

# CA TISSUE SUITE V1.0

*Integrated Biospecimen Banking  
Information System*

## END USER MANUAL

April 07, 2008

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Developers	Adopters	User's Guide	Program Management
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Customer support contact	<a href="mailto:catissue_support@mga.wustl.edu">catissue_support@mga.wustl.edu</a>
Public demo site	<a href="http://catissuemore.wustl.edu">http://catissuemore.wustl.edu</a>

LISTSERV	URL	Name
caTissue help forum	<a href="http://gforge.nci.nih.gov/forum/forum.php?forum_id=49">http://gforge.nci.nih.gov/forum/forum.php?forum_id=49</a>	caTissue Assistance

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## Chapter 1: Introduction to the Manual

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This chapter outlines the caTissue Suite user manual and gives you a brief description of all the chapters in this manual.

### Using the caTissue User Manual

---

This section outlines the organization of the caTissue Suite user manual.

Topics in this chapter include:

- Introduction
- Organization
- Document text conventions

### Introduction

---

The caTissue Suite user manual outlines the caTissue Suite. It includes information and instructions for using caTissue Suite. It also suggests ways to maximize the usefulness of the caTissue Suite. This manual is intended for the system Administrators, Supervisors, Technician, and Scientists.

### Organization

---

This manual contains the following chapters:

**Table 1: User Manual Chapter Organization**

Chapter	Description
<b>What's New in caTissue Suite v1.0?</b>	This chapter outlines the new features in this release of caTissue Suite. This chapter helps you to get started with evaluating caTissue Suite and includes subsequent steps for using caTissue Suite.
<b>Introduction to caTissue Suite</b>	This chapter outlines a high-level overview of caTissue Suite workflow, data, and features.
<b>Few First Steps – System Administrator</b>	This chapter outlines step-by-step instructions for configuring caTissue Suite after it is installed. It outlines the instructions to add administrative data objects.
<b>Consent Tracking</b>	This chapter outlines the process to register and track consent of participants on specimen collection, storage, and distribution.
<b>Handling Biospecimens – Technicians and Supervisors</b>	This chapter outlines the process of adding the biospecimen data for the tissue bank user, who registers the participants.
<b>Introduction to Clinical Annotations</b>	This chapter outlines all the clinical annotations available in the caTissue Suite.
<b>Ordering Biospecimens</b>	This chapter outlines the biospecimen

<b>Chapter</b>	<b>Description</b>
	ordering functionality.
<b>Search Data – Simple Search and Advanced Query Wizard</b>	This chapter outlines the steps to perform a query, view results, and export data.
<b>Appendix 1:</b>	This appendix outlines the common Tasks you can perform using the Biospecimen Data tab.
<b>Appendix 2:</b>	This appendix outlines the clinical annotations.
<b>Appendix 3:</b>	This appendix outlines the examples of complex queries.
<b>Appendix 4:</b>	This appendix outlines the error messages.
<b>Appendix 5:</b>	This appendix outlines the Indexes.
<b>Appendix 6:</b>	This appendix outlines the glossary terms.

## Document Text Conventions

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The following table outlines the conventions used in this manual:

**Table 2: Text Conventions**

Courier typestyle	Used for filenames, directory names, commands, file listings, source code examples, and anything that appears in a Java program, such as methods, variables, and classes.
<b>Bold</b>	Used to highlight the click items in procedures.
<i>Italic</i>	Used to denote words that need user attention.
	Notes of particular interest to the end user.
<b>Note:</b>	Used to provide additional information.
<b>Caution:</b>	Used to caution the user against performing certain activities.
Numbered Screenshots	Used to denote the workflow of the procedures.

## Chapter 2: What's New in caTissue Suite 1.0?

caTissue Suite is a tissue banking application. It incorporates several features of the existing caBIG™ TBPT (Tissue bank and pathology Tools). The three applications developed by the TBPT Workspace, are:

**caTissue Core v1.2:** caTissue Core provides the central biospecimen management functionalities needed in biobanking facilities.

**cancer Text Information Extraction System (caTIES) v2.3:** caTIES provides a means to automate the process of coding, de-identifying, storing, and retrieving data from free-text pathology reports.

**caTissue Clinical Annotation Engine:** caTissue Clinical Annotation Engine provides a Web-based user interface for standards-based manual annotation of biospecimens with clinical information.

The caTIES and CAE features include:

1. Load, de-identify, view, and query on free-text surgical pathology reports.
2. Record discrete clinical annotations and CAP (College of American Pathologists) based checklists and clinical annotations for the following:

**Table 3: Clinical and Pathology Annotations Supported in caTissue Suite**

Clinical annotations	Pathology annotations
<ul style="list-style-type: none"> <li>• Smoking and Alcohol Use</li> <li>• Family History</li> <li>• Laboratory Test Values</li> <li>• Treatment Information</li> <li>• Comorbidities - Health Examination, New disease</li> <li>• Follow up Information – Recurrent disease</li> </ul>	<ul style="list-style-type: none"> <li>• All tumor types (<i>Base</i> pathology annotations)</li> <li>• CAP protocol based organ specific pathology annotations: <ul style="list-style-type: none"> <li>• Breast</li> <li>• CNS</li> <li>• Colorectal</li> <li>• Hematology</li> <li>• Kidney</li> <li>• Lung</li> <li>• Melanoma</li> <li>• Pancreas</li> <li>• Prostate</li> </ul> </li> </ul>

In addition to this, the new features available in caTissue Suite are:

- Add new classes and attributes dynamically to record new annotations.
- Record and track consent.
- Order biospecimens.
- Define collection protocols including information about specimens collected per protocol.
- Perform bulk data entry based on the protocol definition.
- Query any caTissue Suite object and save queries.
- Perform bulk operations on specimens. For example, transfer and bulk edit.

## Getting Started

---

This section outlines the following features:

- Viewing the public demo site
- Evaluating caTissue Suite locally
- Requesting a demo

### [Viewing the Public Demo Site](#)

---

To learn more about caTissue Suite login to the publicly accessible demo website with the following details:

URL	<a href="http://catissuecore.wustl.edu/catissuecore">http://catissuecore.wustl.edu/catissuecore</a>
Login id	<a href="mailto:admin@admin.com">admin@admin.com</a>
Password	Login123

### [Evaluating caTissue Suite Locally](#)

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caTissue Suite is a lightweight Web application. It is easy to install on any standard desktop computer or a laptop.

To install caTissue Suite:

1. Download the latest installable from <http://catissuecore.wustl.edu>.
2. Click `Suite` under the Application Installer tab.

### [Requesting a Demo](#)

---

If you want to adopt caTissue Suite, a demo of the application is available. To request a demo, please email [catissue\\_support@mga.wustl.edu](mailto:catissue_support@mga.wustl.edu) for details.

## Chapter3: Introduction to caTissue Suite

---

Advances in molecular technologies and sophistication in clinical trial design have increased the importance of biospecimen banks in collecting, processing, storing, and distribution of human specimens for correlative science cancer research. Once regarded as *wax museums* that simply doled out paraffin tissue sections for immunohistochemical analysis, biospecimen banks are now responsible for collecting and distributing multiple human specimen types for molecular studies.

In order to accommodate the evolving functional complexity of the 21st century, biospecimen banks and informatics systems need functionality to track multiple specimens from the same participant, track refined materials (RNA, DNA, and Protein etc) that are used for molecular analysis, and annotate specimens with accumulating experimental data, as they are successively used for clinical correlative studies.

Existing tissue banking systems have some of the above mentioned features. For example: some systems have specimen tracking capability, while others provide billing and financial capability. Still others have automated pathology and clinical annotation or associated experimental data for specimens. There is however to date, no single system capable of handling all desired functions.

caTissue Suite is a comprehensive solution for biospecimen inventory, tracking, and annotation that may be used by biospecimen resource facilities, regardless of the nature of biospecimen transactions that occur or the type of biospecimens involved in the transaction.

### Overview of caTissue Suite Features at a High Level

---

This section provides a high level overview of the features in caTissue Suite.

1. Adding users and assigning roles.
2. Creating collection and distribution protocols.
3. Providing flexible storage container hierarchy to support any container configuration.
4. Defining collection protocols with description of multiple event points and specimens to be collected per event point.
5. Detecting duplicate participants while registering participants.
6. Performing bulk operations on specimens like transfer, distribute, and edit.
7. Supporting recording of clinical and pathology annotations.
8. Loading and viewing associated surgical pathology reports.
9. Supporting a flexible query interface that includes shopping-cart like *My List* feature.
10. Saving queries and exporting data.
11. Generating customizable barcodes and labels.
12. Assigning or revoking privileges on storage containers and collection protocols.
13. Creating dynamic extensions specific to collection protocols.

## User Roles

The caTissue Suite provides the following user roles:

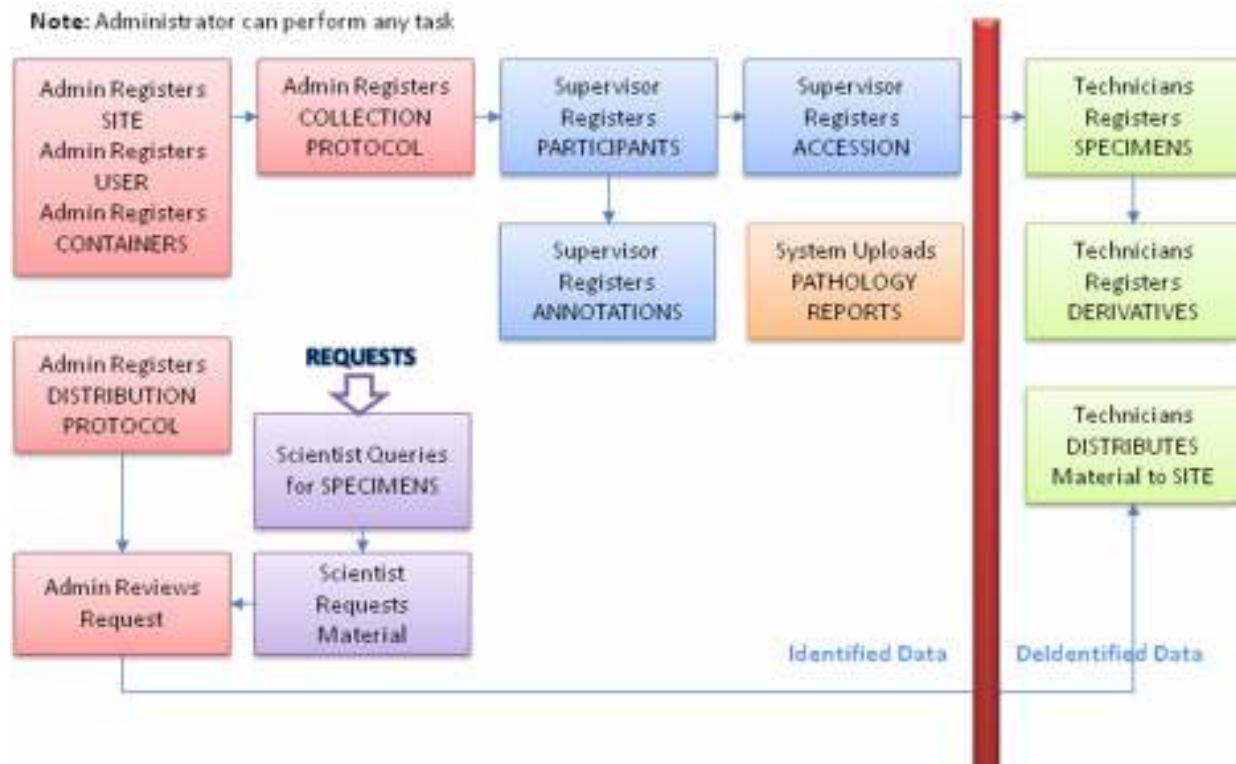
**Table 4: User Roles in caTissue Suite**

Role	Description
Administrator	An Administrator registers new users, sites, containers, and collection and distribution protocols into the system.
Supervisor	A Supervisor adds participants and registers them to a collection protocol.
Technician	A Technician adds specimens into the system.
Scientist	A Scientist performs a query and adds specimens, pathology cases, or arrays of interest to My List.

## Basic Tissue Banking Workflow using caTissue Suite

The following figure provides an overview of the essential workflow associated with caTissue Suite.

**Note:** Administrator can perform any task



**Figure1: Biospecimen Banking Workflow Using caTissue Suite**

The following steps describe the workflow associated with caTissue Suite:

1. The Administrator registers new users, sites, containers, and collection and distribution protocols into the system.
2. The Supervisor registers a new participant (associated with a protocol) into the system.
3. Once a participant is registered into the system, Supervisor or Technicians may register accessions (biospecimen collection events) associated with the participant.
4. For surgical specimens, the caTissue Suite accession number is the same as the surgical pathology report number.

5. For any given accession, one or more specimen may be added as per the collection protocol or user-defined requirements.
6. The Technician may then manipulate the specimen to generate aliquots and/or derived specimens (for example: molecular specimens like DNA, RNA, and so on).
7. General properties concerning specimen quality assurance (QA), location, and tracking history may also be recorded by the Supervisor or Technician in the system.
8. Any specimen may be moved from a site as a result of a Biospecimen Distribution.
9. Authorized users may query the system for available biospecimens either as Administrator and Supervisor (using identified data), or Technician and Scientist (using de-identified data).

### caTissue Suite Data Objects and their Categorization

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In caTissue Suite, data is categorized into two categories: Administrative and Biospecimen.

Administrative data is created by the Administrators. This type of data is rarely created and it provides the infrastructure within which the tissue bank operates. For example: collection protocols and storage containers. The Biospecimen data is registered by Supervisors and Technicians or only Technicians, and is used for the day-to-day operations of the tissue bank.

The following table outlines the various administrative and biospecimen data objects associated with caTissue Suite.

## Chapter3: Introduction to caTissue Suite

**Table 5: caTissue Suite Data Objects**

<b>Administrative Data</b>	
User	A registered individual who interacts with the application for performing various activities like setting up the tissue bank and participates in biospecimen collection, processing, or utilization process.
Institution	An institution that employs users of caTissue Suite. Each user of the system is associated to one of these institutions.
Department	The Departments within an institute that wish to store their samples.
Cancer Research Group	A group of people who are working for a particular research study. For example: Breast Cancer Research Group.
Site	A physical location where a biospecimen is collected, processed, stored, or analyzed.
Storage Container Type	A template for storage of biospecimens. For example: the general definition of a freezer or a shelf.
Storage Container	A physical container used for storing collected biospecimens.
Collection Protocol	A set of guidelines that explains what, how, and when biospecimens are to be collected in an order to be utilized for a particular research study.
Distribution Protocol	An abbreviated set of written procedures that outlines what, how many, and how much of a biospecimen or biospecimens will be utilized for the research.
Specimen Array Type	A definition of the class and types of specimens that can be stored in an array type (for example: a 96 well PCR plate holding molecular specimens) along with the dimensions of the array.
<b>Biospecimen Data</b>	
Participant	Participant is not necessarily a patient. Participant is an individual from whom biospecimens are collected.
Participant Registration	Participants that are registered to a specific collection protocols to collect specimens.
Specimen Collection Group	A group of one or more biospecimens collected at a single point in time from a Participant registered under a particular study.
Specimen	A circumscribed piece of tissue or body fluid that is collected from a Participant as part of a Specimen Collection Group.
Specimen Array	A collection of biospecimens arranged in an ordered pattern (for example: a 96 well PCR plate).

## Chapter 4: Few First Steps – System Administrator

caTissue Suite is a lightweight web application which is easy to install on any standard desktop computer or a laptop. To install caTissue Suite, you can download the latest installable from <http://catissuemcore.wustl.edu> and click the Suite link under the Application Installer tab.

Before configuring the administrative data, you may want to customize the roles and privileges, and the label/barcode generation schemes. Refer to the *Administrative Guide* located at:

[http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/catissuemcore/caTissueSuite%20Phase%202/WashU%20Deliverables/Docs/caTissueSuiteV10\\_Technical\\_Guide.doc](http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/catissuemcore/caTissueSuite%20Phase%202/WashU%20Deliverables/Docs/caTissueSuiteV10_Technical_Guide.doc)

for details.

When you complete the customization, proceed to configure the administrative data and grant access to your tissue bankers for entering the biospecimen data.

### Setting up caTissue Suite for Biospecimen Bank – System Administrator Tasks

Before you can access caTissue Suite, the Administrator has to create the administrative data. This chapter will help the Administrator to make caTissue Suite operational and grant access to various users.

The following figure shows the process of setting up a biospecimen bank.

#### Setting up a biospecimen bank – order of administrative tasks

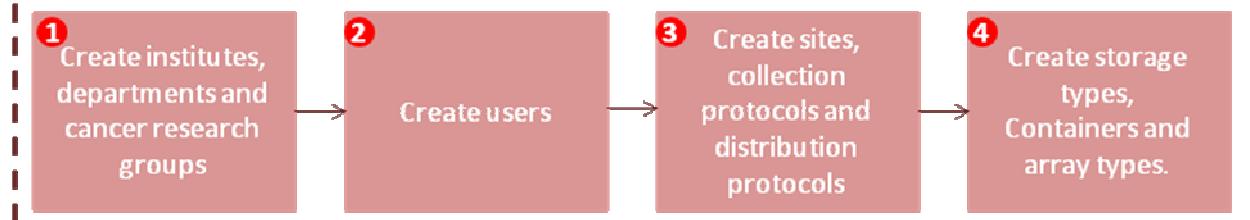


Figure2: Setting Up a Biospecimen Bank – Order of Administrative Tasks

 <b>F.Y.I.</b>	<p>Due to interdependencies in the data, you must create the setup in the same order mentioned above. For example: to create a user, you have to create institution first, then departments, followed by the Cancer Research Group.</p>
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### Creating an Institute, Department and Cancer Research Group

To create an institute:

1. Click the **Administrative Data** tab.
2. Click **Add** under Institution. The Add Institution page is displayed.
3. In the **Name** field, enter the desired name of the institute.
4. Click **Submit**.

The following figure shows the sequence to add an institute.

**Figure3:** Creating an Institute

You can add a *Department* and a *Cancer Research Group* in a similar fashion.

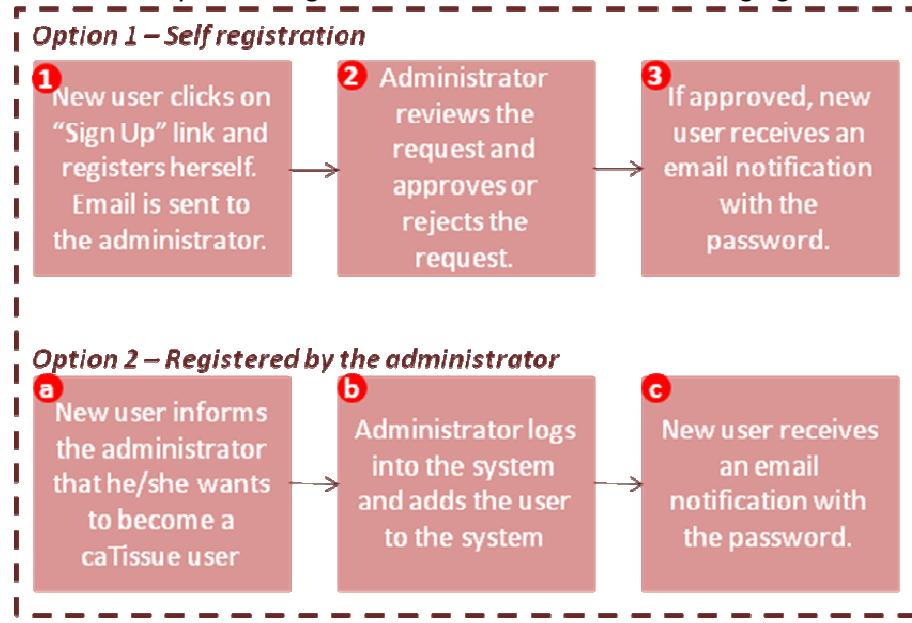
### Provisioning Users

Due to the sensitive nature of data stored in caTissue Suite, users have to be registered and approved by the Administrator, before they can log into the system.

A new user may be added to caTissue Suite in one of these two ways:

1. User submits a request to the Administrator
2. Administrator directly adds information about a user to the system

These two ways of adding a user are as shown in the following figure:



**Figure4:** Basic Workflow for User Provisioning

The following figure displays the Add User page.

**Figure5:** Adding a New User

As an Administrator, to approve new users:

1. Click the **Administrative Data** tab.
2. Click **Approve New Users** under User. The Approve Users page is displayed.
3. Select the email address of the user you wish to approve.

#	Login Name	User Name	Email Address	Registration Date
1	catissue_guru@persistent.co.in	guru, catissue	catissue_guru@persistent.co.in	2007-11-07

**Figure6:** Approving New Users

Selecting the email address of the new user displays the details of the user registration request. The Administrator can approve or reject the registration request. If approved, the Administrator must also specify the role of the new user.

## Creating Sites

A site represents a physical location associated with a biospecimens collection, storage, processing or utilization. There are four types of sites:

**Table 6: Site Types**

Type	Description
Collection Site	Location where biospecimens are collected.
Laboratory	Location where biospecimens are processed.
Repository	Location where biospecimens are stored.
Not Specified	Location is not specified.

Only an Administrator can create a site. A site must be created for a collection protocol to be defined or for storage to be created. To create a site:

1. Click the **Administrative Data** tab.
2. Click **Add** under Site. The Add Site page is displayed.
3. Enter the mandatory details like **Name**, **Type**, **Coordinator**, **Street**, **City**, **State**, **Country**, and **Zip Code**.
4. Click **Submit** as shown in the following figure.

**Figure7: Creating a Site**

## Setting up Storage Containers

The storage container structure in caTissue Suite is very flexible and aimed at supporting any type of storage hierarchy. Due to its flexible nature, setting up storage containers is one of the most complex tasks in the caTissue Suite.

Before creating a storage hierarchy, it is necessary to understand some basic properties of caTissue Suite storage containers.

### Storage Types and Storage Containers

Storage type, as the name suggests, is type of a container. Storage types are not physical entities but only contain basic properties and default values that can be applied to all containers of that type. For example: Freezer, Rack, and Box are types of containers. A storage container is the actual physical entity and is always of a certain Storage Type. For example: Freezer *F1*, Rack *F1\_R1*, Box *F1\_R1\_B1*, and so on are actual physical locations of containers.

### Container Restrictions

You can define restrictions to the kinds of specimen that can be stored in a container, such as specimens from a particular protocol, a specimen of a particular specimen class, and so on. While creating the container, you can restrict the container based on factors like:

1. Certain types of containers (freezer can only hold racks and racks can only hold boxes).
2. Certain types of biospecimens (tissue box can only hold tissues specimens).
3. Collection protocols (box 1 can only hold biospecimens from the *Breast Cancer Research* collection protocol).



You can apply more than one of the above restrictions to make the restriction more specific. For example, a container can be restricted by collection protocol and type of biospecimen, say Blood box for the collection protocol Breast Cancer Research.

## Creating a Storage Type

The most important option while creating a storage type is the *Can hold* option. It defines what other types of storage containers or biospecimen this storage type can hold. For example: a Freezer can hold a Rack, a Rack can hold Box, and a Box can hold tissues. Therefore it is important that the smallest container types be created first, that is, *bottom-up* order. For example: the Box type should be created before the Rack type is created so that while creating the Racks you can set the can hold to Box.

To create a storage type:

1. Click the **Administrative Data** tab.
2. Click **Add** under Storage Type. The Add Storage Type page is displayed.
3. Enter the **Name** for the storage type.
4. Enter the **Can hold** details.
5. Under Default Capacity, enter the details of the container. Default capacity is the capacity of what the given container can hold for a particular dimension. For example: Capacity in Dimension One is Row in the following figure and this freezer has four rows. Capacity in Dimension Two is the capacity of what the given container can hold for its second dimension. For example: in the following figure, Capacity in Dimension Two is Column and the freezer has three columns.

- Click **Submit** as shown in the following figure.

The screenshot shows the 'ADD STORAGE TYPE' page in the caTissue Suite. The 'ADMINISTRATIVE DATA' tab is selected. The 'Name' field is populated with 'Freezer'. The 'Default Temperature' dropdown is set to '-20'. In the 'Storage Type' section, '-20 Back' is selected from a dropdown menu. The 'Specimen Class' radio button is selected. Below that, there's a section for 'DEFAULT CAPACITY' with fields for 'Capacity in Dimension One' (set to 4) and 'Text Label for Dimension One' (set to 'Rows'). There are also fields for 'Capacity in Dimension Two' (set to 3) and 'Text Label for Dimension Two' (set to 'Columns'). At the bottom right are 'Submit' and 'Add Container' buttons, with 'Submit' being highlighted with a red circle containing the number 6.

Figure8: Creating a Storage Type

### Creating a Storage Container

A storage container is the actual physical entity and is always of a certain Storage Type.

To add a storage container:

- Click the **Administrative Data** tab.
- Click **Add** under Storage Container. The Add Storage Container page is displayed.
- Select the storage type from the **Type** drop-down list.
- Select the **Site or Parent Container** radio button to specify location of the container.
- Specify the **Number of Containers** that you want to create.
- Specify the CP restrictions for the container in **Collection Protocol Title**.
- Edit the **Can Hold** section if required.
- The Capacity field gets populated automatically based on the storage type created. You can edit the capacity if required.
- Click **Submit**.

The screenshot shows the 'caTissue Suite' software interface. On the left is a vertical navigation menu with various links like 'USER', 'INSTITUTION', 'DEPARTMENT', 'STORAGE TYPE', 'STORAGE CONTAINERS', 'REPORTED PROBLEMS', 'LOCAL EXCEPTIONS', and 'CONFLICTING REPORTS'. The main area is titled 'ADD STORAGE CONTAINER'. It contains several input fields and dropdown menus. Red numbers 1 through 9 are overlaid on the form to highlight specific fields:

- Type**: A dropdown menu set to '-80 Freezer' with an 'Add New...' link.
- Site**: A dropdown menu set to 'MD Anderson Cancer Centre' with an 'Add New...' link.
- Parent Container**: A radio button option.
- Name**: An input field containing 'AZOC\_AZOC\_freezer\_31' with dropdowns for 'Pos1' (1), 'Pos2' (1), and 'Pos3'.
- Number of Containers**: An input field set to '1'.
- Temperature**: A dropdown menu set to '-80.0 °C'.
- Collection Protocol Title**: A dropdown menu listing 'ALL-1 AZOC sample BSB RNAW BPF'.
- Container Type**: A dropdown menu set to '-80 Freezer'.
- Specimen Class**: A dropdown menu set to '...All...'.
- Specimen Array Type**: A dropdown menu set to 'None'.
- Can Hold**: A dropdown menu set to '-80 Rack'.
- shelves**: An input field set to '5'.
- columns**: An input field set to '6'.
- Submit**: A button at the bottom right.

Figure9: Creating a Storage Container

The following table outlines the fields on the Add Storage Container page:

Table 7: Field Description – Add Storage Container Page

Type	Select the type of the container being created. If the type does not exist, click the Add New link next to the drop-down list and create the new type.
Site or Parent Container	<p>Indicates if the container will be stored within another container or in a site. For example: a rack will be stored in a freezer, while a freezer will be stored in a site.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>The topmost container in the hierarchy is always stored in a site.</li> <li>The system automatically suggests the next available parent container and the position within it. If incorrect, you can change the parent container suggested by the system.</li> </ul>
Restrictions	<p>You can restrict the items stored in the container based on</p> <ol style="list-style-type: none"> <li>Collection protocol</li> <li>Container type</li> <li>Specimen class or specimen array type</li> </ol> <p><b>Applying restrictions:</b></p> <p>If the container is the smallest container (lowest in hierarchy), such as a box, apply the restriction based on collection protocol and/or specimen class.</p> <p>If the container is not the smallest container, for example: rack, shelf, or freezer, in which you would not directly store the specimens, apply restrictions based on the</p>

	<p>container type. For example, create a storage container with the hierarchy that a freezer is stored at a site. This freezer can hold racks, which can hold test tubes and the test tubes can hold a blood sample. Thus, you can apply the restriction to the freezer that it can hold only racks and to the test tube which is the smallest in the hierarchy you can apply a restriction that it can hold only blood samples from a particular study.</p> <p>Storage container can be restricted for a particular Collection Protocol. For example, in the preceding figure, <i>-80 Freezer</i> is restricted to CP <i>B&amp;B Study</i> and <i>BCP</i>, meaning it can only be used for specimens collected under these two CPs and not for specimens collected under other CPs.</p> <p>Note that applying a restriction on the parent container does not automatically apply to the containers placed in that container. For example, if a freezer is restricted by a collection protocol, then it does not mean that all the containers within the freezer are automatically restricted by that collection protocol.</p> <p>If you do not apply restrictions based on the collection protocol, container type, specimen class, or specimen array type; biospecimens will be stored at any available location. This will lead to disorganized storage container. For example: in your bank, you have freezers that hold boxes which hold only tissue. But consider that you have not applied any restriction on this freezer. Due to lack of restrictions on the storage container, you will be able to store fluid specimens in this freezer, as well.</p>
Capacity	By default, values are copied from the storage container type. However you can change the capacity of the container to a different value.

### *[Viewing the Storage Container Hierarchy](#)*

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To view the storage container hierarchy:

1. Click the **Administrative Data** tab.
2. Click **View Map** under Storage Container.
3. A new window appears and the complete storage container hierarchy is displayed as shown in the following figure.
  - a. Select the required container name from the left pane.
  - b. The top right pane displays the selected restrictions on that container.
  - c. The bottom right pane displays the dimensions and the contents of the container.

The screenshot shows the caTissue Suite application running in Mozilla Firefox. On the left is a vertical navigation menu with items like 'HOME', 'ADMINISTRATIVE DATA', 'BIOSPECIMEN DATA', 'SEARCH', 'SUMMARY', and 'HELP'. Below these are sections for 'USER', 'INSTITUTION', 'DEPARTMENT', 'CANCER RESEARCH GROUP', 'SITE', 'STORAGE TYPE', 'STORAGE CONTAINER', 'SPECIMEN ARRAY TYPE', 'STANDARD', 'COLLECTION PROTOCOL', 'DISTRIBUTION PROTOCOL', 'REPORTED PROBLEMS', 'LOCAL EXTENSIONS', 'DATA', and 'COMPLIANCE REPORTS'. The main content area has three tabs at the top: 'ADMINISTRATIVE DATA' (selected), 'BIOSPECIMEN DATA', and 'SEARCH'. The 'ADMINISTRATIVE DATA' tab shows a tree view of storage containers under 'caTissue Suite'. A red circle labeled 'a' is on the 'Penn' node. Another red circle labeled 'b' is on the 'Molecular' node in a dropdown menu. To the right is a table titled 'Collection Protocol' with columns 'Row', '1', '2', '3', '4', and '5'. The table contains 5 rows of specimen information, with a red circle labeled 'c' on the '3' header.

Row	1	2	3	4	5
1	Container_Penn_Biot_7	Specimen_112_1	Specimen_112_2	Specimen_101_1	Specimen_101_2
2	Specimen_101_3	Specimen_101_4	Specimen_101_5	Container_Penn_Vial_40	Container_Penn_Vial_40
3	Container_Penn_Vial_40	Container_Penn_Vial_40	Container_Penn_Vial_40	Specimen_114_1	Specimen_114_2
4	Specimen_120_1	Specimen_120_1	Specimen_127_6	Specimen_127_7	Specimen_127_8
5	Specimen_129_2	Container_Penn_Deepfreez_118	Unused	Unused	Unused

Figure10: Storage Container Hierarchy

## Specimen Array Type

A specimen array in caTissue Suite is a collection of biospecimens arranged in an ordered pattern. For example: a 96 well PCR plate. In the caTissue Suite, you can create an array based on an array type, create aliquots, store and distribute them to investigators.

To create specimen arrays, you have to first create an array type. The array type allows you to predefine the class and types of specimens that can be stored in that array type. For example: a 96 well PCR plate holding molecular specimens) along with dimensions for the array.

To create a specimen array type:

1. Click the **Administrative Data** tab.
2. Click **Add** under Specimen Array Type. The Add Specimen Array Type page is displayed.
3. Enter a **Name** for the array.
4. Select a Specimen Class from the drop-down list.
5. Select the Specimen Type that auto populates based on the selected Specimen Class.
6. Specify the capacity of the array under Capacity.
7. Click **Submit**.

The screenshot shows the 'caTissue Suite' interface with a sidebar containing various administrative links. The main window is titled 'ADD SPECIMEN ARRAY TYPE'. It has several input fields:

- Name:** DNA Array (with a red circled '3')
- Specimen Class:** Molecule (with a red circled '4')
- Specimen Type:** DNA (selected from a dropdown menu with a red circled '5')
- Capacity:**
  - Dimension One:** 8 (with a red circled '6')
  - Dimension Two:** 13
- Submit:** A button with a red circled '7'.

Figure11: Creating a Specimen Array Type

## Collection Protocols

A collection protocol contains a set of guidelines that delineate what, how and when the biospecimens are to be collected. The principle investigator (PI) of the study will decide the guidelines of the protocol and apply for an IRB (Institutional Review Board) approval. Once approved, the PI requests the caTissue Suite Administrator to add the protocol to the system. There are two types of collection protocols:

- Planned specimen collection protocol
- Unplanned specimen collection protocol or general tissue banking protocol

A collection protocol contains the following information:

1. Basic information like title, short title and IRB ID.
2. Consent tiers.
3. Events (time points).
4. Specimen requirements per time point.

### Planned Specimen Collection Protocol

This CP has a pre defined set of specimen requirements. It facilitates the collection of specimen as per the scheduled plan. The following figure outlines the basic structure of the caTissue Suite collection protocol.

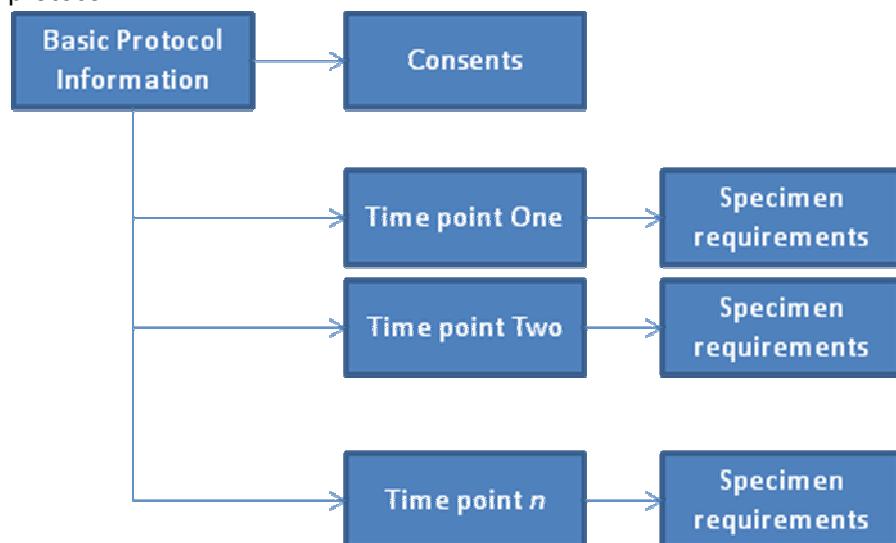


Figure12: caTissue Suite Collection Protocol Structure

The process to create a collection protocol is divided into five steps:



Figure13: Workflow to Create a Collection Protocol

1. To create a collection protocol:
  - a. Click the **Administrative Data** tab.
  - b. Click **Add** under Collection Protocol. The Add Collection Protocol page is displayed as shown in the following figure.

The screenshot shows the 'caTissue Suite' interface. The left sidebar has a tree view with nodes like 'USER', 'INSTITUTION', 'DEPARTMENT', 'CANCER RESEARCH GROUP', 'SITE', 'STORAGE TYPE', 'STORAGE CONTAINER', 'SPECIMEN ARRAY TYPE', 'RISPARMD', 'COLLECTION PROTOCOL' (with a red circle 'b' over it), 'DISTRIBUTION PROTOCOL', and 'REPORTED PROBLEMS'. The main window title is 'Add Collection Protocol'. It has tabs: 'Collection Protocol' (selected), 'Consents', 'Define Events', and 'View Summary'. The 'Collection Protocol' tab contains fields: 'Principal Investigator' (dropdown menu showing 'Stevens, Martha' and other options like '... Select ...', '... Add ...', '... Edit ...', '... Delete ...', with a red circle 'c' over the dropdown), 'Protocol Coordinator' (dropdown menu showing 'Chatterjee, D' selected, with a red circle 'c' over the dropdown), 'Title' (text input 'Ovarian Cancer Protocol'), 'Short Title' (text input 'O.C.P.'), 'IRB ID' (text input), 'Start Date' (date input '02-29-2008' with a calendar icon), 'Consent Waived' (radio buttons 'Yes' (selected), 'No', 'Maybe'), 'Number of Participants Anticipated' (text input), 'Description URL' (text input), and a checkbox 'Do you want to store all aliquot(s) in same container?' (unchecked). At the bottom right is a button 'Add Consents >>' with a red circle '2' over it.

Figure14: First Step of Creating a Collection Protocol

- c. Enter the mandatory information, such as like **Principal Investigator**, **Title**, **Short Title**, and **Start Date**. You may also provide optional description regarding the collection protocol, like Protocol Coordinators, Consent Waived and Number of Participants Anticipated. Description URL field allows you to enter a web address, where additional information regarding the Collection Protocol may be obtained from.



If you want all aliquots from this collection protocol to be stored together, select the Do you want to store all aliquots in same container? Check box located at the bottom of the page.

2. Click **Add Consents** to define consents. The Add Consents page is displayed as shown in the following figure.



You can add as many consent tiers as needed. Click **Add More** to add new consent tiers. To delete any unwanted consent tiers, select the check box next to the required statement and click **Delete**.

#	Statements
2.	Consent to store specimen for future ovarian cancer studies
1.	Consent to use specimen for current protocol

**Figure15: Second Step of Creating a Collection Protocol**

	When you add or edit a collection protocol, adding consent data is not mandatory. You can submit a collection protocol without associated consent data.
--	---

Consent tiers can be edited or deleted till a participant gets registered to that protocol. Once a participant is registered to a CP, you cannot edit or delete Consent tiers. You can add Consent tiers to a collection protocol at any time even if a participant has been previously registered under this protocol. Additional Consent tiers can be applied on the future registrations of a participant to that protocol.

- Click **Define Events**. The Define Events page is displayed as shown in the following figure.

The screenshot shows a software interface for defining events in a collection protocol. At the top, there are tabs for 'Collection Protocol', 'Consents', 'Define Events' (which is highlighted with a red circle labeled '3'), and 'View Summary'. Below the tabs, a left pane titled 'Specimen Events' lists an item '1.0 Pre Surgery' with a red circle labeled 'c'. The main area is titled 'Protocol Event Details' and contains a form for 'Define Events'. The form fields are: 'Study Calendar Event Point' (1.0 Days), 'Collection Point Label' (Pre Surgery), 'Clinical Diagnosis' (Not Specified, with a red circle labeled 'a' next to it), and 'Clinical Status' (Pre-Operative). At the bottom of the form are 'Submit' and 'Add Specimen Requirements' buttons, with red circles labeled 'b' and '4' respectively. At the very bottom of the page, there are buttons for 'Add New Event' (with a red circle labeled 'd'), '<< Add Consents', and 'View Summary >>'.

**Figure16: The Define Events Page**

To add events:

- Enter the details of the events like **Study Calendar Event Point**, **Collection Point Label**, and other details as shown in the preceding figure. The Clinical Diagnosis can be selected by clicking the icon.
- Click **Submit** to add an event.
- The newly added event will be visible under Specimen Events on the left pane.
- Click **Add New Event** to add another event.

The following table outlines the fields on the Define Events Page.

**Table 8: Field Description - Define Events Page**

Study Calendar Event Point	Time point (in number of days) within the study calendar on which the specimen collection or registration is due.
Collection point label	A name or designation for this time point. For example: Pre-Therapy, Surgery, 90 day follow-up, Relapse, and so on.
Clinical status	The current position of the participant at a particular time point in the collection protocol. For example: Pre-Surgery, Post-Surgery, or Control.
Clinical diagnosis	The determination of a disease in a participant based on the study of signs and symptoms.

4. Click **Add Specimen Requirements** as shown in the preceding figure to add specimen details to each event. Enter the specimen details such as **Class**, **Type**, and **Quantity** on the Add Specimen Requirements page as shown in the following figure.

**Figure17: Creating a CP - Add Specimen Requirements Page**

On the Add Specimen Requirements page, you can:

- Add aliquots details that will be created from the specimen.
- Add derivatives details that will be created from the specimen.

Mention storage location details for the specimen, its aliquots, and derivatives. You can specify storage location as auto, manual, or virtual. Auto storage means when a specimen is collected, the system automatically assigns a storage location to the specimen. Manual storage means the system allows you to select a storage container using the MAP option. Virtual storage means the storage location is not assigned to the specimen. For example: fluid specimen is to be aliquoted as soon as it is received. In such a situation, there is no need to assign storage location to the fluid specimen since it is going to get aliquoted. The storage location for such a specimen is mentioned as virtual.

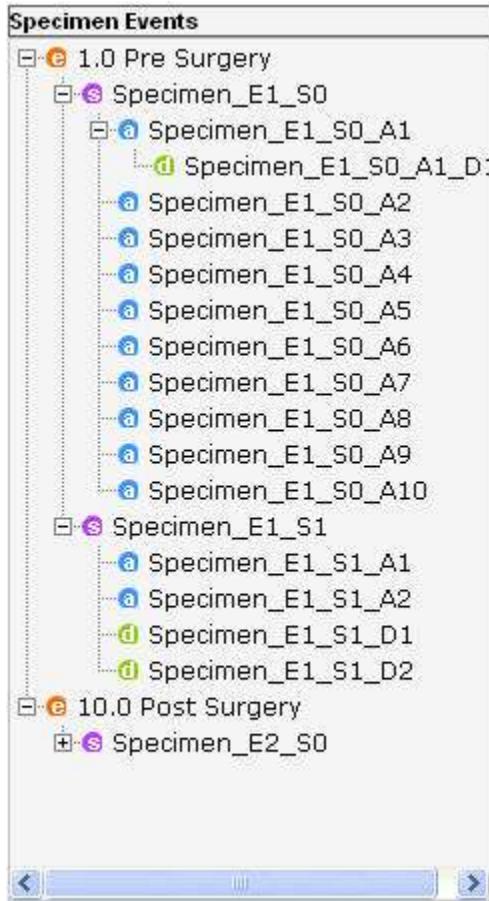
- Click **Save Specimen Requirements**.



Once you define a specimen requirement with aliquots or derivatives, the tree on the left pane is refreshed to display them. Click the child specimens (that is, any of the aliquot or derivatives) to create additional aliquots or derivatives of the child specimen.

### Understanding the Specimen Events Tree

The specimen events tree shown in the following figure indicates the summary of the event points and specimens collected in this collection protocol. The tree grows with every new event or specimen requirements along with the aliquots and derivatives added to the protocol.



The icons indicate:

- Indicates Event
- Indicates Specimen
- Indicates Aliquots
- Indicates Derivatives

A sample specimen events tree shown in the adjacent figure:

- Contains two events: *PreSurgery* at time point 1.0 and *PostSurgery* at time point 10.0.
- The time point *PreSurgery* contains two parent specimens.
- From the first parent specimen, ten aliquots are created.
- From the first aliquot, a derivative is created.
- From the second parent specimen, two aliquots and two derivatives are created.
- The time point *PostSurgery* contains one parent specimen.

**Figure18: Specimen Events Tree**

5. Click **View Summary** to view the summary and proceed to save the collection protocol as shown in the following figure.

- a. The View Summary page is displayed. On the left pane, click an event to view the summary for that event. For example: the preceding figure displays a summary page for the event *Pre Surgery*. It means *Specimen\_E1\_S0* has ten aliquots and the aliquot *Specimen\_E1\_S0\_A1* has a single derivative *Specimen\_E1\_S0\_A1\_D1*.



If there are multiple parent specimens collected, then clicking the radio button next to the parent specimen will display the details of its child specimens.

- b. Click **Save Collection Protocol** to save the CP.

