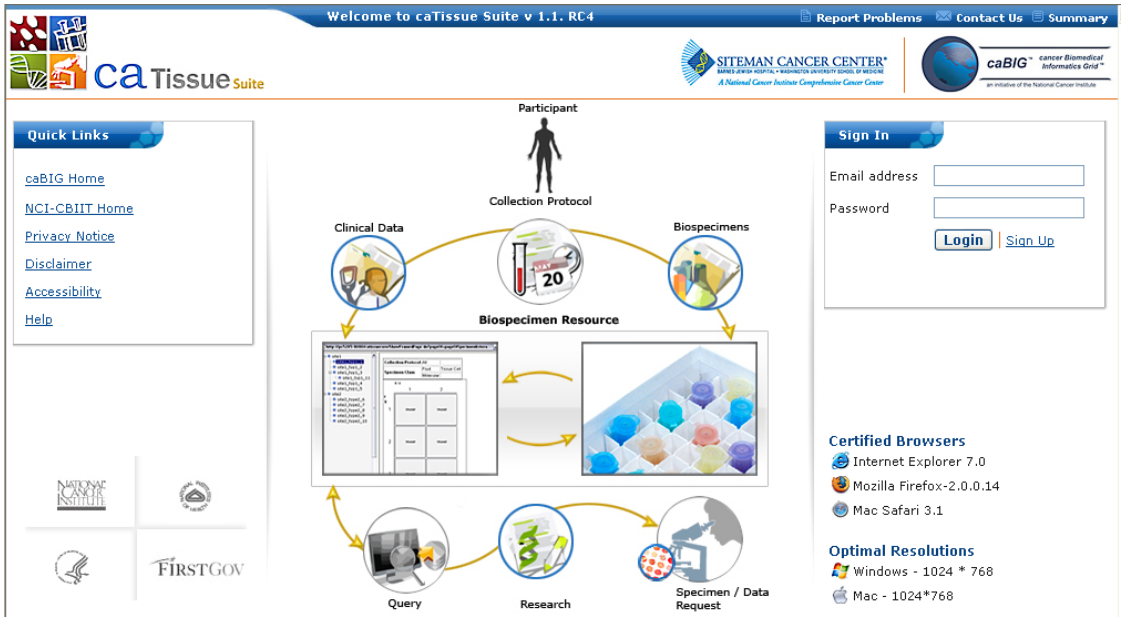
Cut slides and distribute



Challenges in Biospecimen Informatics

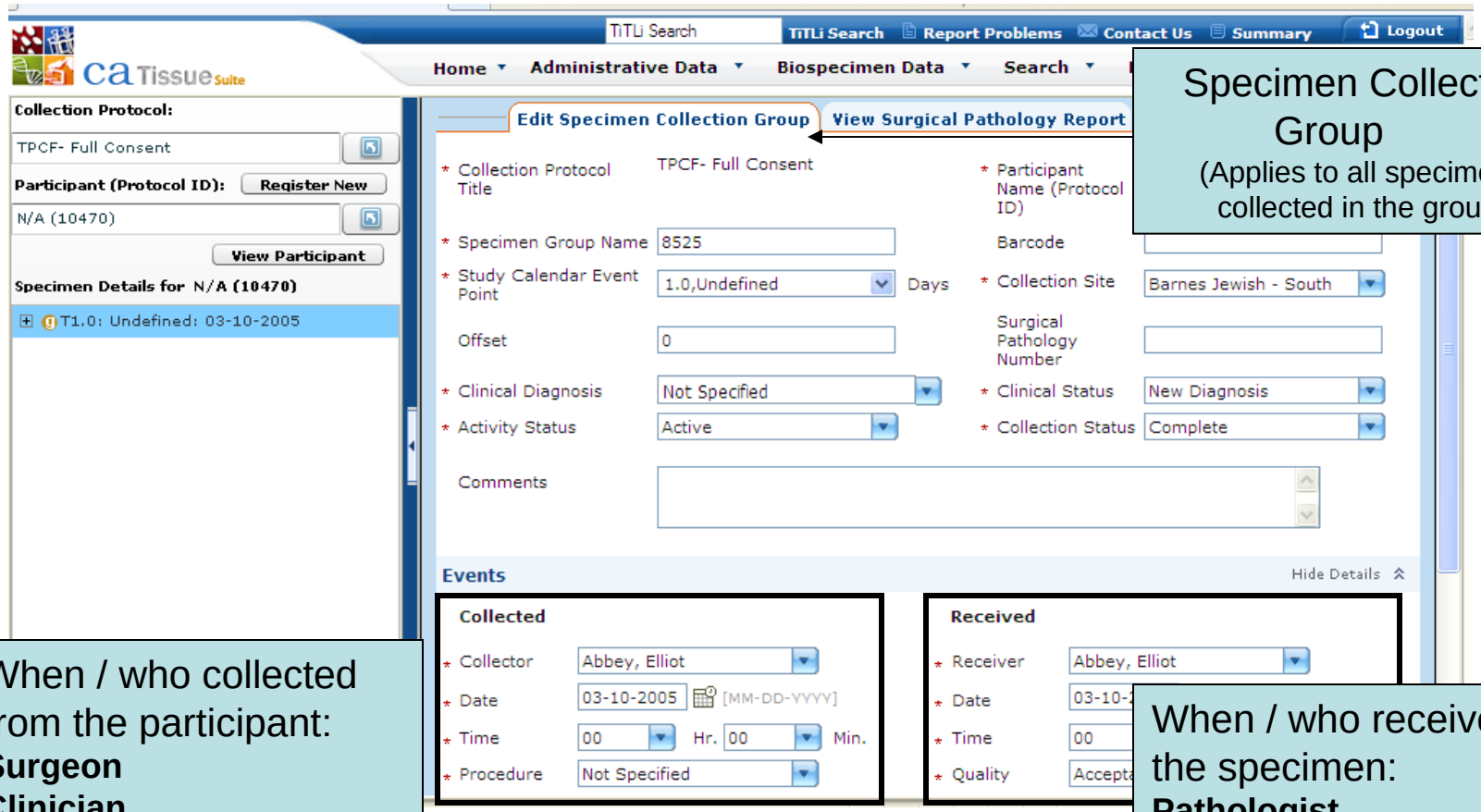
- **Workflows that are facility-specific**
- **Workflows that are protocol-specific**
- **Requirement for flexibility and extensibility**
- **Access by multiple user roles for diverse purposes**
- **Requirement to accurately gather large amounts of data**
- **Data can be diverse, complex, and hierarchical**
- **Limited personnel / financial resources for data entry**
- **Requirement for data sharing using common vocabularies**

caTissue Suite v1.1(P4.1)



- **Web-based application for biospecimen information management**
- **Professional approach to software design**
- **Open source / Open access (Free)**
- **Iterative development cycle (Always improving)**
- **Flexible to meet the needs of varying biobank environments**
- **Multiple sources of electronic and human support**
- **Tracks many events in the biospecimen lifecycle**

Lifecycle: Collection / Receipt

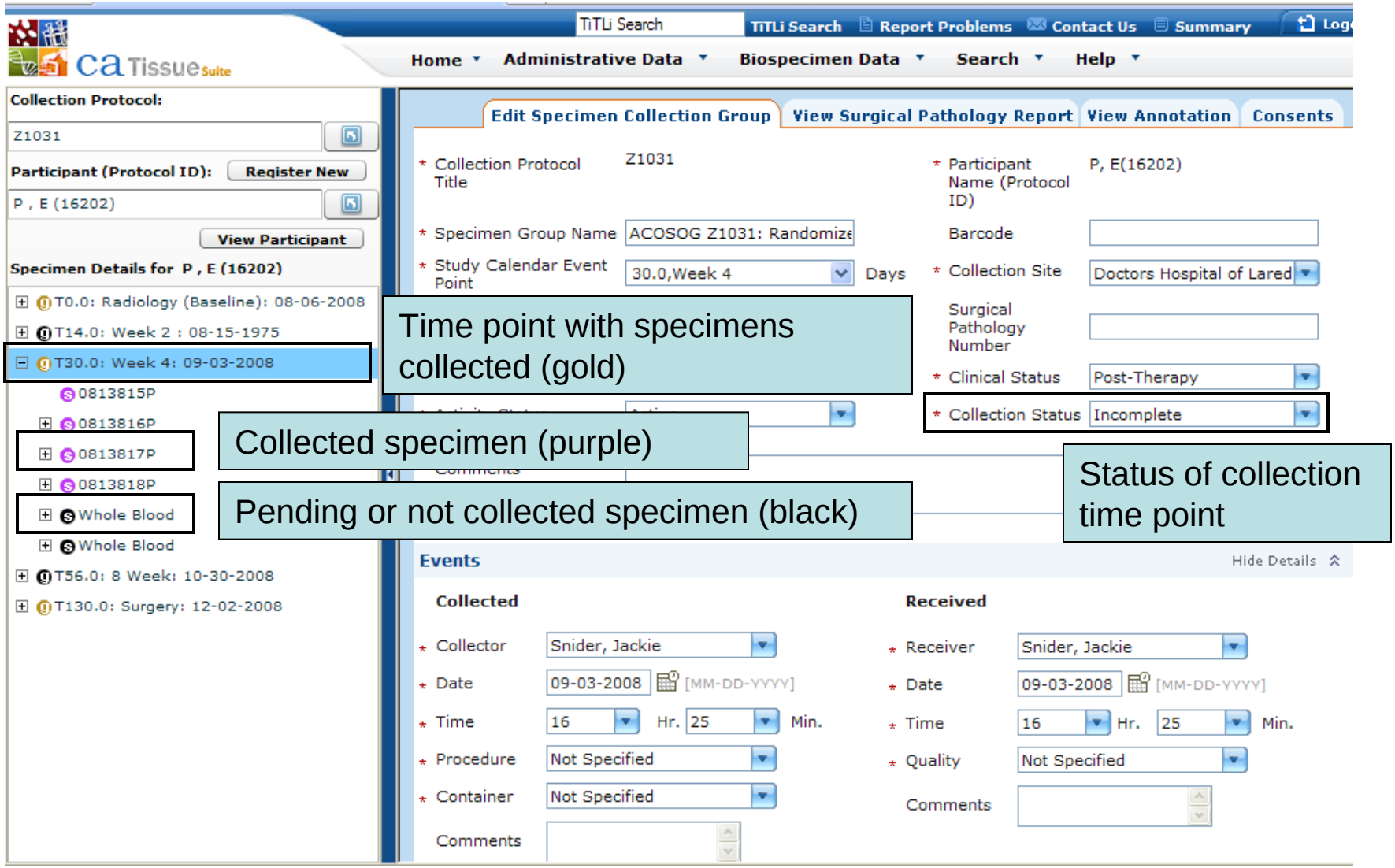


Specimen Collection Group
(Applies to all specimens collected in the group)

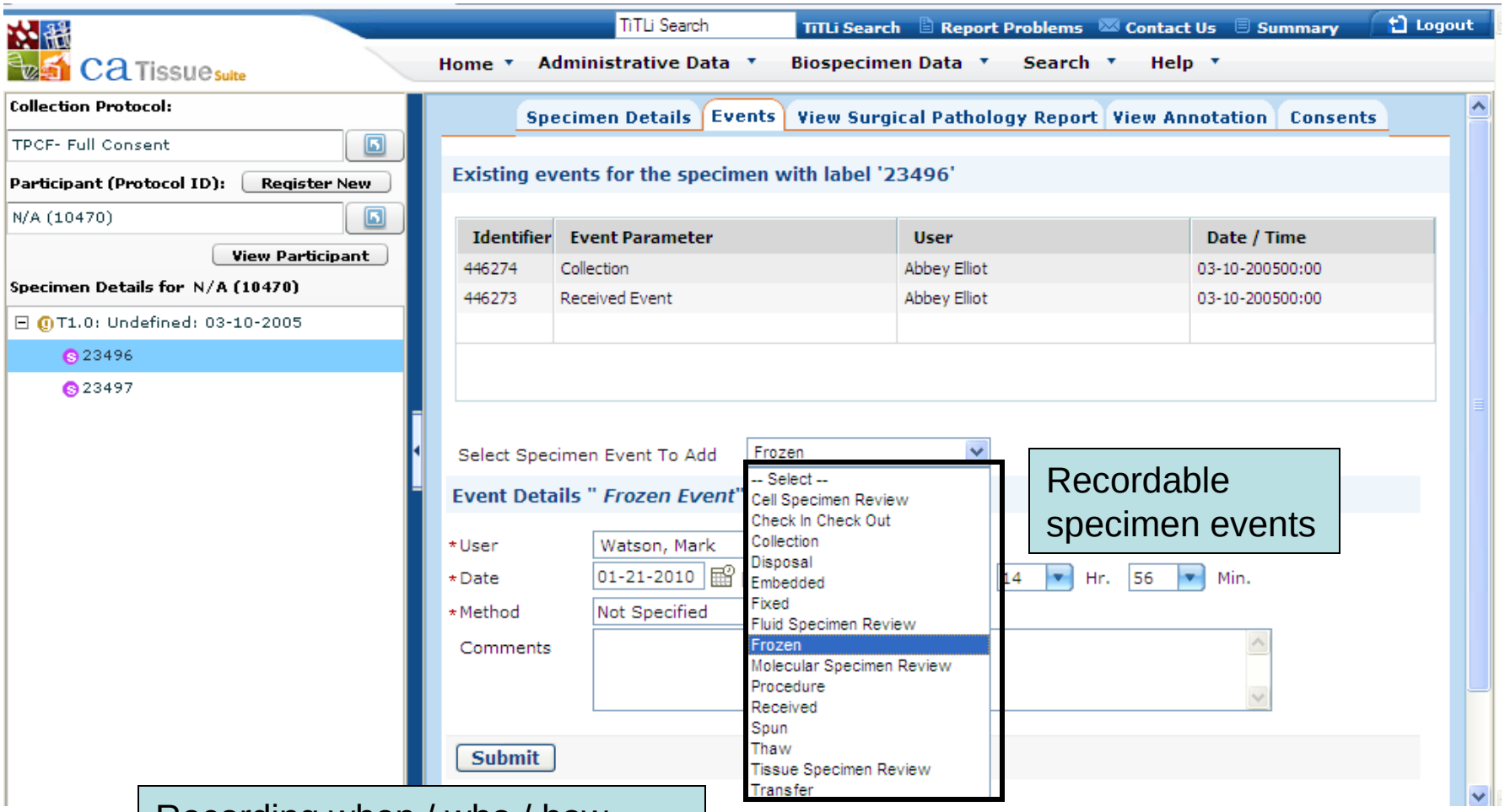
When / who collected from the participant:
Surgeon
Clinician
CRA
Pathologist