Collection Protocol	Consents	Define Events	5	View Summary																																												
<b>Specimen Events</b> <input checked="" type="checkbox"/> 1.0 Pre Surgery <input checked="" type="checkbox"/> 10.0 Post Surgery																																																
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Specimen_E1_S0_A1	Specimen_E1_S0_A1_D1	Molecular	RNA	50	Manual	0																																										
<input type="button" value="Add New Event"/> <input type="button" value="&lt;&lt; Define Events"/> <input type="button" value="Save Collection Protocol"/> <span style="color: red; font-size: 2em;">b</span>																																																

Figure19: Creating a CP – View Summary Page

#### Unplanned Specimen Collection Protocol or General Tissue Banking Protocol

This CP does not have a pre-defined set of specimen requirements. Once you add an event, add a single specimen requirement to each event. This will allow you to save the collection protocol. If a specimen requirement is not added, an error message is displayed. These specimen requirements are dummy requirements and the specimen will not be collected. To create an unplanned CP, perform the same steps used in creating a planned CP. For more information on creating a planned CP, refer to [Planned Specimen Collection Protocol](#)[Error! Reference source not found..](#)

The following figures show the specimen events for unplanned and planned specimen collection protocol respectively.

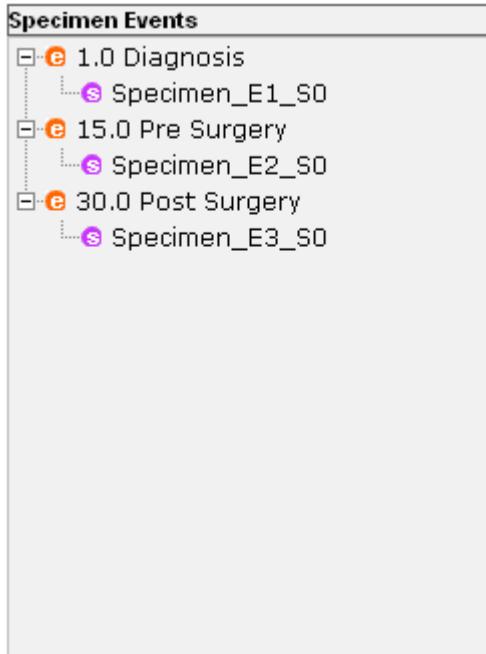


Figure20: Unplanned Specimen Collection Protocol

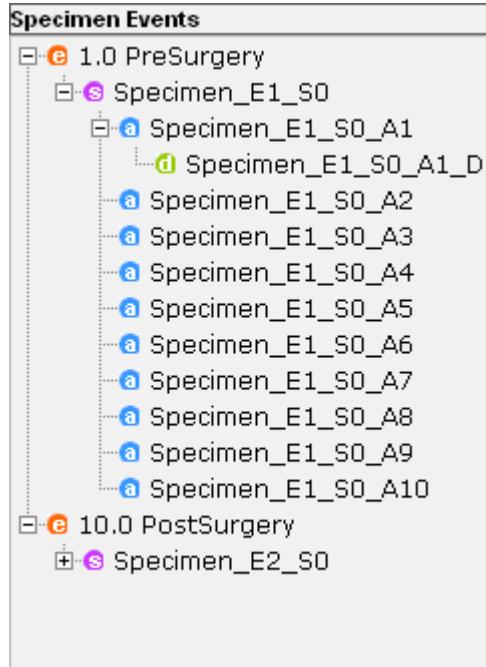


Figure21: Planned Specimen Collection Protocol

### *Complex Longitudinal Collection Protocols*

A Longitudinal Collection Protocols is a collection protocol that requires many samples at multiple time points to be collected for proteomic, genomic, metabolomic, or pharmacokinetic studies. Essentially, most cancer studies have study arms and study phases. The arms and phases are defined as sub-protocols in caTissue Suite v1.0. Sub-protocols introduce one more level in the hierarchy in the collection protocol definition.

- Study arms are alternative pathways with alternative visit timelines, and participants are assigned to one of these alternative arms by inclusion criteria and/or randomization. Collection time points are often different on different arms.
- Study phases are successive pathways that may or may not apply in the cause of a treatment for one participant. Some phases may apply to all participants and some phases are used for unplanned course of disease progression or relapse. For example: many studies may include pre-surgical treatment phase with chemo and/or radio therapy to reduce tumor mass. This tends to be a single protocol for all newly diagnosed patients. Based on the surgical and pathological findings after the surgical removal of the tumor, the participant may be assigned to one of the treatment arms according to their inclusion criteria and randomization. Thus in the pre-surgery phase, only the time points till the surgery can be planned. In the post-surgery phase, when the participant is assigned to one of the arms, the next set of SCGs for the respective CP events of that arm can be scheduled. A participant will not be assigned to a relapse phase and the disease progression phase unless the cancer reoccurs.
- Cycles are groups of study events that follow in regular intervals. A cycle can include multiple specimen collections either during one visit or during a close succession of visits. A cycle functions like a phase, but it has sequences of actions that are usually repeated multiple times within a phase.

**Note:** Currently there is no UI support to define a longitudinal collection protocol in caTissue Suite v1.0. The protocols are defined and inserted via the API.

The following figure displays the basic structure of a longitudinal collection protocol.

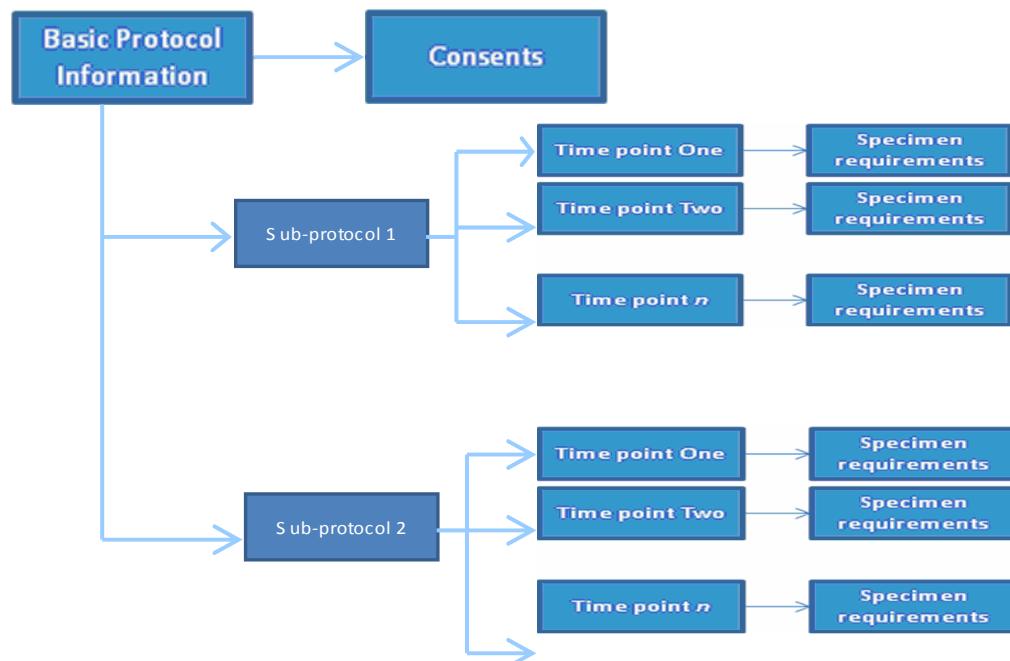


Figure22: Basic Structure of a Longitudinal Collection Protocol

### Understanding the Specimen Details Tree

The specimen details tree shown on the left pane displays the hierarchy of sub-protocols present within the main longitudinal protocol. Sub-protocols can be added under the main protocol and can also be added within other sub-protocols. Each sub-protocol further contains specimen collection groups.

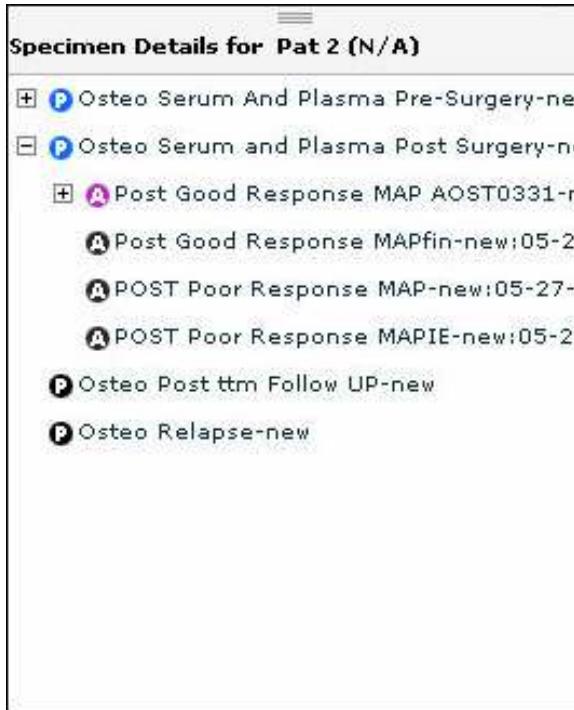


Figure23: Longitudinal CP Specimen Events Tree

The icons indicate:

- **O** Indicates the current participant is not registered to this cycle.
- **C** Indicates the current participant is registered to this cycle.
- **P** Indicates the current participant is not registered to this phase.
- **P** Indicates the current participant is registered to this phase.
- **A** Indicates the current participant is not registered to this arm.
- **A** Indicates the current participant is registered to this arm.

A sample specimen details tree:

- Contains four phases:
  - Osteo Serum and Plasma Pre-Surgery-new
  - Osteo Serum and Plasma Post Surgery-new
  - Osteo Post ttm Follow UP-new
  - Osteo Relapse-new

where the participant is registered to the first two phases and it is denoted by the blue colored icon. The participant is not yet registered to the remaining two phases and it is denoted by the black colored icon.

- Contains four arms under the second phase:
  - Post Good Response MAP
  - Post Good Response MAPfin-new
  - POST Poor Response MAP-new
  - POST Poor Response MAPIE-new

where the participant is registered to the first arm and it is denoted by the magenta colored icon. The participant is not registered to the remaining three arms and it is denoted by the black colored icon.

## Assigning Privileges

Depending on the user roles, each user is assigned a pre-defined set of privileges. The Administrator or other users can assign privileges other than the ones already defined. Privileges can be assigned to a group - as represented by one of the four roles that are pre-defined in the application – or to an individual.

To assign privileges:

1. Click the **Home** tab.
2. Click **Assign** under Privileges. The Assign Privileges page is displayed.
3. Select **Allow** or **Disallow** from the Assign drop-down list to access a privilege.
4. Select **Read** or **Use** from the Privilege drop-down list. The options under Object Type, Record Id, and Group/User are refreshed based on the selected Privilege.
  - a. If you select the **Use** option under Privilege, **Site** and **Storage Container** are displayed under the Object Type. Select the required option. All the site's or storage containers in the system are populated under Record ID.
  - b. Select the required option under Record ID.
  - c. Select the Group/User to whom you want to allow or disallow the Use privilege.
- OR
- d. If you select the **Read** option under Privilege, **Collection Protocol** is displayed under the Object Type. Select the required Collection Protocol. All the CPs in the system will be populated under the Record ID.
- e. Select the required CP.
- f. Select the Group/User whom you want to allow or disallow reading the CP.

5. Click **Assign** as shown in the following figure.

Once you grant privilege to the user by selecting Allow, you can also Disallow the same privilege to that user.

ASSIGN PRIVILEGES		
Assign <b>3</b>	Privilege <b>4</b>	
Allow	USE	
<b>Object Type</b>	<b>Record Id</b>	<b>Group/User</b>
Site Storage Container <b>a</b>	Avion Labs_BloodBox_2 Avion Labs_BloodBox_3 Avion Labs_BloodBox_4 Avion Labs_Box_5 Avion Labs_Tanks_1 Penn_Box_8 Penn_Freezer_6 Penn_Rack_7 <b>b</b>	Supervisor Technician last1203401282358, name120340 last1203401285209, name120340 <b>c</b>
<b>5</b> Assign		

Figure24: Assigning Privileges

The following two examples illustrate how the assign privilege functionality is used by various users.

- Scientist A is the Principle Investigator of a collection protocol (CP1). By default, all Scientists have *Read* privilege for all Collection Protocols (CP), meaning Scientists can search for and order specimens associated with any other CP. Now, if Scientist A does not want Scientist B to view specimens under CP1, then Scientist A can *Disallow* the *Read* privilege to Scientist B. Now Scientist B will not be able to view specimens collected under CP1.
- By default, Supervisors and Technicians do not have access to the sites and storage containers. The Administrator has to assign the *Use* privilege to a Technician to access specific storage containers. Now, this Technician will be able to store the specimens he collects, in the assigned storage container.

## Distribution Protocols

The Administrator follows a set of guidelines designed by the Principle Investigator (PI) to distribute the biospecimens as requested by his users. In order to distribute a specimen to a PI, that PI should have a distribution protocol registered in the system. The system administrator can create the distribution protocol based on the guidelines submitted by the (PI).

To create a new distribution protocol:

1. Click the **Administrative Data** tab.
2. Click **Add** under Distribution Protocol. The Add Distribution Protocol page is displayed.
3. Enter the mandatory details for the distribution protocol.
4. Enter the required details under Specimen Requirements.
5. Click **Submit** as shown in the following figure.

	<p>To add a new row under Specimen Requirements, click Add More. To delete a row, select the check box corresponding to the specimen that is to be deleted and click Delete.</p>
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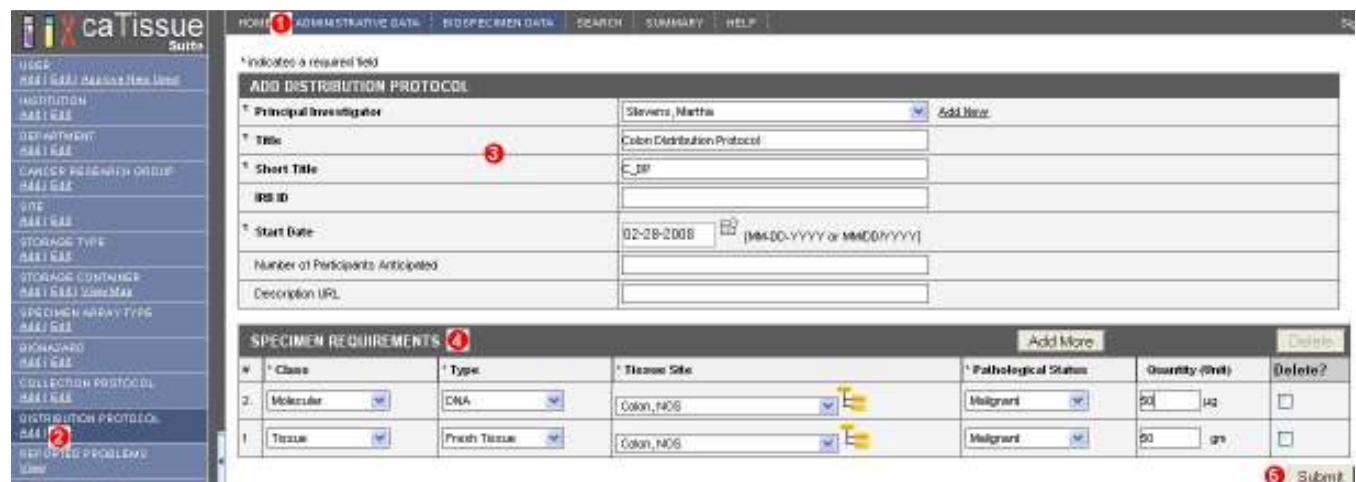


Figure25: Adding a Distribution Protocol

A distribution protocol contains the following information:

1. Basic information such as Principal Investigator, Title, and so on. You can also give a Description URL, which is the web address having details of the IRB approved distribution protocol.
2. Specimen requirements (that is the details of the specimen to be distributed to this protocol).



Even though the specimen requirements data is collected in the distribution protocol, it is currently not used by the system to validate the distributions.

## Editing Administrative Objects

You can edit all the objects under the Administrative Data tab except Reported Problems and Conflicting Reports. The following procedure outlines how you can perform basic editing.

To perform an edit operation:

1. Click **Edit** button under the required object on the Administrative Data tab. For example: User, Institution, and so on. The relevant search window is displayed.
2. Select the required Attribute, Condition, and Value.
3. Click **Search**. The Search Result page displays the matching records.
4. Double-click the record of interest. The Edit page is displayed. For example: if you are searching for storage type, the Edit Storage Type page will be displayed.
5. Make the desired changes and click **Submit**. A success message is displayed if the record is updated.

## Creating New Dynamic Extensions Using the User Interface

The caTissue Suite application captures data related to common annotations. However, there might be a requirement to capture additional data which the application does not support. Since it is not possible to customize the application for each institute separately, the Dynamic Extensions, also known as Local Extensions feature enables you with Administrator privileges to add local requirements to your system depending on the kind of study. For example: a dynamic extension form could be defined to capture data about a fixation event for a specimen

The four main features of local extensions are:

- Form Creation
- Containment
- Linking
- Inheritance

The following table explains the terms which will be used in this document to describe creating local extensions:

**Table 9: Local Extension Terms**

Term	Definition
Attribute	An Attribute is a property of an individual entity. For example: name of person, length of a box, and so on.
Entity	An entity is an individual unit consisting of multiple attributes.
Entity Group	An entity group is a logical grouping of entities.
Association	An Association is a relationship between any two entities.

Term	Definition
Inheritance	Inheritance is a process to form new entities using other entities that have already been defined.

## Creating a Form

This section explains the procedure to build a simple form using dynamic extensions. Only a user with administrative privileges can execute these procedures.

To create a new form:

1. Click the **Administrative Data** tab.
2. Click **Define** under Local Extensions on the left pane. A Warning page is displayed as shown in the following figure. This message warns you that the tables in the caTissue database will be created or altered if you create or edit a DE.

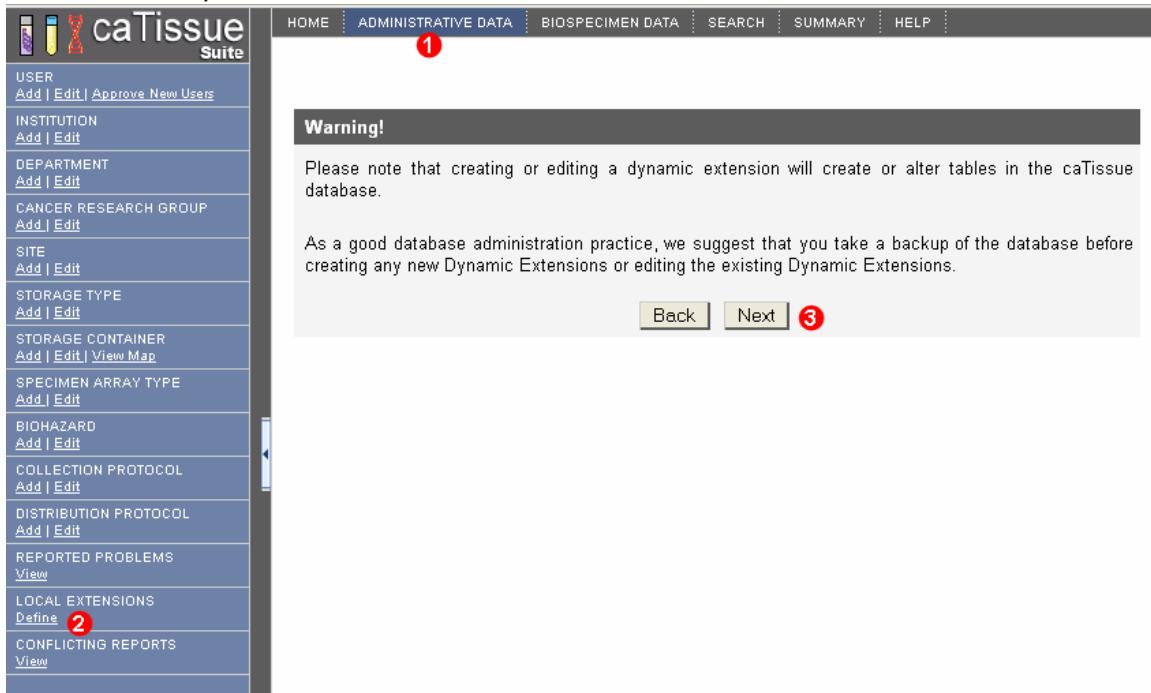


Figure26: Creating a New Form

3. Click **Next**. The Build Annotation Form page is displayed as shown in the following figure.
4. Every local extension created must be associated to a Participant, Specimen, or Specimen Collection Group; and to one or more collection protocols for which you will create the annotation form. To create a simple form:
  - a. Select **Participant** as the entity under Hook Entity. Hook Entity is a static class in caTissue to which the dynamically created annotation form is linked. A hook entity can be Participant, Specimen Collection Group, or Specimen. The entity you choose depends on the annotations you are defining. If your form contains fields (attributes) like hair color, height, and sexual orientation, you can associate it with a *Participant*, since these attributes are characteristics of a person. In case your form is used to record the details of the analysis of a particular block of tissue, you can associate the annotation form with *Specimen*. For our example, we choose Participant.

- b. Select the collection protocol to which the form is relevant. The annotation form will be available on the User Interface (UI) to all users who enter or query for data under that protocol. For example: select the protocol *B & B study (Blood and Biopsy study)*. Once created, the form will appear for all the participants registered under B & B study (Blood and Biopsy study) collection protocol only.

**Figure27: Build Annotation Form Page**

- c. Click **Submit** as shown in the preceding figure. The application navigates to the Define Group page.
5. To define a group, which is a collection of annotations that can be logically clubbed together:
- Select the **Create New** radio button as shown in the following figure.
  - Enter the **Group Title**.
  - Add a **Definition** for the group title if required.
  - Click **Next**. The Define Form page is displayed.

**Figure28: Define Form Page**

 To add a new form to an existing group, select the **Select From Existing** radio button for Group. For Group Title, select the required group from the drop-down list and click Next.

6. To define a form:

- a. Enter the **Form Title** as shown in the following figure. This title will appear as the name of the form when it is displayed in the user interface for data entry.
- b. Enter EVS concept code that defines the form title in the Concept Code(s) field. More information about finding and selecting appropriate concept codes will be provided in a separate document.
- c. Enter a free text definition of the form in the Definition field.
- d. Select the **New Form** radio button under Create As to create a new form.
- e. Click **Next** as shown in the following figure. The Build Form page is displayed.

The screenshot shows the 'Define Form' interface. At the top, there's a note: '\* Marked fields are mandatory'. The 'Form Title' field contains 'Participant Medical Identifier' with a red circle 'a' above it. The 'Concept Code(s)' field is empty with a red circle 'b' above it. The 'Definition' field contains the text 'Each participant has his unique medical identifier number associated with each hospital' with a red circle 'c' above it. Below these, there's a checkbox for 'Abstract(Not for data entry)' which is unchecked. Under 'Inherit form from', there's a dropdown menu set to 'select...'. At the bottom, there are two radio buttons: 'New Form' (selected) and 'From Previously Created Form', with a red circle 'd' above them. To the right of these buttons is a red circle 'e'. At the very bottom right is a green 'Next' button with a red circle 'f' above it.

**Figure29: Defining a Form**

Once the form is defined, you can build the form as per your requirements.

The attribute types available for forms are:

- Edit Box
- Check Box
- Option button
- List/Combo Box
- Date Picker
- File Upload

Each of these attribute types are explained next.

	User can add a desired combination of attribute types as per requirement.
---	---

#### Edit Box

The Edit Box attribute type is used for a field where you want to enter a value which is not predefined. For example: use Edit Box for an attribute that captures a dimension of a container, age of a patient, or the address of a treatment center.

**Edit BoxProperties**

<b>Display Width :</b>	<input type="text"/>
<b>*Data Input :</b>	<input checked="" type="radio"/> Text <input type="radio"/> Number
<b>*Display :</b>	<input type="radio"/> Single Line <input checked="" type="radio"/> Multi Line
<b>Number Of Lines :</b>	<input type="text"/>
<b>Maximum Characters :</b>	<input type="text"/>
<b>Default Value :</b>	<input type="text"/>
<input type="checkbox"/> Display as URL <input type="checkbox"/> Display as Password	
<b>Validation :</b>	<input type="checkbox"/> Accept only Unique values <input type="checkbox"/> Make this Attribute Mandatory

Figure30: Edit Box

Table 10: Edit Box

Attribute Type	Description
Display Width	Enter the field width, which is the width of the box that will be displayed on the screen. This is not the same as the length of the value that can be entered, which is the Maximum Characters listed below.
Data Input	Text: Select this option if the value to be entered for the attribute is text.
	Number: Select this option if numerical value is to be entered for the attribute.
Display	Single Line: Select this option to keep the data display limited to one line.
	Multi Line: Select this option to display the data across multiple lines. Also, specify the Number Of Lines across which the data is to be displayed. A multi-line display is useful when you expect that the user will be typing more than a few words.
Maximum Characters	Enter the limit for maximum number of characters that can be entered in the data field.
Default Value	Enter a value to display it as the default value for the given attribute. This is optional.

Attribute Type	Description
	Display as URL: Select this option to display the default value entered as URL. Note: To display as URL, setting a default value is mandatory.
	Display as Password: Select this option if you do not want the screen to display the exact letters or numbers a user is typing in, but rather to indicate each character with '#'.
Validation	Accept only Unique values: Select this option to accept only unique values for the attribute. This will allow users to enter only a unique value in each record. Do not select this option if it is ever possible that the same value will be specified for this field in two different instances of this form.
	Make this Attribute Mandatory: Select this option to make data entry mandatory for the given attribute.
	Accept Values Includes Min.& Max.Values: Select this option to restrict the values the user can enter value within a specified range. This option is available only if data input is of type Number.

### Check Box

The Check Box attribute type is used if an attribute has only one out of two values, and the two values are of type *yes* or *no*. For example: a Check Box can be used to ask if the patient has high blood pressure or not, or the tumor stage can be determined or not.

**Check BoxProperties**

\* Default Value :  Checked  Unchecked

Figure31: Check Box

Table 11: Check Box Attribute Type

Attribute Type	Description
Default Value	Select the <code>Checked</code> option to allow the attribute data field to appear as checked. Select <code>Unchecked</code> if you do not want the attribute data field to appear as checked.

### Option Button

The Option Button is a radio button attribute type. Option Button type is used to select one value from a small list of multiple possible values for an attribute. The number of possible values is more than two. For example: an Option Button is used to capture information on Sex, where the values are *Male*, *Female*, and *Unknown*.

**Option ButtonProperties**

Button Options :  User Defined  CDE

#	Option Name	Concept Code(s)	Definition
<input type="checkbox"/>			
<input type="checkbox"/>			

Add Permissible Value    Delete    Make Default

Figure32: Option Button

**Table 12: Option Button**

Attribute Type	Description
Button Options	The default option is User Defined, which allows you to enter permissible values of your choice manually.
Browse	Click this button to browse to the location of a file, which contains permissible values, concept codes, and definition in a CSV format. Once you locate the file, click Upload File.
Add Permissible Value	Click this button to add a row and enter the permissible values, concept code(s), and definition.
	Option Name: Click within the cell on the grid to enter the permissible value.
	Concept Code(s): Click within the cell on the grid to enter the concept code. This is optional.
	Definition: Click within the cell on the grid to add the definition. This is optional.
Delete	Select the check box next to the row(s) for which the permissible value(s) need to be deleted and then click Delete.
Make Default	Select the permissible value you want to make the default selected value on the screen.
	<p>You can upload a file containing the permissible values by clicking Browse and then clicking Upload File. The file should be in comma-separated-value format, with each line containing a permissible value, concept code, and definition. The three elements in each line are separated by commas. You can also enter these values manually under Add Permissible Value. The latter is useful in case certain required values are not available in the uploaded file.</p>

### List Combo Box

The List Combo Box attribute type is used to select one or more values for an attribute from a long list of possible values. For example: a List Box or Combo Box can be used for a long list of anatomical sites in the body and you can select one (Combo Box type) or more than one (List Box type) values from that list.

**List/Combo boxProperties**

\*Display :  Combo Box  List Box

Display Height :

List Options :  User Defined  CDE  Look Up

---

#	Option Name	Concept Code(s)	Definition

---

Validation :  Make this Attribute Mandatory

Figure33: List Combo Box

Table 13: List Combo Box

Attribute Type	Description
Display	Select the Combo Box option to display the permissible values as a drop down list. You can select only one permissible value from the combo box. Select the List Box option to display the data as a list. To select multiple values, click a value, press down the [CTRL] key, and then select another value.
Display Height	Enter a value to specify the height of the List Box (maximum number of permissible values that can be displayed in the list box at a time).
List Options	The default option is User Defined, which allows you to enter permissible values of your choice manually. Click the Look Up option to link forms. For more information, refer to Linking Forms.
Browse	Click this button to browse to the location of a file, which contains the permissible values, concept codes, and definition in a CSV format. Once you locate the file, click Upload File.
Add Permissible Value	Click this button to add a row and enter the permissible values, concept code(s), and definition.  Option Name: Click within the cell on the grid to enter the permissible value.  Concept Code(s): Click within the cell on the grid to enter the concept code. This is optional.  Definition: Click within the cell on the grid to add the definition. This is optional.

Attribute Type	Description
Delete	Select the check box in front of the rows for which the permissible values need to be deleted and then click Delete.
Make Default	Select the permissible value you want to make the default selected value on the screen.
Validation	Make this Attribute Mandatory: Select this option to make date entry mandatory for the given attribute.

### Date Picker

The Date Picker attribute type is used to enter only date (or time) value for an attribute in a particular date format. For example: Date Picker can be used to enter the date of birth of a patient or the date when a particular treatment began.

**Date PickerProperties**

**\*Format :**  Date Only  Date & Time  Date (Month & Year)  
 Date (Year only)

**Default Value :**  None  Today's Date  Select Date  
 [MM-DD-  
YYYY]

---

**Validation :**  Make this Attribute Mandatory  
 Accept Values (Includes Min. & Max. Date Values)

Min. Date  Max. Date

Figure34: Date Picker

Table 14: Date Picker

Attribute Type	Description
Format	Select one of the options to set format for the date type attribute.
	Date Only: Select this option to display only the date.
	Date & Time: Select this option to display the date as well as the time.
	Date (Month & Year): Select this option to display a month and the year.
	Date (Year only): Select this option to display the year only.

Attribute Type	Description
Default Value	<p>Select one of the three options to set the default date.</p> <p>None: Select this option if you do not want to set a default date.</p> <p>Today's Date: Select this option to set the current date as the default.</p> <p>Select Date: Select this option to set a date-default of your choice. Select the date (and/or time) from the calendar displayed.</p>
Validation	<p>Make this Attribute Mandatory: Select this option to make data entry for the given attribute mandatory.</p> <p>Accept Values Includes Min.&amp; Max.Date Values): Select this option to allow the user to enter the date value within a specified range.</p>

### File Upload

Use the File Upload attribute type to upload a file of particular type. For example: the Upload File attribute type can be used to upload the photograph of a patient as a JPEG file. Or a DOC file containing the details of a collection protocol can be uploaded.

The screenshot shows a configuration dialog box titled "File UploadProperties". It contains the following fields:

- Display Width :** A text input field.
- Accept file formats :** A dropdown menu containing "bmp", "jpeg", and "gif".
- Other File Formats :** A text input field.
- Accept Maximum File Size :** A text input field followed by "MB".
- Validation :** A checkbox labeled "Make this Attribute Mandatory".

Figure35: File Upload

**Table 15: File Upload**

<b>Attribute Type</b>	<b>Description</b>
Display Width	Enter the field width, which will be displayed on the screen.
Accept File Formats	Select the required format for the file that you want to upload. The available formats are bmp, jpg, gif, doc, and pdf.
Other File Formats	Enter the file format, which is other than the ones available in Accept File Formats option.
Accept Maximum File Size	Enter the maximum limit for file size in MB. If the file is larger than the specified size, it will not be uploaded.
Validation	Make this Attribute Mandatory: Select this option if you want to make data entry for the given attribute mandatory.

7. To build a form:

- a. Enter a **Label** for the attribute. Also, enter values for **Concept Code(s)** and **Definition** if required.
- b. Select the required attribute type. For example: Edit Box, Date Picker, and so on.
- c. Enter the properties for the selected attributes. For example: Display Width, Permissible Value, and so on.
- d. Select the **Make this Attribute Mandatory** check box if required to make data entry for an attribute mandatory.
- e. Click **Submit Attribute**. The attribute gets added to the Form Attributes List on the right pane as shown in the following figure.

#	Name	Type
1	Name	Edit Box
2	Birth Date	Date Picker

Figure36: Build a Form – Add Form Attribute Page

- f. Click **Next** once you have added all the required attributes. The Preview tab displays the form you created as shown in the following figure.
- g. Click **Back** to navigate back to the Build Form page.

Figure37: Build a Form – Preview Page

- h. Click **Save** to save the form.

## Containment

You can add a sub form to the current or main form if required. Sub forms contain data that is related to the main form.

To add a sub form:

Perform the steps mentioned in the *To create a new form* procedure to create the main form.

To add a sub form, navigate to the Build Form tab of the main form:

1. Click **Add Sub Form**. The system navigates to the Define Sub Form page.
2. Enter the **Form Title**.
3. Select the **Form or SpreadSheet (Allows multiple entries)** radio button under View As. If you select Form, you can add a single record for the sub form. If you select SpreadSheet (Allows multiple entries), you can add multiple records to the sub form.
4. Click **Next** as shown in the following figure.

**Figure38: Add Sub Form: Define Sub Form Page**

5. Add attributes to this sub form.
6. Click **Next** to navigate to the Preview page. The preview page will displayed as shown in the following figure.

**Figure39: Add Sub Form – Preview Page**

	<p>To add rows to the sub form, click Add Row. To delete a row, select the check box next to the required row and click Delete.</p>
---	---

## n Level Containment

The caTissue Suite supports n level containment. For example, consider there is a main form *Participant Medical Identifier*. This form has an attribute *Medical Record Number* and a sub form called *Site*. Now, the *Site* form has its own attributes *Site Name* and *Site Type*. The *Site* sub form also contains a sub sub form called *Coordinator*. This sub form has attributes like *First Name*, *Last Name*, and *Email Address*. The *Coordinator* form contains a nested sub form *Address*, which has attributes *Street*, *City*, *State*, and *Country*.

The sub sub sub form *Address* can further nest another sub form. This type of containment is called n level containment where a form can have a sub form up to unlimited levels contained in it.

The following figure shows n level containment.

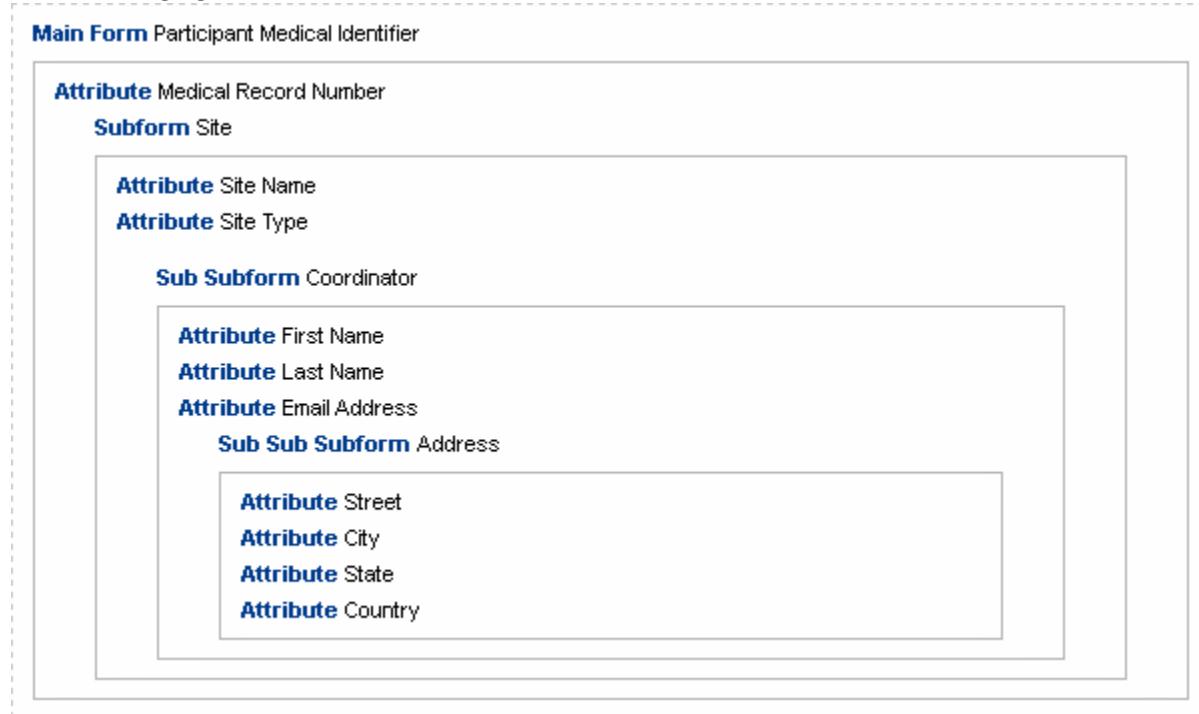


Table 16: n Level Containment

## Lookup Associations

You can link various forms across any groups. This feature is useful to access data across various forms. That is, the values entered for attribute(s) of one form can be available as permissible values of an enumerated attribute in another form.

For example, there is a form called *Participant Medical Identifier* with an attribute *Medical Record Number*. Data entry is done for this attribute. Create another form called *Participant* with attributes *First Name*, *Last Name*, *Date of Birth*, and so on. Now, make the data entered for *Medical Record Number* attribute of the *Participant Medical Identifier* form available to the *Participant* form. To do this, create an attribute *MRN* in the *Participant* form and link it to the *Medical Record Number* attribute of the *Participant Medical Identifier* form.

The following procedure explains the preceding example.

To link forms:

1. Create a form called **Participant Medical Identifier**, with an attribute called **Medical Record Number**.
2. Create another form called **Participant** with attributes **First Name**, **Middle Name**, and so on.
3. Add another attribute called **MRN** to link to the Medical Record Number attribute of Participant Medical Identifier form as follows:
  - a. Select the **List/Combo** box option.
  - b. Select the **Look Up** radio button from the List Options.
  - c. Select the required **Group**. Based on the group selected, data is populated in the Form field.
  - d. Select the required form. In this example, Participant Records is the Group and Participant Medical Identifier is the Form.
  - e. Select the attribute **Medical Record Number** under Available Attributes.
  - f. Click **Add** to add this attribute to the list of Selected Attributes.

	<p>To add multiple attributes from the Available Attributes list, select the attributes and click Add to add them to the Selected Attributes list. To add more than one attribute, select a separator to separate the values that will be entered for each of these multiple attributes. To do this, select an option from the Separate with drop-down list. The available options are Colon, Comma, Dot, and Space. The attribute values, separated by the chosen separator are represented as a single-line permissible value combination.</p>
---	--

- g. Click **Submit Attribute** as shown in the following figure.

**Form Name :Participant**

**Add Form Attribute**

\*Label : MRN

Concept Code(s) :

Definition :

PHI Attribute

**List/Combo boxProperties**

\*Display :  Combo Box  List Box

List Options :  User Defined  CDE  Look Up b

\*Look into :  User Forms  System Forms

Group : Participant Records c

Form : Participant Medical Identifier d

**Available Attributes** f **Selected Attributes**

Medical Record Number e	Add	Medical Record Number
	Remove	

Separate with : Colon

Validation :  Make this Attribute Mandatory g

Cancel Submit Attribute Up Down Remove

Figure40: Linking Forms

4. Click Next. The Preview page is displayed as shown in the following figure.

1. Define Group    2. Define Form    3. Build Form    4. Preview

\* indicates required fields.

**Participant**

First Name	
Last Name	
Date of Birth	[MM-DD-YYYY]
MRN	<input type="button" value="▼"/>

Back

Figure41: Linking Forms – Preview Page

5. Click Save.

**Note:** Records entered for the Medical Record Number attribute of Participant Medical identifier form are populated in the MRN drop-down list of the Participant form.

## Inheritance

This feature is useful when you want attributes of a certain form to appear across various forms. Instead of creating the same attributes across multiple forms, you can inherit them from a common form. For

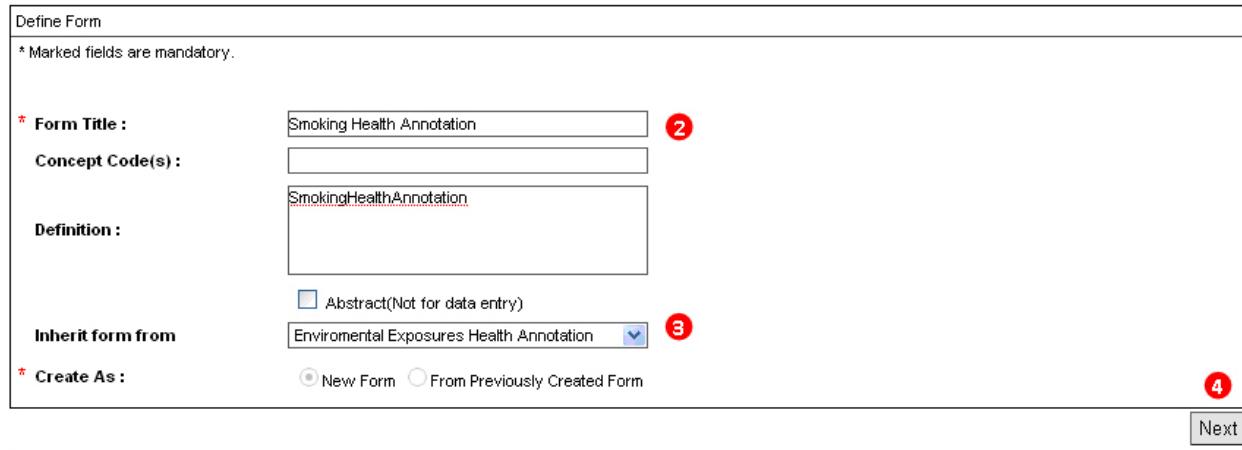
example: you have a form **Environmental Exposures Health Annotation** and it contains attributes like **Agent**, **Other Agent**, and so on. To import all these attributes in some other form, for example **Smoking Health Annotation** and **Alcohol Health Annotation**, use the Inherit form from option while creating these child forms. This will populate the child forms with all the attributes from the parent form. The following procedure explains how to inherit a form based on the preceding example.

To inherit a form:

1. Create a parent form **Environmental Exposures Health Annotation** with attributes like **Agent**, **Other Agent**, **Years Agent Free**, and so on.

	<p>Select the Abstract (Not for data entry) option on the Define Form page if you do not want to use the parent form for any data entry.</p>
---	--

2. Create a child form **Smoking Health Annotation**.
3. Select the parent form **Environmental Exposures Health Annotation** from the Inherit form from drop-down list on the Define Form page as shown in the following figure.
4. Click Next.

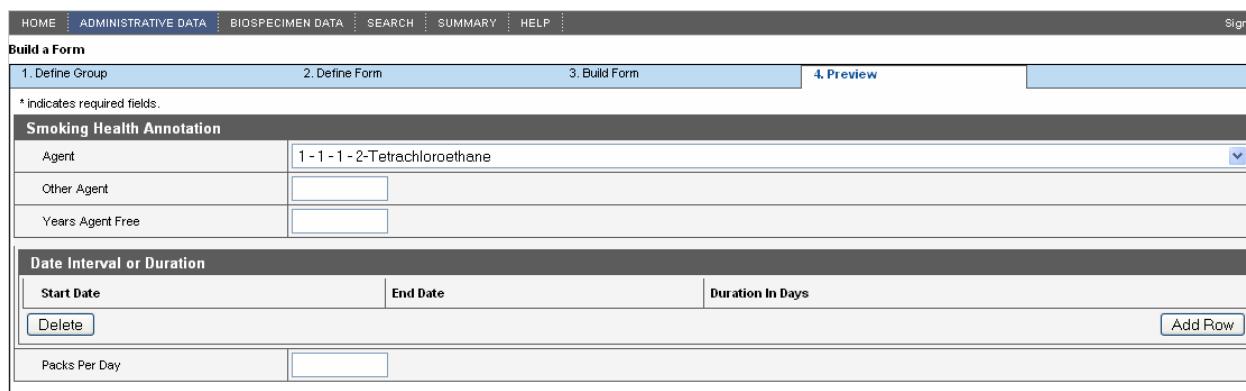


The screenshot shows the 'Define Form' page with the following details:

- Form Title:** Smoking Health Annotation (marked with red circle 2)
- Inherit form from:** Environmental Exposures Health Annotation (marked with red circle 3)
- Create As:** New Form (marked with red circle 4)
- Next** button at the bottom right

Figure42: Inheriting Form – Define Form Page

5. On the Build form page, add the unique attributes of the derived form (if any).
6. Click Next.
7. The Preview page displays the attributes you created, as well as the inherited attributes of the parent form Environmental Exposures Health Annotation as shown in the following figure.



The screenshot shows the 'Build a Form' page for 'Smoking Health Annotation' with the following details:

- Agent:** 1 - 1 - 1 - 2-Tetrachloroethane
- Other Agent:** (empty)
- Years Agent Free:** (empty)
- Date Interval or Duration:**
  - Start Date: (empty)
  - End Date: (empty)
  - Duration In Days: (empty)
- Buttons:** Delete (next to Start Date), Add Row (bottom right)

Figure43: Inheriting Form – Preview Page

F.Y.I.