When / who received the specimen:
Pathologist
Pathology Assistant
Biospecimen Bank Staff

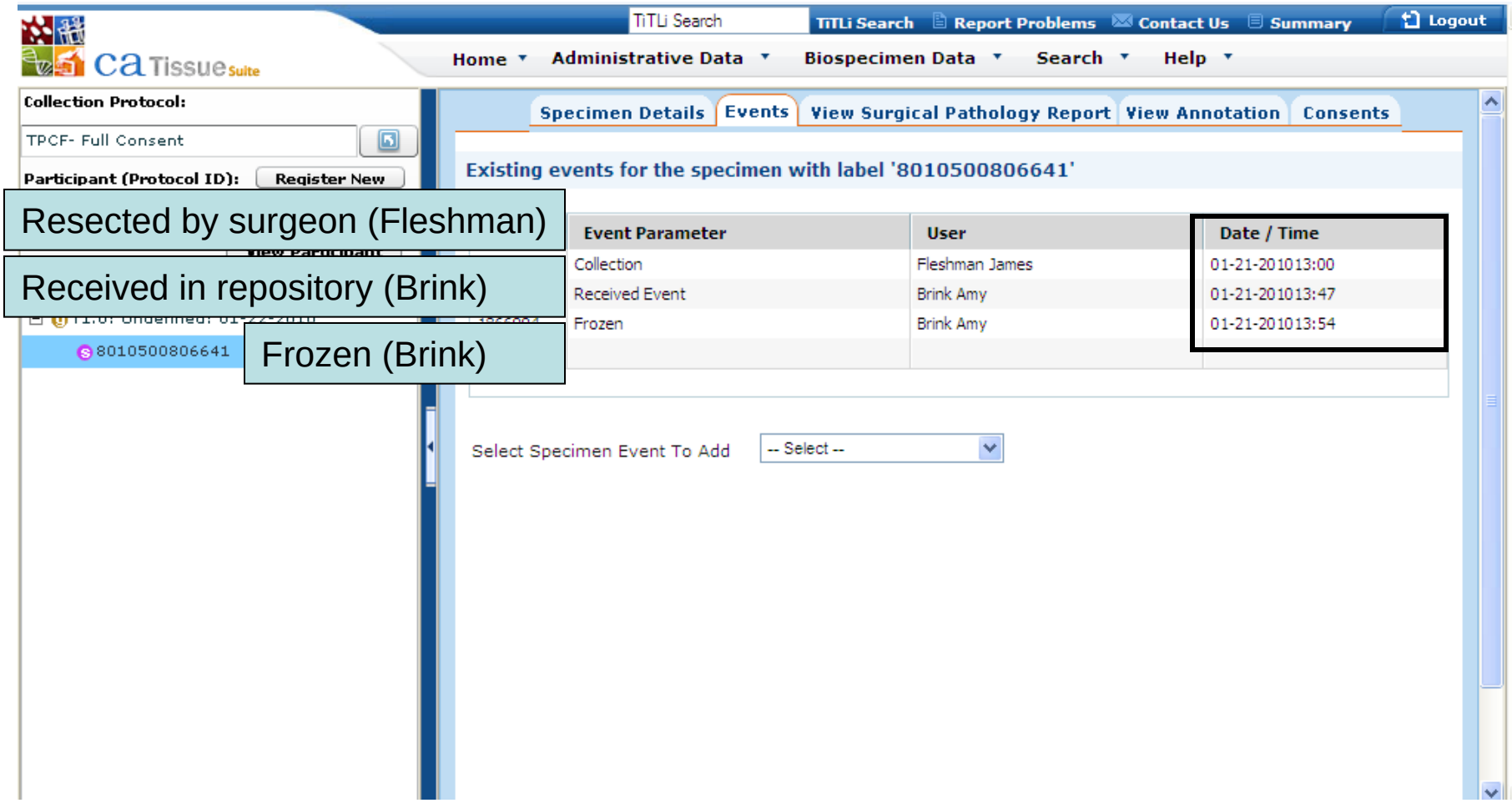
Lifecycle: Tracking Collection Timepoints