The caTissue Suite supports n level inheritance. This means the child form, for example: *Smoking Health Annotation* will inherit all the attributes of the parent form *Environmental Exposure Health Annotation*, and the *Smoking Health Annotation* form can also be a parent form to another form, for example: *Participant Medical Identifier*. Hence, the form *Participant Medical Identifier* will contain the attributes of its parent form (*Smoking Health Annotation*) as well as the parent of the parent form (*Environmental Exposure Health Annotation*).

You can view this form by navigating to the collection protocol based view under Biospecimen Data.

To view a form:

1. Click the **Biospecimen Data** tab.
2. On the left pane, select the corresponding collection protocol.
3. Since the dynamic extensions created have been hooked to an entity, each form would be visible only under that entity. Select the hook entity (in our example: Participant).
4. Click the **View Annotation** tab.
5. Select the **Smoking Health Annotation** form from the Annotation Forms drop-down list as shown in the following figure.

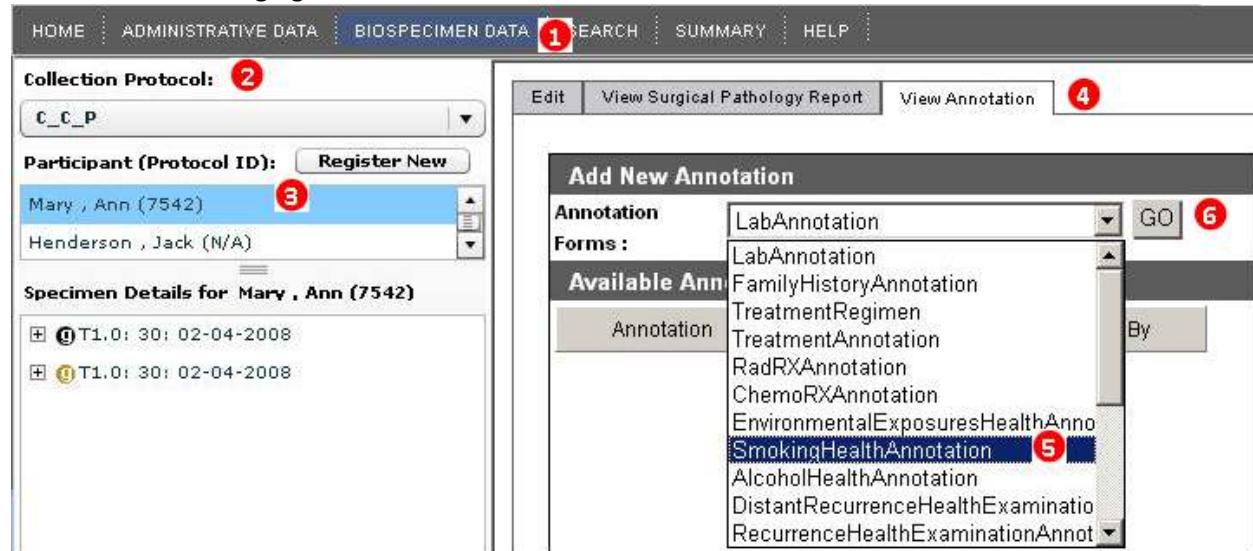


Figure44: Viewing Form

6. Click **Go**. The result screen is displayed as shown in the following figure.

Smoking Health Annotation		
Agent	1 - 1 - 1 - 2-Tetrachloroethane	
Other Agent		
Years Agent Free		
Duration		
Start Date	End Date	Duration In Days
<input type="button" value="Delete"/>		
Packs Per Day		
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>		

Figure45: Viewing Form – Result Page

Sometimes a particular annotation that is restricted to one CP may be required in another CP, or a particular annotation that is restricted to multiple CPs is required only under a subset of those CPs. To make an annotation available or unavailable under that CP or CPs, you need to edit the conditions on the CPs. The following procedure explains how to edit conditions for a collection protocol.

To edit conditions for a collection protocol:

1. Select the required group under Group on the Build Annotation Form page.
2. Click **Edit** under Conditions for the required form under Form Title as shown in the following figure.

Existing annotations :					
Group	Form Title	Entity	Date	Created By	Conditions
clinical_annotation	LabAnnotation	Participant	01-21-2008		<input type="button" value="Edit"/> ②
pathology_specim	FamilyHistoryAnnotation	Participant	01-21-2008		<input type="button" value="Edit"/>
pathology_scg	TreatmentRegimen	Participant	01-21-2008		<input type="button" value="Edit"/>
Common Entity Gr	TreatmentAnnotation	Participant	01-21-2008		<input type="button" value="Edit"/>
CancerStudy	RadRXAnnotation	Participant	01-21-2008		<input type="button" value="Edit"/>
test	ChemoRXAnnotation	Participant	01-21-2008		<input type="button" value="Edit"/>
Test_Group_koma	EnvironmentalExposu	Participant	01-21-2008		<input type="button" value="Edit"/>
Breast Biomarkers	SmokingHealthAnnot	Participant	01-21-2008		<input type="button" value="Edit"/>
LindaGroup	AlcoholHealthAnnotat	Participant	01-21-2008		<input type="button" value="Edit"/>
	HealthExaminationAn	Participant	01-21-2008		<input type="button" value="Edit"/>
	RecurrenceHealthExa	Participant	01-21-2008		<input type="button" value="Edit"/>

Figure46: Editing Conditions for a Collection Protocol

3. Select the required collection protocol or collection protocols under Title as shown in the following figure.
4. Click **Submit** to update the changes.

Build Annotation Form :	
* Hook Entity	<input type="button" value="Participant"/>
Conditions on Collection Protocol:	
Title	--All-- ALL-1 (ALL-1) ③ B&B Study (Blood and Biopsy Study) Breast cancer (Breast Cancer in women)
<input type="button" value="Submit"/> ④ <input type="button" value="Cancel"/>	

Figure47: Editing Conditions for a Collection Protocol – Build Annotation Form Page

You can modify a form based on your requirements. For example: editing the form title, editing the parent form from which the child form inherits attributes or data, editing attribute properties, or the attribute data type.

Modification on attribute data type and attribute properties is not allowed once records are entered for that form. Similarly, you cannot change the parent form for inheritance after data entry. However, you can change the validations as well as order of attributes in the form. The following procedure explains how to edit a form.

To edit a form:

1. Select the required group under Group, and then click a link corresponding to the required form under Form Title on the Build Annotation Form page as shown in the following figure.

Existing annotations :					
Group	Form Title	Entity	Date	Created By	Conditions
clinical_annotation	LabAnnotation ①	Participant	01-21-2008		<a href="#">Edit</a>
pathology_specim	FamilyHistoryAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
pathology_scg	TreatmentRegimen	Participant	01-21-2008		<a href="#">Edit</a>
Common Entity Gr	TreatmentAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
CancerStudy	RadRXAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
test	ChemoRXAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
Test_Group_koma	EnvironmentalExposu	Participant	01-21-2008		<a href="#">Edit</a>
Breast Biomarkers	SmokingHealthAnnotat	Participant	01-21-2008		<a href="#">Edit</a>
LindaGroup	AlcoholHealthAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	HealthExaminationAn	Participant	01-21-2008		<a href="#">Edit</a>
	RecurrenceHealthExa	Participant	01-21-2008		<a href="#">Edit</a>

Figure48: Editing Form

2. The Select From Existing radio button is selected and the form that you want to edit is displayed under Group Title as shown in the following figure. Click **Next** and proceed to the Build Form page.

1. Define Group    2. Define Form    3. Build Form    4. Preview

\* Marked fields are mandatory.

**Group :**  Create New  Select From Existing ②

**Group Title :** clinical\_annotation

**Definition :**

Save    Cancel    Next ②

Figure49: Editing Form – Define Group Page

3. On the Build Form page, as shown in the following figure:
  - a. Edit the **Form Title**.
  - b. If the form does not inherit data from any other form, then select a parent form from the Inherit Form From drop-down list.

- c. If the form inherits data from another parent form, select a different parent form from the Inherit Form From drop-down list.
- d. Enter or edit the **Definition** for the Form Title if required.
- e. Enter or edit the **Concept Code(s)** for the Form Title.
- f. Click **Next** to navigate to the Build Form page.

The screenshot shows the 'Build a Form' interface. The top navigation bar has tabs: 1. Define Group, 2. Define Form (selected), 3. Build Form, 4. Preview. The left sidebar has an 'Add Form' button and a list: clinical\_annotation, Rad RX Annotation (with a red circled '3'). The main right pane has a 'Define Form' section with the following fields:  
**Form Title:**  (red box 'a')  
**Concept Code(s):**  (red box 'e')  
**Definition:**  (red box 'd')  
 Abstract(Not for data entry)  
**Inherit form from:**  (red box 'c') (red box 'b')  
**Create As:**  New Form  From Previously Created Form  
At the bottom are 'Save' and 'Cancel' buttons, and a 'Next' button with a red circled 'f'.

**Figure50: Editing Form – Build Form Page**

The following procedure explains how to edit an attribute.

To edit an attribute:

1. Select the required attribute under Form Attributes List on the right pane on the Build Form page.
2. The Edit Form Attribute page is displayed as shown in the following figure. Edit the attribute.
  - a. Edit the **Label** of the attribute.
  - b. Change the data type of the attribute.
  - c. Edit the properties of the attribute.
  - d. Edit the **Validation** on the attribute.
  - e. Click **Submit Attribute** to save the changes.

**Form Name :RadRXAnnotation**

**Edit Form Attribute**

\*Label: **a** Name

Concept Code(s):

Definition:

**b**  PHI Attribute

**Edit BoxProperties**

Display Width: **c** 0

Data Input:  Text  Number

Display:  Single Line  Multi Line

Maximum Characters: 0

Default Value:

Display as URL  
 Display as Password

Validation: **d**  Accept only Unique values  
 Make this Attribute Mandatory

**e**  Save

#	Name	Type
1	Name	Edit Box
	Birth Date	Edit Box
	Participant PhdFile Upload	

Figure51: Editing an Attribute

3. Click **Save** to update the changes made to the form and its attributes.

 To change the display order of the attributes, use the Up and Down buttons. To remove an attribute from the Form Attributes List, select the check box against it and click Remove.

## Entering Data for Dynamic Extensions

There is always a requirement to annotate a patient, accession, or biospecimen data with varied kind of information from time to time. To do so, you need enter relevant data for the dynamic extensions.

To perform data entry for dynamic extensions:

1. Click the **Biospecimen Data** tab.
2. Select the required Collection Protocol from the drop-down list to which your annotation is restricted. The system displays the list of participants already registered to the selected collection protocol under Participant (Protocol ID).
3. Select the appropriate hook entity under which the annotation is available. For example: Participant, Specimen Collection Group, or Specimen.
4. Click the **View Annotations** tab to navigate to the Add New Annotation page.
5. Select the required annotation from the Annotation Forms drop-down list as shown in the following figure.
6. Click **Go**.

**Figure52: Data Entry for Dynamic Extensions**

7. The selected annotation data entry page is displayed as shown in the following figure. Enter data in the respective fields. For example: consider the fields mentioned in following figure:
  - a. Select an option from the Agent drop-down list.
  - b. Enter **Other Agent** if the required agent name is not available in the Agent drop-down list.
  - c. Enter the number of **Packs Per Day**.  
Similarly, add other details if required.
  - d. Click **Submit**.

<b>Smoking Health Annotation</b>	
Agent	Tobacco smoking and tobacco smoke
Other Agent	<input type="text"/>
Years Agent Free	2
<b>Duration</b>	
Start Date	End Date
<input type="text"/> 04-07-1998  [MM-DD-YYYY]	<input type="text"/> 04-29-1998  [MM-DD-YY]
<input type="button" value="Delete"/>	
Packs Per Day	4
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>	

Figure53: Data Entry for DE - Data Entry Page

## Creating New Dynamic Extensions Using XMI Import

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You can create dynamic extensions by importing XMI (XML metadata interchange) into the application.

### Importing Classes from XMI:

The XMI Import feature of dynamic extensions allows you to create UI forms, corresponding to UML classes by importing the XMI for the UML model. To import an XMI, perform the following steps:

1. Create UML model for the desired extensions using Enterprise Architect (v6.1) (UML modeling tool).

The prerequisites to create UML model are:

- The names of the classes, attributes, associations should not contain spaces in it.
- Associations should have link names. This name will be the name given to the association on the UI.
- The name of the XMI file generated will be the name of the Entity Group on UI.
- For a form to be a sub form on the UI, containment type for the association must be specified as *Reference* or *Value* in the source and target roles. For containment type *Not Specified*, the target class will be generated as a drop-down list on the UI.

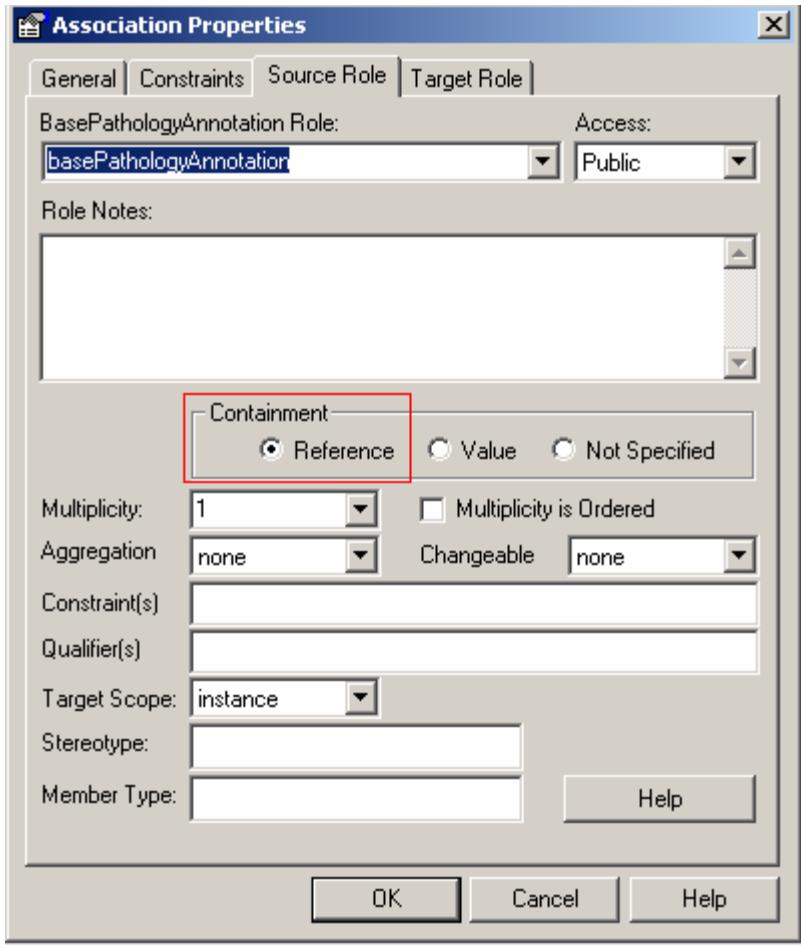


Figure54: Association Properties Dialog Box

- Delete the association and add a new association while changing the containment type from EA.
- EA version 6.1 should be supported

For example, consider the following model created in EA:

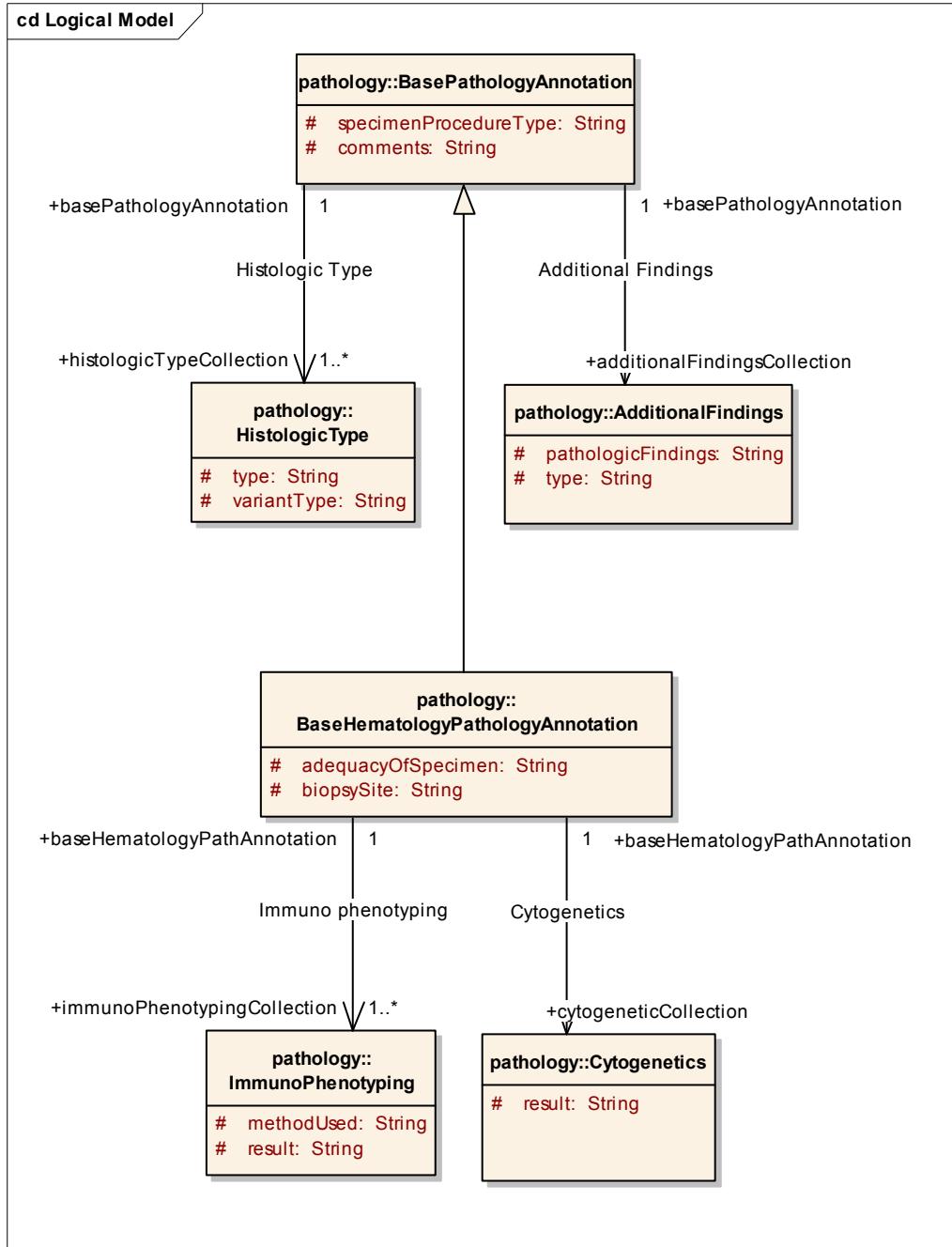


Figure55: UML Model Created in EA

2. Under Project View window of EA, right-click **Logical Model** and select **Export**. Export the XMI format of the UML model created in Step1 using Enterprise Architect by selecting options:
  - a. Select the **Format XMI Output** and **Use DTD** check box under General Options,
  - b. Select **UML 1.4 (XMI v1.2)** from the XMI Type drop-down list under For Export to Other Tools.
  - c. Click **Export**.

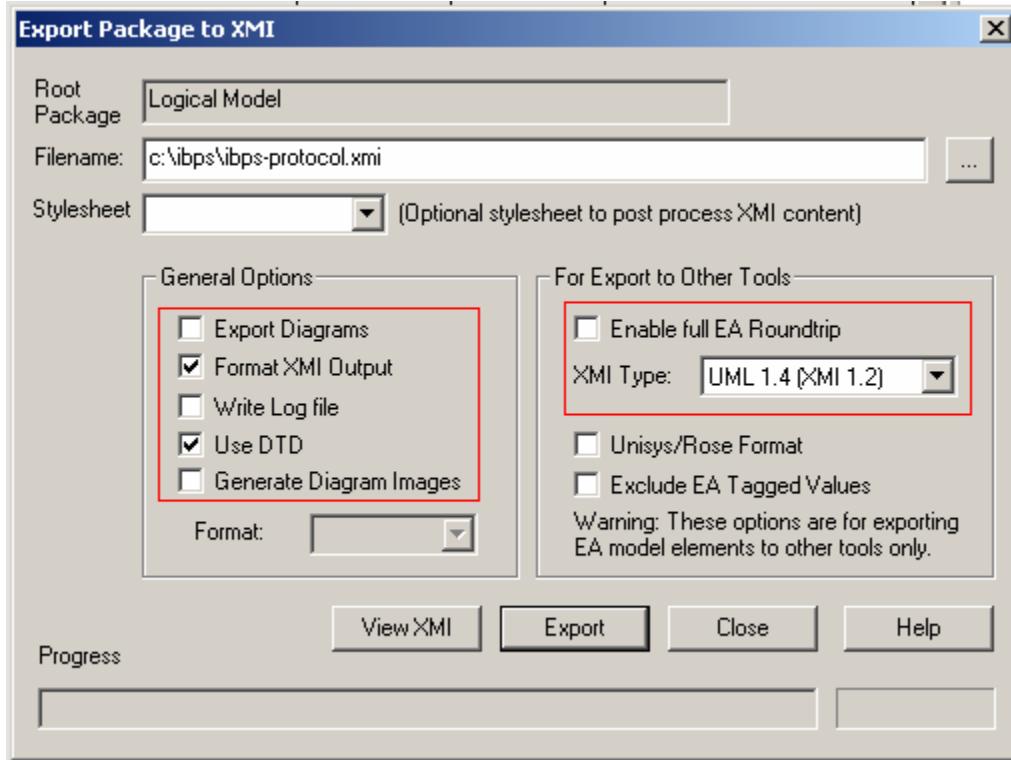


Figure56: Exporting UML Model from Enterprise Architecture

3. Run the ant task to import the XMI of the model into caTissue Suite as follows:

- Unzip the caTissue Suite installable zip at an appropriate location.
- Go the command prompt and change the directory to the unzipped folder.
- From this directory, run the following ant target:

```
ant -f deploy.xml import_xmi -Dfilename=<FILENAME> -
Dhookentity=<HookEntityClassName> -
DmainContainerList=<MainContainerCSVFileName> -Dpackage=<Package> -
Dcondition=<ConditionCSVFileName>
```

Table 17: ANT File Field Description

Parameter	Description	Mandatory
<FILENAME>	Path and name of XMI file exported from EA in the previous step. For example: C:\Annotations.xmi.	Yes
<HookEntityClassName>	<p>Complete name of the class to which the dynamic annotation is to be linked.</p> <p>The three permissible hook entity class names are:</p> <ul style="list-style-type: none"> <li>• edu.wustl.catissuecore.domain.Participant</li> <li>• edu.wustl.catissuecore.domain.Specimen</li> <li>• edu.wustl.catissuecore.domain.Specimen</li> </ul>	Yes

Parameter	Description	Mandatory
	enCollectionGroup	
<MainContainerCSVFileName>	Path and name of the CSV file containing the main form names. These will be the name of the classes that are directly linked to static caTissue Suite hook objects.	Yes
<Package>	Package name from the UML model which has to be imported into the application. For example: you have defined classes under two packages in the UML model, but you might want to import only the classes under one of the packages.	Yes
<ConditionCSVFileName>	Path and name of CSV file containing collection protocol titles to which the extensions can be restricted to. By default it is set to all collection protocols. Restricting to collection protocol means the extensions defined will be available for data entry only for the data under that particular protocol.	No

**Caution:** The order of parameters in the ant task should be the same as specified in the above example. The JBoss server has to be restarted once the above target has been executed.

**Example:**

```
ant -f deploy.xml import_xmi -Dfilename="D:\import.xmi" -
Dhookentity="edu.wustl.catissuecore.domain.Specimen" -
DmainContainerList="D:\mainContainerList.csv" -Dpackage="pathology"
```

4. On successful completion of the task, a message is displayed.

Log on to the caTissue Suite application using the UI and perform the following checks:

1. Click the **Administrative Data** tab.
2. Select **Define** under Dynamic Extensions. Under Existing annotations, check the group that has been created.

The screenshot shows the caTissue Suite administrative interface. On the left, a sidebar lists various administrative categories: USER, INSTITUTION, DEPARTMENT, CANCER RESEARCH GROUP, SITE, STORAGE TYPE, STORAGE CONTAINER, SPECIMEN ARRAY TYPE, BIOHAZARD, COLLECTION PROTOCOL, DISTRIBUTION PROTOCOL, REPORTED PROBLEMS, LOCAL EXTENSIONS (which is highlighted with a red box), and CONFLICTING REPORTS. The 'ADMINISTRATIVE DATA' tab is selected and highlighted with a red box at the top of the page.

**Build Annotation Form :**

- \* Hook Entity: A dropdown menu showing options like "Select", "All", and "None".
- Conditions on Collection Protocol:**

  - Title: A dropdown menu showing "All".

**Existing annotations :**

Group	Form Title	Entity	Date	Created By	Conditions
clinical_annotation	LabAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
pathology_specim	FamilyHistoryAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
pathology_scg	TreatmentRegimen	Participant	01-21-2008		<a href="#">Edit</a>
	TreatmentAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	RadRXAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	ChemoRXAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	EnvironmentalExposures	Participant	01-21-2008		<a href="#">Edit</a>
	SmokingHealthAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	AlcoholHealthAnnotation	Participant	01-21-2008		<a href="#">Edit</a>
	HealthExaminationAnnotation	Participant	01-21-2008		<a href="#">Edit</a>

Figure57: Importing XMI: Groups Created

- Click the **Biospecimen Data** tab and check the data entry forms. To do this, navigate to the edit page of the hook entity object and click the **View Annotations** tab.

The screenshot shows the caTissue Suite biospecimen data entry form. The 'BIOSPECIMEN DATA' tab is selected at the top.

**Collection Protocol:**

- A dropdown menu showing "sg".
- Participant (Protocol ID):** A dropdown menu showing "patil , rajesh (N/A)".

**Specimen Details for patil , rajesh (N/A)**

- A list item: "T1.0: fh: 01-25-2008".

**Lab Annotation**

Test Date	<input type="text"/> [MM-DD-YYYY]
Result Units	<input type="text"/>
Result	<input type="text"/>
Other Lab Test Name	<input type="text"/>
Lab Test Name	<input type="text"/>

**Buttons:**

- Submit
- Cancel

Figure58: Importing XMI: Data Entry Form

**Note:** The data entry form fields are created based on the data type of the attribute as defined in the UML model. The form field properties (field names, data types, length, and so on) can be edited using the form builder.

## Exporting Forms to XMI

The XMI export feature in caTissue Suite helps institutions to share their extensions and to maintain cabIG™ compatibility. The extensions defined in the application can be exported as an XMI file. This can be imported in EA and edited for any local customizations or sharing it with another institution. The procedures mentioned in XMI import can be used to add the updated model to the application.

To export extensions from caTissue Suite application as an XMI file:



Only one entity group can be exported to a XMI file.

1. Unzip the caTissue Suite installable zip and perform the configuration for the following properties in `caTissueInstall.properties`.

**Table 18: caTissue Install Properties**

Parameter	Description
<code>database.type</code>	Oracle or MySQL
<code>database.host</code>	Hostname or IP address of the machine on which the database server is running.
<code>database.port</code>	Port number to connect with the database server #Default port for MySQL : 3306 #Default Port for Oracle: 1521
<code>oracle.tns.name</code>	Oracle TNS name, applicable only when <code>database.type=oracle</code>
<code>database.name</code>	Database name
<code>database.username</code>	Database user name
<code>database.password</code>	Database password

Go to the command prompt and change the directory to the unzipped folder.

2. Run the following ant target:

```
ant -f deploy.xml export_xmi -Dgroupname <groupname> -Dfilename <export filename> -
Dversion <version>
```

**Table 19: ANT File Field Description**

<b>Parameter</b>	<b>Description</b>	<b>Mandatory</b>
<group name>	The group name in which the forms are created in the application.	Yes
<export filename>	Name of the file to which the model will be exported.  If this file exists, it will be overwritten. If it does not exist, a new file will be created.	Yes
<version>	Version of the XMI being exported:  XMI Version should be 1.1 for caCore generation.  XMI Version should be 1.2 to import the XMI in DE or in EA.  Default value is 1.2.	No

**Example:**

```
ant -f deploy.xml export_xmi -Dgroupname="IPBS" -Dfilename=" D:\build\DE Import-Export\export_demo.xmi" -Dversion="1.1"
```

On successful completion of the export XMI task, XMI Successfully Exported message is displayed at the command prompt.

**Note:** The model exported will also contain the static hook entity. Remove this hook entity if you want to import it back in the application.

### Steps to Generate caCore APIs for Dynamic Extensions

Data entry for dynamic extensions can also be done using caCore APIs (Application Program Interface). In order to do this, these APIs needs to be generated first. The caCore like API for Dynamic Extensions is used to insert, update, or query data through a client program. This section outlines the steps to be taken to run the client program

1. Copy caCore sdk 3.2 from the following location:

<http://gforge.nci.nih.gov/projects/cacoresdk/>

2. Make the following change in the code:

File: gov\nih\nci\system\applicationservice\ ApplicationServiceProvider.java

Method: public synchronized static ApplicationService getRemoteInstance(String URL)

Remove the if loop – in case(applicationService == null)

3. Copy the XMI file generated under cacoretoolkit\models\xmi folder.

Change deploy.properties under conf folder in cacoretoolkit folder hierarchy.

Change System Properties, Project Properties, Model Properties (The GroupName used for exporting XMI is the Package Name) and Database Properties in the file. Set “start\_container=no” and “disable\_writable\_api\_generation=no” in the deploy.properties file.

For more information on caCore, refer to the *caCore User Guide*.

4. Run build-system target in build.xml
5. Copy <project\_name>-client.jar from cacoretoolkit\output\<project\_name>\package\client\lib to catissue\_de\_integration\_client\lib
6. Run copyDeIntegrationWar target in catissue\_de\_integration\_client build.xml.
7. Run modifyDEJar target in catissue\_de\_integration\_client build.xml.
8. Run modifyProjectWar target in catissue\_de\_integration\_client build.xml. Now start the jBoss server.
9. Change application username and password in ClientDemo.java under catissue\_de\_integration\_client folder in catissuecore folder hierarchy.
10. Change application service URL in ClientDemo.java for caTissue Service, DE Service, DE Integration service.

The DE service context Name should be the same as the project\_name in the deploy.properties file in cacore sdk project.

11. Change the packageName for the DE Classes that are being used. For example, import declarations and class name as follows:

```
import PatientHistory.Participant;
import PatientHistory.SmokingHistory;
```

Also searching of participant is by ID. Change the ID if needed.

12. Run runDemo target in catissue\_de\_integration\_client build.xml.  
This should insert record successfully for the DE entities.
13. Go to the caTissue Suite application. Select the **Biospecimen Data** tab and select an appropriate hook entity like Participant, SCG, or Specimen. All the records added from ca-core Client are visible under the View Annotation tab.

## Known Issues in Dynamic Extensions

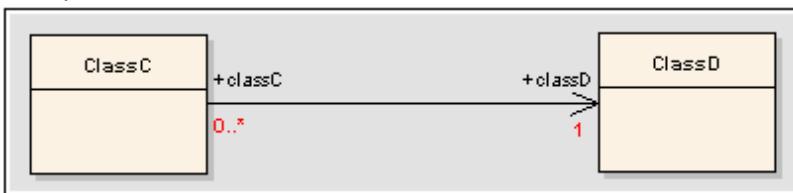
---

The following list mentions the known issues in DE, XMI Import, XMI export, and caCore like API generation:

- DE does not support bi-directional association specified in the UML model. For example:



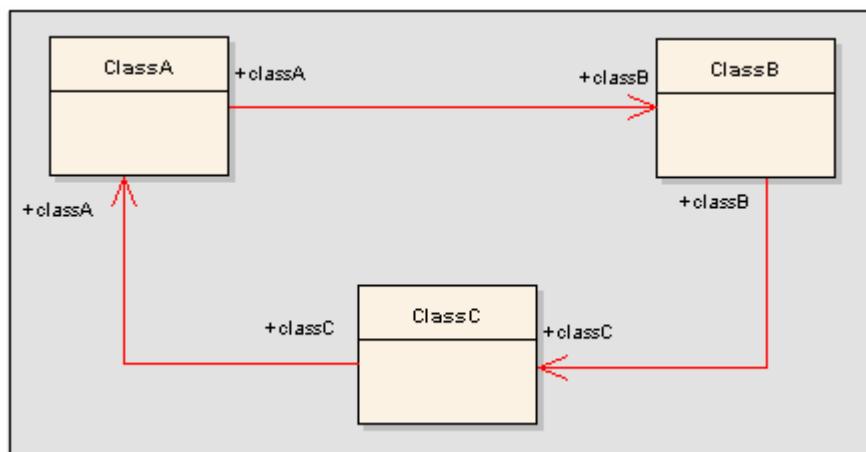
- DE does not support importing *many to many* association specified in the UML model. For example:



- XMI Import does not support the functionality of specifying the permissible values for enumerated attributes (for example: drop down, list box, or option button) within the UML model and then importing them into caTissue Suite. Similarly, XMI Import does not support the functionality of specifying concept codes for a Group, Form Title, and Attribute Labels within UML model and then importing them into caTissue Suite.

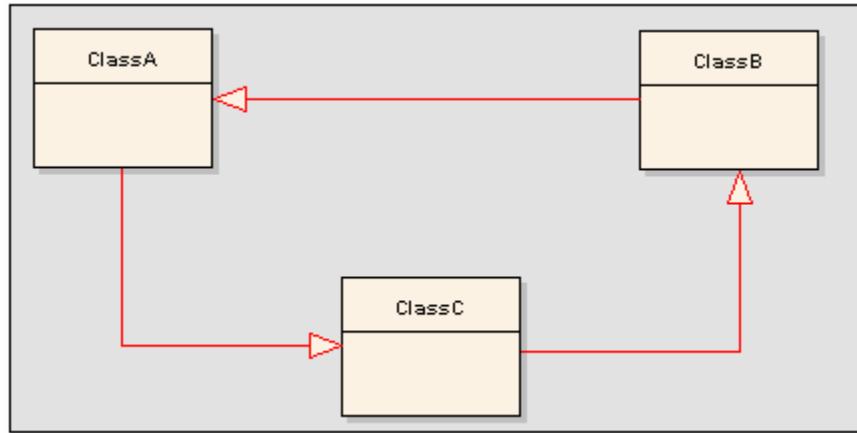
**Note:** You can specify permissible values and concept codes through the UI.

- Few unique cases of association between classes are not supported in XMI Import. They are:
  - Class A contains Class B, Class B contains Class C, and Class C contains Class A.



**Note:** You may however, create the same by first importing model having associations as Class A contains Class B, Class B contains Class C, and then later adding the containment association from Class C to Class A through the UI.

- b. Class C inherits from Class B, Class B inherits from Class A, and Class A inherits from Class C.



5. Unique case of hook entity linkage is not supported in XMI Import. That is:

Class B inherits from Class A. Class A is linked to hook entity P. Also, Class B is linked to hook entity P. Such a linkage gives error while querying on parent or child attributes from caCore like API due to ambiguity.

**Note:** You may however, just link the Class B to hook entity P, that is only the child or derived class to hook entity. This will not generate error while querying through API.

6. Collection data type is not recognized in XMI Import.

## Chapter 5: Consent Tracking

---

Informed consent refers to the process where a participant provides specific permissions for their collected biospecimens. These biospecimens are used for research purposes. Informed consent is related to a specific collection protocol. The collection protocol includes the definition of the informed consents associated with that protocol. Sometimes a participant can use the collected biospecimen under one or more circumstances. These specific permissions are referred to as *Consent Tiers*.

Examples of consent tiers are:

- Consent to allow use of collected biospecimen for specific studies described in the protocol.
- Consent to store and allow future use of collected biospecimen for IRB approved studies related to this disease.
- Consent to store and allow future use of collected biospecimen for IRB approved studies related to other diseases.
- Consent to establish contact in the future to gather additional medical information or to participate in other studies.
- Consent to allow genetic data generated from biospecimens to be shared with other authorized investigators through the Internet.
- Consent to allow anonymized genetic data generated from biospecimens. This data is posted to a publicly accessible data repository.
- Consent to allow collected biospecimens to be propagated *in vitro* or in living organisms.

In some cases, a collection protocol does not require informed consent. An Institutional Review Board (IRB) rules that a protocol does not require participant consent. It depends on the way in which the biospecimens are collected (For example, pre-existing vs. prospectively collected) and identified For example, anonymous, de-identified, or identified in the system.



Consent is not associated with a Distribution Protocol. However, if there is a direct one-to-one relationship between a collection protocol and a distribution protocol, the consent that is defined in the collection protocol directly pertains to the use of biospecimens as dictated by the distribution protocol.  
In the current version, the system does not support any association between collection and distribution protocol.

Consent tracking is a multi-step process outline in the figure below:

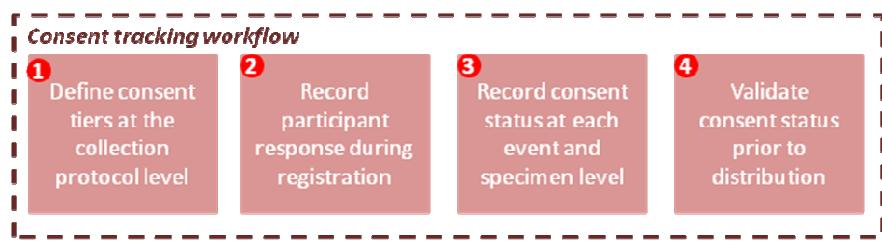


Figure 59: Consent Tracking Workflow

The consent tracking workflow is:

1. Defining consent tiers at the collection protocol level. For more information, refer to [Collection Protocols](#)**Error! Reference source not found..**
2. Registering a participant to the collection protocol where responses to consent, agree/disagree to individual consent tiers, by participant are recorded. For more information, refer to [Registering a Participant to a Collection Protocol](#).
3. Tracking consent tier status at the individual specimen level.
4. Validating consent status at the individual specimen level prior to distribution of biospecimen. For more information, refer to [Distribution of Ordered Items](#).

Custom consent tiers are required occasionally. The following procedure explains how to create a custom consent tier:

1. Navigate to the edit collection protocol page and select the required collection protocol.
2. Click **Add Consents**.
3. Click **Add More** to add a consent tier.
4. Navigate to **Define Events > View Summary > Save Collection Protocol**.

	<p>You cannot edit the consent tier after saving it. You can delete a consent tier before saving the collection protocol. If you change other attributes, an error message is displayed.</p>
---	--

The prerequisite for an informed consent process is that a participant agrees or disagrees to one or more consent tiers while registering the participant to a collection protocol.

A participant can respond to each consent tier by specifying one of the following options:

Table 20: Consent Status

Consent Status	Description
Yes	Participant agrees to the consent tier.
No	Participant does not agree to the consent tier
Not Specified	Participant does not record any response for a particular consent tier.
Withdrawn	Participant has withdrawn the agreement from the consent tier.

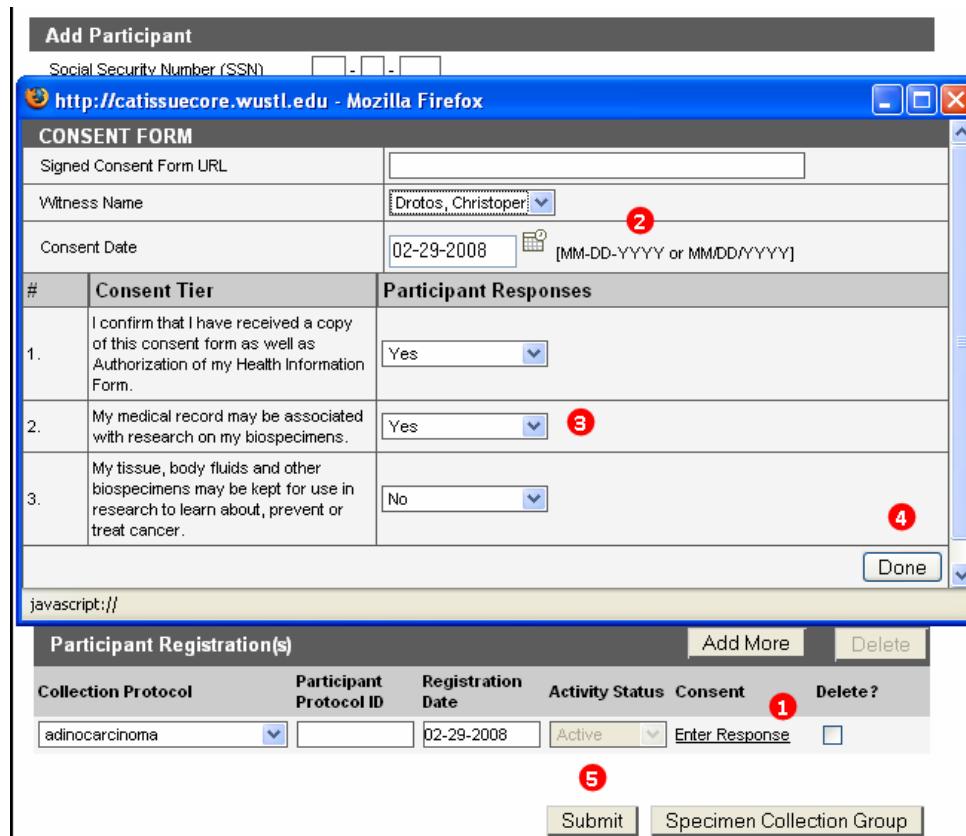
To capture participant responses at participant registration level:

1. After entering the participant details on the Add Participant page, click **Enter Response** under the Participant Registration(s) section. The Consent Form page is displayed.

2. Enter details such as Witness Name, Consent Date, and so on.
3. Enter **Participant Responses**. While registering a participant to a collection protocol that is, on the Add Participant page the Participant Responses can be recorded as Yes, No, or Not Specified.

	<p>You can set the consent status on the Edit Participant Registration page to Withdrawn. The other options are Yes, No, and Not Specified.</p>
---	---

4. Click **Done**.
5. Click **Submit** on the Add Participant page as shown in the following figure:



The screenshot shows the 'Add Participant' interface. At the top, there's a 'CONSENT FORM' section with fields for 'Signed Consent Form URL' (empty), 'Witness Name' (set to 'Drotos, Christopher'), and 'Consent Date' (set to '02-29-2008'). Below this is a table titled 'Participant Responses' with three rows. Row 1: 'I confirm that I have received a copy of this consent form as well as Authorization of my Health Information Form.' Response: 'Yes'. Row 2: 'My medical record may be associated with research on my biospecimens.' Response: 'Yes'. Row 3: 'My tissue, body fluids and other biospecimens may be kept for use in research to learn about, prevent or treat cancer.' Response: 'No'. Red numbers 2, 3, and 4 are placed over the 'Yes' dropdowns in rows 2 and 3, and over the 'No' dropdown in row 3. At the bottom of the consent form section is a 'Done' button. Below it is a 'Participant Registration(s)' table with one row. The table columns are: Collection Protocol (set to 'adnocarcinoma'), Participant Protocol ID (empty), Registration Date (set to '02-29-2008'), Activity Status (set to 'Active'), Consent (with a red '1' over it), and Delete? (checkbox). A red number '5' is placed over the 'Delete?' checkbox. At the bottom of the table are 'Submit' and 'Specimen Collection Group' buttons.

Figure60: Capturing Responses at Participant Registration Level

	<p>You can submit a participant registration without capturing the Participant Responses.</p>
---	---

The participant responses captured at participant registration level are reflected down the hierarchy on the Specimen Collection Group page and on the Specimen page. On Specimen Collection Group page or Specimen page, you cannot edit the Participant Responses field. You can enter the consent status for the consent on the Add Specimen Collection Group page as Yes, No, and Not Specified. You can also enter the consent status on the Edit Specimen Collection Group page as Yes, No, Not Specified, and Withdrawn.

To capture responses at Specimen Collection Group level:

- 1) Click the **Consents** tab on the Specimen Collection Group page.
- 2) Select the required responses.

- 3) Click the **Edit Specimen Collection Group** tab.
- 4) Click **Submit** to submit the consent status at SCG level.

CONSENT FORM		Withdraw All	
#	Consent Tier	Participant Responses	Verify Consent Status
1.	My tissue, body fluids and other biospecimens may be kept for use in research to learn about, prevent or treat cancer.	No	No
2.	My medical record may be associated with research on my biospecimens.	Yes	Yes
3.	I confirm that I have received a copy of this consent form as well as Authorization of my Health Information Form.	Yes	Yes

**Figure61: Capturing Responses at SCG Level**

After submitting the consent status, if the consent status at the SCG level is different than the consent status at the Participant registration level, then the system displays the following figure:

Label	Type	Storage Container Location	Class Name
1343	Fresh Tissue	Virtually Located	Tissue
1343_3	Fresh Tissue	Virtually Located	Tissue
1343_1	Fresh Tissue	Virtually Located	Tissue
1344	DNA	Virtually Located	Molecular
1343_2	Fresh Tissue	Virtually Located	Tissue

Apply the current status to only non-conflicting specimen(s)

Apply the current status on all specimens

Done

**Figure62: Varying Consent Status – SCG Level**

You can select Apply or ApplyAll. If you select Apply, it preserves the status of all conflicting consent status at specimen level. If you select ApplyAll, it overrides the individual consent status at specimen level.

**F.Y.I.** You can submit a specimen collection group without any associated consent data.

To capture responses at Specimen level:

- 1) Navigate to the specimen page.
- 2) Click **Consents** on the Specimen page.

## Chapter 5: Consent Tracking

- 3) Select the required responses.
- 4) Click **Submit** as shown in the following figure:

The screenshot shows a web-based consent form interface. At the top, there are tabs: Specimen Details, Events, View Surgical Pathology Report, View Annotation, and **Consents**. The **Consents** tab is highlighted with a red circle labeled **1**. Below the tabs is a header bar with the title "CONSENT FORM" and a "Withdraw All" button. The main area contains a table with three columns: "#", "Consent Tier", and "Participant Responses". The rows represent different consent tiers:

#	Consent Tier	Participant Responses	Verify Consent Status
1.	I confirm that I have received a copy of this consent form as well as Authorization of my Health Information Form.	Yes	Yes
2.	My tissue, body fluids and other biospecimens may be kept for use in research to learn about, prevent or treat cancer.	No	Not Specified
3.	My medical record may be associated with research on my biospecimens.	Yes	Yes

At the bottom of the form are four buttons: **Submit**, **Derive**, **More**, and **Derive Multiple**. A red circle labeled **4** is positioned over the **Submit** button.

Figure63: Capturing Responses at Specimen Level

If the consent status at the specimen level is different than the Participant responses at participant registration level, then the system displays the following figure:

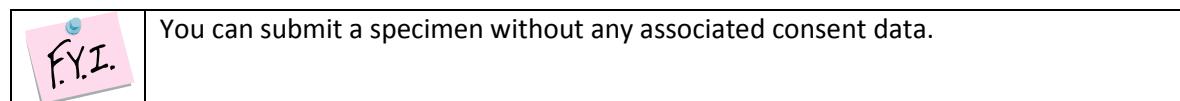
The screenshot shows a table of specimen details with columns: Label, Type, Storage Container Location, and Class Name. The data is as follows:

Label	Type	Storage Container Location	Class Name
1343	Fresh Tissue	Virtually Located	Tissue
1343_3	Fresh Tissue	Virtually Located	Tissue
1343_1	Fresh Tissue	Virtually Located	Tissue
1344	DNA	Virtually Located	Molecular
1343_2	Fresh Tissue	Virtually Located	Tissue

Below the table are two buttons: "Apply the current status to only non-conflicting specimen(s)" with an **Apply** button, and "Apply the current status on all specimens" with an **ApplyAll** button. A "Done" link is also present.

Figure64: Varying Consent Status – Specimen Level

You can select Apply or ApplyAll. If you select Apply, it preserves the status of all conflicting consent status at specimen level. If you select Apply All, it overrides the individual consent status at specimen level.



A participant can withdraw the consents for using specimen and associated data for studies. The system allows you to change the consent status of one or more consent tiers to withdrawn at edit participant registration or specimen group or specimen level. When one or more but not all consents are withdrawn

at participant registration or specimen group or specimen level, the system displays the following figure:

Label	Type	Storage Container Location	Class Name
1343	Fresh Tissue	Virtually Located	Tissue
1343_1	Fresh Tissue	Christiana Care biospecim	Tissue
1344	DNA	Christiana Care biospecim	Molecular
1343_3	Fresh Tissue	Christiana Care biospecim	Tissue
1343_2	Fresh Tissue	Christiana Care biospecim	Tissue
1345	Serum	Virtually Located	Fluid

**What do you want to do with the withdrawn specimen/s?**

Discard the Specimen and all Sub Specimen(disable)	<input type="button" value="Discard"/>
Return Specimen to Collection Site	<input type="button" value="Return"/>
Perform no action on the Specimens	<input type="button" value="Reset"/>

Done

Figure65: Withdraw Consent

You can withdraw consent and specify to return or discard the specimens. You can withdraw the consents at following levels:

A) Participant level

- i. All specimens are marked as unavailable. That is, the value in the IsAvailable field is set as *False*.
- ii. All specimens add a Disposal Event or a Distribution Event.
- iii. All specimens have a activity status as *Disabled*.
- iv. All parent SCG activity status is set as *Disabled*.
- v. Participant Registration activity status is set as *Disabled*.

	<p>The participant registration is not disabled if one or more consent is withdrawn. You cannot withdraw all the consents. The withdrawn status at the participant registration level is propagated to the SCG and specimens under it. If you withdraw all the consents, you can dispose or return all the specimens. Once you dispose all the specimens you can disable the registration. You cannot disable a registration until all the SCGs and Specimens in that registration are disabled.</p>
---	--

B) SCG level

Steps i-iv from Participant level are applicable only for the selected SCG.

The registration remains active and the concerned consent tier(s) are marked as *Withdrawn*.

C) Specimen level

Steps i-iii from Participant level are applicable only for that specimen.

The registration remains active and the concerned consent tier(s) are marked as *Withdrawn*.

If you select Perform no action on the Specimens, then the consent status is updated to *Withdrawn* and no action is taken on the specimens.

## **Chapter 6: Handling Biospecimens – Technicians and Supervisors**

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You can perform all the biospecimen operations on the Biospecimen Data tab. In this tab, you can perform the following operations:

1. Register a participant to a protocol.
2. Accession new specimens.
3. Create aliquots and derivatives of specimens.
4. Edit specimens and add new events like Thaw, Frozen, and so on to specimens.
5. Create specimen arrays.
6. Distribute specimens and arrays.
7. Track consents.



In case the Supervisor or Technician encounters any issues, they can contact the Administrator. For example, if there are not enough storage containers to place aliquots, you can contact the Administrator. The Administrator then adds new storage containers or assigns privileges to access other storage containers.

### **Registering Participants and Collecting Biospecimens**

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A participant is an individual from whom specimens are collected. This version of caTissue Suite supports human participants only. In caTissue Suite, you can collect the biospecimens from a participant only under an IRB approved collection protocol, that is, you must register a participant to a collection protocol in order to collect specimens.

The figure below outlines a high level look at different workflows:

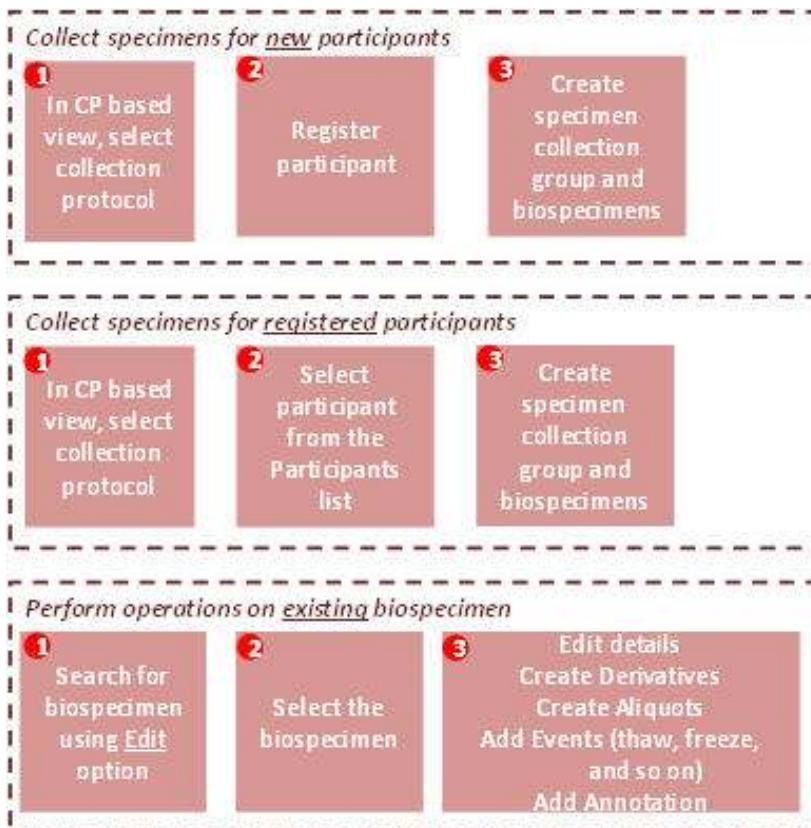


Figure66: Workflow to Collect Specimens and Performing Operations on them

### Collection Protocol (CP) Based View

The Collection Protocol (CP) based view is an integrated view of the entire biospecimen data in the system. The collection protocols defined using the administrative tab is populated in the CP based view. Anticipated events are generated according to the events that were specified in the collection protocol. The system generates the anticipated specimens according to the specimen requirements. The specimen requirements are mentioned under events. You can define the requirements when you define the collection protocols. As a result, when a participant is registered to a collection protocol, the anticipated SCGs and anticipated specimens are listed under the Specimen Details section.

Using the CP based view one can perform the following actions:

- Register a new participant to a protocol.
- Create, edit, or view specimen collection groups.
- Create, edit, or view new specimens, derivatives and aliquots.
- Add new events to specimens.

The screenshot shows the Biospecimen Data interface. The top navigation bar includes links for HOME, ADMINISTRATIVE DATA, BIOSPECIMEN DATA (highlighted with a red circle containing '1'), SEARCH, SUMMARY, and HELP. The left sidebar contains a 'Collection Protocol' dropdown (marked 2) set to 'generic collection protocol', a 'Participant (Protocol ID)' dropdown (marked 3) showing 'CIDTEN, PATIENT (N/A)', and a 'Specimen Details for CIDTEN, PATIENT (N/A)' section listing two collection points (marked 4). The main right pane is titled 'Edit Participant' and shows fields for Social Security Number (SSN), Name (CIDTEN, PATIENT), Birth Date (10-15-1988), Vital Status (Alive), Death Date, Gender (Female Gender selected), Sex Genotype, Race (Unknown selected), Ethnicity, and Activity Status (Active). Below these are sections for 'Medical Identifier(s)' and 'Participant Registration(s)', both with 'Add More' and 'Delete' buttons. At the bottom are 'Submit' and 'Specimen Collection Group' buttons.

Figure67: Collection Protocol Based View

1. Click the **Biospecimen Data** tab. The CP based view opens as shown in the preceding figure.
2. Select a CP from the collection protocol drop-down list. The system displays the list of participants already registered to the selected collection protocol.
3. To register a new participant, click **Register New**.
4. When you select an existing participant, the system auto populates event points and the specimen hierarchy fields in the specimen details window.
5. The right pane of the screen displays the details of the participant. (Marked 5 in the preceding figure).



When you click any node on the tree, the participant or specimen details list is refreshed on the right pane of the screen. It displays the details of the selected object. You can perform all the biospecimen operations on this screen.

## Registering a Participant to a Collection Protocol

The Supervisor performs the activity of registering a participant to a collection protocol.

To register a participant to a protocol:

1. Click the **Biospecimen Data** tab. The CP based view opens as shown in the following figure.
2. Select the collection protocol for which you want to register the participant.
3. Click **Register New**. The right pane of the screen displays the participant form.

The screenshot shows the 'Add Participant' screen in the caTissue Suite. The participant is registered under the 'BRCA1' protocol. The registration date is 03-07-2008. The activity status is set to 'Active'. There is a note indicating that consent tiers are defined for this protocol.

Collection Protocol	Participant Protocol ID	Registration Date	Activity Status	Consent
BRCA1	BRCA1-2	03-07-2008	Active	None Defined
B_C_I_P	12548	03-07-2008	Active	Edit Response

Figure68: Registering a Participant

4. Enter the available information about the participant  
**Note:** The Participant attributes are not mandatory.
5. You can enter one or more medical identifiers for a participant. The source indicates the site that generated the ID.
6. To register a participant based on deidentified id, enter a Participant Protocol ID.
7. If consent tiers are defined for a collection protocol, click **Edit Response** under Consent to capture the Participant response.



Use the Add More button next to Participant Registration(s) to register the same participant to more than one CP.

8. Click **Submit**.



The Activity Status of a participant is set to *Active* by default. If a participant does not want to participate in the Collection Protocol, then the Activity Status of the participant changes to *Closed* or *Disabled*. *Closed* means no future biospecimen collection is possible but SCG and already accessioned biospecimens associated with the participant are visible for query and distribution. *Disabled* means already present biospecimens are not visible for query or distribution and that no future collections can take place. It indicates that the participant and associated SCGs and specimens are deleted from the system.

On submitting a participant, the system scans the database to check if you are entering an existing participant. This is called as the participant duplicate check. The duplicate check algorithm is a sophisticated point-based system. In this system the points are assigned to each attribute and matches are selected based on a cut-off value. The system then displays all possible participant matches.

Possible Participant Matches								
	Last Name	First Name	Middle Name	Birth Date	Death Date	Vital Status	Gender	S N
<input type="radio"/> ①	Man	Super				Unknown	Unspecified	
<input type="radio"/>	man	bat				Unknown	Unspecified	

**2**  Ignore matches and create new participant
 Lookup again **3**

**4** Submit
Specimen Collection Group

**Figure69: Participant Duplicate Check**

After reviewing the matches, you can select one of the following actions:

1. Select one of the matches as the new participant as shown in the preceding figure.
2. Select **Ignore matches and create new participant** to ignore all the matches and create a new participant.
3. Select **Lookup again** to look up again after making some changes in the participant details.
4. After selecting one of the above options, click **Submit**.

The participant is registered to that CP. The system populates the anticipated SCGs and specimens of the participant in the specimen detail window.

 The participant-matching algorithm is written based on a similar algorithm used at Barnes Jewish Hospital, Washington University, Saint Louis. However, the system is designed in such a way that the algorithm can be replaced or customized easily. Please refer to the caTissue Technical Guide for more details or if you wish to customize this algorithm.

### *Registering a Participant to a Longitudinal Collection Protocol*

Registering a participant to a longitudinal collection protocol follows the same steps as described in registering a participant to a protocol. Once the participant is registered to the main CP, the specimen details tree displays the hierarchy of sub-protocols and specimen collection groups present within the main CP.

Each sub-protocol requires a registration like its parent protocol. Once the participant is registered to the parent protocol, the caTissue Suite creates automatic registrations for the sub-protocols. The sub-protocols can be predicted until a set of arms is encountered. All anticipated specimen collection groups and specimens are created for that sub-protocol along with automatic registrations. The participant needs to be registered on any one arm from a set of arms. Registration to one of the selected arms can only be predicted after the participant completes his set of specimen collections under the prior sub-protocols.

The screenshot shows the Biospecimen Data tab of a clinical information system. At the top, there are tabs for Home, Administrative Data, Biospecimen Data (highlighted with a red circle 1), Search, Summary, and Help. The Biospecimen Data tab has a sub-menu with Collection Protocol, Clinical Participant, and View Specimen Details. The Collection Protocol section shows 'Osteosarcoma' selected from a dropdown (2). The Clinical Participant section shows 'Pat 2 (N/A)' in the Name field (3). The View Specimen Details section shows a tree view of specimen details for 'Pat 2 (N/A)' with numbered callouts: (4) indicates the tree icon; (5) points to 'Osteo Pre-Surgery'; (6) points to 'T1:01 Wk 1'; (7) points to 'Post OP MAP'. Below the tree, there are sections for Medical Identifier(s) and Participant Registration(s).

Figure70: Registering a participant to a longitudinal protocol

To register a participant to a longitudinal protocol:

1. Click the **Biospecimen Data** tab. The CP based view is displayed.
2. Select the longitudinal protocol from the collection protocol drop-down list.
3. Click **Register New** to register a new participant as shown in the preceding figure. The Add participant page is displayed.
4. Enter the participant details and click **Submit**.
5. On submitting a participant the specimen details tree is refreshed to show the sub-protocol hierarchy. Automatic registrations are created for sub-protocols that can be predicted, that is until a set of arms is reached.
6. Anticipated specimen collection groups and specimens are created for sub-protocols to which the participant is registered.
7. Once a set of arms is encountered, no further automatic registration occurs. A manual registration is required to register an arm or any other following sub-protocol to begin the automatic registration process until another set of arms is encountered.



Selecting a sub-protocol in the specimen details tree displays the participant registration details to the sub-protocol.

### Registering a Participant to an Arm Manually

Automatic registration ceases once a set of arms is encountered. You must do a manual registration to register the participant under an arm or to register the participant to other following sub-protocols. This triggers the automatic registration process on following sub-protocols until another set of arms is encountered.

The screenshot shows the 'Biospecimen Data' tab selected in the top navigation bar. On the left, a 'Collection Protocol' dropdown is set to 'Osteosarcoma' (marked with red circle 2). Below it, a 'Participant (Protocol ID)' dropdown shows 'Pat 1 (N/A)' and 'Pat 2 (N/A)', with 'Pat 2 (N/A)' selected (marked with red circle 3). The main area is titled 'ADD PARTICIPANT REGISTRATION'. It includes fields for 'Sub Collection Protocol' (Post GR MAPfin), 'Participant Name' (Pat 2), 'Participant Protocol ID' (empty), 'Study Calendar Event Point' (7.0 Days), 'Registration Date' (01-16-2008, marked with red circle 6), and 'Offset' (0). A 'Submit' button is at the bottom left (marked with red circle 7). To the right, a 'Specimen Collection Group' section is visible. On the left, a 'Specimen Details for Pat 2 (N/A)' tree view shows various sub-protocols and their anticipated dates, with 'Post GR MAPfin' expanded (marked with red circle 5) and 'Post GR MAP' highlighted (marked with red circle 4).

**Figure71: Manual Registration to an Arm**

To register a participant to an arm manually:

1. Click the **Biospecimen Data** tab. The CP based view is displayed.
2. Select the longitudinal collection protocol.
3. Select an already registered participant.
4. The specimen details tree displays the sub-protocol hierarchy. It also displays the anticipated SCGs under the sub-protocol to which the participant is registered.
5. Click an arm to manually register the participant to the selected arm.
6. The Add Participant Registration page is displayed.
7. Click **Submit** to register the participant to the selected arm as shown in the preceding figure.



On registering the participant to an arm, the system creates anticipated SCGs for the arm as well as automatic registrations are carried out for the following sub-protocols till the next set of arms is encountered.

### Offsetting a Registration or Specimen Collection and Shift of Anticipated Dates

Biospecimen banks need to anticipate the biospecimen date. At the same time it must also allow for shifts of anticipated time points. For example: the shifts in time points are observed frequently in chemotherapy protocols.

Once a participant is registered to the parent protocol, anticipated dates are displayed on all the sub-protocols. The sub-protocols have a study calendar event point in the specimen details tree. The SCGs

within the sub-protocols display the anticipated dates if the participant is registered to it. If at any time there is a delay in either participant registration to a sub-protocol or in specimen collection, then an offset is entered corresponding to the sub-protocol registration or to the anticipated SCGs. The offset entered to a registration or to a SCG is carried forward to all the following objects and the recalculated anticipated dates are displayed in the specimen details tree.

The screenshot shows the 'Edit Participant Registration' screen. At the top, there's a navigation bar with 'HOME', 'ADMINISTRATIVE DATA', 'BIOSPECIMEN DATA' (highlighted with a red circle 1), 'SEARCH', 'SUMMARY', and 'HELP'. Below the navigation is a 'Collection Protocol' dropdown set to 'Osteosarcoma' (red circle 2). A 'Participant (Protocol ID)' dropdown below it shows 'PAT 55 (N/A)' and 'Pat 99 (N/A)' (red circle 3). To the right, the main form is titled 'EDIT PARTICIPANT REGISTRATION' with a note '\* indicates a required field'. It includes fields for 'Sub Collection Protocol' (set to 'Osteo Pre-Surgery'), 'Participant Name' (set to 'Pat 99'), 'Participant Protocol ID', 'Study Calendar Event Point' (set to '0.0 Days'), 'Registration Date' (set to '01-01-2001' with a calendar icon), 'Offset' (set to '5'), and 'Activity Status' (set to 'Active'). At the bottom are 'Submit' (red circle 7) and 'Specimen Collection Group' buttons. On the left, a sidebar titled 'Specimen Details for Pat 99 (N/A)' lists events: 'Osteo Pre-Surgery: 2001-01-01' (red circle 4), 'Osteo Post Surgery: 2001-01-08', 'Osteo Post ttm Follow UP: 2001-01-28', and 'Osteo Relapse: 2001-01-31'.

**Figure72: Display of anticipated dates and offsetting a registration or specimen collection**

To add an offset to a sub-protocol registration:

1. Click the **Biospecimen Data** tab. The CP based view is displayed.
2. Select a longitudinal collection protocol.
3. Select an already registered participant.
4. The specimen details tree displays the sub-protocol hierarchy along with the anticipated dates.
5. Select a sub-protocol to display the registration details of the sub-protocol as shown in the preceding figure.
6. Enter a value in the Offset field. It signifies a delay in anticipated registration.
7. Click **Submit**.



Similar offsets can also be applied to specimen collection groups. The system applies the offsets to all following sub-protocols and specimen collection groups and displays the recalculated anticipated dates in the specimen details tree.

## CP Based Data Entry (New Feature in Suite Release)

The CP based data entry is a new feature in Suite, which allows you to enter all the specimens for a particular event in a single-click. This feature can be used only if you have specified the specimen details during creation of the protocol, that is for planned protocols.

The CP based data entry is based on the following principles:

- In case of planned protocols, the details of specimens collected for each event is predefined during collection protocol creation.
- The tissue bank receives all the defined specimens as per protocol definition during the actual collection process.
- However, it is possible that the tissue bank can receive specimens that are inconsistent with the defined protocol. Therefore, there needs to be a provision for receiving more or less number of specimens that is a deviation from the protocol definition.



For more information on creating a collection protocol, refer to [Collection Protocols](#).

### What are anticipated specimens?

When a participant is registered to a protocol, the system automatically creates *anticipated* specimens for the events based on the protocol definition. The anticipated specimen is similar to the actual specimen except for the Collection status of the specimen is set to *Not collected*.

If you do not receive all the anticipated specimens at a given time or you do not expect them in the near future:

- a) Navigate to the Edit Specimen Collection Group page for that SCG under which specimens can be collected.
- b) Set the SCG Collection Status to Complete and click Submit. The application navigates to specimen details page.
- c) If the specimen is not received, clear the Collected check box for the parent specimen or Created check box for the child specimen. These specimens remain as anticipated specimens.
- d) You can also fire a disposal event for the required specimen by setting its Activity Status to Disabled.

### How does CP based data entry work?

Whenever a participant is registered, the system automatically creates *anticipated* specimens for all the events in the protocol. The following diagram depicts the workflow of using the CP based data entry feature:

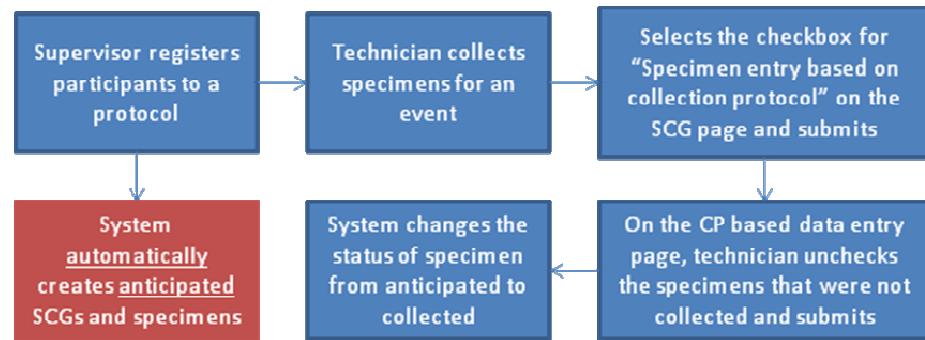


Figure73: CP based data entry workflow

The figure consists of two screenshots of a software interface for biospecimen management.

**Step One – Specimen collection group page:**

- Collection Site: BWH (highlighted with a red circle labeled 1).
- Collection Status: Complete (highlighted with a red circle labeled 2).
- Comments: A note says "Specimen entry based on collection protocol".
- Buttons: "Submit" (highlighted with a red circle labeled 3), "Add Specimen", and "Add Multiple Specimens".

**Step Two: CP based data entry page:**

- Specimen Details table:
 

Label	Barcode	Type	Qty	Conc.	Location	Apply First to All	Collected?
122	122	Fresh Tissue	10.0		Virtual	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
121	121	Vehicle Blood	20.0			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

 (highlighted with a red circle labeled 5).
- Aliquot Details table:
 

Parent	Label	Barcode	Type	Qty	Conc.	Locations	Apply First to All	Created?
122	122_1	122_1	Fresh Tissue	5.0		Wat_Tissuebox	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
122	122_2	122_2	Fresh Tissue	5.0		Wat_Tissuebox	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

 (highlighted with a red circle labeled 6).
- Buttons: "Submit" (highlighted with a red circle labeled 7).

Figure74: Workflow to perform CP based data entry

A specimen Collection Group (SCG) is an event that results in the collection of one or more biospecimens from a participant at the given time.

Click anticipated specimen collection group ①. The SCG page is displayed on the right pane of the screen.

#### Step One: Specimen collection group (SCG) page:

1. Select a collection site from the Collection Site drop-down list as shown in the preceding figure.
2. Set the Collection Status of the SCG to **Collected**.

	<p>If a specimen is collected and it is not part of the collection protocol, you can add it as a new specimen using the CP based view. Click Add Specimen or Add Multiple Specimen on the Edit Specimen Collection Group page.</p>
--	--

3. Check the Specimen entry based on collection protocol check box.
4. Click **Submit**.

#### Step Two: Click **Submit** to view the CP based data entry page.

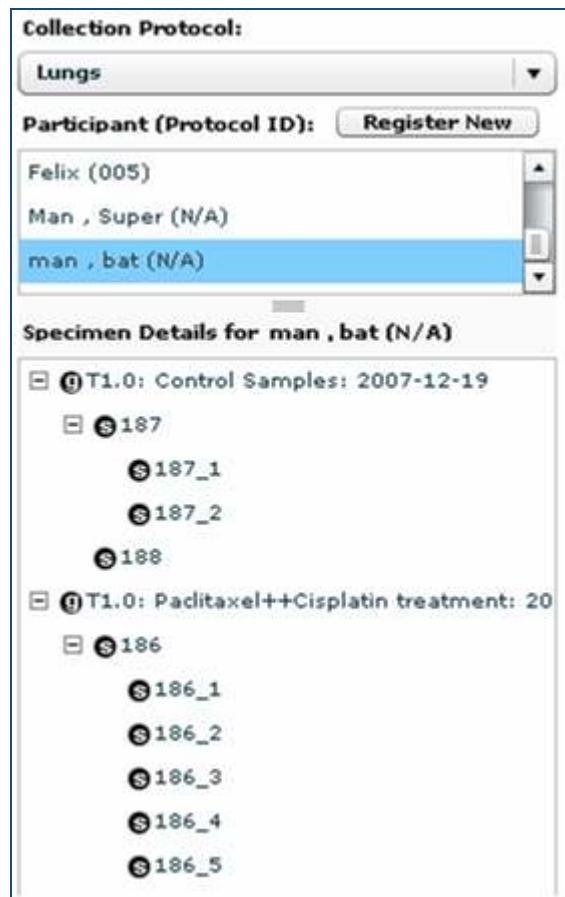
5. Review the specimen details and clear the specimens that are not collected. Storage location gets assigned to each of the specimen based on the CP design as shown in the following figure:

Specimen details						
	Type	Qty	Conc.	Location	<input type="checkbox"/> Apply First to All	
<input checked="" type="radio"/>	Whole Blood	50.0	[a]	Virtual		
<input type="radio"/>	Fresh Tissue	25.0	[b]			
<input type="radio"/>	Total Nucleic Acid	100.0	[c]	Avion Labs_-80	2	5 

Figure75: CP based Data Entry: Specimen Details Page

- a. Indicates the whole blood specimen is stored virtually.
  - b. Indicates that the fresh tissue specimen was allocated a manual location. You can click the  icon and choose a valid location from the map.
  - c. Indicates that the total nucleic acid specimen was allocated an auto location. In this case the location is auto populated in the boxes based on the container restrictions.
6. Review the child specimens and clear the specimens that are not created.
7. Click **Submit**.

The system assigns storage locations to each of the specimen based on the collection protocol design.



**Collection Protocol:**  
Lungs

**Participant (Protocol ID):** Register New  
Felix (005)  
Man , Super (N/A)  
**man , bat (N/A)**

**Specimen Details for man , bat (N/A)**

- ⊖ ① T1.0: Control Samples: 2007-12-19
  - ⊖ ② 187
    - ③ 187\_1
    - ③ 187\_2
    - ③ 188
- ⊖ ① T1.0: Paclitaxel++Cisplatin treatment: 20
  - ⊖ ② 186
    - ③ 186\_1
    - ③ 186\_2
    - ③ 186\_3
    - ③ 186\_4
    - ③ 186\_5

Figure76: Specimen Details before Specimen Collection

In the preceding figure, icons for the specimen collection group and specimens are in **black** color indicating that they are not yet collected. That is, they are anticipated.

The screenshot shows a software interface for managing biospecimens. At the top left, there is a dropdown menu labeled "Collection Protocol" with "Lungs" selected. Below it is a "Participant (Protocol ID)" field containing "Felix (005)" with a "Register New" button. A scrollable list displays participants: "Man , Super (N/A)" and "man , bat (N/A)", with the latter being the active participant.

Under the active participant, a section titled "Specimen Details for man , bat (N/A)" is shown. It contains two main entries under a tree view:

- T1.0: Control Samples: 2007-12-19**
  - 187
    - 187\_1
    - 187\_2
  - 188
- T1.0: Paclitaxel+++Cisplatin treatment: 20**
  - 186
    - 186\_1
    - 186\_2
    - 186\_3
    - 186\_4
    - 186\_5

**Figure77: Specimen Details after Specimen Collection**

In the preceding figure, the icons for the first specimen collection group and first three specimens are changed to indicate that they are actual specimens. Specimen labeled 188, the second event, and specimens of the second event are in black color icons indicating that they are not yet collected.

## Specimen Operations

---

You can perform the following operations on a specimen:

1. Aliquoting a biospecimen.
2. Creating a biospecimen derivative.
3. Adding multiple specimens.
4. Adding an event. For example: thawing, freezing, checkin, checkout, and so on.
5. Tracking consent tier status at specimen level.
6. Performing bulk operations.

A technician can perform all the preceding activities related to specimen and specimen arrays. The Technician does not have access to track consent responses. A Supervisor can perform this activity.

### What is the difference between an aliquot and a derivative?

Both aliquots and derivatives are child specimens, that is they are created from another specimen which is a parent specimen. An aliquot is a division of the parent specimen (fluid) where the child inherits **all** the properties of the parent other than the quantity. For example: five 2ml blood aliquots are created from a 10ml blood specimen. In case of the derived biospecimen, the child specimen is a processed derivative from the parent specimen. For example: DNA is extracted from tissue.

## Aliquoting a Biospecimen

The following procedure outlines how to aliquot a biospecimen:

1. On the Biospecimen Data tab, click **Aliquot** under Specimen.
2. Enter the Parent Specimen Label or Barcode of which a derivative is to be created.
3. Enter the Aliquot Count.

The screenshot shows the caTissue Suite software interface. The left sidebar has a blue background with white text and icons. The 'SPECIMEN' option is highlighted with a red circle containing the number '1'. The main area has a white background with a dark header bar. The header bar includes links for HOME, ADMINISTRATIVE DATA, BIOSPECIMEN DATA, SEARCH, SUMMARY, and HELP. Below the header is a message: '\* indicates a required field'. The main form is titled 'Create Aliquot'. It has two radio buttons: 'Parent Specimen Label' (selected) and 'Barcode' (unselected). To the right of these buttons are input fields: 'IBB.' and 'Barcode'. Below these fields are two input fields: 'Aliquot Count' (containing '2') and 'Quantity per Aliquot' (containing '10'). At the bottom right of the form is a 'Submit' button with a red circle containing the number '5'.

Figure78: Aliquoting Biospecimen: Create Aliquot Page

4. Enter the Quantity per Aliquot if required as shown in the preceding figure.



If Quantity per Aliquot is not entered, then the system divides the available quantity in equal amounts in each of the aliquot.

5. Click **Submit**. The Create Aliquot page is displayed as shown in the following figure:

\* indicates a required field

Create Aliquot <span style="color: red;">6</span>			
<input checked="" type="radio"/> Parent Specimen Label	186	* Aliquot Count	2
<input type="radio"/> Barcode		Quantity per Aliquot	10
<input type="button" value="Resubmit"/>			

Aliquot <span style="color: red;">7</span>			
Class	Molecular	Type	DNA
Tissue Site	Not Specified	Tissue Side	Not Specified
Pathological Status	Not Specified	Concentration	0.0 µg/µl
Initial Available Quantity	30.0 µg	Current Available Quantity	10.0 µg
Created On	02-21-2008 <input type="button" value="Calendar"/>	[MM-DD-YYYY or MM/DD/YYYY]	
#	* Initial Quantity	* Location	<span style="color: red;">c</span>
1.	<span style="color: red;">b</span> 10.0 µg	<input type="radio"/> Is Virtually Located? <input checked="" type="radio"/> Name Avion Labs_BloodBox_2 <input type="button" value="Pos1"/> 9 <input type="button" value="Pos2"/> 1 <input type="button" value="MAP"/>	
2.	10.0 µg	<input type="radio"/> Is Virtually Located? <input checked="" type="radio"/> Name Avion Labs_BloodBox_2 <input type="button" value="Pos1"/> 9 <input type="button" value="Pos2"/> 2 <input type="button" value="MAP"/>	
<span style="color: red;">d</span> <input type="checkbox"/> Do you want to store all aliquot(s) in same container?		<span style="color: red;">e</span> <input type="checkbox"/> Do you want to dispose parent specimen?	
<span style="color: red;">f</span> <input type="checkbox"/> Print Labels		<span style="color: red;">8</span> <input type="button" value="Submit"/>	

**Figure79: Creating Aliquot**

6. The Create Aliquot section displays the aliquots details specified earlier. You can change the Aliquot Count and Aliquot Quantity using the Resubmit button. The Aliquot page is refreshed based on the count and quantity entered.
7. The Aliquot section displays the following information:
  - a. Characteristics of the parent specimen. For example, Type, Class, and so on.
  - b. Quantity of the aliquots you have specified.
  - c. Storage location for each of the aliquots that you can specify.
  - d. Aliquot storage in same container. Select the Do you want to store all aliquot(s) in same container? check box to store all the aliquots created in one container. The storage locations are refreshed accordingly.
  - e. Activity Status of the parent specimen. Select the Do you want to dispose parent specimen? check box to set the activity status of the parent specimen to Closed in the system.
  - f. Print Labels. Select the Print Labels check box to print the label for the derived specimen. For more information on print labels, refer to the *Administration Guide*.
8. Click **Submit**. The Aliquot Creation Summary page is displayed as shown in the following figure:

Aliquot Creation Summary <span style="color: red;">9</span>				
<b>Class</b>	Fluid			
<b>Type</b>	Gastric Fluid			
<b>Tissue Site</b>	OROPHARYNX			
<b>Tissue Side</b>	Not Specified			
<b>Pathological Status</b>	Non-Malignant			
<b>Available Quantity</b>	5.0 ml			
<b>Concentration</b>	µg/µl			
<b>Created On</b>	03-10-2008 [MM-DD-YYYY]			
#	Label	Initial Quantity	Barcode	Location
1.	1025_1_3	5.0 ml	1025_1_3	BJH_Vial_34 1 1
2.	1025_1_4	5.0 ml	1025_1_4	BJH_Vial_35 1 1

[More](#)

**Figure80: Aliquot Creation Summary**

- The Aliquot Creation Summary page displays all the details for the newly created aliquots. For example: Class, Type, Label, Storage location, and so on.

You can also perform aliquoting using the CP based view.

### Creating Biospecimen Derivative

You can create a derivative from the existing biospecimen.

To create a derivative biospecimen:

- Click the **Biospecimen Data** tab.
- Click **Derive** under Specimen on the left pane of the screen. The system displays the derive specimen page on the right pane of the screen as shown in the following figure.
- Enter the Parent Specimen Label or Barcode.
- Enter all the details of the child specimen.
- Enter the details of any aliquots you wish to create from the derived specimen.
- Check the **Print Labels** check box to print the label for the derived specimen. For more information on print labels, refer to the *Administration Guide*.
- Click **Submit** to create the derived specimen.

**Create Derived Specimen**

\*  Parent Specimen Label: 1025\_1  
 Parent Specimen Barcode: 2

\*  Class: Molecular  
 Type: DNA

Created On: 03-10-2008 [MM-DD-YYYY or MM/DD/YYYY]

Concentration: 50  $\mu\text{g}/\mu\text{l}$

\* Initial Quantity: 50  $\mu\text{g}$

Is Virtually Located?

\* Storage Position:  
 Name: BJH\_Vial\_36 Pos1: 1 Pos2: 1  
 [ ] [ ] [ ] MAP

Comments:

External Identifier(s)		Add More	Delete
#	Name	Value	Delete?
1.	[ ]	[ ]	<input type="checkbox"/>

Do you want to create aliquot(s)? Aliquot Count: [ ] Quantity per Aliquot: [ ]

Print Labels

**Submit** **More**

Figure81: Creating Derivatives

### Adding Multiple Specimens

This feature allows you to add multiple specimens into the system without having to go through the entire process of repeatedly adding specimen. This is a time saving feature and does not require the specimens being entered to share the same characteristics.

To add multiple specimens into the system, perform the following steps:

1. Click the **Biospecimen Data** tab.
2. Click **Multiple** under Specimen on the left pane. The Multiple Specimen page is displayed as shown in the following figure:

The screenshot shows the 'caTissue Suite' software interface. On the left, a sidebar lists 'Collection Protocol Based View', 'PARTICIPANT', 'SPECIMEN' (with 'Blood and Biopsy Study' highlighted), 'SPECIMEN ARRAY', 'GROWTH', 'Specimen Report Generation', and 'Order Selection'. The main area is titled 'Multiple Specimen' and contains a table with four rows. Each row represents a specimen with columns for 'Specimen ID', 'Specimen Name', and 'Status'. Row 1: Specimen 1, Blood and Biopsy Study\_15, Not Specified. Row 2: Specimen 2, Blood and Biopsy Study\_15, Not Specified. Row 3: Specimen 3, Blood and Biopsy Study\_15, Not Specified. Row 4: Specimen 4, Blood and Biopsy Study\_15, Not Specified. Above the table are buttons for 'Copy' (labeled 'b'), 'Paste' (labeled 'd'), 'Add More' (labeled 'IV'), 'Delete' (labeled 'I'), and 'Submit' (labeled 'D'). To the left of the table, there are sections for 'Specimen Group Name' (labeled 'II') and 'Class' (labeled 'a'). Below the table, there are sections for 'Type', 'Tissue Site', 'Tissue Side', 'Pathological Status', 'Created on', 'Quantity', 'Concentration', 'Storage', 'Comment', 'Collected Event', 'Received Event', 'External Identifier', 'Biohazard', and 'Derivative'. Each section has a checkbox followed by a dropdown or input field.

**Figure82: Multiple Specimen Page**



Click Add More to add additional columns for entry of specimen data. Click Delete to delete a specimen. It deletes the last specimen column.

3. Enter the required details of the specimen. For example: Specimen Group Name, Class, Type, and so on.
4. To copy attributes of Specimen1 to Specimen3:
  - a. Select the required attributes of Specimen 1. For example: Class, Type, and so on.
  - b. Click **Copy**.
  - c. Select the check box corresponding to Specimen 3.
  - d. Click **Paste**. The selected attribute details of Specimen 1 are copied to Specimen 3.



For the current version of caTissue Suite, you can only copy attributes of Specimen 1 to another specimen.

5. To copy all the attributes of Specimen 2 to Specimen 4:
  - I. Select the check box corresponding to Specimen 2.
  - II. Click **Copy**.
  - III. Select the check box corresponding to Specimen 4.
  - IV. Click **Paste**. The selected attribute details of Specimen 2 are copied to Specimen 4.



This functionality is used to copy all attributes from any selected specimen to any another specimen. You cannot select specific attributes to copy.

6. Click **Submit**.

	Derivative of a specimen can be specified using the Derivative button. This displays the Create Derivative page. Click Add More on the Create Derivative page to specify more derivatives of the parent specimen.
---	---

[Adding a Biospecimen Event](#)

Any action performed on a biospecimen is referred to as an *event*. Events include transfer, review of the specimen, frozen, thaw, fixed, disposal, spun, and so on.

**Table 21: Various Events in caTissue Suite**

Name of the Event	Description
Cell Specimen Review	This refers to performing quality assurance actions on a cell specimen.
Check In Check Out	This refers to temporary movement of specimens from stored location.
Collection	This refers to collection of a specimen from participant under a collection protocol.
Disposal	This refers disposing or rejecting a specimen. The Activity Status of the specimen can be set to Disabled (deletes the specimen completely from system) or Closed (Specimen is visible in the system but unavailable for specimen operations such as aliquoting, deriving, and so on).
Embedded	This refers to embedding a specimen in paraffin, plastic material, and so on.
Fixed	This refers to fixing a specimen in a fixing medium like formaldehyde, ethanol, and so on.
Fluid Specimen Review	This refers to performing quality assurance actions on a fluid specimen.
Frozen	This refers to freezing a specimen at certain temperature using a freezing method such as Liquid Nitrogen, Dry Ice, and so on.
Molecular Specimen Review	This refers to performing quality assurance actions on a molecular specimen.
Procedure	This refers customized procedure that is applied on a specimen to process it. You can fill in details like URL for the procedure, procedure name, and so on.
Received	This refers to receiving a specimen in the tissue bank.
Spun	This refers to spinning the specimen.
Thaw	This refers defrosting a specimen.
Tissue Specimen Review	This refers to performing quality assurance actions on a tissue specimen.
Transfer	This refers to moving specimen from one storage location to another storage location.

To add an event to a biospecimen:

1. Click the **Biospecimen data** tab.

2. Click **Events** under Specimen on the left pane.
3. Select Specimen Label or Barcode.
4. From the Event drop-down list, select an event that has to be added to the specimen.
5. Click **Add Event**.
6. Enter all the details for the event and click **Submit** as shown in the following figure:

The screenshot shows the 'caTissue Suite' software interface. On the left, there's a sidebar with navigation links: 'Collection Protocol Based View', 'PARTICIPANT', 'SPECIMEN' (with a red '2' badge), 'SPECIMEN ARRAY', 'DISTRIBUTION', and 'Order'. The main area is titled 'Add Specimen Event'. It has two radio button options: 'Specimen Label' (selected) and 'Barcode'. The 'Specimen Label' field contains '968\_1'. To the right of these fields is an 'Event' dropdown set to 'Transfer'. Below this is a 'NEW TRANSFER EVENT PARAMETERS' section. It includes fields for 'User' (set to 'Admin, Admin'), 'Date' (set to '02-21-2008'), 'Time' (set to '6 Hr 24 Min'), 'From Position' (set to 'virtual Location'), 'To Position' (set to 'Name: Penn\_Freezer\_6, Pos1: 1, Pos2: 4'), and a 'Comments' text area. At the bottom right of the dialog is a 'Submit' button. The entire dialog is numbered with red circles: 1 (BIOSPECIMEN DATA tab), 2 (SPECIMEN link), 3 (Barcode radio button), 4 (Event dropdown), 5 (Add Event button), and 6 (Submit button).

**Figure83: Adding a Biospecimen Event**

The event gets registered for the specimen. You can view this event under the *Existing events for the specimen* section under the Events tab for the specimen.

## Bulk Operations

Bulk operation is a time saving feature that helps you to add an event to multiple specimens at one time. Bulk operations also include editing several specimens at the same time.

Prerequisites for adding an event to specimens or editing multiple specimens are:

- b. Perform an advanced search for the specimens that are to be edited or to which an event has to be added. For more information on performing advance search, refer to the [Chapter 9: Search Data – Simple Search and Advanced Query Wizard](#) chapter.
- c. On the View Results page, select the specimens as shown in the following figure:
- d. Click **Add to My List** to add specimens to My List.