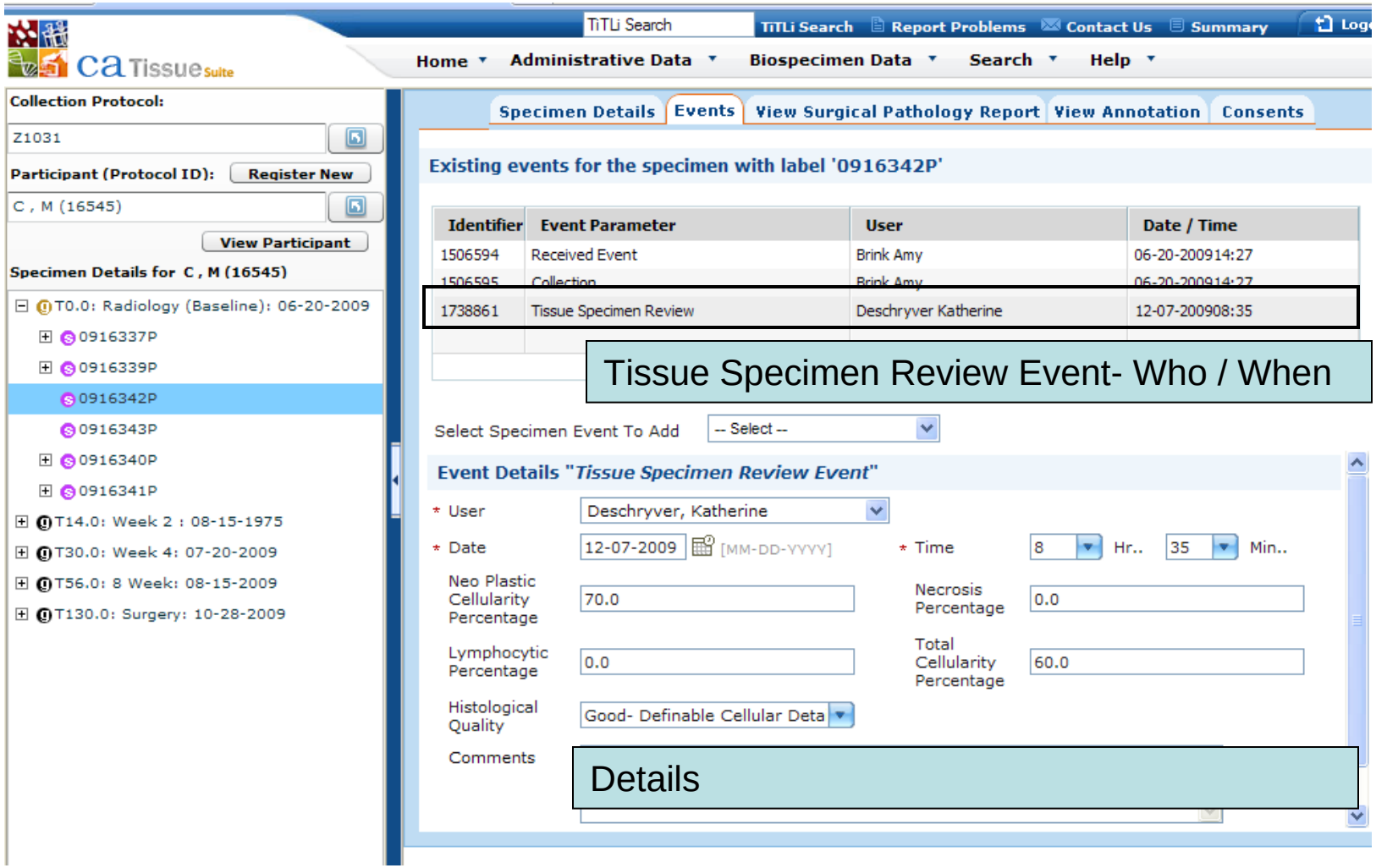
Lifecycle: Specimen Processing Events



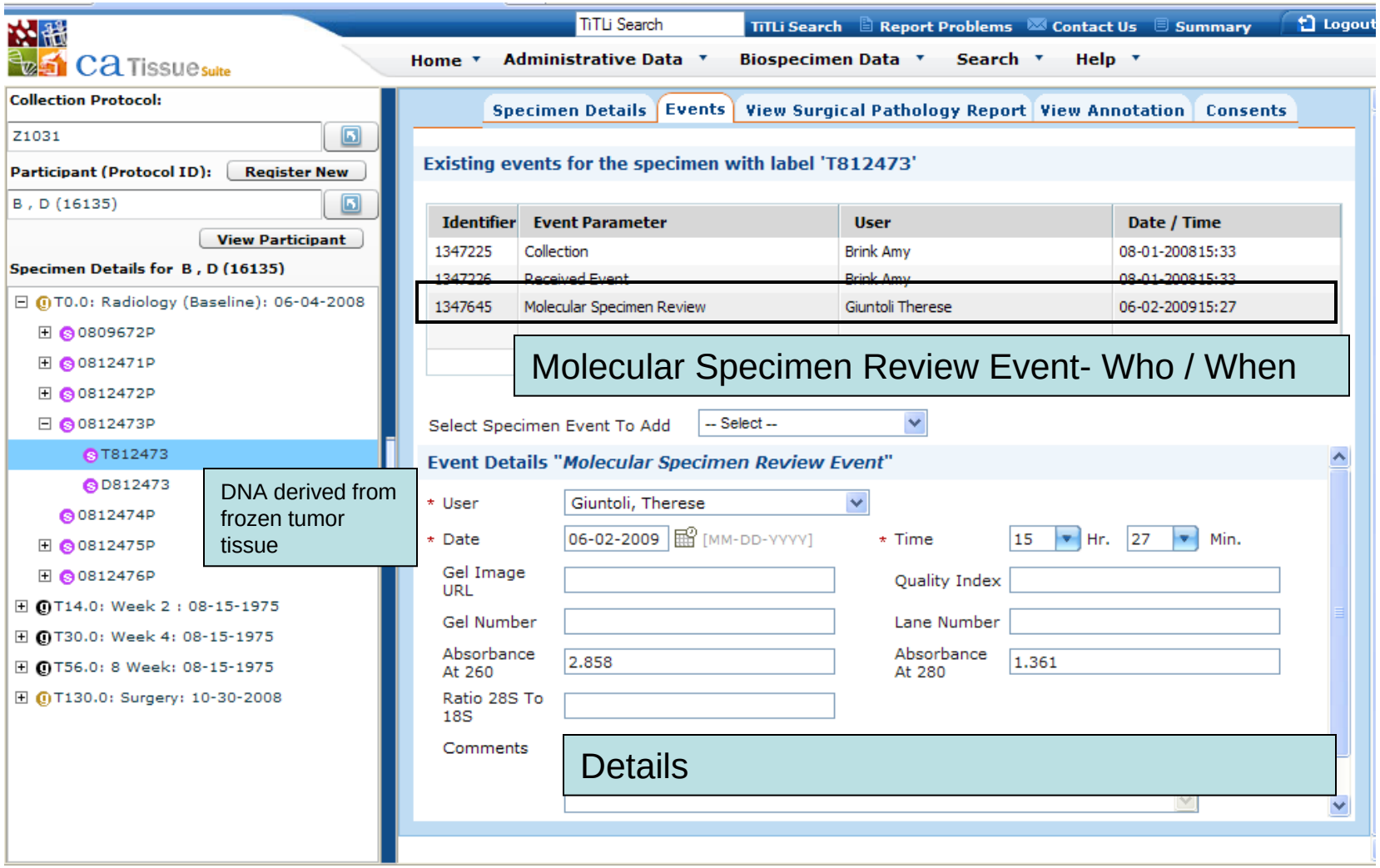
Lifecycle: Creating a Biospecimen CV



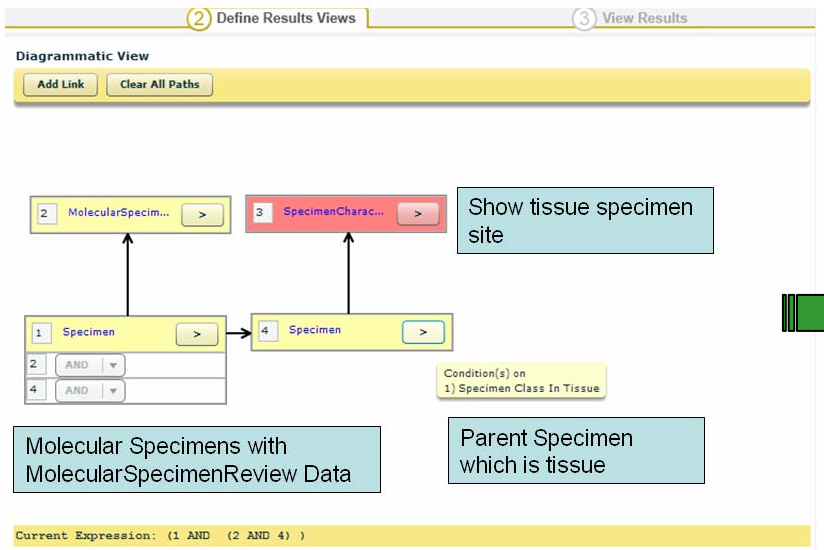
Lifecycle: Biospecimen QA



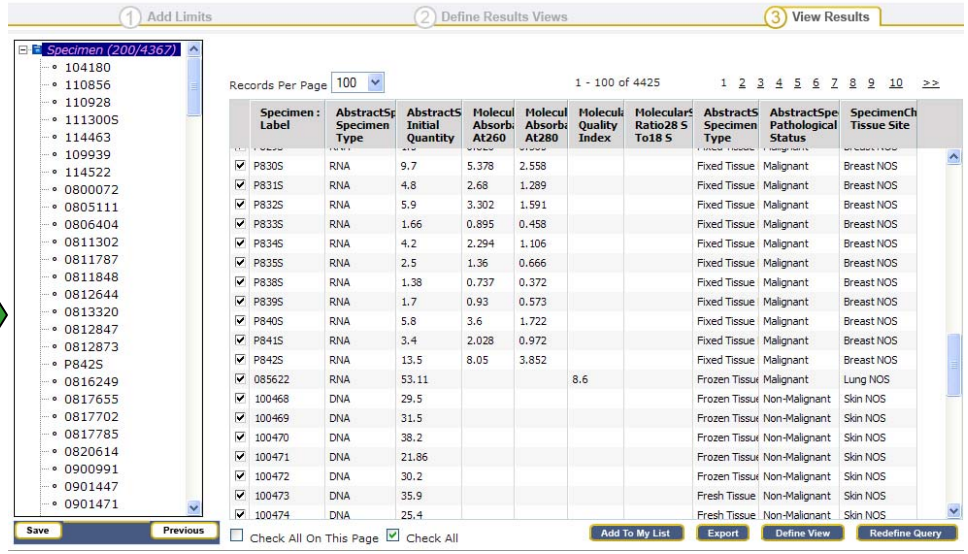
Lifecycle: Biospecimen QA



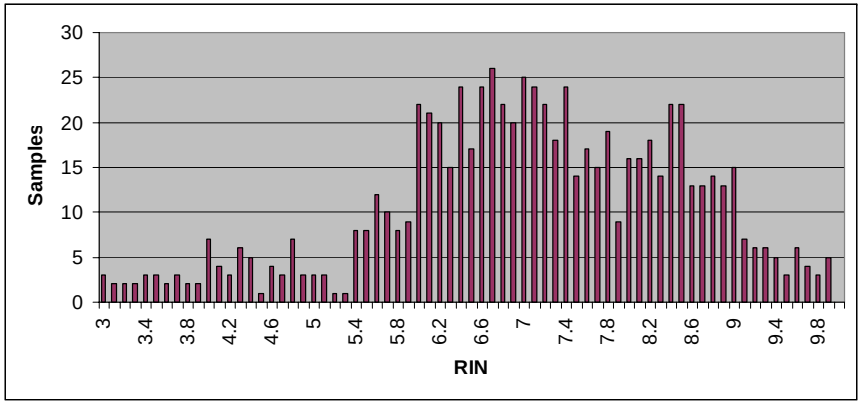
Lifecycle: Biospecimen QA



QUERY

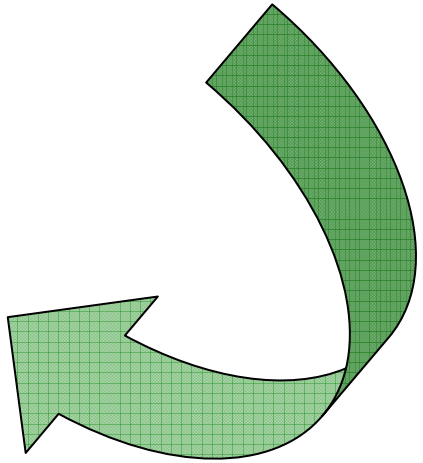


REPORT



ANALYZE

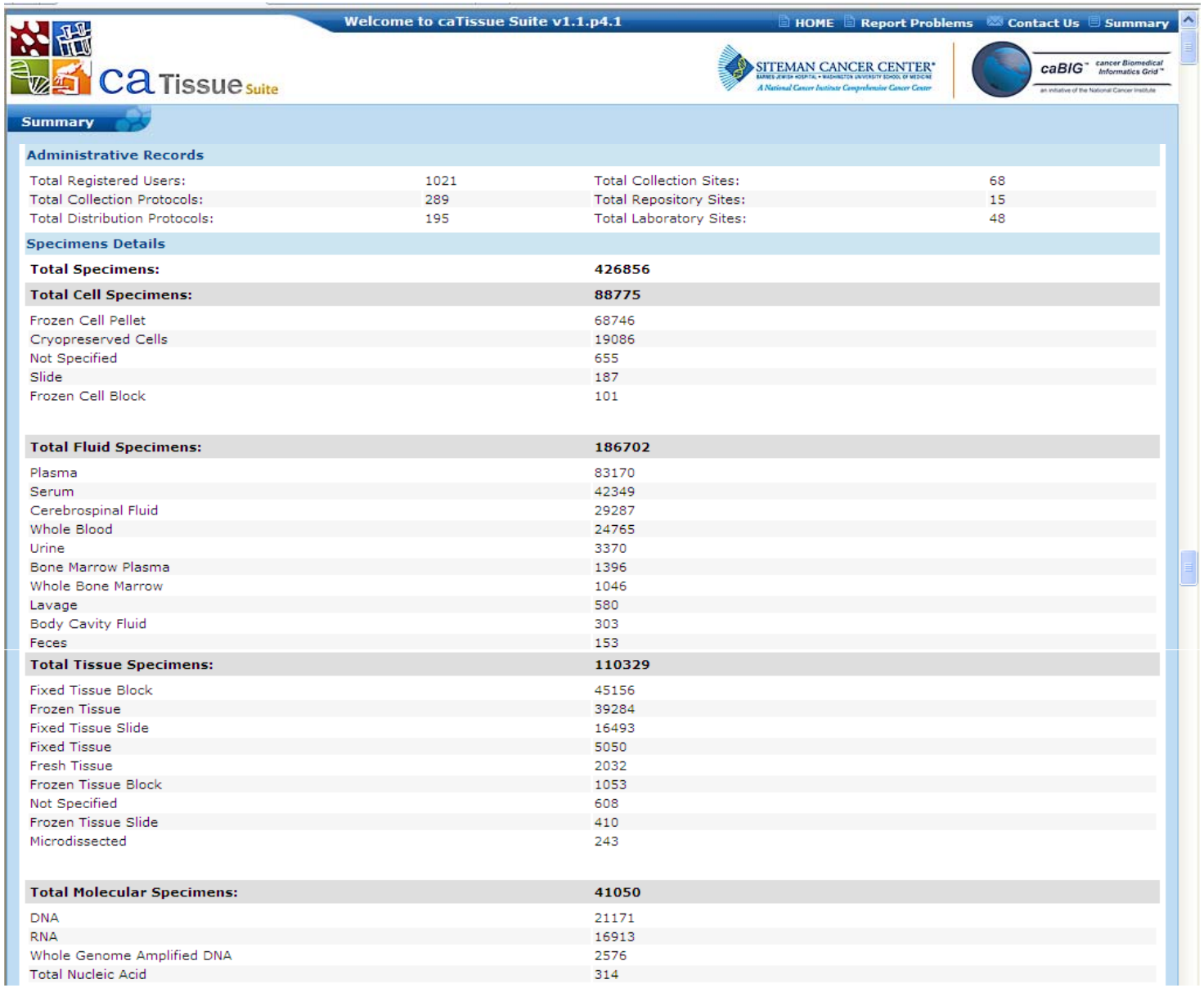
Distribution of RNA RIN Scores for Frozen Tissue Specimens