The screenshot shows the caTissue Suite software interface. On the left, there is a sidebar with a search bar and a 'My List' section. The main area has tabs for 'HOME', 'ADMINISTRATIVE DATA', 'BIOSPECIMEN DATA', 'SEARCH', 'SUMMARY', and 'HELP'. A navigation tree on the left shows 'Protocol (7)', 'Blood', 'Specimen (72)', and 'Specimen (72)'. The central part of the screen displays a table of search results with columns: Specimen Label, Specimen Initial Quantity, Specimen Available Quantity, Specimen Position Dimension One, Specimen Collection Status, Specimen Position Dimension Two, Specimen ID, Specimen Pathological Status, and Specimen Available. There are 72 records per page, with 1-72 of 72 shown. A red circle labeled 'a' is on the 'Specimen (72)' link in the tree. A red circle labeled 'b' is on the first row of the table. A red circle labeled 'c' is on the 'Add To My List' button at the bottom.

Specimen Label	Specimen Initial Quantity	Specimen Available Quantity	Specimen Position Dimension One	Specimen Collection Status	Specimen Position Dimension Two	Specimen ID	Specimen Pathological Status	Specimen Available
114	20.0	15.0	1	Collected	1	122	Malignant	true
114_1	4.0	3.0	1	Collected	2	123	Malignant	true
115	5.0	0.0	1	Collected	4	124	Malignant	false
114_2	4.0	3.0	1	Collected	3	125	Malignant	true
115_1	2.0	1.0	1	Collected	5	134	Malignant	true
115_2	2.0	2.0	2	Collected	1	135	Malignant	true
120	200.0	0.0		Collected		136	Malignant	false
120_1	100.0	100.0	2	Collected	3	137	Malignant	true
120_2	100.0	100.0	2	Collected	4	138	Malignant	true
185	50.0	5.0		Collected		4120	Not Specified	true
188	50.0	24.0		Collected		4121	Not Specified	true
116	20.0	15.0	2	Collected	2	126	Malignant	true

**Figure84: Search Results**

To add an event, perform the following steps:

1. Click **Search**.
2. Click **View** under My List on the left pane of the screen.
3. Click the Specimen Event radio button as shown in the following figure.
4. From the Specimen Event drop-down list, select the event that has to be added to the specimens.

	<p>Currently only bulk transfer and bulk disposal events can be performed in this version of caTissue Suite.</p>
--	--

5. Click **Submit**.

The screenshot shows the caTissue Suite software interface. On the left, there is a sidebar with a logo, search functions, and a 'My List' section where a user named 'User 2' is listed. The main area has a title bar with 'HOME', 'ADMINISTRATIVE DATA', 'BIO SPECIMEN DATA', 'SEARCH', 'SUMMARY', and 'HELP'. A red number '1' is placed above the 'SEARCH' button. Below the title bar is a sub-header 'My List' with a red number '2' next to it. A checkbox labeled 'Check All' is checked. To its right are buttons for 'Delete' and 'Export'. The main content area displays a table of specimen details:

Initial Quantity : Specimen	Available Quantity : Specimen	Position Dimension One : Specimen	Collection Status : Specimen	Position Dimension Two : Specimen	Id : Specimen	Pathological Status : Specimen	Available : Specimen	Is Coller Proto Required : Specim
<input checked="" type="checkbox"/> 1.0	1.0	2	Collected	5	27	Not Specified	true	false
<input checked="" type="checkbox"/> 5.0	5.0	1	Collected	1	25	Not Specified	true	false
<input checked="" type="checkbox"/> 1.0	1.0	2	Collected	4	28	Not Specified	true	false
<input checked="" type="checkbox"/> 1.0	1.0	3	Collected	1	26	Not Specified	true	false

Below the table, a message says 'Select operations to be performed on the selected specimens'. There are three radio buttons: 'Specimen Event' (selected), 'Multiple Specimen Page', and 'Order BioSpecimens'. The 'Specimen Event' button has a red number '3' next to it. To its right is a text input field containing 'Transfer' with a red number '4' next to it. At the bottom is a 'Submit' button with a red number '5' next to it.

**Figure85: Adding an Event**

6. Enter details of the event. For example: for transfer event, specify the Destination Container name.
7. Click **Submit**.

To edit several specimens at one time, perform the following steps:

1. The specimens of interest must be added to My List before proceeding. Click **View** under My List on the left pane.
2. Select the **Multiple Specimen Page** radio button as shown in the following figure:
3. Click **Submit**. The multiple specimen page is displayed.

The screenshot shows the 'catissue Suite' interface with the 'My List' page selected. At the top, there are links for HOME, ADMINISTRATIVE DATA, BIOSPECIMEN DATA, SEARCH, SUMMARY, and HELP. Below this is a toolbar with SEARCH, Single Advanced, My List, and a red-highlighted 'New 1'. The main area is titled 'My List' and contains a table with columns: Initial Quantity : Specimen, Available Quantity : Specimen, Position Dimension One : Specimen, Collection Status : Specimen, Position Dimension Two : Specimen, Id : Specimen, Pathological Status : Specimen, Available Specimen, and Is Called Proto Specimen. A checkbox labeled 'Check All' is checked at the top left of the table. Buttons for Delete and Export are at the top right. Below the table, a message says 'Select operations to be performed on the selected specimens'. There are three radio button options: 'Specimen Event' (Transfer), 'Multiple Specimen Page' (selected), and 'Order BioSpecimens'. A 'Submit' button is at the bottom.

**Figure 86:** My List

4. Edit the fields for the specimens.
5. Click **Submit** as shown in the following figure.

This screenshot shows the 'Multiple Specimen Page' edit screen. It displays two rows of specimen details. Row 1: Specimen 1 (Label: 234353949, Barcode: 234353949, Class: Molecular, Type: DNA, Tissue Site: Not Specified, Tissue Side: Nipple, Pathological Status: Not Specified, Created on: 02-19-2008, Quantity: 0.01 μg, Concentration: 0 μg/μl). Row 2: Specimen 2 (Label: 204, Barcode: 204, Class: Molecular, Type: DNA, Tissue Site: Blood, Tissue Side: Not Specified, Pathological Status: Malignant, Created on: 02-19-2008, Quantity: 0.01 μg, Concentration: 0 μg/μl). On the left, there are 'Copy' and 'Paste' buttons. On the right, there is a 'Submit' button with a red circle containing the number 5. A red circle with the number 4 is placed over the dropdown menu for 'Tissue Site' in the first row.

**Figure87:** Multiple Specimen Page

## Adding Specimen Array

A specimen array in caTissue Suite is a collection of biospecimens arranged in an ordered pattern. For example, 96 well PCR plate.

Prerequisite for adding specimen array:

- a. A specimen array type should exist in the system.
- b. Storage containers should be added for this specimen array type.

To add a specimen array, perform the following steps:

1. Click the **Biospecimen Data** tab.
2. Click **Add** under Specimen Array on the left pane. The Add Specimen Array page is displayed.
3. Select an array type from the Array Type drop-down list. According to the array type, the system generates the array label.
4. The system auto populates available Storage Position for the array. Alternatively, select **Map** and select the storage position.
5. In the grid, which has dimension as that of array type, add compatible specimens that is, belonging to the same Specimen Class and Specimen Type as that of array type. You can type either specimen labels or barcodes in the grid.
6. For molecular specimens you have to specify Concentration and Quantity. For example: to make the quantity 10 micrograms and the concentration 1 microgram/microliter for all wells:
  - A. Set the Concentration to **1**.
  - B. Set the Quantity to **10**.
  - C. Select all the wells. To do this, right-click and drag it across all the wells.
  - D. Click **Apply**.



Use Copy and Paste buttons to copy label or barcode, quantity, and concentration of one specimen to another specimen.

7. Click **Upload Specimen Array** to submit this specimen array as shown in the following figure.

The screenshot shows the 'caTissue Suite' software interface. On the left, a sidebar lists 'PARTICIPANT', 'SPECIMEN', and 'SPECIMEN ARRAY' sections. The 'SPECIMEN ARRAY' section is selected and highlighted in blue, with a red number '2' next to it. The main area displays the 'ADD SPECIMEN ARRAY' form. The form includes fields for 'Array Type' (set to 'DNA array', red number 3), 'Array Label' ('DNA array\_78'), 'Created By' ('A, Paul'), 'Barcode' (empty), 'Specimen Class' ('Molecular'), 'Specimen Type' ('Not Specified'), 'Storage Position' (with a dropdown menu 'Name: TJU-ArrayStorage\_1' and 'Pos1: 1, Pos2: 2', red number 4), 'Comments' (empty), and 'Capacity' (Dimensions One: 2, Dimension Two: 2). Below this is the 'Add Specimens' section, which contains a table with two rows of specimen details: Row 1 (1121, 2114) and Row 2 (1122, 3321). The table has columns for 'Concentration' (1), 'Quantity' (10), 'Label' (radio button selected), 'Barcode' (radio button), 'Apply' (button), and 'Paste' (button). A red number '5' is placed to the left of the table. A red number '7' is located at the bottom right of the 'Add Specimens' section.

Figure88: Specimen Array Creation

To add specimen array aliquot:

1. Click the **Biospecimen Data** tab.
2. Click **Aliquot** under Specimen Array on the left pane. The Create Specimen Array Aliquot page is displayed.
3. Enter either Parent Specimen Array Label or Barcode of the specimen array of which aliquot is to be created.
4. Enter the Aliquot Count.
5. Click **Submit** as shown in the following figure.

The screenshot shows the 'Create Specimen Array Aliquot' page. The sidebar on the left shows the 'SPECIMEN ARRAY' section selected with a red number '2'. The main form has a header 'Create Specimen Array Aliquot' with a red number '1'. It contains two radio button options: 'Parent Specimen Array Label' (selected, red number 3) and 'Barcode' (red number 2). To the right of these options are two input fields: 'Aliquot Count' (set to '4', red number 4) and a 'Submit' button (red number 5).

Figure89: Adding Specimen Array Aliquot

6. When you fill all the details and click **Submit**, the Specimen Array Aliquot page is displayed. Click **Create** to create this specimen array aliquot.

Specimen Array Aliquot		
* Specimen Array Type	DNA Array	
* Specimen Class	Molecular	
* Specimen Type	DNA	
# * Label	Barcode	* Location
1. DNA_Array_10_196		<input checked="" type="radio"/> Name BJH_Incubator_9 Pos1 16 Pos2 1 <input type="radio"/> <span style="background-color: #e0e0e0; border: 1px solid #ccc; padding: 2px;"> </span> <span style="background-color: #e0e0e0; border: 1px solid #ccc; padding: 2px;"> </span> <span style="background-color: #e0e0e0; border: 1px solid #ccc; padding: 2px;"> </span> MAP
		<span style="border: 1px solid #ccc; border-radius: 50%; padding: 2px 5px; margin-right: 5px;">6</span> <input type="button" value="Create"/>

**Figure90: Specimen Array Aliquot Page**

- The system navigates to Specimen Array Aliquot Creation Summary page and a success message is displayed, which informs you that the Aliquot(s) are created successfully.

- Aliquot(s) have been created successfully.

Specimen Array Aliquot Creation Summary		
* Specimen Array Type	DNA Array	
* Specimen Class	Molecular	
* Specimen Type	DNA	
# Label	Barcode	Location
1. DNA_Array_10_196		BJH_Incubator_9 16 1

**Figure91: Specimen Array Aliquot Creation Summary page**

### Unplanned Specimen Collection

Unplanned specimen collection is defined as the collection of specimen that does not have a pre-defined specimen requirement.

To work with an unplanned specimen collection:

- Register a participant to the required CP.
- Click **Specimen Collection Group** on the Participant page as shown in the following figure. The system navigates to the Add Specimen Collection Group page.

The screenshot shows the 'Add Participant' page. On the left, a sidebar lists 'Collection Protocols' and 'Participant (Protocol ID)'. A red circle labeled '1' is over the 'Participant (Protocol ID)' dropdown, which contains 'adnocarcinoma'. Below it is a list of participants: Jones, J. Jones (N/A), Jones, J. Jones (N/A), Martha (001), 050001 (05/0001), unknown (N/A), and ccc (ccc). A red circle labeled '2' is over the 'Specimen Details for' section, which is currently empty.

**Add Participant**

Social Security Number (SSN):  -  -

Name:  Jones  Jones

Last:  First:  Middle:

Birth Date:  [MM-DD-YYYY or MM/DD/YYYY]

Vital Status:  Alive  Dead  Unknown  Unspecified

Death Date:  [MM-DD-YYYY or MM/DD/YYYY]

Gender:  Female Gender  Male Gender  Unknown  Unspecified

Sex Genotype:  Unknown

Race:  Black or African American  Native Hawaiian or Other Pacific Islander  Not Reported  Unknown

Bhnicity:  Unknown

**Medical Identifier(s)**

Source	Medical Record Number	Delete ?
-- Select --	<input type="text"/>	<input type="checkbox"/>

**Participant Registration(s)**

Collection Protocol	Participant Protocol ID	Registration Date	Activity Status	Consent	Delete ?
2_18 Demo	<input type="text"/>	03-17-2009	Active	<input type="button" value="Enter Response"/>	<input type="checkbox"/>

2

**Figure 92: Unplanned Specimen Collection**

3. On the Add Specimen Collection Group page, select the Study Calendar Event Point under which the specimens are to be added.
4. Enter all other details such as Clinical Diagnosis, Clinical Status, and so on.
5. Clear the **Specimen entry based on collection protocol** check box.
6. Click **Add Specimen** or **Add Multiple Specimens** to add single specimen or multiple specimens as shown in the following figure. To add multiple specimens, enter the required number in the Number of Specimen(s) field.

**Figure93: Adding specimen**

To create an unplanned CP, refer to [Unplanned Specimen Collection Protocol or General Tissue Banking Protocol](#).

### Surgical Pathology Report (SPR)

A Surgical Pathology Report (SPR) is an important clinical document that plays a vital role as source of data in cancer research. SPRs are stored in hospital IT systems. These reports contain vital information based on the surgeon's pathological observations about the patient and biospecimens. There are two types of reports:

- Identified Surgical Pathology Reports
- Deidentified Surgical Pathology Reports

The cancer Text Information Extraction System (caTIES) is used to:

- Extract coded information from free text SPRs using controlled terminologies to populate caBIG compliant data structures.

- Provide researchers with the ability to query, browse, and acquire annotated tissue data and physical material across a network of federated sources.

Refer to the *Deployment Guide* for detailed instructions on installing the server components for caTIES.

You can access the SPRs using the three classes under the Biospecimen Data tab.

To view a surgical pathology report:

- Click the **Biospecimen Data** tab.
- Select a collection protocol that has SPRs associated with it. The CPs with associated SPRs are not marked on the interface. Your system administrator or the PI of your study can inform you whether SPRs have been loaded for your protocol.
- Select any one of three classes, namely: Participant, Specimen Collection Group, or Specimen. The respective Edit page is displayed.
- Click **View Surgical Pathology Report** to view the report.
- Select the required option under View to view the report. The default value is Identified Report as shown in the following figure.

Figure94: View Surgical Pathology Report

### *What can Users do in the View Surgical Pathology Report Tab?*

The surgical pathology report page displays identified or deidentified reports based on the role and privileges assigned to the user.

**Table 22: User Access to SPR system:**

Users	User Access to SPR
Administrator	<ul style="list-style-type: none"> <li>• View identified and deidentified reports.</li> <li>• Compare reports using the user interface.</li> <li>• Use the concept highlighter to color code the report.</li> <li>• Perform review of the report.</li> <li>• Quarantine the requested report.</li> </ul>
Supervisor	<ul style="list-style-type: none"> <li>• View identified and deidentified reports using the advanced query option.</li> <li>• Use the concept highlighter to color code the report.</li> <li>• Request a review of the report.</li> <li>• Request to quarantine a deidentified report.</li> </ul>
Technician	<ul style="list-style-type: none"> <li>• View deidentified reports using the advanced query option.</li> <li>• Use the concept highlighter to color code the report.</li> <li>• Request a review of the report.</li> <li>• Request to quarantine the report.</li> </ul>
Scientist	<ul style="list-style-type: none"> <li>• View the SPRs using the advanced query option. If you are the PI for that CP, you can view the identified reports. By default, you can view only the deidentified reports. You can also export the data to Excel.</li> <li>• Use the concept highlighter to color code the report.</li> <li>• Request a review of the report.</li> <li>• Request to quarantine a deidentified report.</li> </ul>

#### **Compare Identified-DeIdentified Reports**

If you select this option, the Participant Information section is hidden, and the Identified Report Information and De-Identified Report Information is displayed.

#### **Category Highlighter**

The Category Highlighter is enabled for De-Identified reports. It is displayed if you select the Show De-Identified Report option or the Compare Identified-DeIdentified Reports option. Selecting the Procedure, Organ, Modifier, or Diagnosis check box highlights the selected categories in a particular color under De-Identified Report Information. You can select multiple highlighters at the same time.

The screenshot shows a software interface for viewing surgical pathology reports. At the top, there are buttons for 'Edit', 'View Surgical Pathology Report' (which is selected), and 'View Annotation'. Below this is a dropdown menu labeled 'Surgical Pathology Number' containing the value 'tpmc2657183'. A 'View' button is highlighted in grey.

The main content area is titled 'De-Identified Report Information'. It features a 'Category Highlighter' with four checkboxes: 'PROCEDURE' (unchecked), 'ORGAN' (checked), 'Modifier' (unchecked), and 'DIAGNOSIS' (checked). The report text is displayed below, with certain words highlighted in purple (e.g., 'STOMACH', 'ANTRUM', 'H. PYLORI') and others in blue (e.g., 'CHRONIC INACTIVE GASTRITIS', 'MODERATE REACTIVE AND REGENERATIVE EPITHELIAL CHANGES').

**PART 1: STOMACH, ANTRUM, BIOPSY-**

- A. ANTRAL MUCOSA WITH MODERATE CHRONIC INACTIVE GASTRITIS AND MODERATE REACTIVE AND REGENERATIVE EPITHELIAL CHANGES.
- B. NEGATIVE FOR H. PYLORI ORGANISMS (DIFF-QUIK STAIN).

**PART 2: CARDIA, BIOPSY-**

- A. ANTRAL MUCOSA WITH MILD CHRONIC INACTIVE GASTRITIS AND MODERATE REACTIVE AND REGENERATIVE EPITHELIAL CHANGES.
- B. NEGATIVE FOR H. PYLORI ORGANISMS (DIFF-QUIK STAIN).

At the bottom of the report text area, there are two buttons: 'Request for Review' and 'Request for Quarantine'.

**Comment**

Below the comment field, there is a large empty text area for entering comments.

Figure95: Category Highlighter

### Quarantine Request

If you have access to a deidentified report and get to view identified data to which you do not have access, you can request to quarantine the report. For this, enter the required comment in the Comment field and click Request for Quarantine. This operation immediately makes the report invisible to all users other than the Administrator. Each institution that uses caTissue Suite develops its own procedures for reviewing quarantined reports and making them available again once they are fully deidentified.

### Review Request

If you see any kind of discrepancy in the report, for example: a term is not properly concept coded, then you can request that the report be reviewed. For this, enter the required comment in the Comment field and click Request for Review. Each institution that uses caTissue develops its own procedures for reviewing reports.

## Editing Biospecimen Objects

You can perform editing on all the objects under the Biospecimen Data tab except Distribution and Order. The following procedure outlines how you can perform basic editing:

To perform an edit operation:

1. On the Biospecimen Data tab, click **Edit** under the required object on the left pane of the screen. For example, Participant, Specimen, and so on. The relevant search window is displayed.
2. Select the required **Attribute, Condition, and Value**.
3. Click **Search**. The Search Result page displays the matching records.
4. Double-click the record of interest. The Edit page is displayed. For example: if you are searching for a participant, the Edit Participant page is displayed.
5. Make the desired changes and click **Submit**. A success message is displayed if the record is successfully updated.

## Performing CP Based Editing

You can also perform edit operations using the CPbased view. The following procedure outlines how to perform CP based editing:

To perform CP based editing:

1. Select the required Collection Protocol.
2. Select the required participant under Participant (Protocol ID) or the required SCG or Specimen under the Specimen Details tree on left pane of the screen. Based on the selection, each selection displays the edit mode on right pane.
3. Edit the required fields. Properties inherited from parent specimens in case of aliquots are not editable. For example: Class, Type, and so on.
4. Make the desired changes and click **Submit**. A success message is displayed, if the record is successfully updated.

## Editing a Participant Registration on an Arm

It is possible that the participant can drop out of one arm and get registered to another arm at the same level, or can be accidentally registered to the wrong arm.

The screenshot shows the Biospecimen Data interface. At the top, there are tabs for HOME, ADMINISTRATIVE DATA, BIOSPECIMEN DATA (highlighted with a red circle 1), SEARCH, SUMMARY, and HELP. Below the tabs, the 'Collection Protocol' dropdown is set to 'Osteosarcoma' (highlighted with a red circle 2). The 'Participant (Protocol ID)' dropdown shows 'Pat 1 (N/A)' and 'Pat 2 (N/A)' (highlighted with a red circle 3). On the left, the 'Specimen Details for PAT 55 (N/A)' section lists 'Osteo Pre-Surgery: 2008-01-02', 'Osteo Post Surgery: 2008-01-09', and 'Post GR MAP: 2007-01-16'. A message at the bottom left says: 'Participant is already registered on one arm. You want to create a new registration and change the status of the Specimen collection groups under which no specimen have been collected in the old arm to Not Collected.' (highlighted with a red circle 5). In the center, a 'EDIT PARTICIPANT REGISTRATION' dialog box is open (highlighted with a red circle 4). It contains fields for 'Collection Protocol' (Post GR MAP), 'Participant Name' (PAT 55), 'Participant Protocol ID' (empty), 'Registration Date' (01-16-2007), and 'Activity Status' (Active). At the bottom of the dialog box are 'Submit' and 'Specimen Collection Group' buttons.

**Figure96:** Editing a Participant Registration to a Different Arm

To edit a participant registration on an arm:

1. Click the **Biospecimen Data** tab. The CP based view is displayed.
2. Select the required longitudinal collection protocol as shown in the preceding figure.
3. Select a participant registered to the main protocol.
4. Register the participant to arm one. For more details on registering a participant to an arm, refer to

5. [Registering a Participant to an Arm Manually.](#)
6. Once you try to register the participant to another arm at the same level, the “Participant is already registered on one arm. You want to create a new registration and change the status of the Specimen Collection Groups under which no specimens are collected in the old arm as Not Collected” message is displayed. Click **OK**.



Once you click OK, the participant is registered to the new arm. The collection status of the SCGs under which no specimens are collected is marked as Not Collected. If arm two is of a different duration, that is containing more or less time points as compared to arm one, then all the future sub-protocols and SCGs are readjusted to display the updated anticipated dates.

## Chapter 7: Introduction to Clinical Annotations

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The Clinical Annotations (CA) module allows you to collect clinical and pathological information of the participant, accession, and biospecimens. It is divided into:

- Pathology Information
- Clinical and Health Information

### Pathology Information

This section outlines CAP-based (College of American Pathologists) pathology annotations. It involves collection of information on a broad spectrum of tumors. It captures information about various features associated with tumors such as TNM staging (tumor, node, and metastasis stage determination), histologic grading, histo-pathological examination, positive or negative margins, and other fundamental pathology details. The module consists of nine organ systems and data for these organ systems is independently captured. The nine organ systems are:

1. Prostate
2. Pancreas
3. Kidney
4. Lung
5. Blood/Bone Marrow (labeled as *Heme* in the UI)
6. CNS
7. Colon and Rectum
8. Breast
9. Skin (labeled as *Melanoma* in the UI)

To accommodate pathology data for tumors that do not fall under the nine organ systems, there is a generic annotation which can be used to capture information specific to that organ system.

### Clinical and Health Information

This section records clinical information about the participant's:

- Medical history
- Follow-up
- Medications administered (such as chemotherapy, radiation therapy, and so on)
- Social history (smoking and alcohol history)
- Environmental exposure history (for example: exposure to asbestos)
- Physical examinations
- Laboratory test details
- Family health history

The clinical annotations available in caTissue Suite can be found under the hook entities as outlined in the following table:

**Table 23: Clinical Annotations under Various Hook Entities**

<b>Participant</b>	<b>Specimen Collection Group</b>	<b>Specimen</b>
1. Lab Annotation 2. Family History Annotation 3. Treatment Annotation 4. Rad RX Annotation 5. Chemo RX Annotation 6. Treatment Regimen 7. Environmental Exposure Health Annotation 8. Alcohol Health Annotation 9. Smoking Health Annotation 10. Health Examination Annotation 11. New Diagnosis Health Annotation 12. No Evident Disease Health Annotation 13. Recurrence Health Examination Annotation 14. Local Recurrence Health Examination Annotation 15. Distant Recurrence Health Examination Annotation	16. Base Solid Tissue Pathology Annotation 17. Base Hematology Pathology Annotation 18. Radical Prostatectomy Pathology Annotation 19. Needle Biopsy Prostate Pathology Annotation 20. Retropubic Enucleation Pathology Annotation 21. Transurethral Prostatic Resection Pathology Annotation 22. Pancreas Pathology Annotation 23. Lung Biopsy Pathology Annotation 24. Lung Resection Based Pathology Annotation 25. Kidney Biopsy Based Pathology Annotation 26. Kidney Nephrectomy Pathology Annotation 27. Melanoma Pathology Annotation 28. CNS Pathology Annotation 29. Breast Pathology Annotation 30. Local Excision Based Colorectal Pathology Annotation 31. Excisional Biopsy Based Colorectal Pathology Annotation 32. Resection Based Colorectal Pathology Annotation	33. Specimen Based Solid Tissue Pathology Annotation 34. Colorectal Specimen Pathology Annotation 35. Pancreas Specimen Pathology Annotation 36. Melanoma Specimen Pathology Annotation 37. CNS Specimen Pathology Annotation 38. Prostate Specimen Pathology Annotation 39. Kidney Specimen Pathology Annotation 40. Lung Specimen Pathology Annotation 41. Breast Specimen Pathology Annotation

## Features of Clinical Annotations

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The Clinical Annotations module provides the following features:

1. Assign CA selectively to specific collection protocols.
2. Enter data for organ specific or generic pathology annotations.
3. Query on annotation data.

## Clinical Annotations Workflow

The clinical annotation workflow has three types of activities: assign annotations to protocols, enter annotations data, and query on annotation data. The following steps describe a typical clinical annotations workflow.

1. Administrator associates annotations to one or more than one relevant collection protocols.
2. Administrator, Supervisor, or Technician enters clinical data or pathological data for the annotations.
3. Administrator, Supervisor, Technician, or Scientist queries on the data entered for the specific annotations under specific collection protocols.

### Assigning Annotations to a Collection Protocol

Various clinical annotations capture data that is specific to a particular collection protocol. For example: annotations related to prostate cancer can be associated with only prostate cancer protocol. Using the Conditions on Collection Protocol feature of DE, the Administrator can restrict specific annotations to specific protocols.

To assign clinical annotations, to a particular collection protocol, the Administrator will:

1. Click the **Administrative Data** tab.
2. Click **Define** under Local Extensions on the left pane of the screen. A warning message is displayed. It warns about the possible alterations to the database tables while creating or editing the dynamic extensions.
3. Click **Next** as shown in the following figure.

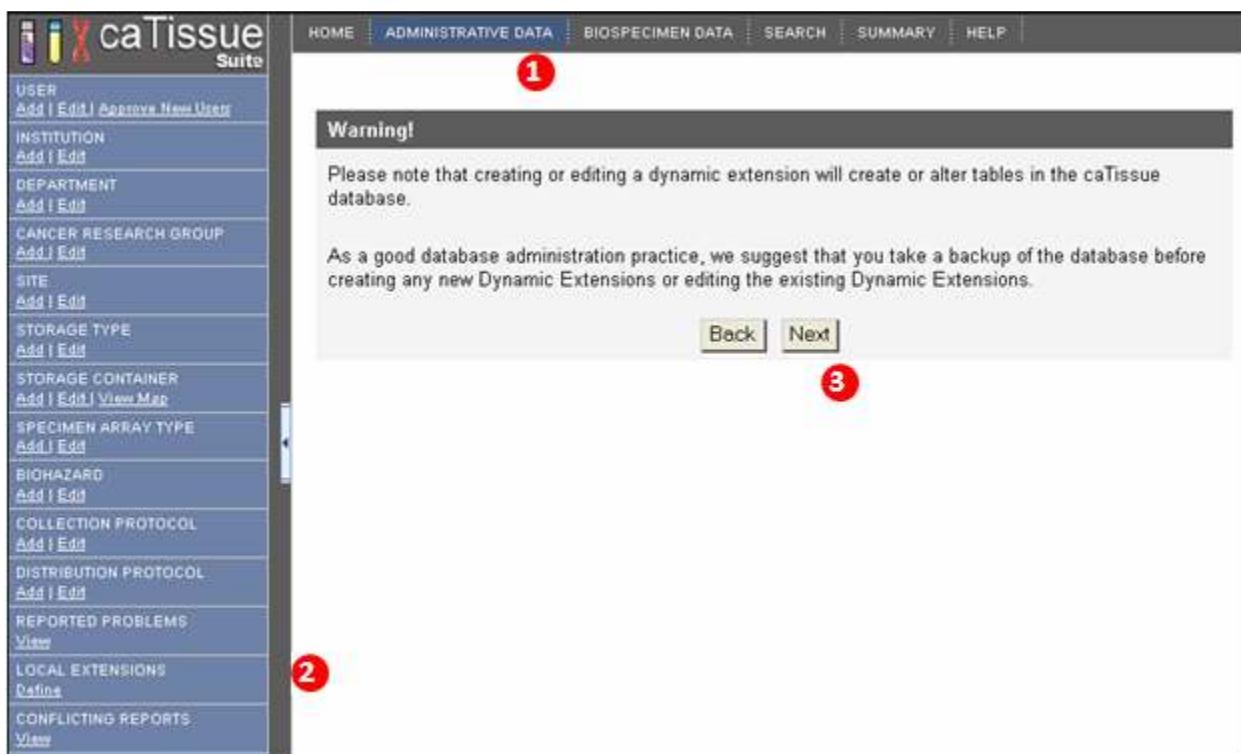


Figure97: Assign Clinical Annotations - Warning Page

4. Select the required CA group under Group on the Build Annotation Form page. All the forms created for the selected group are displayed under Form Title. For example: if you select the

pathology\_specimen group, all the CA forms created under this group are displayed under Form Title.

- Click the **Edit** link under Conditions for the annotation on which collection protocol restrictions are to be set. Refer the following figure. For example, click **Edit** next to Colorectal Specimen Pathology Annotation.

Group	Form Title	Entity	Date	Created By	Conditions
clinical_annotation	SpecimenBaseSolidTissuePat	Specimen	01-21-2008		<a href="#">Edit</a>
④ pathology_specim	ColorectalSpecimenPathology	Specimen	01-21-2008		<a href="#">Edit</a> ⑤
pathology_scg	PancreasSpecimenPathology	Specimen	01-21-2008		<a href="#">Edit</a>
Common Entity Gr	MelanomaSpecimenPathology	Specimen	01-21-2008		<a href="#">Edit</a>
CancerStudy	CNSSpecimenPathologyAnnot	Specimen	01-21-2008		<a href="#">Edit</a>
	ProstateSpecimenPathologyAr	Specimen	01-21-2008		<a href="#">Edit</a>
	KidneySpecimenPathologyAnn	Specimen	01-21-2008		<a href="#">Edit</a>
	LungSpecimenPathologyAnnot	Specimen	01-21-2008		<a href="#">Edit</a>
	BreastSpecimenPathologyAnn	Specimen	01-21-2008		<a href="#">Edit</a>

Figure98: Assign Clinical Annotations – Edit Annotation

- Select or update the required collection protocol in the Title list box to set restrictions on the availability of that annotation as shown in the following figure. For example: select **C\_C\_P (Colon Cancer Protocol)**.

Figure99: Build Annotation Form

- Click **Submit** to save the changes.

Click Cancel to ignore the changes made to the collection protocol restrictions.

Similarly, you can assign other annotations to specific collection protocols. For example: the Local Excision Based Colorectal Pathology Annotation can be assigned to the Colon Cancer Protocol and the Generic Collection Protocol.



You can select multiple collection protocols. Select the required collection protocol, press the [CTRL] key, and select another collection protocol.

## Entering Clinical Data and Pathological Data for Annotation

Once an annotation is assigned to a collection protocol, you can enter the clinical and pathological data in the annotation.

To enter data in the associated clinical annotation; the Administrator, Supervisor, or Technician performs the following steps:

1. Click the **Biospecimen Data** tab.
2. Select the required Collection Protocol from the drop-down list to which your annotation is restricted. The system displays the list of participants already registered to the selected collection protocol under Participant (Protocol ID).
3. Select one of the hook entities with which the CP is associated.
  - a. Participant
  - b. Specimen Collection Group
  - c. Specimen
4. Click the **View Annotation** tab to navigate to the Add New Annotation page as shown in the following figure.

Edit Specimen Collection Group		View Surgical Pathology Report		View Annotation		Consents	
* Collection Protocol Title	C_C_P	HENDERSON, Robert(N/A)		Baylor College of Medicine			
* Participant Name (Protocol ID)	HENDERSON, Robert(N/A)	Colon Cancer Protocol_3_5		1.0,Pre treatment		Days	
* Collection Site	Baylor College of Medicine	Offset		0			
* Specimen Group Name	Colon Cancer Protocol_3_5	Study Calendar Event Point		1.0,Pre treatment		Days	
* Clinical Diagnosis	Not Specified	Clinical Status		Pre-Therapy			
Medical Record Number		-- Select --					

Figure100: Add New Annotation

5. Select the required annotation form from the Annotation Forms drop-down list as shown in the following figure.

**Add New Annotation**

Annotation Forms :	<input type="text" value="ResectionBasedColorectalPathologyAnnotation"/> GO	6
Available Annotation	BaseHaematologyPathologyAnnotation BaseSolidTissuePathologyAnnotation RadicalProstatectomyPathologyAnnotation NeedleBiopsyProstatePathologyAnnotation RetropubicEnucleationPathologyAnnotation TransurethralProstaticResectionPathologyAnnotation PancreasPathologyAnnotation LungBiopsyPathologyAnnotation LungResectionBasedPathologyAnnotation KidneyBiopsyBasedPathologyAnnotation KidneyNephrectomyBasedPathologyAnnotation MelanomaPathologyAnnotation CNSPathologyAnnotation BreastPathologyAnnotation LocalExcisionBasedColorectalPathologyAnnotation ExcisionalBiopsyBasedColorectalPathologyAnnotation <b>5 ResectionBasedColorectalPathologyAnnotation</b>	
Annotation	Updated By	

Figure 101: Annotation Forms

6. Click **Go**. The data entry page for the selected annotation form is displayed as shown in the following figure.
7. Enter the required details in the form.

Edit	<a href="#">View Surgical Pathology Report</a>	<a href="#">View Annotation</a>
* indicates required fields.		
<b>Lab Annotation</b>		
Lab Test Name	<input type="text" value="Allergan Test"/> 8	
Other Lab Test Name	<input type="text"/>	
Test Date	<input type="text"/> 7	[MM-DD-YYYY]
Result	<input type="text"/>	
Result Units	<input type="text"/>	
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>		

Figure102: Annotation Forms: Data Entry Page

8. Click **Submit**.

For more information on default annotations in caTissue Suite, refer to [Appendix 2: Clinical Annotations](#).

## Querying on Annotations

Once you enter data in the annotations, all the users can search for the required annotations under specific collection protocols.

For more information on advance querying, refer to [Advanced Query Wizard](#).

For more information on querying clinical annotations and viewing related examples, refer to Appendix 3, [Queries on Annotations](#).

## Chapter 8: Ordering Biospecimens (New Feature in Suite Release)

This chapter outlines the biospecimen ordering. One of the main goals of collecting biospecimens is to distribute them to the investigators for research. This process is known as biospecimen distribution. In earlier versions of caTissue Core, distribution support was not automated. It meant users had to query for the biospecimens, export the data into a CSV file, and send it manually to the Administrator. In caTissue Suite this process has been automated. The users can directly submit orders using the application.

Any researcher having a registered distribution protocol in the system can order:

1. Biospecimens or arrays that reside in the tissue bank (for example: tissue, DNA, RNA, serum, and plasma).
2. Biospecimens that do not exist, but can be derived from an existing biospecimen in the system.  
For example: a user identifies a frozen tissue specimen of prostate tumor and requests 3 µg RNA from that tumor tissue. RNA for this sample does not exist in the system. Therefore, RNA will be first created from the tissue, accessioned into the system, and then distributed.
3. Biospecimens that are part of a surgical pathology case but do not exist in the system as individual specimens (paraffin blocks), or derived specimens or aliquots (cut sections). For example: a user identifies a particular surgical pathology report and wants ten uncut slides from the tumor and metastatic lymph node block from that case. The biospecimen resource retrieves the appropriate blocks from the requested case and accessiones them into the system as individual specimens. These individual specimens or aliquots from each block will be cut (that is, sections cut into slides) and then distributed.

## Ordering Workflow

The following figure outlines the workflow of ordering biospecimens.



Figure 103: Biospecimen Ordering Workflow

To order biospecimens:

1. A Scientist or Administrator performs a query and adds specimens, pathology cases or arrays of interest to *My List*. This step can be repeated across multiple queries.
2. Once you have accumulated the items you want to order in *My List*, the order can be submitted. Once you submit the order, the Administrator views the order on the Order View page.
3. Administrator reviews the request and approves or rejects the order. For more information, refer to [Distribution of Ordered Items](#).
4. If approved, Technicians create new specimens if required and distributes them. For more information, refer to [Distribution of Ordered Items](#).
5. Once an order is processed and distributed, a distribution report is generated. For more information, refer to [Distribution of Ordered Items](#).



You can order biospecimens if you are the Principle Investigator of a Distribution Protocol in caTissue Suite. Contact your Administrator for more details.

Step 1: Add specimens of interest to *My List*.

**Table 24: Objects in My List**

Ordered Items	Objects to Add to <i>My List</i> from the Query Results
Biospecimens, or their aliquots or its derivatives	Specimen, MolecularSpecimen, TissueSpecimen, FluidSpecimen, CellSpecimen
Arrays	SpecimenArrays
Pathological case	IdentifiedSurgicalPathologyReport or DeidentifiedSurgicalPathologyReport (Specimens and specimen arrays from these reports can be ordered.)

Step 2: Order biospecimens from *My List*.

To order biospecimens from *My List*, perform the following three steps.

The screenshot shows the 'caTissue Suite' application interface. The top navigation bar includes links for HOME, ADMINISTRATIVE DATA, BIOSPECIMEN DATA, SEARCH, SUMMARY, and HELP. The main title is 'My List'. On the left, there's a sidebar with a search bar ('SEARCH Simple | Advanced'), a 'View' dropdown set to '2' (highlighted with a red circle), and a 'My List' section. The main content area displays a table of selected specimens:

Initial Quantity : Specimen	Available Quantity : Specimen	Position Dimension One : Specimen	Collection Status : Specimen	Position Dimension Two : Specimen	Id : Specimen	Pathological Status : Specimen	Available : Specimen	Is Collect Protocol Requirement : Specimen
12.0	12.0	2			110	Not Specified	true	true
2.0	0.0	1	Pending		298	Not Specified	false	false
2.0	0.0	1	Pending		188	Not Specified	false	false
5.0	5.0	3	Collected	2	188	Not Specified	true	false
10.0	10.0	0	Collected		154	Not Specified	true	false
2.0	0.0	1	Pending		299	Not Specified	false	false
5.0	5.0	3	Collected	4	314	Not Specified	true	false
2.0	2.0	1	Collected	5	152	Not Specified	true	false
10.0	0.0	0	Pending		189	Not Specified	false	false
2.0	2.0	5	Collected	4	170	Not Specified	true	false

Below the table, a section titled 'Select operations to be performed on the selected specimens' contains the following options:

- Specimen Event
- Multiple Specimen Page
- Order BioSpecimens (highlighted with a red circle)

A 'Submit' button is at the bottom of this section (also highlighted with a red circle).

**Figure104: Submitting an Order**

Step 2a: To submit an order from *My List*:

1. Click the **Search** tab as shown in the preceding figure.
2. Click the **View** link under *My List* in the left pane.
3. Select the specimens to order.
4. Select **Order Biospecimens**.

For more information on Specimen Event and Multiple Specimen Page, refer to [Bulk Operations](#).

5. Click **Submit**.

	<p>You can place an order based on biospecimens, pathology cases and/or arrays. To place pathology case orders, add IdentifiedSurgicalPathologyReport or DeidentifiedSurgicalPathologyReport to <i>My List</i>.</p>
---	---

Step 2b: Select the distribution protocol.

\* indicates a required field

ORDER BIOSPECIMEN	
* Order Name	User Manual test Order <span style="color: red;">①</span>
* Distribution Protocol	Another Cool Study <span style="color: red;">②</span> <input type="button" value="▼"/>
Comments	<input type="text"/>
<span style="color: red;">③</span> Next	

Figure105: Selecting distribution protocol

1. Specify the **Order Name** as shown in the preceding figure.
2. Select the appropriate **Distribution Protocol** from the drop-down list for the specimens being ordered.
3. Click **Next**.

	<p>To distribute a specimen to a PI, the PI should have a distribution protocol registered in the system.</p>
---	---

Step 2c: Prepare order list

The detailed steps to prepare order lists are enumerated under the following sections.

<p>Biospecimen <span style="color: red;">A</span> Pathological Case <span style="color: red;">B</span> Biospecimen Array <span style="color: red;">C</span> Define Array</p> <p>* indicates a required field</p> <p><b>Specimen List</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">* Request For</td> <td><input checked="" type="radio"/> Existing Specimen <input type="radio"/> Derivative Specimen</td> </tr> <tr> <td>Required Quantity</td> <td><input type="text"/> Apply To All</td> </tr> <tr> <td colspan="2"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"><input type="checkbox"/></th> <th style="width: 20%;">Specimen Name</th> <th style="width: 15%;">Available Quantity</th> <th style="width: 15%;">Required Quantity</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>114</td> <td>15.0 ml</td> <td><input type="text"/> 5 ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>115</td> <td>1.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>116</td> <td>15.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> </tbody> </table> </td> </tr> <tr> <td colspan="2" style="text-align: center; padding-top: 5px;">         Array Name : <input type="text"/> None <input type="button" value="Add To Order List"/> </td> </tr> </table>	* Request For	<input checked="" type="radio"/> Existing Specimen <input type="radio"/> Derivative Specimen	Required Quantity	<input type="text"/> Apply To All	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"><input type="checkbox"/></th> <th style="width: 20%;">Specimen Name</th> <th style="width: 15%;">Available Quantity</th> <th style="width: 15%;">Required Quantity</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>114</td> <td>15.0 ml</td> <td><input type="text"/> 5 ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>115</td> <td>1.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>116</td> <td>15.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> </tbody> </table>		<input type="checkbox"/>	Specimen Name	Available Quantity	Required Quantity	Description	<input checked="" type="checkbox"/>	114	15.0 ml	<input type="text"/> 5 ml	<input type="button" value="▼"/>	<input type="checkbox"/>	115	1.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>	<input type="checkbox"/>	116	15.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>	Array Name : <input type="text"/> None <input type="button" value="Add To Order List"/>		<p>Order List <span style="color: red;">D</span></p> <p><b>Order Name:</b> Existing Specimen Order  <b>Distribution Protocol:</b> Blood Samples</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Requests</td> <td style="width: 50%;"><input type="checkbox"/> Quantity/Count</td> </tr> <tr> <td colspan="2" style="text-align: right;"> <input type="button" value="Remove"/> <input type="button" value="Order"/> </td> </tr> </table>	<input type="checkbox"/> Requests	<input type="checkbox"/> Quantity/Count	<input type="button" value="Remove"/> <input type="button" value="Order"/>	
* Request For	<input checked="" type="radio"/> Existing Specimen <input type="radio"/> Derivative Specimen																																
Required Quantity	<input type="text"/> Apply To All																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"><input type="checkbox"/></th> <th style="width: 20%;">Specimen Name</th> <th style="width: 15%;">Available Quantity</th> <th style="width: 15%;">Required Quantity</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>114</td> <td>15.0 ml</td> <td><input type="text"/> 5 ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>115</td> <td>1.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td>116</td> <td>15.0 ml</td> <td><input type="text"/> ml</td> <td><input type="button" value="▼"/></td> </tr> </tbody> </table>		<input type="checkbox"/>	Specimen Name	Available Quantity	Required Quantity	Description	<input checked="" type="checkbox"/>	114	15.0 ml	<input type="text"/> 5 ml	<input type="button" value="▼"/>	<input type="checkbox"/>	115	1.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>	<input type="checkbox"/>	116	15.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>												
<input type="checkbox"/>	Specimen Name	Available Quantity	Required Quantity	Description																													
<input checked="" type="checkbox"/>	114	15.0 ml	<input type="text"/> 5 ml	<input type="button" value="▼"/>																													
<input type="checkbox"/>	115	1.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>																													
<input type="checkbox"/>	116	15.0 ml	<input type="text"/> ml	<input type="button" value="▼"/>																													
Array Name : <input type="text"/> None <input type="button" value="Add To Order List"/>																																	
<input type="checkbox"/> Requests	<input type="checkbox"/> Quantity/Count																																
<input type="button" value="Remove"/> <input type="button" value="Order"/>																																	

Figure106: Preparing order list

- A. To order biospecimens and its derivatives, click the **Biospecimen** tab. For more information, refer to [Ordering Specimen and Specimen Derivatives from Existing Specimen](#).
- B. To order specimens or specimen arrays based on surgical pathology report (SPR), click the **Pathological Case** tab. For more information, refer to [Ordering Associated with Surgical Pathology Report \(SPRs\)](#).
- C. To order existing and user defined arrays, click the **Biospecimen Array** tab. For more information, refer to [Ordering Biospecimen Arrays](#).

- D. To view the current contents of the order request, refer to the Order List section. The list will refresh as you add new items to the order.

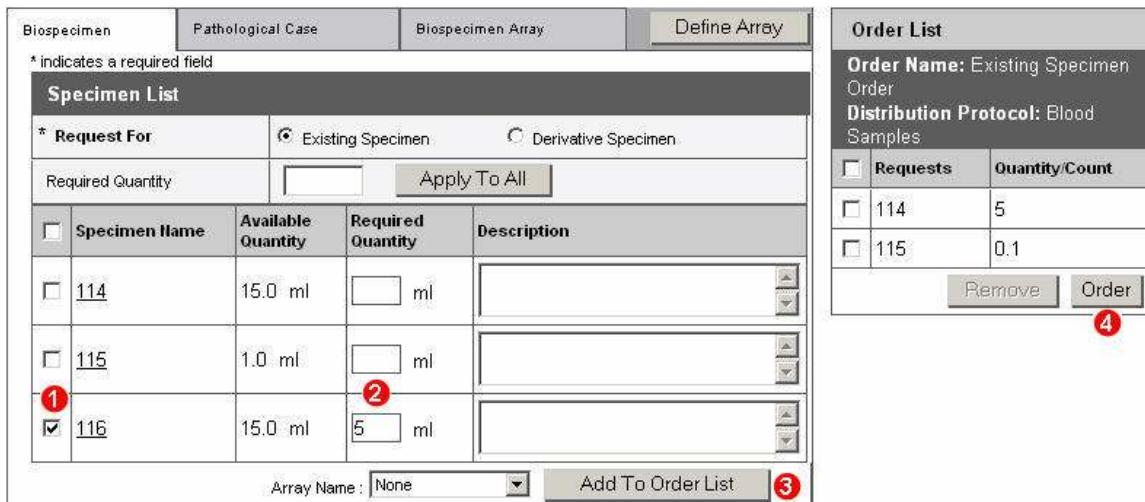
	Once you submit an order, an email notification is sent to the Administrator.
---	---

## Ordering Specimen and Specimen Derivatives from Existing Specimen

You can order a specimen that is already in the system and its derivatives. You can request for specimens and derivatives in one order or in separate order as per your requirement. The following procedure outlines how to order an existing specimen.

To order an existing specimen:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Specimen List page is displayed. Select the specimens you want to order.
2. Enter the **Required Quantity** for the biospecimen you want to order as shown in the following figure. Enter comments in the **Description** field while placing an order.



Specimen List		Order List							
<input type="checkbox"/> <b>Request For</b> <input checked="" type="radio"/> Existing Specimen <input type="radio"/> Derivative Specimen		<b>Order Name:</b> Existing Specimen <b>Order</b> <b>Distribution Protocol:</b> Blood Samples							
Required Quantity <input type="text"/> <b>Apply To All</b>		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Requests</th> <th style="width: 90%;">Quantity/Count</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> 114</td> <td>5</td> </tr> <tr> <td><input type="checkbox"/> 115</td> <td>0.1</td> </tr> </tbody> </table>		Requests	Quantity/Count	<input type="checkbox"/> 114	5	<input type="checkbox"/> 115	0.1
Requests	Quantity/Count								
<input type="checkbox"/> 114	5								
<input type="checkbox"/> 115	0.1								
<input type="checkbox"/> <b>Specimen Name</b>	<b>Available Quantity</b>	<b>Required Quantity</b>	<b>Description</b>						
<input type="checkbox"/> 114	15.0 ml	<input type="text"/> ml	<input type="text"/>						
<input type="checkbox"/> 115	1.0 ml	<input type="text"/> ml	<input type="text"/>						
<b>①</b> <input checked="" type="checkbox"/> 116	15.0 ml	<b>②</b> <input type="text"/> ml	<input type="text"/>						
Array Name : <input type="text" value="None"/>		<b>Add To Order List</b> <b>③</b>	<b>Remove</b> <b>Order</b> <b>④</b>						

Figure107: Order Existing Specimen

3. Click **Add to Order List**. The requested specimens are displayed in the Order List.
4. Click **Order**. A success message is displayed and the system navigates back to *My List*.

	To delete items added to the Order List, select the items and click Remove.
---	---

To order a derivative from an existing specimen:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Specimen List page is displayed. Select the **Derivative Specimen** radio button as shown in the following figure.
2. Select the required Specimen Class and Specimen Type for the required derivative.
3. Select the check box next to specimens that you want to order.
4. Enter the Required Quantity for the derivative being ordered.

The screenshot shows the Biospecimen ordering interface. The Specimen List panel on the left contains fields for Request For (radio buttons for Existing Specimen (1) and Derivative Specimen), Specimen Class (Molecular (2)), Specimen Type (RNA), and Required Quantity (μg). Below these are tables for Available and Required Quantities. The Order List panel on the right shows a summary of the order: Order Name: Derived Specimen Order, Distribution Protocol: Blood Samples, Requests: 114, Quantity/Count: 10. Buttons for Remove and Order are at the bottom.

Specimen List			
* Request For	<input type="radio"/> Existing Specimen <input checked="" type="radio"/> Derivative Specimen (1)		
* Specimen Class	Molecular (2)		
* Specimen Type	RNA		
Required Quantity	μg <input type="button" value="Apply To All"/>		
<input type="checkbox"/> Specimen Name	Available Quantity	Required Quantity	Description
<input type="checkbox"/> 114	15.0 ml	<input type="text"/> ml	<input type="button"/>
<input type="checkbox"/> 115	1.0 ml	<input type="text"/> ml	<input type="button"/>
<input checked="" type="checkbox"/> 116	15.0 ml	<input checked="" type="text"/> 5 ml (3) (4)	<input type="button"/>

Order List

Order List	
Order Name: Derived Specimen Order	Distribution Protocol: Blood Samples
Requests	Quantity/Count
<input type="checkbox"/> 114 (5)	10

(6)

Figure108: Order Derivative from Existing Specimen

5. Click **Add to Order List**. The requested derivatives are displayed in the Order List.
6. Click **Order**. A success message is displayed and the system navigates back to *My List*.



A derived specimen is denoted by the **d 114** icon in the Order List. The number 114 denotes the parent specimen label from which you derive the specimen.

## Ordering Associated with Surgical Pathology Report (SPRs)

You can order specimen and its derivatives associated with a Surgical Pathology Report (SPR) that exists in the system. The caTissue Suite accession number for surgical specimen is same as the surgical pathology report number. The following procedures describe how to order specimen.

To order a specimen associated with SPR:

If specimens associated with SPR are collected, refer to the [To order an existing specimen](#) procedure.

Requested specimens may or may not exist in the biospecimen resource. An order has biospecimens that are part of a surgical pathology case (that is a Specimen Collection Group), but which do not exist in the system as individual specimens (paraffin blocks), or derivative specimens or aliquots (for example: cut sections). For example: a Scientist identifies a particular surgical pathology report or case that is of interest to him and wants ten, uncut slides from the tumor and metastatic lymph node block from that case. The biospecimen resource needs to retrieve the appropriate blocks from the requested case and accession them into the system as individual specimens. Then, specimens or aliquots from each block are created (that is sections cut to slides) and distributed.

To order a specimen associated with an SPR that has not been collected:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Biospecimen tab is displayed. Click the **Pathological Case** tab. The Case List page is displayed.
2. Select the **Specimens** or **Block** radio button under Request For.

3. Enter the Specimen Class and Specimen Type. These options are disabled if you select the **Block** option.
4. Select the required Tissue Site and Pathological Status.
5. Select the check box next to the associated SPR for these specimens or block as shown in the following figure.
6. Enter the Required Quantity for the biospecimens or block being ordered.

The screenshot shows two main panels: the 'Case List' on the left and the 'Order List' on the right.

**Case List:**

- Request For: Specimens (radio button selected) ②
- \* Specimen Class: Molecular ③
- \* Specimen Type: DNA ④
- \* Tissue Site: Abdomen, NOS
- \* Pathological Status: Malignant
- Required Quantity:  μg

SPR Accession Number	Required Quantity	Description
SMS05-4	<input type="text"/>	<input type="button"/>
MHS05-5	<input type="text"/>	<input type="button"/>
LRS05-4	<input type="text"/>	<input type="button"/>
<input checked="" type="checkbox"/> MWS05-5 <span style="color:red;">⑤</span>	<input type="text" value="10"/> <span style="color:red;">⑥</span>	<input type="button"/>
HHS05-4	<input type="text"/>	<input type="button"/>

Buttons at the bottom: Array Name: None, Add To Order List ⑦, Remove, Order ⑧.

**Order List:**

Order Name: SPR\_Specimen  
Distribution Protocol: Blood Samples

Requests	Quantity/Count
<input type="checkbox"/> MHS05-5	5000
<input type="checkbox"/> SMS05-4	5000
<input type="checkbox"/> LRS05-4	1 count

Figure109: Order a Specimen Associated with an SPR that has not been Collected

7. Click **Add to Order List**. The requested specimens or blocks are displayed in the Order List.
8. Click **Order**. A success message is displayed and the system navigates back to *My List*.

To order a user defined specimen array associated with SPR:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Biospecimen tab is displayed. Click **Define Array**. The Define array page is displayed. Enter the required details to proceed.
2. Click the **Pathological Case** tab. The Case List page is displayed.
3. Select the **Specimens** radio button under Request For.
4. Enter the Specimen Class and Specimen Type.
5. Select the required Tissue Site and Pathological Status.
6. Select the check box next to the required SPR from which you want to order the specimen arrays.
7. Enter the Required Quantity for the biospecimen being ordered as shown in the following figure.

CASE LIST																				
* Request For	<input checked="" type="radio"/> 3 Specimens <input type="radio"/> Block																			
* Specimen Class	4 Tissue																			
* Specimen Type	Fresh Tissue																			
* Tissue Site	Abdominal esophagus																			
* Pathological Status	Metastatic																			
Required Quantity	<input type="text"/>	Apply To All																		
<table border="1"> <thead> <tr> <th>SPR Accession Number</th> <th>Required Quantity</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> SMS05-4</td> <td>20</td> <td></td> </tr> <tr> <td><input type="checkbox"/> MHS05-5</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> LRS05-4</td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> 6 MWS05-5</td> <td>20</td> <td></td> </tr> <tr> <td><input type="checkbox"/> HHS05-4</td> <td></td> <td></td> </tr> </tbody> </table>			SPR Accession Number	Required Quantity	Description	<input checked="" type="checkbox"/> SMS05-4	20		<input type="checkbox"/> MHS05-5			<input type="checkbox"/> LRS05-4			<input checked="" type="checkbox"/> 6 MWS05-5	20		<input type="checkbox"/> HHS05-4		
SPR Accession Number	Required Quantity	Description																		
<input checked="" type="checkbox"/> SMS05-4	20																			
<input type="checkbox"/> MHS05-5																				
<input type="checkbox"/> LRS05-4																				
<input checked="" type="checkbox"/> 6 MWS05-5	20																			
<input type="checkbox"/> HHS05-4																				
<b>8</b> Array Name : <input type="text"/> None <b>9</b> Add To Order List																				

Order List		
<b>Order Name:</b> Specimen Array_SPR_UD <b>Distribution Protocol:</b> Blood Samples		
<input type="checkbox"/> Requests	Quantity/Count	
<b>Array Name :</b> DNA Array <b>Dimensions:</b> 2 , 2 <b>Type:</b> DNA Arr		
<b>Class:</b> Molecular		
<input type="checkbox"/> Specimen Name	Quantity/Count	
<input type="checkbox"/> MHS05-5	10	
<input type="checkbox"/> LRS05-4	10	
		<b>10</b> Remove Order

Figure110: Order a User Defined Specimen Array Associated with SPR

8. Select the required Array Name from the drop-down list.
9. Click **Add to Order List**. The requested specimen arrays are displayed in the Order List.
10. Click **Order**. A success message is displayed and the system navigates back to *My List*.

## Ordering Biospecimen Arrays

You can order existing specimen arrays or define arrays based on your requirements. The following procedures describe how to proceed with the ordering.

To order an existing biospecimen array:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Biospecimen tab is displayed. Click the **Biospecimen Array** tab. The Request Details-Array page is displayed.
2. Select the check box next to the required array under Array Name as shown in the following figure.

Figure111: Order an Existing Biospecimen Array

3. Click **Add to Order List**. The requested specimen arrays are displayed in the Order List.
4. Click **Order**. A success message is displayed and the system navigates back to *My List*.

To order a user defined array:

1. Once you perform steps 2a and 2b (that is, submit *My List* and select a distribution protocol), the Biospecimen tab is displayed. You can define an array based on the specimens displayed under the Specimen List. Click **Define Array**. The Define array page is displayed.
2. Enter the **Array Name** and **Array Type**. The Array Dimensions field will populate based on the Array Type selected.

Figure112: Order a User Defined Array – Define Array

3. Click **Create**. The system navigates back to the Biospecimen tab.
4. Select the check box next to the required specimen under Specimen Name.
5. Enter the Required Quantity for the ordered biospecimen.
6. Select the Array Name that was created from the drop-down list.
7. Click **Add to Order List**. The requested specimens are displayed in the Order List as shown in the following figure. The arrays will be created based on the selected specimens.

Figure113: Order a User Defined Array

8. Click **Order**. A success message is displayed and the system navigates back to *My List*.



Click Apply To All after you add the Required Quantity for the ordered items. This value will then populate all the rows under the Required Quantity column.

## Distribution of Ordered Items

Once the Principle Investigator (PI) places an order for a specimen, the Administrator will view the order and decide to distribute or reject the order depending on the circumstances. The distribution is performed for the following three types:

- Distribution of parent and derived specimen.
- Distribution of existing array and user defined array.
- Distribution of specimen and arrays associated with surgical pathology report (SPR).

The Administrator sets the status of each specimen, specimen array, and specimen and specimen arrays associated with SPR. The following figure displays the available options under Status on the Specimen Requests and Array Requests tab. These tabs are located under Order View of the Biospecimen Data tab.

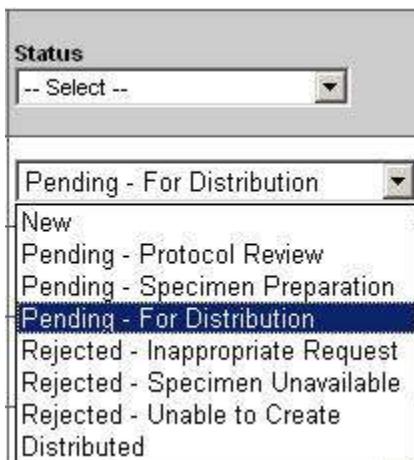


Figure114: Specimen Order Status

## *Distribution of Parent and Derived Specimen*

The following procedure outlines how the Administrator distributes an order based on a parent and derived specimen.

To view and distribute ordered items:

1. Click the **Biospecimen Data** tab.
2. Click **Order View** under Order. The Requests List page is displayed.
3. Click the link for the required order under Order Name as shown in the following figure. The Order Details page is displayed.

## Chapter 8: Ordering Biospecimens (New Feature in Suite Release)

#	Order Name	Distribution Protocol	Requested By	Email Address	Requested Date	Status
1	TJU_Order5 <span style="color: red;">3</span>	TJU_DP1	Scientist, User	deven@mail.jci.tju.edu	02-19-2008	New
2	TJU_Order1 <span style="color: red;">2</span>	TJU_DP1	Scientist, User	deven@mail.jci.tju.edu	02-19-2008	New
3	TJU_Order2	TJU_DP1	Scientist, TJU	TJU_Scientist@mail.com	02-19-2008	New
4	TJU_AmOrder1	TJU_DP1	Scientist, TJU	TJU_Scientist@mail.com	02-19-2008	New
5	TJU_Order3	TJU_DP1	Scientist, TJU	TJU_Scientist@mail.com	02-19-2008	Pending
6	TJU_Order4	TJU_DP1	Scientist, TJU	TJU_Scientist@mail.com	02-19-2008	Pending
7	new_array	Blood Samples	Paul, Sci	paul@sci.com	02-19-2008	Pending
8	array_order	Blood Samples	Paul, Sci	paul@sci.com	02-19-2008	New
9	Existing Specimen Order	Blood Samples	Paul, Sci	paul@sci.com	02-19-2008	New

**Figure115:** View and Distribute Ordered Items - Order Details Page

- The Specimen Requests tab is selected by default. You can view the details of the requested specimen, namely: Specimen Label, Request For, Type, Quantity, and Available Quantity.

F.Y.I.

The Administrator views the Specimen Details page by clicking the required specimen link under Specimen Label. The Administrator can also view other tabs like Events, View Surgical Pathology Report, View Annotations, and Consent.

- Change the quantity under Assign Quantity if required as shown in the following figure.

Specimen Requests		Array Projects	
Requested specimen details			
Specimen Label	Request For	Type	Available Quantity
<span style="color: red;">4</span> S_1	<span style="color: red;">5</span> E	Whole Genome Amplified DNA	5.0 µg
<span style="color: red;">10</span> S_10	<span style="color: red;">11</span> E	Whole Genome Amplified DNA	10.0 µg
S_2	2_2	DNA	5.0 µg
10	16	DNA	5.0 µg

Consent: 10

Distribution Site: 11

12 Submit

**Figure116:** View and Distribute Ordered Items – Specimen Requests Page

- Click the link next to the required specimen under Consent for Specimen to view the consent.
- Select the I have verified that distribution of the specimen is as per consent of Participant check box as shown in the following figure.

## Chapter 8: Ordering Biospecimens (New Feature in Suite Release)

CONSENT FORM					
Signed Consent Form URL					
Witness Name					
Consent Date		02-12-2008			
#	Consent Tier	Participant Responses			Verify Consent Status
1.	Current study	Yes			Not Specified
2.	Store	Yes			Not Specified
3.	Genetic study	No			Not Specified
<input type="checkbox"/>	I have verified that distribution of the specimen is as per consent of Participant				
7					
<input type="button" value="8 Done"/>					

Figure117: View and Distribute Ordered Items - Consent Form

- Click **Done**. The Order Details page is displayed and the selected link under Consent for Specimen is changed from View to Verified as shown in the following figure.

Specimen Requests		Array Requests					
Requested specimen details				Available Quantity	Assign Quantity	Consent for Specimen	Status
Specimen Label	Request For	Type	Quantity			<a href="#">View All</a>	-- Select --
<input checked="" type="checkbox"/> 208	208	Whole Blood	1.0 ml	20.0 ml	1.0 ml	<a href="#">View</a>	Pending - For Distribution
<input checked="" type="checkbox"/> 206	206	Whole Blood	1.0 ml	15.0 ml	1.0 ml	<a href="#">Verified</a>	Pending - For Distribution
<input checked="" type="checkbox"/> 209	209	Fixed Tissue Block	1.0 count	10.0 count	1.0 count	<a href="#">Verified</a>	Pending - For Distribution
<input checked="" type="checkbox"/> 207	207	Fixed Tissue Block	1.0 count	10.0 count	1.0 count	<a href="#">View</a>	Pending - For Distribution

Comment:

\*Distribution Site :

Figure118: View and Distribute Ordered Items – Consent Change

 When the waived consent for a collection protocol is true, then during distribution of specimens under this collection protocol, you do not have to verify the consent data of these specimens.

- Update the Status for the specimen as required.
- Add a **Comment** if required.
- Select a Distribution Site from the drop-down list.
- Click **Submit**. The following Distribution Report is generated after distributing a specimen. Similar reports are generated after distribution of specimen arrays, and distribution of specimen and specimen arrays associated with SPR.

<b>DISTRIBUTION REPORT</b>	
<b>Distribution Identifier</b>	27
<b>Distribution Protocol</b>	TJU_DP1
<b>User</b>	Admin, Admin
<b>Date</b>	03-18-2008
<b>Time</b>	5:10
<b>To Site</b>	Penn
<b>Comments</b>	

<b>DISTRIBUTED ITEM(S)</b>					
#	Label : Specimen	Type : Specimen	Tissue Site : Specimen	Tissue Side : Specimen	Pathological Status : Specimen
1	206	Whole Blood	Not Specified	Not Specified	Not Specified
2	209	Fixed Tissue Block	Not Specified	Not Specified	Not Specified
3	208	Whole Blood	Blood	Not Specified	Not Specified
4	207	Fixed Tissue Block	Blood	Not Specified	Not Specified

[Export](#) [Define View](#)

**Figure119: Distribution Report**

The Administrator can export the distribution report data into a CSV <sup>1</sup>format text file. To export the data, click Export. Click Define View and select a set of attributes. These attributes are displayed in the spreadsheet.

**Table 25: Specimen Icons and its Description**

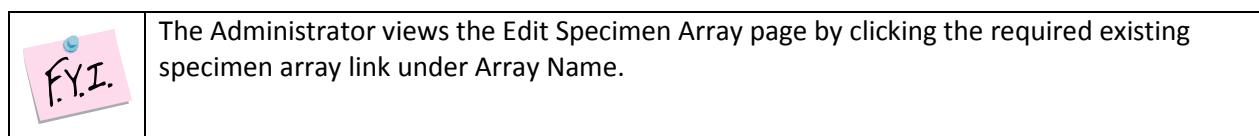
Icon	Description
	Indicates that the specimen is a derived specimen.
	Indicates the specimen tree.
	Indicates the expanded specimen tree. To expand the specimen tree, click the specimen tree icon. <b>Note:</b> The number 11 appears dark as it is a newly created derivative of parent specimen 10.

### *Distribution of Existing Array and User Defined Array*

The following procedure outlines how the Administrator distributes an order based on an existing array and user defined array.

To view and distribute existing arrays:

1. Click the **Biospecimen Data** tab.
2. Click **Order View** under Order. The Requests List page is displayed.
3. Click the link for the required order under Order Name. The Order Details page is displayed. The Administrator can view the details of the requested user defined array, namely: Array Name, Quantity, Available Quantity, Description, Add Description, and Status. Refer to the first figure in the [To view and distribute ordered items](#) procedure.



4. Click the **Array Requests** tab as shown in the following figure.

<sup>1</sup> [http://en.wikipedia.org/wiki/Comma-separated\\_values](http://en.wikipedia.org/wiki/Comma-separated_values)

## Chapter 8: Ordering Biospecimens (New Feature in Suite Release)

**Order Details For : Existing array order 2**

\* indicates a required field

**Requestor Name :** Williams, Derek    **Requested Date :** 02-11-2008  
**Distribution Protocol :** Colon\_DP  
**Comment :**

Specimen Requests		Array Requests		4	
<b>Existing Array</b>					
Array Name	Quantity	' Assign Quantity	Description	Add Description	Status
TJU-ArrayB_89	NA	NA			Distributed
Penn-Tissue Array_A	NA	NA			New

**Comment** 7      \*Distribution Site : 8

Submit 9

**Figure120: View and Distribute Existing Array – Array Requests Page**

5. Add details in the Add Description field if required.
6. Update the Status as required.
7. Add a Comment if required.
8. Select the Distribution Site from the drop-down list.
9. Click **Submit**. The Distribution Report is displayed.

To view and distribute user defined arrays:

1. Click the **Biospecimen Data** tab.
2. Click **Order View** under Order. The Requests List page is displayed.
3. Click the link for the required order under Order Name. The Order Details page is displayed. The Administrator can view the details of the requested user defined array, namely: Specimen Label, Request For, Class and Type, Quantity, and Available Quantity. Refer to the first figure in the [To view and distribute ordered items](#) procedure.

**Order Details For : User Defined Array**

\* indicates a required field

Requestor Name : Williams, Derek      Requested Date : 02-18-2008  
 Distribution Protocol : Colon\_DP  
 Comment :

Specimen Requests		Array Requests <span style="color: red;">4</span>			
DNA Array Array Dimensions : 2,2 Class : Molecular Type : DNA Array Status: New					
Requested				Available Quantity	Status
Specimen Label	Request For	Class, Type	Quantity		
[+]	2	Molecular, DNA	6.0 µg	45.0 µg	Ready For Array Preparation <span style="color: red;">6</span>
[+]	6	Molecular, DNA	6.0 µg	42.0 µg	Ready For Array Preparation

5 Create Array

**Existing Array**

Array Name	Quantity	' Assign Quantity	Description	Add Description	Status
Comment	<span style="color: red;">7</span>			'Distribution Site : <span style="color: red;">8</span> -- Select --	

Submit 9

**Figure121: View and Distribute User Defined Arrays – Array Requests Page**

4. Click the **Array Requests** tab as shown in the preceding figure.
5. Click **Create Array**.
6. Once the array is created, the system navigates back to the Order Details page. Update the array Status as required.
7. Add a Comment if required.
8. Select the Distribution Site from the drop-down list.
9. Click **Submit**. The Distribution Report page is displayed.

### *Distribution of Specimen and Arrays associated with Surgical Pathology Reports*

The specimen or arrays associated with the surgical pathology reports are distributed in two ways:

- Specimens associated with SPR are already collected.
- Specimen or arrays associated with SPR that are yet to be collected.

#### *Specimens associated with the surgical pathology reports are already collected*

The user placing an order queries on specimens associated with a particular SPR. To view and distribute specimen associated with the SPR that are already collected, refer to [Distribution of Parent and Derived Specimen](#).

#### *Specimen or arrays associated with the surgical pathology reports that are yet to be collected*

The user placing an order queries on the SPR. The order is placed for a specimen or an array associated with a SPR.

To distribute specimen associated with SPR:

1. Navigate to the Order Details page.

To do this, click the **Biospecimen Data** tab. Then, click **Order View** under Order. The Requests List page is displayed. Click the link for the required order under Order Name. The Order Details page is displayed.

## Chapter 8: Ordering Biospecimens (New Feature in Suite Release)

2. The requested Specimens are visible under the Specimen Requests tab.
3. Once the specimen is ready for creation, click **Create** as shown in the following figure.

**Order Details For : SPR Order 1** 1

\* indicates a required field

Requestor Name : Williams, Derek Requested Date : 02-14-2008  
 Distribution Protocol : Colon\_DP  
 Comment :

Specimen Requests		Array Requests					
Requested specimen details				Available Quantity	Assign Quantity	Consent for Specimen	Status
Specimen Label	Request For	Type	Quantity			<a href="#">View All</a>	-- Select --
+ LRS05-4	2911 <span style="color: red;">4</span>	Whole Genome Amplified DNA	50.0 µg	50.0 µg	50.0 µg	No Consents	New <span style="color: red;">5</span>
+ SMS05-4	<span style="color: yellow;">Create</span> <span style="color: red;">3</span>	Frozen Tissue Slide	1.0 count	NA count	1.0 count	No Consents	New
+ MHS05-5	2691	Whole Genome Amplified DNA	10.0 µg	0.0 µg	10.0 µg	No Consents	Distributed

Comment 6

Distribution Site : 7 Genetics Storage

Submit 8

**Figure122: Distribute Specimen Associated with SPR**

4. Once the specimen is created, the label number will be populated in the Request For box.
5. Update the specimen Status as required.
6. Add a Comment if required.
7. Select the **Distribution Site** from the drop-down list.
8. Click **Submit**. The Distribution Report page is displayed.

To distribute specimen array associated with SPR:

1. Navigate to the Order Details page.  
 To do this, click the **Biospecimen Data** tab. Then, click **Order View** under Order. The Requests List page is displayed. Click the link for the required order under Order Name. The Order Details page is displayed.
2. The requested arrays are visible under the Array Requests tab.
3. Click **Create** to collect the specimens as shown in the following figure.

**Order Details For : Array from SPR** 1

\* indicates a required field

**Requestor Name :** Williams, Derek    **Requested Date :** 02-14-2008

**Distribution Protocol :** Colon\_DP

**Comment :**

Specimen Requests	Array Requests <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">2</span>
-------------------	--

**DNA Array from SPR Array Dimensions : 2,2 Class : Molecular Type : DNA Array Status: New** 6

Requested				Available Quantity	Status
Specimen Label	Request For	Class, Type	Quantity		
<input checked="" type="checkbox"/> SMS05-4	<input type="text" value="2692"/> <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">3</span>	Molecular, DNA	6.0 µg	6.0 µg	New <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">4</span>
<input checked="" type="checkbox"/> MHS05-5	<input type="text"/> <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">3</span>	Molecular, DNA	6.0 µg	NA µg	New

5 Create Array

**Existing Array**

Array Name	Quantity	* Assign Quantity	Description	Add Description	Status
Comment <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">7</span>				'Distribution Site : <input type="text" value="-- Select --"/> <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">8</span>	<span style="border: 1px solid red; border-radius: 50%; padding: 2px;">9</span> Submit

Figure123: Distribute Specimen Array Associated with SPR

4. Once the specimen is created, select the Status as **Ready for Array Preparation**.
5. The Create Array button is enabled. Click **Create Array**.
6. Once the array is created, the system navigates back to the Order Details page. Update the Array Status as required.
7. Add a Comment if required.
8. Select the Distribution Site from the list.
9. Click **Submit**. The Distribution Report page is displayed.



If a user places an order and the item is delayed, rejected, or not available for distribution; the Administrator informs the user about the status by email or phone. The system does not send any auto notification.

## **Chapter 9: Search Data – Simple Search and Advanced Query Wizard**

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This chapter outlines the search engines that caTissue Suite supports. These search engines are:

- Simple
- Advanced

Each of the search engines is described in the following sections.

### **Simple Search**

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This interface is ideal for simple queries based on one or more objects. For example: you can search for Participants whose Last Name begins with a specific letter. Once you add an object to the simple search, you can add new objects that are subsequently filtered based on the previously added object. For example: if you select Participant as the first object, the subsequent objects available for selection will be Collection Protocol Registration and Participant.

The following table outlines the various fields that you need to select to perform a simple search.

**Table 26: Simple Search Field Names**

Field Name	Description
Object	This includes all Administrative Data classes and Biospecimen classes for query.
Attribute	This includes multiple characteristics related to the object you select.
Condition	This includes various situations on which you can perform the search.
Value	This field is related to the Condition field. Depending on the condition selected, you need to enter appropriate values. The values entered in this field are alphanumeric.
Operators	This includes operators <i>AND</i> or <i>OR</i> . They are used to perform a search on more than one object. They are used as connectors between two or more objects. The expressions are evaluated from top to bottom and they do not have any parentheses control.



If you select the Condition as *is Null* or *is Not Null*, the Value field will be disabled.

To perform a simple search:

1. Click the **Search** tab.
2. Click **Simple** under Search on the left pane. The Simple Search page is displayed.
3. Select the required Object from the drop-down list.
4. Select the required Attribute from the drop-down list. The options in this list will be filtered based on the Object you select.
5. Select the appropriate Condition from the drop-down list.
6. Enter a Value if required. If you do not enter a value, all records are displayed based on the selected Object and Attribute.
7. Select an Operator to connect more than one Object.
8. Click **Add More** if required to add a new object row to the search criterion.
9. Click **Search** to view the filtered records as shown in the following figure.

Figure124: Simple Search



To delete the last object row from your query, select the check box next to the row and click Delete.

The Records page has:

- Export button
- Define View button
- Redefine Query button

For more information about these options, refer to point three and four in the [Results View](#) section.

## Advanced Query Wizard

The caTissue Suite advanced query wizard provides a powerful and flexible query interface where you can query and view any data in the caTissue database.



The flexible nature of the query interface also makes it complex to use, and therefore in the current version the tissue bank Administrator or Data Manager should create the queries and save them for the end users. Scientists or tissue bankers have access to the query interface, but it is strongly recommended that they use the saved queries.

The query interface is a wizard-like interface, which takes you through a series of steps with each step having sub-steps within it. The following figure outlines these steps.

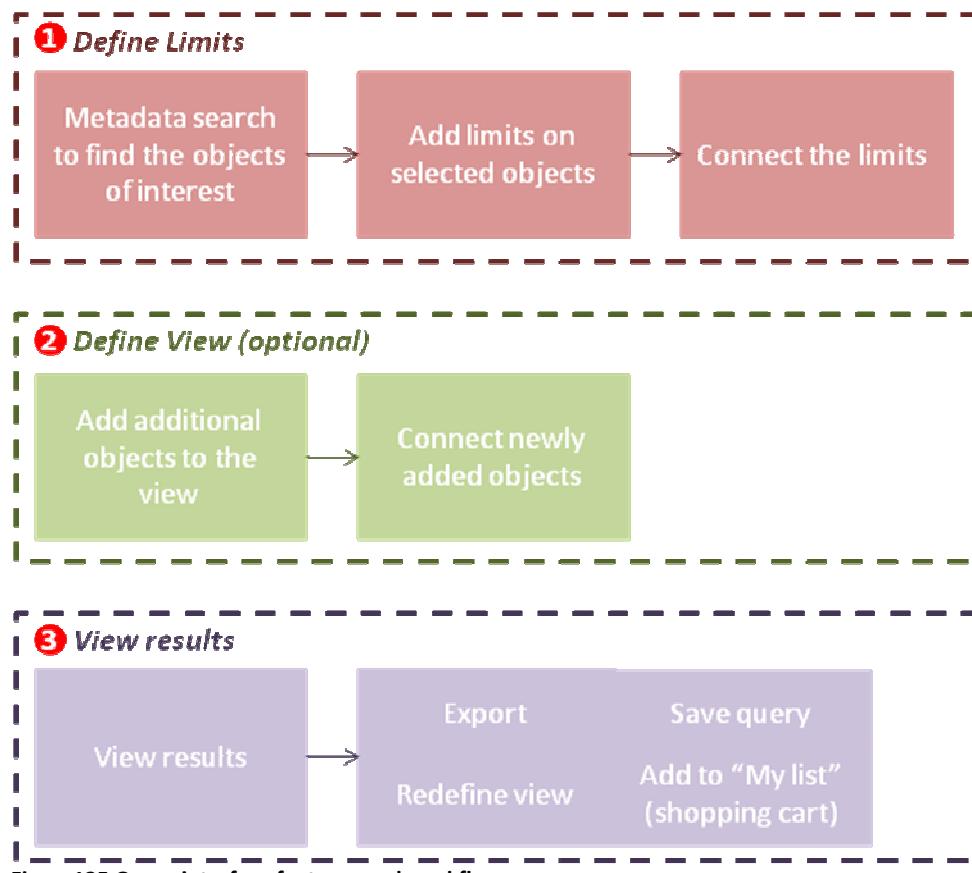


Figure125 Query interface features and workflow

This section explains the search workflow in detail. To navigate to the advanced query interface:

1. Click the **Search** tab.
2. Click **Advanced** under Search as shown in the following figure.



Figure126: Advanced Search Link

The query wizard contains the following three steps:

1. Add Limits – define the limits (criteria or predicates) of the query.
2. Define Results View.
3. View Results.

### Add Limits

A limit is a condition (or criterion or predicate) on an object. One or more limits together form a query. For example: in the *all active male participant* query, *active* and *male* are limits on the participant object.

### Advanced Options

If you expand the Advanced Options **list**, it displays the options that help you refine the category search. The following figure displays the default selection of the available options:



Figure127: Advanced Options

If the system returns too many results for the category search, use Advanced Options to narrow your search.

Table 27: Advanced Options and its Description

Option	Description
<b>Check Boxes</b>	
Class	Includes the class names in the search.
Attribute	Attribute (also known as data element) is the lowest unit of the items that can be searched. A class contains many attributes. Select this check box to include the individual attribute names in the search. For example: if you select <i>attribute</i> and search for <i>gender</i> , the system will display the Participant category as it contains the <i>Gender</i> attribute.
Permissible Values	Some attributes contain a fixed set of values. For example: Gender can be Male, Female, or Unspecified. Organ can be heart, lung, breast, and so on. This fixed set is known as Permissible Values. Select this check box to include the permissible values in the search. For example: if you select the permissible value as <i>Male</i> , the system will display the Participant class as it contains the <i>Gender</i> attribute. This attribute contains a permissible value <i>Male Gender</i> .
Include Description	Includes the description text in the search. This option is disabled if you select the Permissible Values check box.
<b>Option Buttons</b>	
Text	The system matches the search string that you type with the name of the class, its attributes, or the permissible values based on the text. This is the simplest, most commonly used, and default way of searching a category.
Concept Code	A concept code is a concept unique identifier within the NCI Enterprise Vocabulary Service's NCI Thesaurus. The system treats the search string you type as an EVS concept code. The system matches this concept code with the concept code of the class, its attributes, or the permissible values. The results contain matching categories. <b>Note:</b> The Include Description check box is enabled only for a <i>text based search</i> if you select the Class check box, the Attribute check box, or both. This option is currently disabled as the functionality is under construction.



Advance query wizard is a text based or concept code based search. You are not required to use *wildcards* to perform the search.

The screenshot shows the 'Add Limits' step of the Advanced Query Wizard. On the left, a sidebar lists search results for 'Participant', including 'Participant', 'ParticipantMedicalIdentifier', 'AbstractSpecimenCollectionGroup', 'CollectiveProtocolEvent', 'CollectionProtocol', 'Specimen', 'TissueSpecimen', 'FluidSpecimen', 'CollectionEventParameters', 'CollectionProtocolRegistration', 'SpecimenCollectionGroup', and 'SpecimenCollectionRequirementGroup'. Step 1, 'Add Limits', is highlighted with a red circle. Step 2, 'Go', is also highlighted with a red circle. Step 3, 'Search Results', is shown below the sidebar. The main pane, labeled 'Define Limits For 'Participant'' (step b), contains several filter criteria:

- Activity Status:** Equals active
- Birth Date (MM-dd-yyyy):** Between [text box] and [text box]
- Death Date (MM-dd-yyyy):** Between [text box] and [text box]
- Ethnicity:** In: Hispanic or Latino, Not Hispanic or Latino, Not Reported
- First Name:** Contains [text box]
- Gender:** In: Female Gender, Male Gender, Unknown

An 'Add Limit' button is located at the top right of the limits pane. Below the limits pane is a 'Diagrammatic View' (step c) which shows a single node 'Participant' with two conditions listed:

- Condition(s) on
  - 1) Gender Is Male Gender
  - 2) Activity Status Equals active

A message at the bottom of the diagrammatic view states: 'Current Expression: Expression 1 is not connected.'

Figure128: Add Limits

This section outlines the three steps you need to perform while adding limits:

- a. **Metadata Search:** This step helps you to search the objects on which you want to add limits. For example: Participant, Specimen, Collection Protocol, and so on. To perform a metadata search:

1. Enter a keyword in the search text box.
2. Click Go.
3. The system displays the list of matching objects.
4. Click the object of interest to enter the details of the limit on the right pane.



If the system returns too many results, you can fine tune the search by using the Advanced Options.

- b. **Define Limit:** The previous step described how to search for the object of interest. In this step, you need to specify the limits on the selected object. The following figure outlines the two limits defined for class participants. For example Activity Status as *Active* and Gender as *Male Gender*.
1. For each attribute there are possible operators depending upon its data type. Select an appropriate operator from the drop-down list.
  2. The limiting value for that attribute can be entered in a text box or can be selected from the drop-down list. Two text boxes are provided when the *Between* operator is selected. Text box will be disabled when operator selected is *Is Null* or *Is Not Null*. Values should be comma

separated when the *In* operator is selected.

Define Limits For 'Participant'		Add Limit
Activity Status :	Equals	active
Birth Date (MM-dd-yyyy):	Between	
Death Date (MM-dd-yyyy):	Between	
Ethnicity :	In	Hispanic or Latino Not Hispanic or Latino Not Reported
First Name :	Contains	
Gender :	In	Female Gender Male Gender Unknown

Figure129 Add limit page for active male participants

- c. **Diagrammatic View:** The diagrammatic (DAG) view displays all the limits you added to the query. Whenever you add a new limit, the system adds a yellow rectangle to the DAG view. As you continue to add limits, the system adds corresponding rectangles to the DAG view.

View details of the limit	Position your mouse over a node to view the details of that limit.    
Edit or Delete the limit	Click the > icon in the yellow box.  

## Connecting the Limits

This is one of the most important steps in forming a query. If you add more than one limit, connect all the limits within the DAG view before proceeding to the next step.

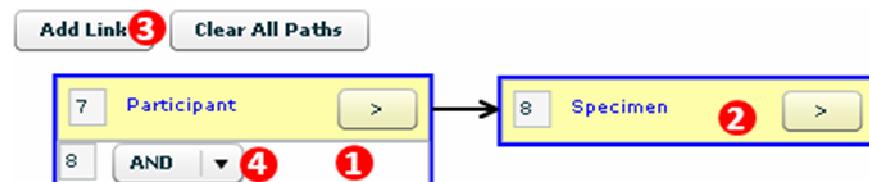


Figure130: Connected Nodes

To connect two nodes:

1. Right-click the first node with the [Shift] button pressed.
2. Right-click the second node with the [Shift] button pressed.
3. Click **Add Link**.
4. By default **AND** operator is selected for every link. If you wish to add an **OR** operator, select **OR** from the drop-down list.

### Why is it important to connect the nodes?

The main purpose of linking the nodes is to form the *query tree*. The query tree is a set of interconnected limits that helps the system in interpreting the query. For example: the following two queries illustrate how the interpretation of query changes depending on how the limits are linked.

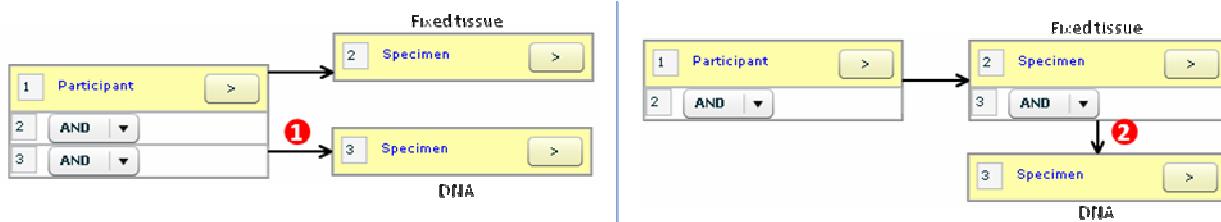


Figure131: Query Tree

In the first example, the query represents, “There exists at least one fixed tissue *and* at least one DNA collected from the same participant”.

In the second example, the query represents, “There exists at least one DNA which has been derived from a fixed tissue collected from a participant”.



Delete a connection by selecting the connection and clicking Delete. Click Clear All Paths to clear all the connections.

### Why a connection is not established between two nodes?

If you connect unrelated classes, for example: Collection Protocol and Specimen, an error message is displayed. This is due to a missing node, which connects these two classes. Under such circumstances, these two nodes will not be connected. To connect a collection protocol to a specimen, the path will be Collection Protocol > Specimen Collection Group > Specimen. For more information on the data model, refer to:

[http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/catissuemodel/caTissueSuite%20Phase%202/WashU%20Deliverables/UML%20model/caTissueSuiteV10\\_UML.zip?cvsroot=cacorecvs](http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/catissuemodel/caTissueSuite%20Phase%202/WashU%20Deliverables/UML%20model/caTissueSuiteV10_UML.zip?cvsroot=cacorecvs)

### The Information Panel

The information panel is located at the bottom of the *Limit Set* panel. It is marked as 1 in the following figure.

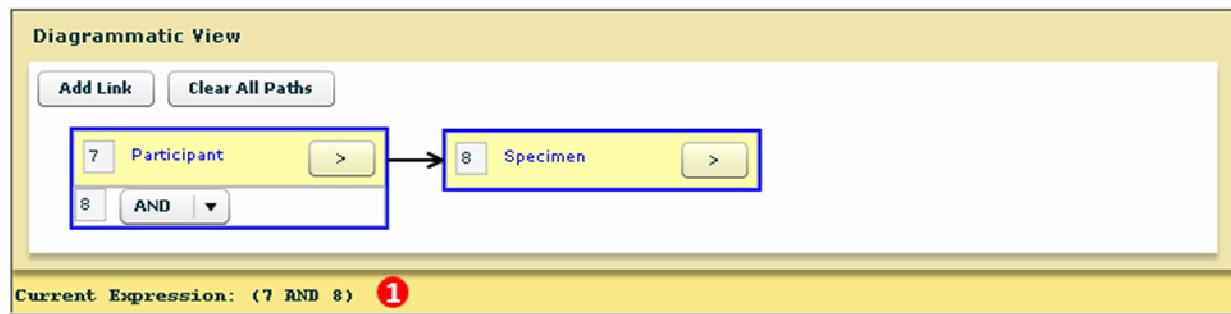


Figure132: The Information Pane

The information panel provides the following:

- Depending on the way you connected the limits, view the expression formed.