Filter based on:

- **RNA / DNA**
- **Fixed / Frozen Tissue**
- **Tissue Site**
- **Collector**
- **Collection Date**
- **Collection Site**
- **Processing Technician**

Deploying caTissue at WUMC



Welcome to caTissue Suite v1.1.p4.1 | HOME | Report Problems | Contact Us | Summary

caTissue Suite

SITEMAN CANCER CENTER — A National Cancer Institute Comprehensive Cancer Center

caBIG™ cancer Biomedical Informatics Grid™

Summary

Administrative Records

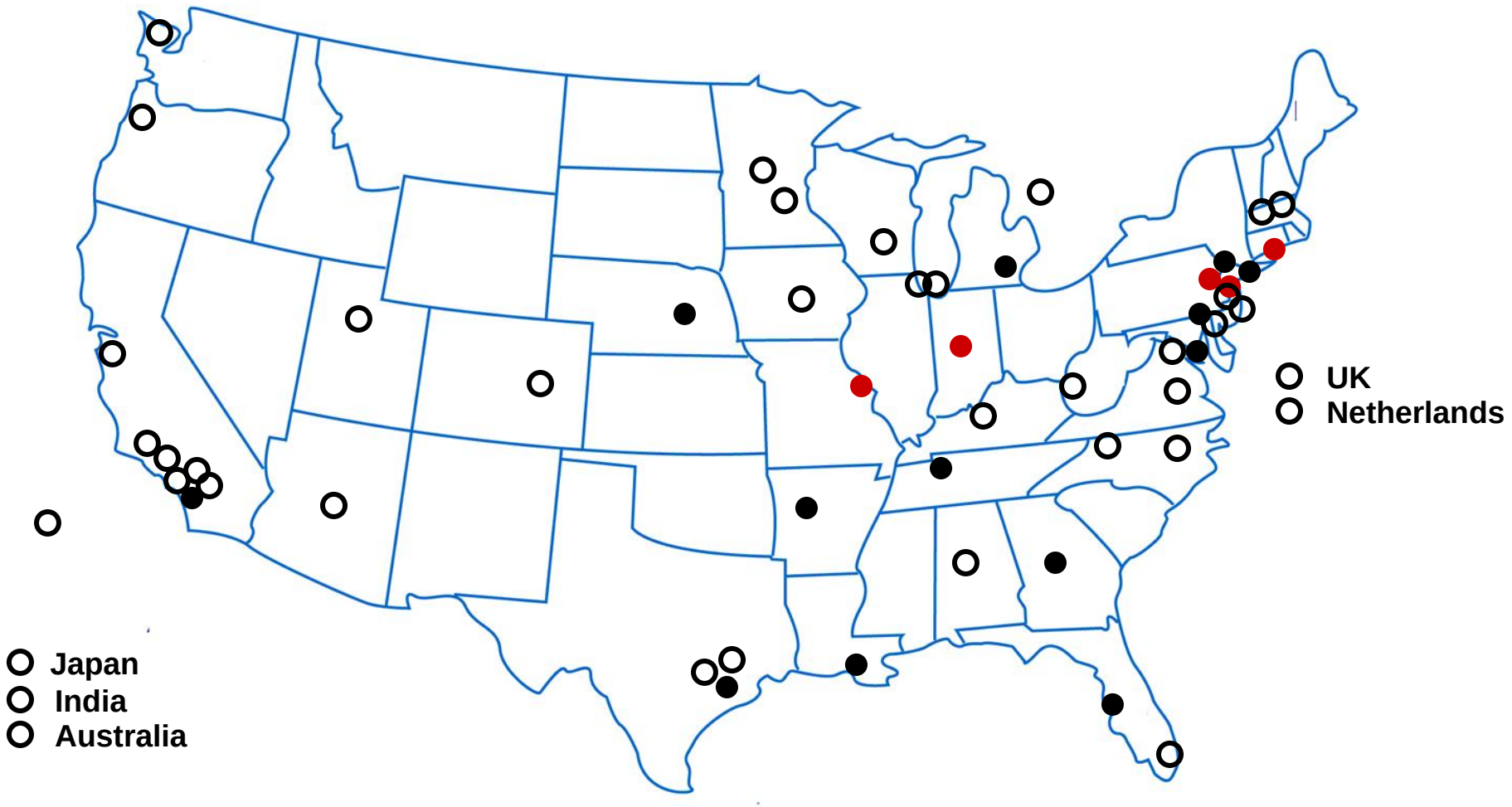
Total Registered Users:	1021	Total Collection Sites:	68
Total Collection Protocols:	289	Total Repository Sites:	15
Total Distribution Protocols:	195	Total Laboratory Sites:	48

Specimens Details

Total Specimens:	**426856**
Total Cell Specimens:	**88775**
Frozen Cell Pellet	68746
Cryopreserved Cells	19086
Not Specified	655
Slide	187
Frozen Cell Block	101
Total Fluid Specimens:	**186702**
Plasma	83170
Serum	42349
Cerebrospinal Fluid	29287
Whole Blood	24765
Urine	3370
Bone Marrow Plasma	1396
Whole Bone Marrow	1046
Lavage	580
Body Cavity Fluid	303
Feces	153
Total Tissue Specimens:	**110329**
Fixed Tissue Block	45156
Frozen Tissue	39284
Fixed Tissue Slide	16493
Fixed Tissue	5050
Fresh Tissue	2032
Frozen Tissue Block	1053
Not Specified	608
Frozen Tissue Slide	410
Microdissected	243
Total Molecular Specimens:	**41050**
DNA	21171
RNA	16913
Whole Genome Amplified DNA	2576
Total Nucleic Acid	314

The caTissue Biospecimen Network

(February 2010)

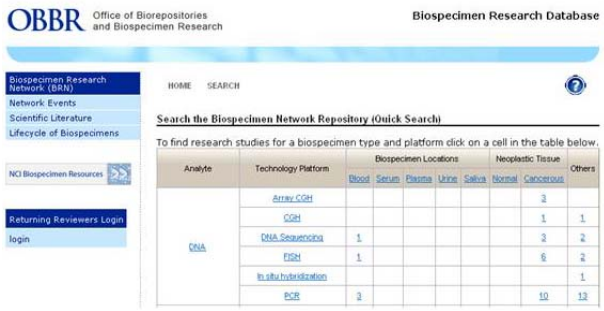


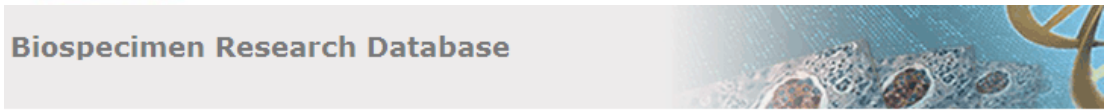
Testing	Production	Grid-enabled Production
48 institutions	13 institutions	5 institutions
10,000 specimens	**470,000 specimens**	**716,000 specimens**