- Viewing limits that are not yet connected to any other limit.
- Connecting all limits before executing the query.

## Define Results View

Defining the Results View is the second step in the query wizard. You can add any other object to the view that is not currently present in the DAG. After adding the new objects, connect the new nodes to the existing query tree. You can also hide the objects in the query from the view.

For example: Display the collection protocol details for all participants whose DNA specimen exists in the system. In this query, the query limits are on the participant and specimen, whereas the user wants to view the collection protocol details. The Define Results View window is similar to the add limits window where you perform a metadata search to find the object you want to add to the view. In this example, add the collection protocol object to the view.

The following figure outlines the same.

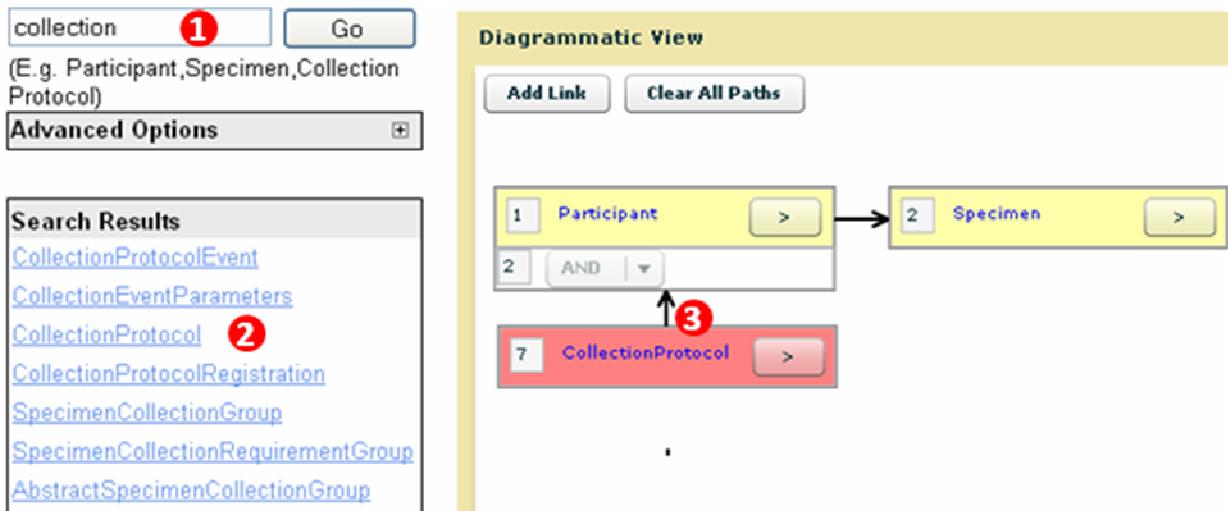


Figure133: Adding Collection Protocol Object to the View

1. Perform metadata search for the collection protocol object.
2. Click **Collection Protocol**. The object is added to the view on the left side in a pink color box. The pink color denotes that no limit is added on that object, but the result for the object can be viewed on the Results View tab.
3. Connect the collection protocol box with the participant box. For more information, refer to [Connecting the Limits](#).
4. Similarly you can add multiple objects to the view.

## Results View

The results view user interface offers:

- Hierarchical data representation with drill-down capabilities. This allows you to filter data based on the selected node in the tree.
- Spreadsheet view. This allows you to view details of specific attributes.
- Attributes definition. This allows you to define attributes that are displayed in the spreadsheet.
- Other features like Export, Add To My List, and Redefine Query.

The following figure illustrates the preceding features available on the View Results page.

Ethnicity : Participant	Last Name : Participant	Birth Date : Participant	Id : Participant	Vital Status : Participant	First Name : Participant	Middle Name : Participant	Gender : Participant	Social Security Number : Participant	Action
Unknown	sg		1	Unknown	sdgfs		Unspecified		Action
Unknown	sdg		2	Unknown	dfg		Unspecified		Action
Unknown	asdf		3	Unknown	erff		Unspecified		Action
Unknown	sgas		4	Unknown	gdfg		Unspecified		Action
Unknown	jmj		5	Unknown	sdf		Unspecified		Action
Unknown	wersdf		6	Unknown	awedf		Unspecified		Action

Figure134: Search Results User Interface

### 1. Hierarchical Data Representation

The hierarchical data tree is similar to the Windows Explorer interface. In Windows Explorer, when you click a folder, it displays the folders or files within the selected folder. Similarly, in caTissue Suite Results View when you select any node, the records related to the next level in the tree are displayed.

### 2. Spreadsheet Data Representation

The spreadsheet contains individual data elements or attributes. For example: if you search for a participant, the attributes displayed in the spreadsheet will be First Name, Last Name, Gender, and so on. The values that are displayed are the individual values of that particular attribute.

### 3. Defining Attributes in a Spreadsheet

There are two types of spreadsheet views:

- a. Default View: This view is displayed when the results view is displayed for the first time.
- b. Defined View: Click Define View and select a particular set of attributes that will be displayed in the spreadsheet.

C.

**Table 28: Spreadsheet Views**

<b>Default View</b>	<b>Defined View</b>
The spreadsheet displays the attributes related to the object selected in the tree. For example: if you select a participant, the page displays the participant objects attributes. If you select a specimen, the page displays the specimen object's attributes.	The spreadsheet view is fixed to display the same set of attributes irrespective of the object selected in the tree. That is, the attribute displayed is always constant.
The number of rows displayed will depend on the number of child nodes in the tree. That is, similar to Windows Explorer.	The number of rows decreases as you move to the lower levels. The number of rows will be the maximum at the highest level.

#### 4. Other Options

- a. **Export:** caTissue Suite provides an option to export your data into a CSV format text file. Select individual records using the check box in each row. To export data, use the following three options:
  - 1. Select the **Check All On This Page** check box to select the records on the current page.  
OR
  - Select the **Check All** check box to select all the records returned in the results.
  - 2. Click **Export** to export the file.
- b. **Redefine Query:** Click **Redefine Query** to navigate back to first step of the query wizard.
- c. **Add to My List:** *My List* is a feature that allows you to records of interest across different queries. This is similar to a shopping cart feature on any shopping site. The features provided in *My List* are:
  - 1. Specimen operations like edit, transfer, and order specimens.
  - 2. Export data.
- d. **Save:** Click **Save** to save the defined query.



You can perform specimen-based operations only if *My List* contains the specimen ID, barcode, or label in the view.

#### Save Query

The Save Query feature lets you save the query in two ways:

1. Canned queries
2. Parameterized queries

#### Canned Queries

Canned queries are queries that Technicians have to execute on a daily basis. They are also the queries required by Scientists, but that are beyond their expertise to create. Administrators can create these queries and save them as canned queries, which can then be executed with one click.

To create canned queries:

1. Define the query and click **Save** on the Redefine Query page or on the View Results page.
2. Enter the query **Title** and **Description**.

3. Click **Save**.

The following figure outlines the steps to create and save a canned query. The query in the following figure searches for samples collected under a particular protocol.

The screenshot shows a search interface with three main tabs at the top: ① Add Limits, ② Define Results Views, and ③ View Results. The ③ View Results tab is active, displaying a table of search results. The left sidebar shows a hierarchical tree view under 'Collection Protocol (1)'. The 'Blood' node is expanded, showing a 'Specimen Collection Group (9)' node which is also expanded, listing items like 'Blood Protocol\_112\_220' through 'Blood Protocol\_191\_454'. The main area displays a table with columns: Id, Activity Status, Comment, Collection Status, Surgical Pathology Number, Clinical Status, Clinical Diagnosis, Name, and Offset. There are 9 records listed, numbered 225 to 229. The table includes checkboxes for 'Check All On This Page' and 'Check All'. Below the table are buttons for 'Add To My List', 'Export', 'Define View', and 'Redefine Query'. At the bottom left is a 'Save' button with a red circled '1' indicating it's the next step. A 'Previous' button is at the bottom right.

Figure135: Save Query from the Results View

The screenshot shows two dialog boxes. The top one is 'Query Information' with fields for 'Title' (set to 'Samples of particular collection protocol') and 'Description' (empty). The bottom one is 'Set Condition Parameters' with a table of conditions:

User defined	Display label	Attribute name	Condition	Value
<input type="checkbox"/>	6.Specimen.Id	Id	Is Not Null	
<input type="checkbox"/>	CollectionProtocol.Id	Id	Is Not Null	
<input type="checkbox"/>	CollectionProtocol.Short Title	Short Title	Starts With	Blood
<input type="checkbox"/>	SpecimenCollectionGroup.Id	Id	Is Not Null	
<input type="checkbox"/>	5.Specimen.Id	Id	Is Not Null	

At the bottom right of the 'Set Condition Parameters' dialog are 'Save' and 'Cancel' buttons, with a red circled '3' above the 'Save' button.

Figure136: Enter Query Description

The query created and saved in the preceding figure will appear in the list of saved queries on the dashboard of the Search tab.

## Parameterized Queries

Parameterized queries are saved queries where you enter data for some or all of the query criteria before executing the query. Thus the query definition is saved, but the condition value on certain parameters can be defined before executing the query.

Steps to create parameterized queries:

1. Define the query and click **Save** on the Redefine Query page or on the View Results page.
2. Enter the query **Title** and **Description**.
3. Select the query conditions that are parameterized so that the user can change the query condition value before executing.
4. Click **Save**.

Consider an example that is described in the following figures based on the preceding procedure. The example saves the query to search for all surgical pathological reports containing particular concept names. The user can change the value of the concept names to be queried before executing the query.

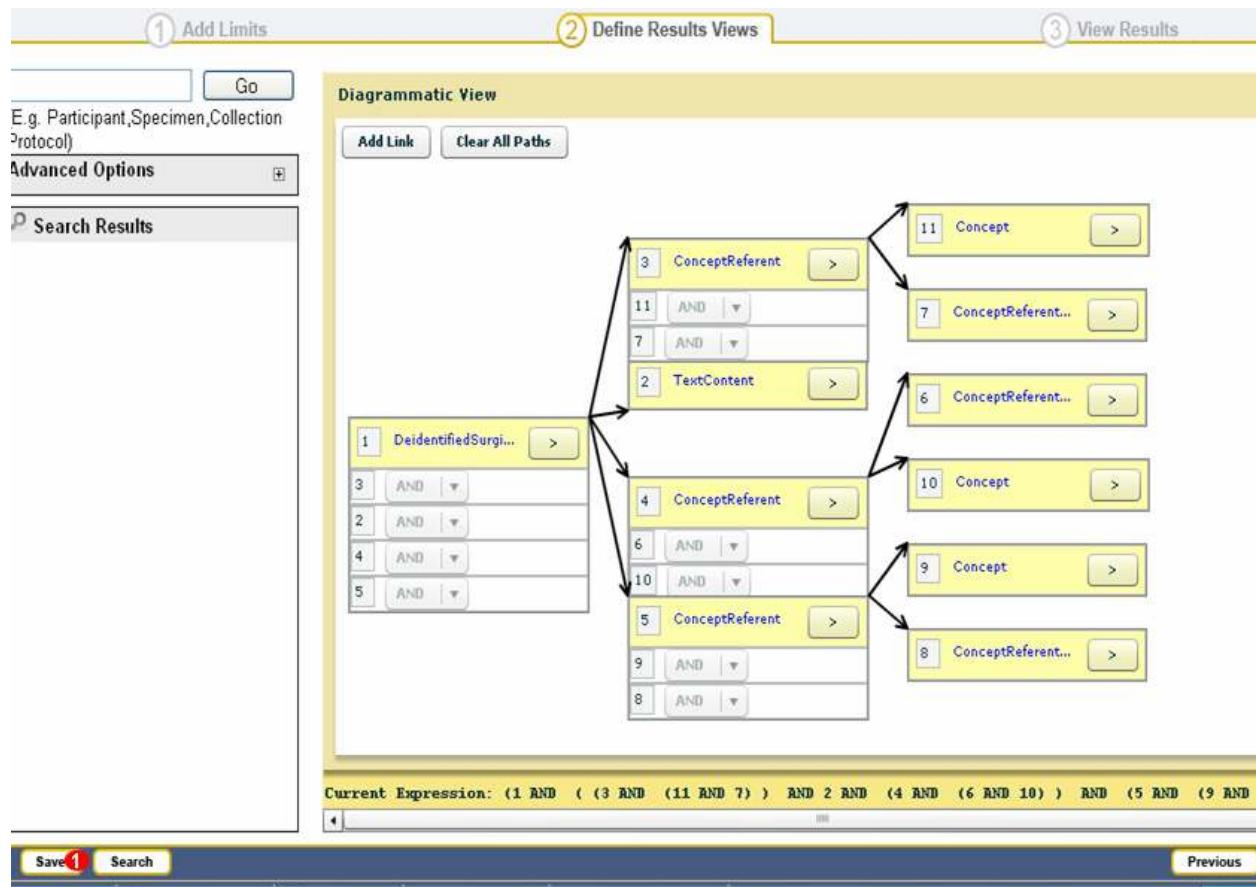


Figure137: Save Query after it is Defined

The screenshot shows the 'Query Information' and 'Set Condition Parameters' sections of the Advanced Query Wizard.

**Query Information:**

- Title:** SPR query
- Description:** This query will search for all the surgical pathological reports having particular report content and concepts

**Set Condition Parameters:**

User defined	Display label	Attribute name	Condition	Value
<input type="checkbox"/>	10.Concept.Id	Id	Is Not Null	
<input checked="" type="checkbox"/>	Procedure name	Name	Contains	excision
<input type="checkbox"/>	8.ConceptReferentClassification.Name	Name	Contains	procedure
<input type="checkbox"/>	6.ConceptReferentClassification.Name	Name	Contains	diagnosis
<input type="checkbox"/>	DeidentifiedSurgicalPathologyReport.Id	Id	Is Not Null	
<input type="checkbox"/>	TextContent.Id	Id	Is Not Null	
<input type="checkbox"/>	4.ConceptReferent.Is Negated	Is Negated	Equals	<input type="radio"/> True <input checked="" type="radio"/> False
<input checked="" type="checkbox"/>	Diagnosis name	Name	Contains	fibroma
<input checked="" type="checkbox"/>	Organ name	Name	Equals	left ring finger
<input type="checkbox"/>	7.ConceptReferentClassification.Name	Name	Contains	organ

**Buttons:**

- Save (with a red circled number 4)
- Cancel

Figure138: Enter Query Description and Define Parameters

**Note:** You can provide a user-friendly display name to the parameters. This will help the user who is executing the query to better understand what can be stipulated. Also, the other query conditions that are not parameterized will be hidden from the user who is executing it.

### Accessing the Saved Queries

Once you save the queries, they are listed in the search tab. Select any query and view the results. If it is a canned query, it takes you directly to the results page. If it is a parameterized query, then you need to first specify the condition values and then view the results that satisfy the conditions. All the four users (Administrator, Supervisor, Technician, and Scientist) have authorization to access and delete the saved queries. You can view the PHI data on the results page if you are the PI for that CP. For example: if the user is a Technician and tries to access a query saved by a Scientist, the user will not be able to view the PHI data in the results view for this query as he is not the PI for that study.

The screenshot shows a list of 12 saved queries:

- 1 Sayali's query  
Description:
- 2 back bone query  
Description:
- 3 textcontent and deidentifiedsurgpathreports  
Description:
- 4 SPR query ② Description: This query will search for all the surgical pathological reports having particular report content and concepts.
- 5 Identified Reports  
Description: Participant>>SCG>>IdentifiedReport>>Text Content
- 6 Samples of Blood Cp  
Description: CP>>SCG>>SPec>>Spec
- 7 CP>>SCG>>SPec>>Spec  
Description:
- 8 New Query Test  
Description:
- 9 Matched tumor and normal - prostate  
Description:
- 10 Identified Surgical Pathology Reports  
Description:
- 11 All specimen arrays  
Description:
- 12 All DNA specimens  
Description:

Figure139: Access the Saved Query

**Title :** Samples of particular collection protocol  
**Description :** Samples of particular collection protocol

Query Conditions		
Display label	Condition	Value
Collection Protocol Title	Starts With	Blood ①

② Execute | Cancel

Figure140: Enter Value For The Parameterized Condition and Execute to View the Results

**Note:** Delete a query by clicking the trash can icon next to each query.

## **Appendix 1: Common Tasks – Using the Biospecimen Tab**

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This section outlines the common tasks you can perform using the Biospecimen tab.

### **Deriving Plasma and Serum from Blood and Aliquoting**

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To derive plasma and serum from blood and aliquot them:

1. Navigate to the **Biospecimen Data** tab.
2. Select the desired CP and then the required participant.
3. Navigate to the blood specimen under Specimen Detail.
4. Select the blood specimen. The specimen details page is displayed.
5. Enter **2** in the Number of Derivative(s) field under Add Multiple Derivatives.
6. Click **Derive Multiple**. The Multiple Specimen Details page is displayed and the Parent Name is auto populated.
7. Select the Class as **Fluid** and Type as **Plasma** under Specimen 1.
8. Enter other required details.
9. Select the Class as **Fluid** and Type as **Serum** under Specimen 2.
10. Enter other required details.
11. Click **Submit**. A success message is displayed and the Specimen details summary page is displayed.
12. Click **Submit** once again. Another success message is displayed.
13. Navigate to the Specimen Details tree and view the newly added derivatives.
14. Select the newly created plasma derivative. The Specimen Details page is displayed.
15. Select the **Do you want to create aliquots?** check box.
16. Enter Aliquot Count and Quantity per Aliquot.
17. Click **Submit**. A success message is displayed and the system navigates to the Create Aliquot page.
18. Confirm the data and click **Submit**. A success message is displayed.
19. To aliquot the newly created serum derivative, repeat the procedure from step 13 till step 18. Enter the details as required to proceed.

## Deriving RNA and/or DNA from Tumor and Matched Non-malignant Tissue in Bulk

To derive RNA and/or DNA from tumor and matched non-malignant tissue in bulk:

1. Navigate to the Biospecimen Data tab.
2. Select the desired CP and then the required participant.
3. Navigate to the tumor specimen under Specimen Detail.
4. Select the tumor specimen. The specimen details page is displayed.
5. Select the Pathological Status as **Malignant** and edit other details if required.
6. Enter **2** in the Number of Derivative(s) field under Add Multiple Derivatives.
7. Click **Derive Multiple**. The Multiple Specimen Details page is displayed and the Parent Name is auto populated.
8. Select the Class as **Molecular** and Type as **RNA** under Specimen 1.
9. Enter other required details.
10. Select the Class as **Molecular** and Type as **DNA** under Specimen 2.
11. Enter other required details.
12. Click **Submit**. A success message is displayed and the Specimen details summary page is displayed.
13. Click **Submit** once again. Another success message is displayed.
14. Navigate to the Specimen Details tree and view the newly added derivatives under the tumor specimen.
15. To derive RNA and DNA from a non malignant tissue specimen, repeat the procedure from step 3 till step 14. Enter the Pathological Status for the specimen as Non Malignant and enter other details as required to proceed.

## Appendix 2: Clinical Annotations

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This section outlines all the clinical annotations available in caTissue Suite.

### Data Entry for Clinical Information Annotation

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This section outlines the various annotations found under the participant hook entity.

#### Lab Annotation

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This annotation helps you to capture information on the clinical and laboratory tests that the participant has undergone or is undergoing.

**Table 29: Lab Annotation**

Attribute and Sub Form Name	Action
Lab Test Name	Select the appropriate laboratory test name from the drop-down list.
Other Lab Test Name	Enter the lab test name if same is not available in the Lab Test Name drop-down list. This field can be left blank.
Test date	Enter the date laboratory test was conducted. To do this, use the calendar.
Result	Enter the result of the test conducted. This data field can store alphanumeric values, which means you can add numeric values and values like <i>positive</i> and <i>negative</i> .
Result Units	Enter the measurement units for quantitative result. You can enter the units as abbreviations, for example: gm, ml; or enter the unit name, for example: gram, milliliter.

#### Family History Annotation

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This annotation helps you to capture the data related to the family medical history of the participant for family members. For each family member, you can capture details of one or more clinical diagnosis.

**Table 30: Family History Annotation**

Attribute and Sub Form Name	Action
Relation	Select the appropriate relation name from the drop-down list.
Other Lab Test Name	Enter the relation name if the same is not available in the previous attribute's (Relation) drop-down list. Data entry in this field is optional.

Attribute and Sub Form Name	Action
General Health Diagnosis	To enter information about the General Health Diagnosis, click the ADD MORE button.
Clinical Diagnosis	Select the appropriate Clinical Diagnosis from the drop-down list.
Other Clinical Diagnosis	Enter the clinical diagnosis value if the same is not available in the previous attribute's (Clinical Diagnosis) drop-down list. Data entry in this field is optional.
Age at Diagnosis	Enter the Age at Diagnosis. This field accepts integer (whole number) values only. If you enter a decimal value, the value is rounded off.

	To delete a General Health Diagnosis record, select the check box next to that record and click Delete.
---	---

### Treatment Annotation

This annotation keeps a track of the general treatments that a participant has undergone or is undergoing.

**Table 31: Treatment Annotation**

Attribute and Sub Form Name	Action
Agent	Select the appropriate Agent name from the drop-down list.
Other Agent	Enter the agent name if it is not available in the previous attribute's (Agent) drop-down list. Data entry in this field is optional.
Dose	Enter the amount or dose of radiation administered to the patient. This field accepts numerical value with decimal.
Dose Unit	Enter the measurement unit for the dose of radiation.
Duration	To enter information about the Duration of the treatment, click the Add More button.
Start Date	Enter the date treatment began using the calendar.
End Date	Enter the date treatment ended using the calendar.

Attribute and Sub Form Name	Action
Duration In Days	Enter the number of days the treatment lasted. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

	To delete a row that contains data about the duration of treatment, select the check box next to the row and click Delete.
---	--

### Rad RX Annotation

This annotation allows you to enter the details about the radiation therapy that the participant is undergoing or has undergone.

**Table 32: Rad RX Annotation**

Attribute and Sub Form Name	Action
Agent	Select the appropriate radiation therapy agent name from the drop-down list.
Other Agent	Enter the radiation therapy agent name if it is not available in the previous attribute's (Agent) drop-down list. Data entry in this field is optional.
Dose	Enter the amount or dose of radiation administered to the patient. This field accepts a numerical value with decimal.
Dose Unit	Enter the measurement unit for the dose of radiation.
Duration	To enter information about the Duration of the treatment, click the Add More button.
Start Date	Enter the date treatment began using the calendar.
End Date	Enter the date treatment ended using the calendar.
Duration In Days	Enter the number of days the treatment lasted. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

### Chemo RX Annotation

This annotation allows you to enter details about the chemotherapy that the participant is undergoing or has undergone.

**Table 33: Chemo RX Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Agent	Select the appropriate chemotherapy agent name from the drop-down list.
Other Agent	Enter the chemotherapy agent name if it is not available in the previous attribute's (Agent) drop-down list. This field can be left blank.
Dose	Enter the amount or dose of chemical agent administered to the patient. This field accepts a numerical value with decimal.
Dose Unit	Enter the measurement unit for the dose of chemical agent.
Duration	To enter information about the Duration of the treatment, click the Add More button.
Start Date	Enter the date treatment began using the calendar.
End Date	Enter the date treatment ended using the calendar.
Duration In Days	Enter the number of days the treatment lasted. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

### Treatment Regimen

This annotation helps you to capture any treatment as a part of a well-defined treatment regimen. A treatment regimen may involve one or more chemotherapy or radiation therapy or a combination of both.

**Table 34: Treatment Regimen**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Treatment Regimen	Enter the name of the treatment regimen.
Treatment Order	To enter information about the Treatment Order, click the Add More button.
Cycle	Enter the sequence or cycle number of the treatment regimen.
Chemotherapy	To enter information about the Chemotherapy, click the Details link. Then, click the Add More button to add records for the same.
Radiation Therapy	To enter information about the Radiation Therapy, click the Details link. Then, click the Add More

Attribute and Sub Form Name	Action
	button to add records for the same.

	Once you add the Chemotherapy or Radiation Therapy information, enter data for each row as described above for Chemo RX Annotation and RAD RX Annotation respectively.
---	--

### Environmental Exposure Health Annotation

This annotation helps in capturing information about the environmental hazards or agents to which the participant is subjected to and the duration of the exposure.

**Table 35: Environmental Exposure Health Annotation**

Attribute and Sub Form Name	Action
Agent	Select the appropriate environmental agent from the drop-down list.
Other Agent	Enter the name of environmental agent if it is not available in the previous attribute's (Agent) drop-down list. Data entry in this field is optional.
Years Agent Free	Enter the number of years the participant was <i>Not</i> subjected to the environmental agent. This field accepts numerical value with decimal.
Duration	To enter information about the Duration, click the Add More button.
Start Date	Enter the date the environmental exposure started using the calendar.
End Date	Enter the date the environmental exposure ended using the calendar.
Duration In Days	Enter the number of days the environmental exposure lasted. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

## Alcohol Health Annotation

---

This annotation captures the data about the alcohol consumption history of the participant.

**Table 36: Alcohol Health Annotation**

Attribute/Sub Form Name	Action
Agent	Select the agent as Ethanol from the drop-down list.
Other Agent	Enter the name of agent if you need to specify a particular alcoholic beverage. Data entry in this field is optional.
Years Agent Free	Enter the number of years participant did Not consume Alcohol. This field accepts numerical value with decimal.
Duration	To enter information about the Duration, click the Add More button.
Start Date	Enter the date when alcohol consumption started using the calendar.
End Date	Enter the date when alcohol consumption ended using the calendar.
Duration In Days	Enter the number of days the participant consumed alcohol. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Drinks Per Week	Enter the number of alcoholic drinks consumed in a week. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

## Smoking Health Annotation

---

This annotation captures information about the smoking history of the participant.

**Table 37: Smoking Health Annotation**

Attribute and Sub Form Name	Action
Agent	Select the agent as Tobacco Smoking And Tobacco Smoke or Tobacco from the drop-down list.
Other Agent	Enter the name of agent if need to specify a particular value. Data entry in this field is optional.
Years Agent Free	Enter the number of years participant did Not smoke or consume tobacco. This field accepts numerical value with decimal.

## Appendix 2: Clinical Annotations

Duration	To enter information about the Duration, click the Add More button.
Start Date	Enter the date when smoking started using the calendar.
End Date	Enter the date when smoking ended using the calendar.
Duration In Days	Enter the number of days the participant smoked. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Packs Per Day	Enter the number of packs of cigarettes consumed in a day. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

### Health Examination Annotation

This annotation covers the participant's health by providing information on various procedures for making a medical diagnosis.

**Table 38: Health Examination Annotation**

Attribute and Sub Form Name	Action
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date the procedure was carried out using the calendar.

### New Diagnosis Health Annotation

This annotation helps you to capture information about any new disease's diagnosed in a participant.

**Table 39: New Diagnosis Health Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date the procedure was carried out using the calendar.

### No Evident Disease Health Annotation

This annotation helps you to capture information about the procedures, which confirms that the participant has no evident disease.

**Table 40: No Evident Disease Health Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date on which the procedure was carried out using the calendar.

### Recurrence Health Examination Annotation

This annotation captures information about the procedures and diagnosis of recurrence of a disease diagnosed in the participant earlier.

**Table 41: Recurrence Health Examination Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date the procedure was carried out using the calendar.
Clinical Diagnosis	Select the appropriate Clinical Diagnosis from the drop-down list.
Other Clinical Diagnosis	Enter the clinical diagnosis value if it is not available in the previous attribute's (Clinical Diagnosis) drop-down list.

<b>Attribute and Sub Form Name</b>	<b>Action</b>
	Data entry in this field is optional.

### Local Recurrence Health Examination Annotation

This annotation captures information about the procedures used to diagnose recurrence of a disease diagnosed in the participant within the local anatomic site (same site where the disease was diagnosed earlier) in the body.

**Table 42: Local Recurrence Health Examination Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date the procedure was carried out using the calendar.
Clinical Diagnosis	Select the appropriate Clinical Diagnosis from the drop-down list.
Other Clinical Diagnosis	Enter the clinical diagnosis value if it is not available in the previous attribute's (Clinical Diagnosis) drop-down list. Data entry in this field is optional.

### Distant Recurrence Health Examination Annotation

This annotation captures information about the procedures used to diagnose recurrence of a disease diagnosed in the participant at a distant anatomic site (site other than where the disease was diagnosed earlier) in the body.

**Table 43: Distant Recurrence Health Examination Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Name of Procedure	Select the procedure from the drop-down list.
Other Procedure	Enter the name of procedure if it is not available in the previous attribute's (Name of Procedure) drop-down list. Data entry in this field is optional.
Date of Examination	Enter the date the procedure was carried out using the calendar.
Clinical Diagnosis	Select the appropriate Clinical Diagnosis from the drop-down list.
Other Clinical Diagnosis	Enter the clinical diagnosis value if it is not available in the previous attribute's (Clinical Diagnosis) drop-down list. Data entry in this field is optional.
Tissue Site	Select the Tissue Site where the disease spread from the

Attribute and Sub Form Name	Action
	drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry in this field is optional.

## Pathology-Specimen Collection Group Clinical Annotation

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This section outlines the various annotations found under Specimen Collection Group.

### Base Solid Tissue Pathology Annotation

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This generic annotation captures the pathological details about a group of specimens collected from any organ in the body by a particular procedure.

**Table 44: Base Solid Tissue Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Enter the name of Other Specimen Procedure if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry in this field is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or other Histologic type. Click Submit to save data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details Link. Click Add More to add a row.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.

Attribute and Sub Form Name	Action
Grading System Name	Select the appropriate grading system name from the drop-down list.
Other Grading System Name	Enter the name of grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry in this field is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details Link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically found. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically found. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for Matted Nodes.

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Attribute and Sub Form Name	Action
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry in this field is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry in this field is optional.
Tissue Side	To enter information about the Tissue Side, click the Details Link. Click Add More to add a row.
Side	Select the appropriate Side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).

## Base Hematology Tissue Pathology Annotation

This annotation captures the pathological details about a group of specimens collected from blood by a particular procedure.

**Table 45: Base Hematology Tissue Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Enter the name of Other Specimen Procedure if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry in this field is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the Additional Finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Biopsy or Aspirate Site	Select appropriate biopsy or aspirate site from the drop-down list.
Other Biopsy or Aspirate Site	Enter the name of Other Biopsy Or Aspirate Site if it is not available in the previous attributes (Biopsy or Aspirate Site) drop-down list. Data entry in this field is optional.
Adequacy of Specimen	Select the radio button for the appropriate value for

<b>Attribute and Sub Form Name</b>	<b>Action</b>
	Adequacy of Specimen.
Cytogenetics	
Status	Select the radio button for the appropriate value for Cytogenetic study status.
Result	Enter the result of the Cytogenetic study in the edit box.
Immuno Phenotyping	
Status	Select the radio button for the appropriate value for Immuno Phenotyping analysis status.
Method Used	Enter the name of the method used to carry out Immuno Phenotyping analysis in the edit box.
Result	Enter the result of the Immuno Phenotyping analysis in the edit box.

### Radical Prostatectomy Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Prostate gland by a procedure called *Radical Prostatectomy*.

**Table 46: Radical Prostatectomy Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Data entry is not required in this field.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or other Histologic type. Click Submit to save data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.

Attribute and Sub Form Name	Action
Details	Enter the details about the Additional Finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry in this field is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details Link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes Involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically found. This field accepts integer values only. If you enter a

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically found. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click the Add More button to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry in this field is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate Tissue Site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry in this field is optional.
Tissue Side	To enter information about the Tissue Side, click the Details Link. Click Add More to add a row.
Side	Select the appropriate Side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.

Attribute and Sub Form Name	Action
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Proportion Or Percent Of Prostatic Tissue Involved By Tumor	Enter the percentage of prostatic tissue involved by tumor. This field accepts numerical value with a decimal between the range (0.0,100.0).
Periprostatic Fat Invasion	Select the radio button for the appropriate value for Periprostatic Fat Invasion.
Seminal Vesicle Invasion	Select the radio button for the appropriate value for Seminal Vesicle Invasion.
Gleason Score	
Primary Pattern Score	Select the appropriate Primary Pattern Gleason Score from the drop-down list.
Secondary Pattern Score	Select the appropriate Secondary Pattern Gleason Score from the drop-down list.
Tertiary Pattern Score	Select the appropriate Tertiary Pattern Gleason Score from the drop-down list.
Extraprostatic Invasion	
Status	Select the radio button for the appropriate value for Extraprostatic Invasion Status.
Is Focal	Select the check box if the extraprostatic invasion Is Focal.
Extraprostatic Extension Tissue Site	To enter information about the Extraprostatic Extension Tissue Site, click the Enter Details link.
Tissue Site	Select the appropriate Tissue Site from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Radical Prostatectomy Margin	
Margin Status	Select the appropriate Margin Status from the drop-down list.
Focality of Involved Margin	Select the radio button for the appropriate value for Focality Of Involved Margin.
Margin Location	To enter information about the Extraprostatic Extension Tissue Site, click the Enter Details link.

Attribute and Sub Form Name	Action
Involved Margin Location	Select the appropriate margin location from the drop-down list.
Other Location	Enter the name of other margin location if it is not available in the previous attribute's (Involved Margin Location) drop-down list. Data entry in this field is optional. Click Submit to save the data entered and to navigate back to the main form.

### Needle Biopsy Prostate Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Prostate gland by a particular procedure called *Needle Biopsy*.

**Table 47: Needle Biopsy Prostate Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Do not enter data in this field.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Comments	Enter additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.

Attribute and Sub Form Name	Action
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry in this field is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes Involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click

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Attribute and Sub Form Name	Action
	the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of the tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional.
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Proportion Or Percent Of Prostatic Tissue Involved By Tumor	Enter the percentage of prostatic tissue involved by tumor. This field accepts numerical value with decimal between the range (0.0,100.0).
Periprostatic Fat Invasion	Select the radio button for the appropriate value for Periprostatic Fat Invasion.

Attribute and Sub Form Name	Action
Seminal Vesicle Invasion	Select the radio button for the appropriate value for Seminal Vesicle Invasion.
Gleason Score	
Primary Pattern Score	Select the appropriate Primary Pattern Gleason Score from the drop-down list.
Secondary Pattern Score	Select the appropriate Secondary Pattern Gleason Score from the drop-down list.
Tertiary Pattern Score	Select the appropriate Tertiary Pattern Gleason Score from the drop-down list.
Total Linear Carcinoma In Millimeter	Enter the length of the carcinoma in millimeters. This field accepts numerical values with decimal.
Core Length In Millimeter	Enter the length of the core in millimeters. This field accepts numerical values with decimal.
Other Quantification	Enter data about any other quantitative information about the tumor.
Number Of Positive Cores	Enter the number of cores found positive for the tumor. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Total Number Of Cores	Enter the total number of cores. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

### Retropubic Enucleation Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Prostate gland by a particular procedure called Retropubic Enucleation.

**Table 48: Retropubic Enucleation Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the Suprapubic or Retropubic Enucleation specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-

Attribute and Sub Form Name	Action
	down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	

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Attribute and Sub Form Name	Action
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Proportion Or Percent Of Prostatic Tissue Involved By Tumor	Enter the percentage of prostatic tissue involved by tumor. This field accepts numerical value with decimal between the range (0.0,100.0).
Periprostatic Fat Invasion	Select the radio button for the appropriate value for Periprostatic Fat Invasion.
Seminal Vesicle Invasion	Select the radio button for the appropriate value for Seminal Vesicle Invasion.
Gleason Score	
Primary Pattern Score	Select the appropriate Primary Pattern Gleason score from the drop-down list.
Secondary Pattern Score	Select the appropriate Secondary Pattern Gleason Score from the drop-down list.
Tertiary Pattern Score	Select the appropriate Tertiary Pattern Gleason Score from the drop-down list.
Specimen Weight (g)	Enter the weight of specimen in grams. This field accepts numerical values with decimal.

### Transurethral Prostatic Resection Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Prostate gland by a particular procedure called Transurethral Prostatic resection.

**Table 49: Transurethral Prostatic Resection Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the Transurethral Prostatic Resection specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the

Attribute and Sub Form Name	Action
	Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional.

Attribute and Sub Form Name	Action
	optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Proportion Or Percent Of Prostatic Tissue Involved By Tumor	Enter the percentage of prostatic tissue involved by tumor. This field accepts numerical value with decimal between the range (0.0,100.0).
Periprostatic Fat Invasion	Select the radio button for the appropriate value for Periprostatic Fat Invasion.
Seminal Vesicle Invasion	Select the radio button for the appropriate value for Seminal Vesicle Invasion.
Gleason Score	
Primary Pattern Score	Select the appropriate Primary Pattern Gleason Score from the drop-down list.
Secondary Pattern Score	Select the appropriate Secondary Pattern Gleason Score from the drop-down list.
Tertiary Pattern Score	Select the appropriate Tertiary Pattern Gleason Score from the drop-down list.
Specimen Weight (g)	Enter the weight of the specimen in grams. This field accepts numerical values with decimal.
Is Tumor Incidental Histologic Finding Above5 Percent	Select the check box if the percentage of incidental histologic finding is more than 5%.

Attribute and Sub Form Name	Action
Number Of Positive Chips	Enter the Number of Positive Chips found for the tumor. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Total Number Of Chips	Enter the Total Number Of Chips. This field accepts integer values only. If you enter a decimal value, the value is rounded off.

### Pancreas Pathology Annotation

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This annotation captures the pathological details about a group of specimen collected from the Pancreas by a particular procedure.

**Table 50: Pancreas Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.

Attribute and Sub Form Name	Action
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Other Resected Organs	To enter information about the Other Resected Organ, click the Add More button.
Other Organs Resected	Select the appropriate resected organ name from the

Attribute and Sub Form Name	Action
	drop-down list.
Other Other Organs Resected	Enter the name of other organ resected if it is not available in the previous attribute's (Other Organs Resected) drop-down list. Data entry is optional.
Pancreas Margin	
Margin Status	Select the appropriate pancreas margin from the drop-down list.
Involved Margin	To enter information about the Involved Margin, click the Enter Details link. Click Add More to add a row.
Margin Location	Select the appropriate location of margin involved by invasive carcinoma from the drop-down list.
Other Margin Location	Enter the name of the other involved margin location if it is not available in the previous attribute's (Margin Location) drop-down list. Data entry is optional.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Enter Details link.
Margin Location	Enter the location of the margin uninvolved by invasive carcinoma in the edit box.
Closest Distance To Tumor	Enter the distance closest to tumor. This field accepts numerical values with decimal.
Carcinoma In Situ Status	To enter information about the Carcinoma In Situ Status, click the Enter Details link. Click Add More to add a row.
Status	Select the appropriate status for the carcinoma in situ from the drop-down list. Click Submit to save the data entered and to navigate back to main form.

### Lung Biopsy Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Lung by a particular procedure Biopsy.

**Table 51: Lung Biopsy Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the Biopsy specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.

Appendix 2: Clinical Annotations

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage,

Attribute and Sub Form Name	Action
	click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Visceral Pleural Invasion	Select the radio button for the appropriate value for Visceral Pleural Invasion.

### Lung Resection Based Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Lung by a procedure called Resection.

**Table 52: Lung Resection Based Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Specimen Procedure	Select the Total Resection specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.

Attribute and Sub Form Name	Action
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.

Attribute and Sub Form Name	Action
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Direct Extension of Tumor	To enter information about the Direct Extension of Tumor, click the Add More button.
Extension of tumor	Select the appropriate tumor extension form the drop-down list.
Other Tumor Extensions	Enter the tumor extension details if it is not available in the previous attribute's (Extension of Tumor) drop-down list. Data entry is optional.
Arterial Invasion	Select the radio button for the appropriate value for Arterial Invasion.
Lung Resection Margin	To enter information about the Lung Resection Margin, click the Add More button.
Margin Status	Select the appropriate Lung Margin Status from the drop-down list.
Margin Location	Select the appropriate margin location involved by invasive carcinoma from the drop-down list.
Other Location	Enter the name of the other involved margin location if it is not available in the previous attribute's (Margin Location) drop-down list. Data entry is optional.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance To Tumor	Enter the distance closest to the tumor. This field accepts numerical values with decimal. Click Submit to save the data entered and to navigate back to the main form.

## Kidney Biopsy Based Pathology Annotation

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This annotation captures pathological details about a group of specimen collected from the kidney by a particular procedure Biopsy.

**Table 53: Kidney Biopsy Based Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Percent Of Sarcomatoid Element	Enter the percentage of Sarcomatoid element observed. This field accepts numerical value with decimal between the range (0.0,100.0)

## Kidney Nephrectomy Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the kidney by a particular procedure Nephrectomy.

**Table 54: Kidney Nephrectomy Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.

Attribute and Sub Form Name	Action
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Percent of Sarcomatoid Element	Enter the percentage of Sarcomatoid element observed. This field accepts numerical value with decimal between the range (0.0,100.0).
Focality	Select the radio button for the appropriate value for Focality of tumor.
Macroscopic Extent of Tumor	To enter information about the Macroscopic Extent of Tumor, click the Add More button.
Extent of Tumor	Select the appropriate tumor extension type from the drop-down list.
Adrenal Gland Stage	Select the radio button for the appropriate value for

<b>Attribute and Sub Form Name</b>	<b>Action</b>
	Adrenal Gland Stage.
Kidney Nephrectomy Margin	
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	To enter information about the Involved Margin, click the Enter Details link. Click Add More to add a row.
Location	Select the appropriate location of the involved margin by invasive carcinoma from the drop-down list.
Other Location	Enter the name of other involved margin location if it is not available in the previous attribute's (Margin Location) drop-down list. Data entry is optional. Click Submit to save the data entered and to navigate back to the main form.

### [Melanoma Pathology Annotation](#)

This annotation captures pathological details about a group of specimen collected from the skin by a particular procedure.

**Table 55: Melanoma Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Enter the name of Other Specimen Procedure if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.

Attribute and Sub Form Name	Action
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value,

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Attribute and Sub Form Name	Action
	the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field

Attribute and Sub Form Name	Action
	accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Macroscopic Tumor	Select the radio button for the appropriate value for Macroscopic Tumor.
Pigmentation	Select the radio button for the appropriate value for Pigmentation.
Ulceration	Select the radio button for the appropriate value for Ulceration.
Depth Of Invasion Cannot Be Determined	Select the check box if the depth of invasion cannot be determined.
Depth Of Invasion(mm)	Enter the value for Depth Of Invasion, if determined. This field accepts numerical value with decimal.
Tumor Infiltrating Lymphocytes	Select the radio button for the appropriate value for Tumor Infiltrating Lymphocytes.
Tumor Regression	Select the radio button for the appropriate value for Tumor Regression.
Mitotic Index	Select the radio button for the appropriate value for Mitotic Index.
Satellite Nodule Status	Select the radio button of the appropriate value for Satellite Nodule Status.
Satellite Nodule	To enter information about the Satellite Nodule, click Add More.
Site	Enter the name of the site where the satellite nodule is observed.
Deep Melanoma Margin	To enter information about the Deep Melanoma Margin, click Add More.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	Enter the appropriate location for the deep melanoma margin in the edit box.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.

Attribute and Sub Form Name	Action
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with decimal. Click Submit to save the data entered and to navigate back to the main form.
Lateral Melanoma Margin	To enter information about the Lateral Melanoma Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	Enter the appropriate location for the lateral melanoma margin in the edit box.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with decimal. Click Submit to save the data entered and to navigate back to the main form.

### CNS Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the Brain or spinal cord by a particular procedure.

**Table 56: CNS Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate specimen procedure from the drop-down list.
Other Specimen Procedure	Enter the name of other Specimen Procedure if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-

Attribute and Sub Form Name	Action
	down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the greatest dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field

Attribute and Sub Form Name	Action
	accepts numerical values with decimal.
Cannot Be Determined	Select the check box if tumor size cannot be determined, else leave un-checked. If this check box is checked the above three fields are to be left empty.
CNS Margin	
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	To enter information about the Tissue Side, click the Enter Details link. Click Add More to add a row.
Margin Location	Enter the appropriate Margin Location in the edit box.
Specimen Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).

### Breast Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the breast by a particular procedure.

**Table 57: Breast Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the appropriate specimen procedure from the drop-down list.
Other Specimen Procedure	Enter the name of other Specimen Procedure if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.