Deploying caTissue: New Challenges

- Unsuspected bugs revealed during ‘real-life’ use
  - Bug reporting, tracking, fixing
- Performance of web interface vs. client software
  - Code improvements
  - GUI improvements
- Necessary workflow modifications
  - Pre-printed barcodes
  - Lab reorganization (benches and webstations)
- More data + Complex data entry = More time consuming
  - More personnel
  - Revised financial model to reflect increased biospecimen cost
- Requirement to train user roles with differing expertise
  - Training program / personnel
- **Logistics of real time, remote data capture**

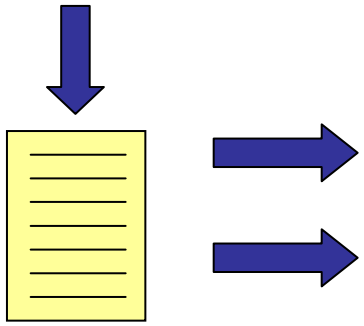
Capturing SOP Data in caTissue



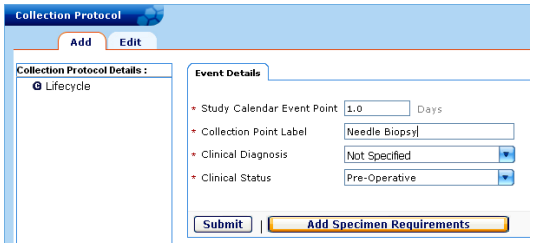


BRD- Peer Reviewed Literature in Biospecimen Science

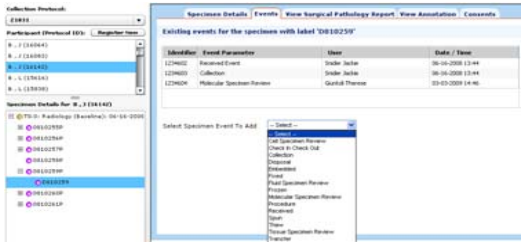
caTissue Suite



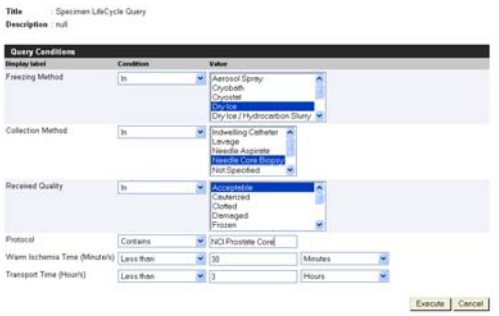
Abstracted SOP for Biospecimen Processing



1. Defining a Collection Protocol to Include Required Processing Events (Future Functionality)

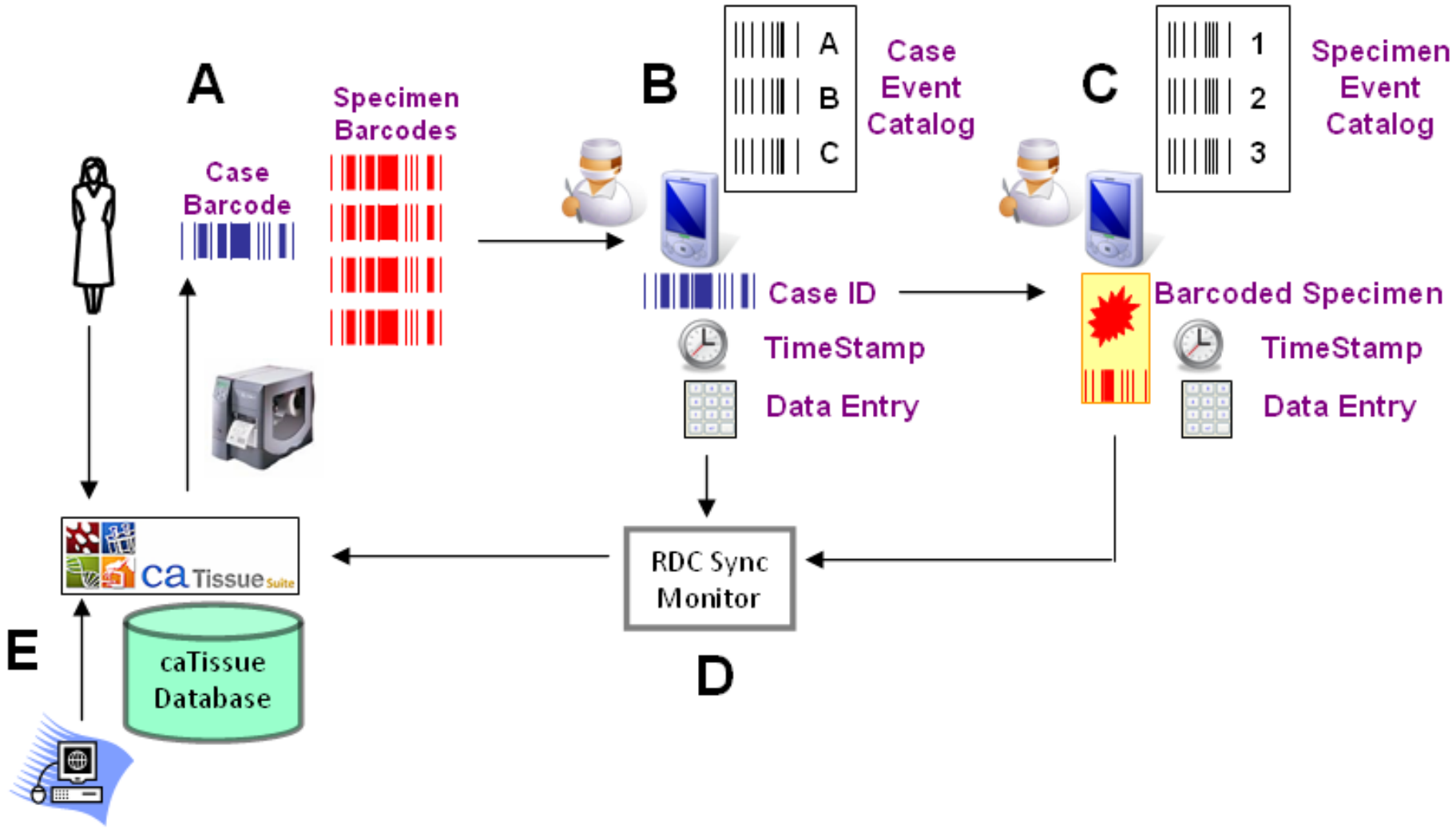


2. Recording Events in the Biospecimen Life Cycle



3. Search Based on Biospecimen Life Cycle Parameters

Remote Data Capture using caTissue



Remote Data Capture Challenges

- Cost of technical implementation and maintenance

- Identification / definition of desired common data attributes associated with pre-analytical variability
  - "Warm Ischemia Time"

- Training and reliable use by personnel other than biobank staff
  - Nurses / CRAs
  - Surgeons / Anesthesiologists
  - Pathologists

- Incentives for routine use
  - Improve the quality of clinical care

caTrack- RDC by Biobank Staff

INDIANA UNIVERSITY SCHOOL OF MEDICINE — Regenstrief Institute

Initialization

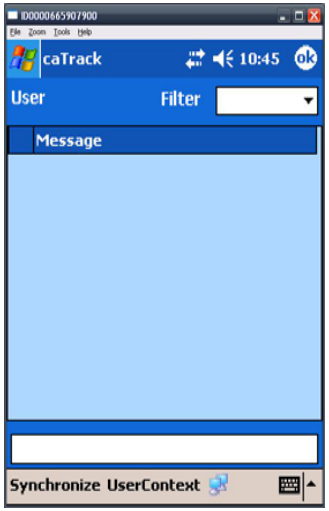
Login and Scan User Batch

Scan centrifuge

Scan Specimens

Scan container

Scan Specimens



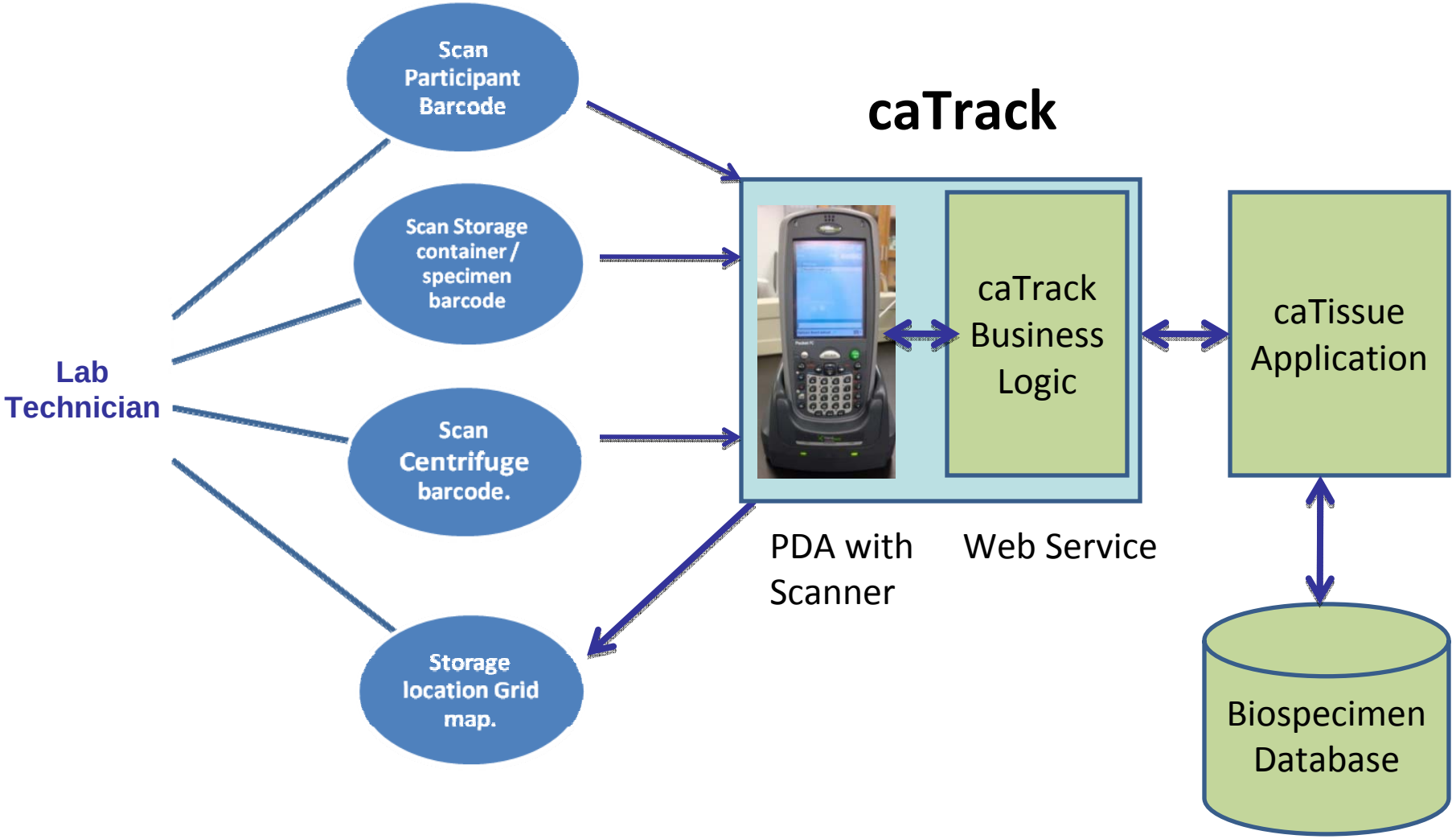
- **Set the collected and received events of a specimen**
- **Assign a storage location to specimens**
- **Transfer specimens or containers within containers**
- **Add frozen, centrifuge events on specimens**

G. Schadow; S. Ragg

caTrack- RDC by Biobank Staff

INDIANA UNIVERSITY SCHOOL OF MEDICINE

Regenstrief Institute



G. Schadow; S. Ragg

Future Directions

- Further application enhancements for performance and usability based on end-user feedback

- Remote data entry and distributed effort by multiple users / roles

- Automated data capture by 2D barcode scanning

- Integration with clinical trials and EMR systems for participant registration and annotation
  - Admission note
  - OR report
  - Anesthesia chart
  - **Pathology report**
  - **Lab Values**
  - **Vitals**
  - **Pharmacy record**
  - Radiology report

caTissue Resources

- **The TBTT KC site-**
  https://cabig-kc.nci.nih.gov/Biospecimen/KC/index.php/Main_Page

- **Log on and try out the demo site for caTissue Suite v1.1-**
  http://catissue.wustl.edu:8080/catissuecore

- **View a narrated video overview of the tool and installation-**
  https://cabig-kc.nci.nih.gov/Biospecimen/KC/index.php/Tissue/Biospecimen_Banking_and_Technology_Tools:Current_events

- **Practice learning how to use the tool on the E-learning portal-**
  http://cabigtrainingdocs.nci.nih.gov/caTissue/index.html

- **Browse through the on-line manual-**
  https://cabig-kc.nci.nih.gov/Biospecimen/KC/index.php/CaTissue_1.1_User_Manual

- **For additional questions, post them to the TBTT KC Forum-**
  https://cabig-kc.nci.nih.gov/Biospecimen/forums/

Acknowledgements

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Rajesh Patil
Madhumita Shrikhande

Ashish Gupta
Komal Gulati
Sachin Lale
Srikanth Adiga
Virender Mehta
Kalpana Thakur
Abhishek Mehta

Deepti Shellar
Poornima Govindrao
Sayali Salodkar
Vaishali Khandelwal
Rushikesh Subedar
Snehil Gupta
Preeti Munot