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Attribute and Sub Form Name	Action
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the

Attribute and Sub Form Name	Action
	drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Lymph Node Sampling	Select the appropriate Lymph Node Sampling option from the drop-down list.
Mitotic Count If Other Grading System Used	Enter the mitotic count if the grading system used is not Nottingham Histologic Score. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Microcalcification	To enter information about the Microcalcification, click the Add More button.
Value	Select the appropriate value for microcalcification from the drop-down list.
Size Of Invasive Carcinoma	
Greatest Dimension	Enter the greatest dimension of the invasive carcinoma. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the invasive carcinoma. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the invasive carcinoma. This field accepts numerical values with decimal.
Cannot Be Determined	Select the checkbox if the invasive carcinoma size cannot be determined. If this checkbox is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Size Of Specimen	

Attribute and Sub Form Name	Action
Greatest Dimension	Enter the greatest dimension of the Specimen. This field accepts numerical values with a decimal.
Additional Dimension One	Enter the first dimension of the Specimen. This field accepts numerical values with a decimal.
Additional Dimension Two	Enter the second dimension of the Specimen. This field accepts numerical values with a decimal.
Cannot Be Determined	Select the checkbox if the specimen size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Nottingham Histologic Score	
Tubule Formation Score	Select the appropriate Tubule Formation Score from the drop-down list.
Nuclear Pleomorphism Score	Select the appropriate Nuclear Pleomorphism score from the drop-down list.
Mitotic Count Score	Select the appropriate Mitotic Count Score from the drop-down list.
Total Nottingham Score	Enter the sum of the three fields, namely: Tubule Formation Score, Nuclear Pleomorphism Score, and Mitotic Count Score). This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Breast Margin	To enter information about the Breast Margin, click the Add More button located.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	Enter the appropriate location for the margin in the edit box.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.
Involved Margin	To enter information about the Involved Margin, click the Details link.
Extent Of Involvement	Select the appropriate Extent Of Involvement option from

Attribute and Sub Form Name	Action
	the drop-down list.
Other Extent Of Involvement	Enter the Other Extent of Involvement if it is not available in the previous attribute's (Extent of Involvement) drop-down list. Data entry is optional.

### Local Excision Based Colorectal Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the colon and rectum by a procedure called Local Excision.

**Table 58: Local Excision Based Colorectal Pathology Annotation**

Attribute and Sub Form Name	Action
Specimen Procedure	Select the Local Excision – Transanal Disk Excision specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the

Attribute and Sub Form Name	Action
	drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Tumor Configuration	Select the appropriate Tumor Configuration form the drop-down list.
Other Tumor Configuration	Enter the name of the tumor configuration if it is not available in the previous attribute's (Tumor Configuration) drop-down list. Data entry is optional.

Attribute and Sub Form Name	Action
Tumor Border Configuration	Select the radio button for the appropriate value for Tumor Border Configuration.
Intratumoral Peritumoral Lymphocytic Response	Select the radio button for the appropriate value for Intratumoral Peritumoral Lymphocytic Response.
Polyp Size	
Greatest Dimension	Enter the Greatest Dimension of the polyp. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the polyp. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the polyp. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the polyp size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Specimen Integrity	
Type	Select the radio button for the appropriate value for the specimen integrity type.
Number of Pieces	Enter the number of specimen pieces if fragmented. This field accepts only integer values. If you enter a decimal value, the value is rounded off.
Distance from Anal Verge	
Distance Known	Select the checkbox if the distance from anal verge has been determined.
Length in Centimeters	Enter the distance from the anal verge in centimeters, if the previous attribute's check box is selected. This field accepts only integer values. If you enter a decimal value, the value is rounded off.
Local Excision Colorectal Deep Margin	To enter information about the Deep Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Local Excision Colorectal Lateral Margin	To enter information about the Lateral Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Margin Location	Enter the appropriate location for the lateral margin in the edit box.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.

### Excisional Biopsy Based Colorectal Pathology Annotation

This annotation captures pathological details about a group of specimen collected from the colon and rectum by a particular procedure Excisional Biopsy.

**Table 59: Excisional Biopsy Based Colorectal Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Specimen Procedure	Select the Excisional Biopsy - Polypectomy specimen procedure from the drop-down list.
Other Specimen Procedure	Leave this field blank.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click

Attribute and Sub Form Name	Action
	Submit to save the data entered and to navigate back to the main form.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be

Attribute and Sub Form Name	Action
	determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Tumor Configuration	Select the appropriate Tumor Configuration from the drop-down list.
Other Tumor Configuration	Enter the name of the tumor configuration if it is not available in the previous attribute's (Tumor Configuration) drop-down list. Data entry is optional.
Tumor Border Configuration	Select the radio button for the appropriate value for Tumor Border Configuration.
Intratumoral Peritumoral Lymphocytic Response	Select the radio button for the appropriate value for Intratumoral Peritumoral Lymphocytic Response.
Polyp Size	
Greatest Dimension	Enter the Greatest Dimension of the polyp. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the polyp. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the polyp. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the polyp size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Extent of Invasion	Select the appropriate Extent Of Invasion from the drop-down list.
Type of Polyp In Which Invasive Carcinoma Arose	Select the appropriate type of polyp in which the invasive carcinoma occurred.
Polyp Configuration	
Configuration	Select the appropriate configuration type from the drop-down list.
Stalk Length (cm)	Enter the length of the stalk if configuration is pedunculated with stalk. This field accepts only numerical values with decimal.
Distance of Adenoma	
Distance Known	Select the check box if the distance from anal verge has been determined.

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Attribute and Sub Form Name	Action
Length in Centimeters	Enter the distance of adenoma from anal verge in centimeters, if the previous attribute's check box is selected. This field accepts only integer values. If you enter a decimal value, the value is rounded off.
Distance of Invasive Carcinoma	
Distance Known	Select the check box if the distance from anal verge has been determined.
Length in Centimeters	Enter the distance of invasive carcinoma from anal verge in centimeters, if the previous attribute's check box is selected. This field accepts only integer values. If you enter a decimal value, the value is rounded off.
Excisional Biopsy Colorectal Deep Margin	To enter information about the Deep Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.
Excisional Biopsy Colorectal Lateral Margin	To enter information about the Lateral Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.

### [Resection Based Colorectal Pathology Annotation](#)

This annotation captures pathological details about a group of specimen collected from the colon and rectum by a particular procedure called Resection.

**Table 60: Resection Based Colorectal Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Specimen Procedure	Select the appropriate Specimen Procedure from the drop-down list.
Other Specimen Procedure	Enter the Other Specimen Procedure name if it is not available in the previous attribute's (Specimen Procedure) drop-down list. Data entry is optional.
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of the grading system if it is not available in the previous attribute's (Grading System Name) drop-down list. Data entry is optional.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for

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<b>Attribute and Sub Form Name</b>	<b>Action</b>
	Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Pathologic Staging	
Primary Tumor Stage	To enter information about the Primary Tumor Stage, click the Enter Details link.
Primary Tumor Stage	Select the appropriate Primary Tumor Stage from the drop-down list.
Regional Lymph Node	To enter information about the Regional Lymph Node, click the Enter Details link.
Lymph Node Stage	Select the appropriate Lymph Node Stage from the drop-down list.
Number Examined	Enter the number of lymph nodes examined. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Involved	Enter the number of lymph nodes involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Macroscopically	Enter the number of lymph nodes macroscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Number Positive Microscopically	Enter the number of lymph nodes microscopically involved. This field accepts integer values only. If you enter a decimal value, the value is rounded off.
Matted Nodes	Select the radio button for the appropriate value for the Matted Nodes.
Distant Metastasis	To enter information about the Distant Metastasis, click the Enter Details link.
Metastasis Stage	Select the appropriate Metastasis Stage from the drop-down list.
Metastasis Tissue Site	To enter information about the Metastasis Tissue Site, click the Enter Details link. Click Add More to add a row.
Tissue Site	Select the appropriate Tissue Site from the drop-down list.
Other Tissue Site	Enter the name of tissue site if it is not available in the previous attribute's (Tissue Site) drop-down list. Data

Attribute and Sub Form Name	Action
	entry is optional.
Tumor Tissue Site	To enter information about the Tumor Tissue Site, click the Add More button.
Site	Select the appropriate tissue site from the drop-down list.
Other Site	Enter the name of tissue site if it is not available in the previous attribute's (Site) drop-down list. Data entry is optional
Tissue Side	To enter information about the Tissue Side, click the Details link. Click Add More to add a row.
Side	Select the appropriate side from the drop-down list. Click Submit to save the data entered and to navigate back to the main form.
Tumor Size	
Greatest Dimension	Enter the Greatest Dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the tumor. This field accepts numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the tumor. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the tumor size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Tumor Configuration	Select the appropriate Tumor Configuration form the drop-down list.
Other Tumor Configuration	Enter the name of the tumor configuration if it is not available in the previous attribute's (Tumor Configuration) drop-down list. Data entry is optional.
Tumor Border Configuration	Select the radio button for the appropriate value for the Tumor Border Configuration.
Intratumoral Peritumoral Lymphocytic Response	Select the radio button for the appropriate value for the Intratumoral Peritumoral Lymphocytic Response.
Polyp Size	
Greatest Dimension	Enter the Greatest Dimension of the polyp. This field accepts numerical values with decimal.
Additional Dimension One	Enter the first dimension of the polyp. This field accepts

Appendix 2: Clinical Annotations

<b>Attribute and Sub Form Name</b>	<b>Action</b>
	numerical values with decimal.
Additional Dimension Two	Enter the second dimension of the polyp. This field accepts numerical values with decimal.
Cannot Be Determined	Select the check box if the polyp size cannot be determined. If this check box is selected, do not enter data in the preceding three fields (Greatest Dimension, Additional Dimension One, and Additional Dimension Two).
Specimen Length (cm)	Enter the length of specimen in centimeters. This field accepts numerical values with decimal.
Intactness of Mesorectum	Select the radio button for the appropriate value for Quantifying Intactness Of Mesorectum.
Radial Margin	To enter information about the Radial Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Margin Location	Enter the appropriate Margin Location in the edit box.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.
Mesentric Margin	To enter information about the Mesentric Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Margin Location	Enter the appropriate Margin Location in the edit box.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.
Distal Margin	To enter information about the Distal Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click

Attribute and Sub Form Name	Action
	the Details link.
Margin Location	Enter the appropriate Margin Location in the edit box.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with decimal. Click Submit to save the data entered and to navigate back to the main form.
Proximal Margin	To enter information about the Proximal Margin, click the Add More button.
Margin Status	Select the appropriate Margin Status from the drop-down list.
Uninvolved Margin	To enter information about the Uninvolved Margin, click the Details link.
Margin Location	Enter the appropriate Margin Location in the edit box.
Closest Distance to Tumor	Enter the distance closest to the tumor. This field accepts numerical values with a decimal. Click Submit to save the data entered and to navigate back to the main form.

## Pathology-Specimen Clinical Annotation

This section outlines the various annotations based on specimens.

### Specimen Based Solid Tissue Pathology Annotation

This generic annotation captures the pathological details about a specimen collected from any organ in the body.

**Table 61: Specimen Based Solid Tissue Pathology Annotation**

Attribute and Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information for the Histologic Variant Type, click the Details link. Click the Add More to add a row.
Other Histologic Type	Enter the variant or other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate pathologic finding from the drop-down list.

## Appendix 2: Clinical Annotations

Attribute and Sub Form Name	Action
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information for the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

	To add more than one row for spreadsheet type of sub form, click Add More. To delete rows, select the check box next to the row and click Delete.
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### Colorectal Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from colon or rectum.

**Table 62: Colorectal Specimen Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type, from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details Link. Click the Add More button to add a record.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a record.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate grading system name from the drop-down list.
Other Grading System Name	Enter the name of grading system if same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

Attribute and Sub Form Name	Action
Tumor Border Configuration	Select the appropriate configuration for the tumor border from the drop-down list.
Intratumoral Peritumoral Lymphocytic Response	Select the appropriate lymphocytic response from the drop-down list.

### Pancreas Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from pancreas.

**Table 63: Pancreas Specimen Pathology Annotation**

Attribute and Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information for the Histologic Variant Type, click the Details Link. Click Add More to add a record.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic Finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click the Add More button to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate grading system name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.

Attribute and Sub Form Name	Action
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

### Melanoma Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from skin.

**Table 64: Melanoma Specimen Pathology Annotation**

Attribute and Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click Add More to add a row.
Other Histologic Type	Enter the variant or other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate pathologic finding, from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter record for the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate grading system name from the drop-down list.

## Appendix 2: Clinical Annotations

Attribute and Sub Form Name	Action
Other Grading System Name	Enter the name of grading system if same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Ulceration	Select the radio button for the appropriate value for the Ulceration.
Depth of Invasion Cannot be determined	Select the check box if the depth of invasion cannot be determined.
Depth of Invasion	Enter the value for Depth of Invasion, if determined. This field accepts numerical value with decimal.
Tumor Infiltrating Lymphocytes	Select the radio button for the appropriate value for Tumor Infiltrating Lymphocytes.
Tumor Regression	Select the radio button for the appropriate value for Tumor Regression.
Mitotic Index	Select the radio button for the appropriate value for Mitotic Index.

### CNS Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from the central nervous system.

**Table 65: CNS Specimen Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details Link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click the Add More button to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

### Prostate Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from the prostate.

**Table 66: Prostate Specimen Pathology Annotation**

<b>Attribute and Sub Form Name</b>	<b>Action</b>
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click the Add More button to add a record.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	

Attribute and Sub Form Name	Action
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for perineural invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Proportion Or Percent Of Prostatic Tissue Involved By Tumor	Enter the percentage of prostatic tissue involved by tumor. This field accepts numerical value with decimal between the range (0.0,100.0).
Gleason Score	
Primary Pattern Score	Select the appropriate Primary Pattern Gleason Score from the drop-down list.
Secondary Pattern Score	Select the appropriate Secondary Pattern Gleason Score from the drop-down list.
Tertiary Pattern Score	Select the appropriate Tertiary Pattern Gleason Score from the drop-down list.

### Kidney Specimen Pathology Annotation

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This organ specific annotation captures the pathological details about the specimen collected from Kidney.

**Table 67: Kidney Specimen Pathology Annotation**

Attribute and Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the DETAILS link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or other Histologic Type. Click the Submit button save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.

Attribute and Sub Form Name	Action
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click the Add More button to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the appropriate value for Lymphatic Invasion.
Venous Invasion	Select the radio button for the appropriate value for Venous Invasion.
Perineural Invasion	Select the radio button for the appropriate value for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

### Lung Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from Lung.

**Table 68: Lung Specimen Pathology Annotation**

Attribute/Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a row.
Other Histologic Type	Enter the variant or Other Histologic Type. Click Submit to

Attribute/Sub Form Name	Action
	save the data entered and to navigate back to the main form.
Additional Finding	To enter more information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding from the drop-down list.
Details	To enter information about the Details, click the Details link. Click the Add More button to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate Grading System Name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the value appropriate for Lymphatic Invasion.
Venous Invasion	Select the radio button for the value appropriate for Venous Invasion.
Perineural Invasion	Select the radio button for the value appropriate for Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.

### Breast Specimen Pathology Annotation

This organ specific annotation captures the pathological details about the specimen collected from the breast.

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**Table 69: Breast Specimen Pathology Annotation**

Attribute and Sub Form Name	Action
Histologic Type	To enter information about the Histologic Type, click the Add More button.
Type	Select the appropriate Histologic Type, from the drop-down list.
Histologic Variant Type	To enter information about the Histologic Variant Type, click the Details link. Click the Add More button to add a record.
Other Histologic Type	Enter the variant or other Histologic Type. Click Submit to save the data entered and to navigate back to the main form.
Additional Finding	To enter information about the Additional Finding, click the Add More button.
Pathologic finding	Select the appropriate Pathologic Finding, from the drop-down list.
Details	To enter information about the Details, click the Details link. Click Add More to add a row.
Details	Enter the details about the additional finding. Click Submit to save the data entered and to navigate back to the main form.
Histologic Grade	To enter information about the Histologic Grade, click the Add More button.
Grading System Name	Select the appropriate grading system name from the drop-down list.
Other Grading System Name	Enter the name of grading system if the same is not available in the previous attribute's (Grading System Name) drop-down list, else leave it blank.
Grade	Enter the Grade. This field accepts alphanumeric values.
Invasion	
Lymphatic Invasion	Select the radio button for the value appropriate for the Lymphatic Invasion.
Venous Invasion	Select the radio button for the value appropriate for the Venous Invasion.
Perineural Invasion	Select the radio button for the value appropriate for the Perineural Invasion.
Comments	Enter any additional information about the specimen, site of specimen, or other basic details.
Mitotic Count if Other Grading System	Enter the mitotic count if the grading system used is not

Attribute and Sub Form Name	Action
Name Used	Nottingham Histologic Score. This field accepts integer values only. If you enter a decimal value, then the value is rounded off.
Nottingham Histologic Score	Enter the values in this field if the grading system is Nottingham Histologic Grading system.
Tubule Formation Score	Select the appropriate Tubule Formation Score from the drop-down list.
Nuclear Pleomorphism Score	Select the appropriate Nuclear Pleomorphism Score from the drop-down list.
Mitotic Count Score	Select the appropriate Mitotic Count Score from the drop-down list.
Total Nottingham Score	Enter the sum total of the (tubule formation score + nuclear pleomorphism score + mitotic count score). This field accepts integer values only. If you enter a decimal value, then the value is rounded off.

## Appendix 3: Complex Querying

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This section explains how you can perform various complex queries based on participants, specimen collection groups, specimens, annotations, orders, and SPRs.

### Queries on Participants

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- A. Find all cases registered under neoadjuvant protocols where prostate tumor tissue is available before and after treatment.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Id		Is Not Null
2	CollectionProtocol	Title	Contains	neoadjuvant
3	SpecimenCollectionGroup	Clinical Status	Equals	Pre-Therapy
4	SpecimenCollectionGroup	Clinical Status	Equals	Post-Therapy
5	TissueSpecimen	Type	Equals	Frozen Tissue
		Pathological Status	Equals	Malignant
		Available		True
6	SpecimenCharacteristics	Tissue Site	In	Prostate Gland

After adding the classes in the Diagrammatic View, connect the following classes:

1. Participant to CollectionProtocol.
2. Participant to SpecimenCollectionGroup (Clinical Status Equals Pre-Therapy).
3. Participant to SpecimenCollectionGroup (Clinical Status Equals Post-Therapy).
4. Both SpecimenCollectionGroup to TissueSpecimen.
5. TissueSpecimen to SpecimenCharacteristics.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the participants registered under neoadjuvant protocols, where prostate tumor tissue is available before and after treatment.

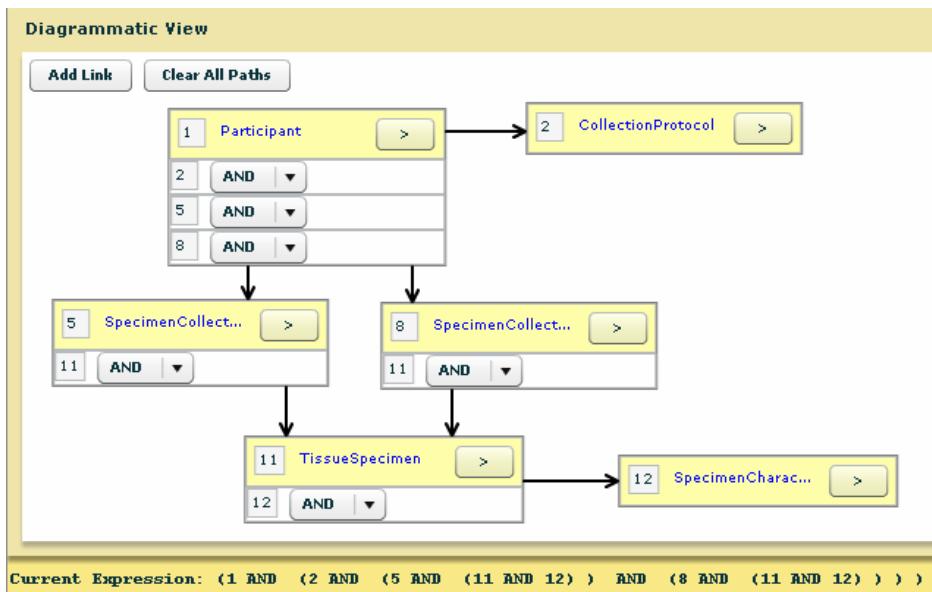


Figure 141: Diagrammatic representation of case A

- B. Find all cases of males over 60 years of age where matching prostate tumor tissue and serum is available at the time of surgery. Also, where serum is available at time of relapse.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Birth Date	Less than or Equal to	09-21-1947
		Gender	In	Male Gender
2	SpecimenCollectionGroup	Clinical Status	In	Operative
3	TissueSpecimen	Pathological Status	In	Malignant
		Available		True
4	SpecimenCharacteristics	Tissue Site	In	Prostate Gland
5	FluidSpecimen	Type	In	Serum
		Available		True
6	SpecimenCollectionGroup	Clinical Status	In	Relapse, Distant Site
7	FluidSpecimen	Type	In	Serum
		Available		True

After adding the classes in the Diagrammatic View, connect the following classes:

1. Participant to both SCG.
2. SpecimenCollectionGroup (with Clinical Status as Operative) to TissueSpecimen and Fluid Specimen.
3. SpecimenCollectionGroup (with Clinical Status as Relapse, Distant Site) to the other FluidSpecimen class.
4. Tissue Specimen to SpecimenCharacteristics.

## Appendix 3: Complex Querying

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the male participants over 60 years of age having matching prostate tumor tissue and serum at the time of surgery. Also, these participants will have serum at the time of relapse.

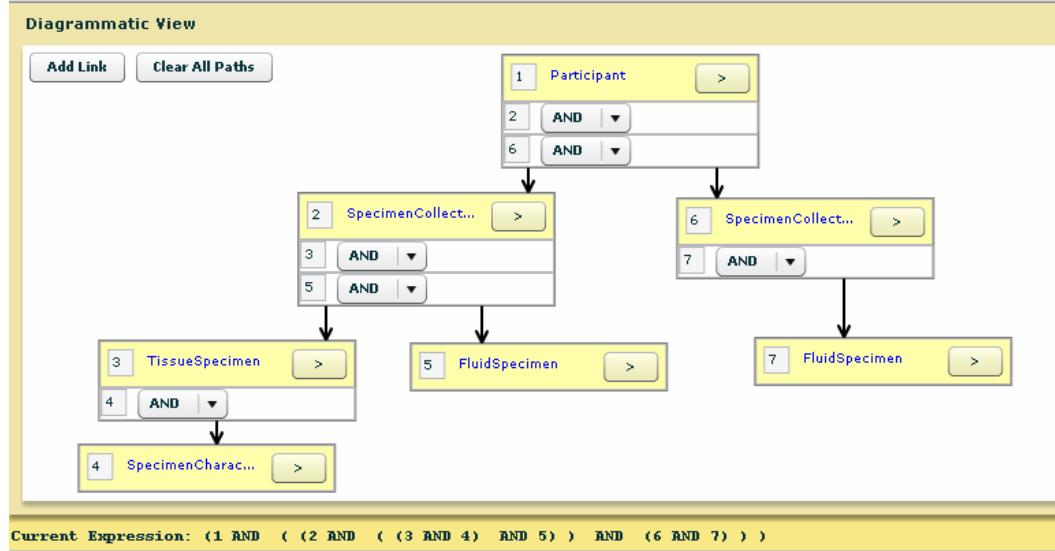


Figure 142: Diagrammatic representation for case B.

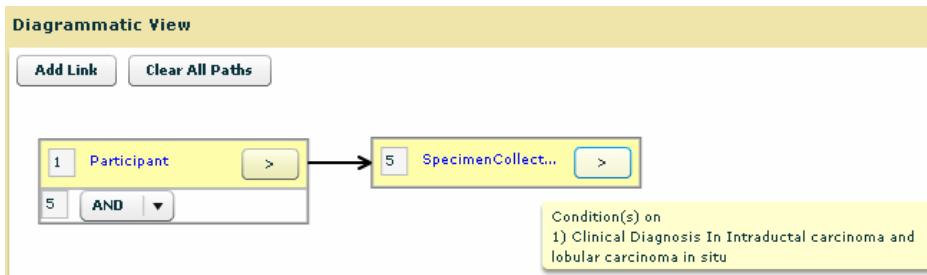
- C. Find all cases of DCIS in women aged between 40 and 60.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Birth Date	Between	09-22-1967 to 09-22-1947
		Gender	In	Female Gender
2	SpecimenCollectionGroup	Clinical Diagnosis	In	Intraductal carcinoma and lobular carcinoma in situ

After adding the classes in the Diagrammatic View, connect the Participant class to SpecimenCollectionGroup class. Click the Search button. The result will display all women participants aged between 40 and 60 having DCIS.

The following figure shows how the diagram will look like.



**Figure 143: Diagrammatic representation for case C**

- D. Find all participants having malignant endometrial tumor and malignant ovarian tumor. The malignant ovary should not have Pathological Status as Metastatic.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Id		Is Not Null
2	SpecimenCollectionGroup	Id		Is Not Null
3	TissueSpecimen	Pathological Status	In	Malignant
4	TissueSpecimen	Pathological Status	In	Malignant
5	TissueSpecimen	Pathological Status	Not In	Metastatic
6	SpecimenCharacteristics	Tissue Site	In	Endometrium
7	SpecimenCharacteristics	Tissue Site	In	Ovary

After adding the classes in the Diagrammatic View, connect the following classes:

1. Participant to SpecimenCollectionGroup.
2. SpecimenCollectionGroup to TissueSpecimen (1 to both).
3. SpecimenCharacteristics (with Tissue Site as Ovary) to TissueSpecimen (with Pathological Status In Malignant and Not In Metastatic).
4. SpecimenCharacteristics (with Tissue Site as Endometrium) to TissueSpecimen (with Pathological Status in Malignant).

The following figure shows how the diagram will look like.

Click the Search button. The result will display all participants having malignant endometrial tumor and malignant ovarian tumor (primary, not metastatic).

## Appendix 3: Complex Querying

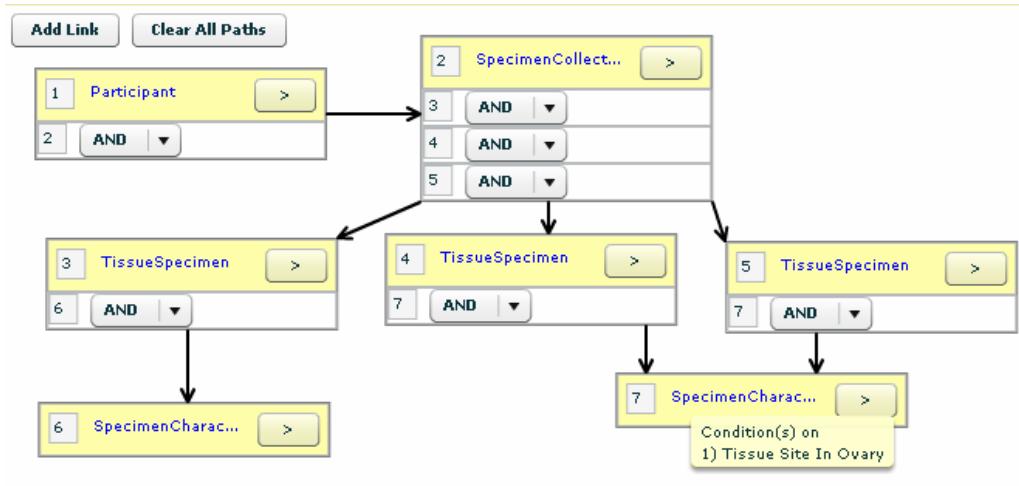


Figure 144: Diagrammatic representation for case D

- E. Find all cases where banked colon tissue and the associated lymph nodes are positive for cancer. For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Id		Is Not Null
2	SpecimenCollectionGroup	Id		Is Not Null
3	TissueSpecimen	Pathological Status	In	Malignant
4	TissueSpecimen	Pathological Status	In	Malignant
5	SpecimenCharacteristics	Tissue Site	In	Colon, Nos.
6	SpecimenCharacteristics	Tissue Site	In	Lymph Node, Nos.

After adding the classes in the Diagrammatic View, connect the following classes:

1. Participant to SpecimenCollectionGroup.
  2. Tissue Specimen to SpecimenCharacteristics (1 to 1).
  3. SpecimenCollectionGroup to TissueSpecimen (1 to both).
- The following figure shows how the diagram will look like.

Click the Search button. The result will display all the participants whose banked colon tissue and the associated lymph nodes are cancerous.

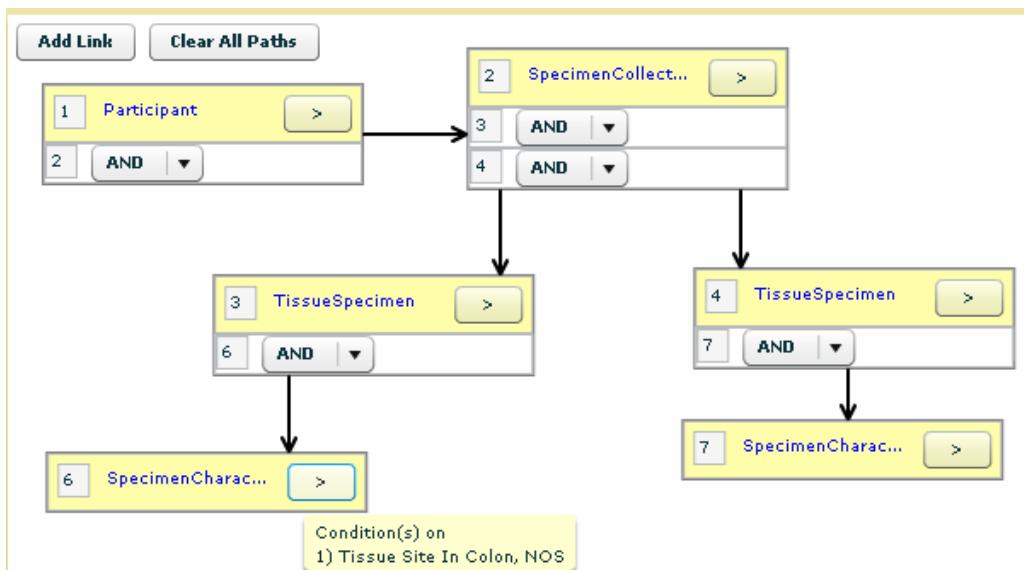


Figure 145: Diagrammatic representation for case E

- F. Find all male participants having lung cancer for which frozen tumor and matching normal tissues are available.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Participant	Gender	In	Male Gender
2	SpecimenCollectionGroup	Id		Is Not Null
3	TissueSpecimen	Pathological Status	In	Malignant
		Type	In	Frozen Tissue
4	TissueSpecimen	Pathological Status	In	Non Malignant
		Type	In	Frozen Tissue
5	SpecimenCharacteristics	Tissue Site	In	Lung, Nos.
6	SpecimenCharacteristics	Tissue Site	In	Lung, Nos.

After adding the classes in the Diagrammatic View, connect the following classes:

1. Participant to SpecimenCollectionGroup.
  2. SpecimenCollectionGroup to TissueSpecimen (1 to both).
  3. TissueSpecimen with SpecimenCharacteristics (1 to 1).
- The following figure shows how the diagram will look like.

## Appendix 3: Complex Querying

Click the Search button. The result will display all the male participants having lung cancer for which frozen tumor and matching normal tissues are available.

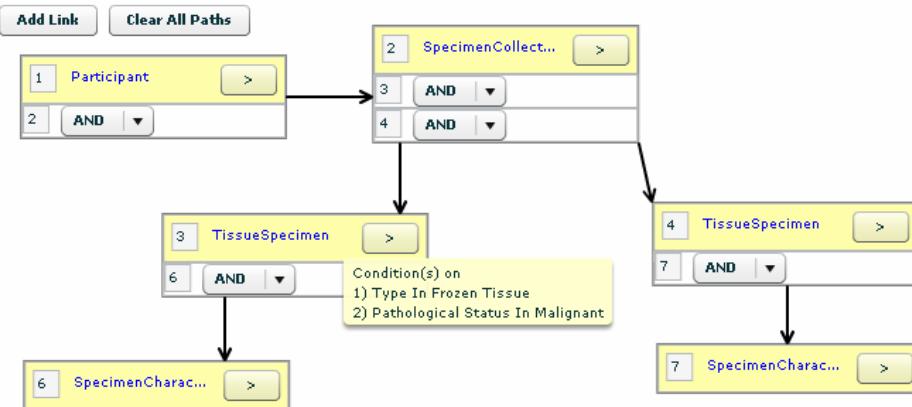


Figure 146: Diagrammatic representation for case F

### Queries on Specimen Collection Group

- G. Find all biopsies where the clinical diagnosis is infiltrating duct and lobular carcinoma.  
For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	SpecimenCollectionGroup	Clinical Diagnosis	In	Infiltrating duct and lobular carcinoma
2	CollectionEventParameters	Collection Procedure	In	Needle Core Biopsy

After adding the classes in the Diagrammatic View, connect class SpecimenCollectionGroup to class Collection Event Parameter. Click the Search button. The result will display all the SCGs having clinical diagnosis as infiltrating duct and lobular carcinoma, and which have the needle core biopsy collection procedure.

The following figure shows how the diagram will look like.

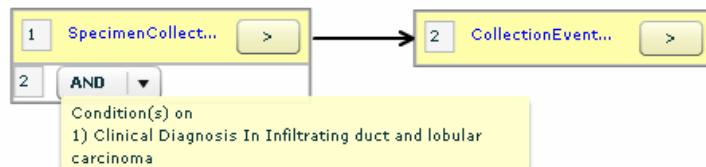


Figure 147: Diagrammatic representation for case G

## Queries on Specimens

- H. Find all specimens having cryopreserved cells from tumor tissue whose neoplastic cellularity is greater than 50%.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	TissueSpecimen	Pathological Status	In	Malignant
2	CellSpecimen	Id		Is Not Null
		Type	In	Cryopreserved Cells
3	CellSpecimenReviewParameters	Neoplastic Cellularity Percentage	Greater Than	50

After adding the classes in the Diagrammatic View, connect the following classes:

1. TissueSpecimen to CellSpecimen.
  2. CellSpecimen to CellSpecimenReviewParameters.
- The following figure shows how the diagram will look like.

Click the Search button. The result will display all the specimens having cryopreserved cells from tumor tissue whose neoplastic cellularity is greater than 50%.

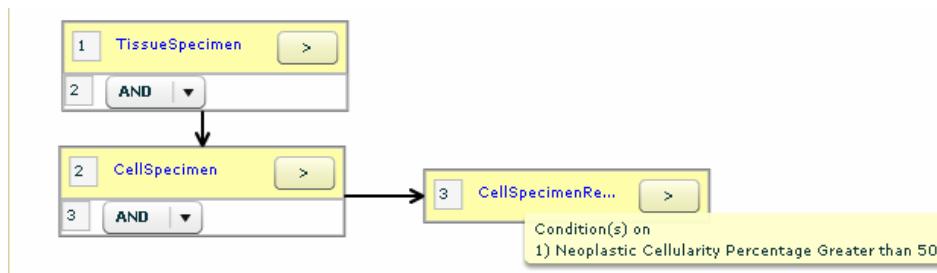


Figure 148: Diagrammatic representation for case H

- I. Find all the collected specimens under the Phase III protocol.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	CollectionProtocol	Title	Contains	Phase III
2	SpecimenCollectionGroup	Id		Is Not Null
3	Specimen	Collection Status	Equals	Collected

After adding the classes in the Diagrammatic View, connect the following classes:

## Appendix 3: Complex Querying

1. CollectionProtocol to SpecimenCollectionGroup.
2. SpecimenCollectionGroup to Specimen.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the specimens collected under the Phase III protocol.

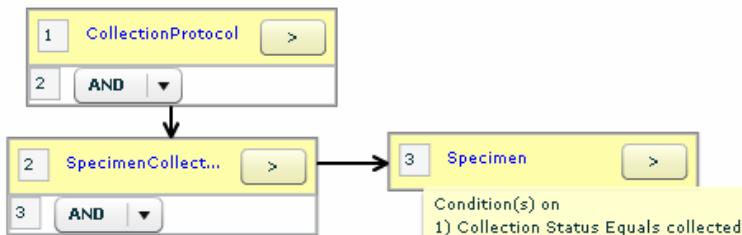


Figure 149: Diagrammatic representation for case I

- J. Find all good quality DNA specimens derived from malignant breast tissue.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	TissueSpecimen	Collection Status	Equals	Collected
		Pathological Status	In	Malignant
2	SpecimenCharacteristics	Tissue Site	In	Breast,NOS
3	MolecularSpecimen	Type	In	DNA
4.	MolecularSpecimenReviewParameter	Quality Index	Equals	Good

After adding the classes in the Diagrammatic View, connect the following classes:

1. TissueSpecimen to SpecimenCharacteristics and MolecularSpecimen.
2. MolecularSpecimen to MolecularSpecimenReviewParameter.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the good quality DNA specimens derived from malignant breast tissue.

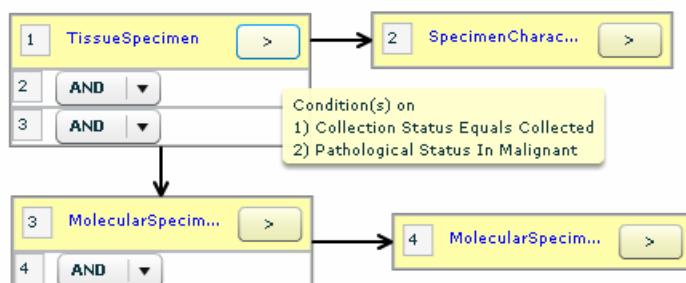


Figure 150: Diagrammatic representation for case J

- K. Find all the pending specimens under the Phase III protocol.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	CollectionProtocol	Title	Contains	Phase III
2	SpecimenCollectionGroup	Id		Is Not Null
3	Specimen	Collection Status	Equals	Pending

After adding the classes in the Diagrammatic View, connect the following classes:

1. CollectionProtocol to SpecimenCollectionGroup.
2. SpecimenCollectionGroup to Specimen.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the pending specimens under the Phase III protocol.

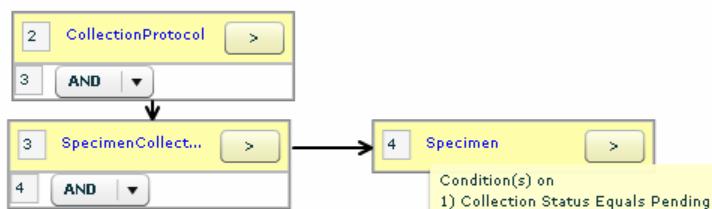


Figure 151: Diagrammatic representation for case K

- L. Find all the specimens that have been collected in an unacceptable quality.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	Specimen	Id		Is Not Null
2	ReceivedEventParameter	Quality	In	Unacceptable, Not Specified

After

adding the classes in the Diagrammatic View, connect the Specimen class to ReceivedEventParameter class and click the Search button. The result will display all the specimens that have been collected in an unacceptable quality.

The following figure shows how the diagram will look like.

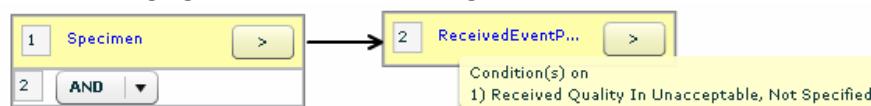


Figure 152: Diagrammatic representation for case L

## Appendix 3: Complex Querying

- M. Find all tumor tissues with Excellent- Definable Nuclear Detail.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	TissueSpecimen	Collection Status	Equals	Collected
		Pathological Status	In	Malignant
2	TissueSpecimenReviewEventParameter	Quality	In	Excellent-Definable Nuclear Detail

After

adding the classes in the Diagrammatic View, connect the class `TissueSpecimenReviewEventParameter` to class `Specimen` and click the `Search` button. The result will display all the tumor tissues with Excellent- Definable Nuclear Detail.

The following figure shows how the diagram will look like.



Figure 153: Diagrammatic representation for case M

## Queries on Orders

- N. Find all the derivative specimens that need to be created for the placed orders.

In the Diagrammatic View, add a class `DerivedSpecimenOrderItem` with limit: `ID Is Not Null`. Click the `Search` button. The result will display all the derivative specimens that need to be created for the placed orders.

The following figure shows how the diagram will look like.

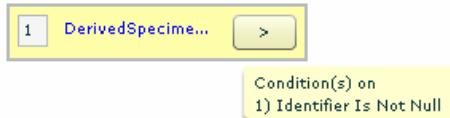


Figure 154: Diagrammatic representation for case N

- O. Find all specimen arrays that are pending for distribution, protocol review, or specimen preparation.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	OrderDetails	Status	Contains	Pending
2.	ExistingSpecimenArrayOrderItem	Id		Is Not Null

After

adding the classes in the Diagrammatic View, connect the OrderDetails class to the ExistingSpecimenArrayOrderItem class. Click the Search button. The result will display all the specimen arrays which are pending for distribution, protocol review, or specimen preparation.

The following figure shows how the diagram will look like.

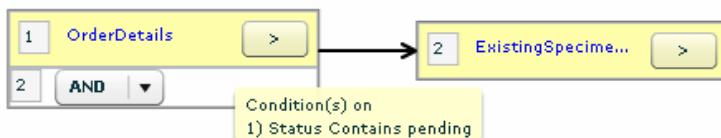


Figure 155: Diagrammatic representation for case O

- P. Find all the orders that are pending for distribution, protocol review, or specimen preparation. In the Diagrammatic View, add a class OrderDetails with limit as ‘status starts with ‘pending’. Click the Search button. The result will display all the orders that are pending for distribution, protocol review, or specimen preparation.

The following figure shows how the diagram will look like.



Figure 156: Diagrammatic representation for case P.

### Queries on Surgical Pathology Reports

- Q. Find all reports that have concept as viral and classification as diagnosis.  
For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	DeidentifiedSurgicalPathologyReport	Identifier		Is Not Null
2	ConceptReferent	Identifier		Is Not Null
3	ConceptReferentClassification	Name	Contains	diagnosis
4	Concept	Name	Is	viral

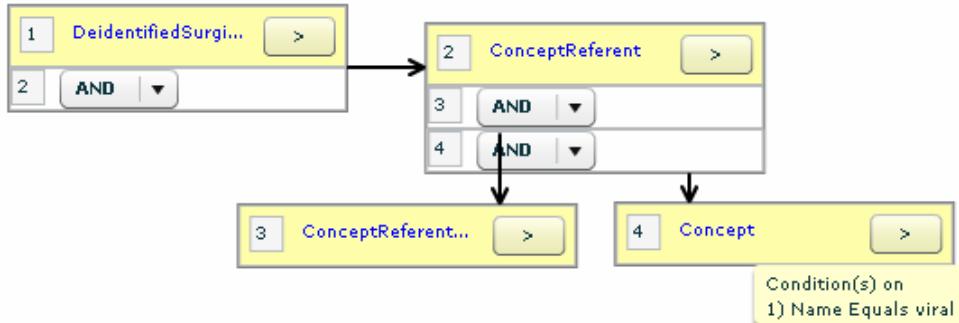
After adding the classes in the Diagrammatic View, connect the following classes:

1. DeidentifiedSurgicalPathologyReport to ConceptReferent.
2. ConceptReferent to Concept.
3. ConceptReferent to ConceptReferentClassification.

## Appendix 3: Complex Querying

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the reports that have concept as viral and classification as diagnosis.



**Figure 157: Diagrammatic representation for case Q**

- R. Find all de-identified surgical pathology reports with any organ, diagnosis, and procedure concept categories, and having text entry.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	DeidentifiedSurgicalPathologyReport	Identifier		Is Not Null
2	ConceptReferent	Is Negated	Equals	False
3	TextContent	Identifier		Is Not Null
4	ConceptReferent	Is Negated	Equals	False
5	ConceptReferent	Is Negated	Equals	False
6	Concept	Identifier		Is Not Null
7	ConceptReferentClassification	Name	Contains	Organ
8	Concept	Identifier		Is Not Null
9	ConceptReferentClassification	Name	Contains	diagnosis
10	Concept	Identifier		Is Not Null
11	ConceptReferentClassification	Name	Contains	procedure

After adding the classes in the Diagrammatic View, connect the following classes:

1. DeidentifiedSurgicalPathologyReport to each of the ConceptReferent.
2. DeidentifiedSurgicalPathologyReport to TextContent.
3. Each of the ConceptReferent class to one Concept class and one ConceptReferentClassification class.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the de-identified surgical pathology reports with any organ, diagnosis, and procedure concept categories, and having text entry.

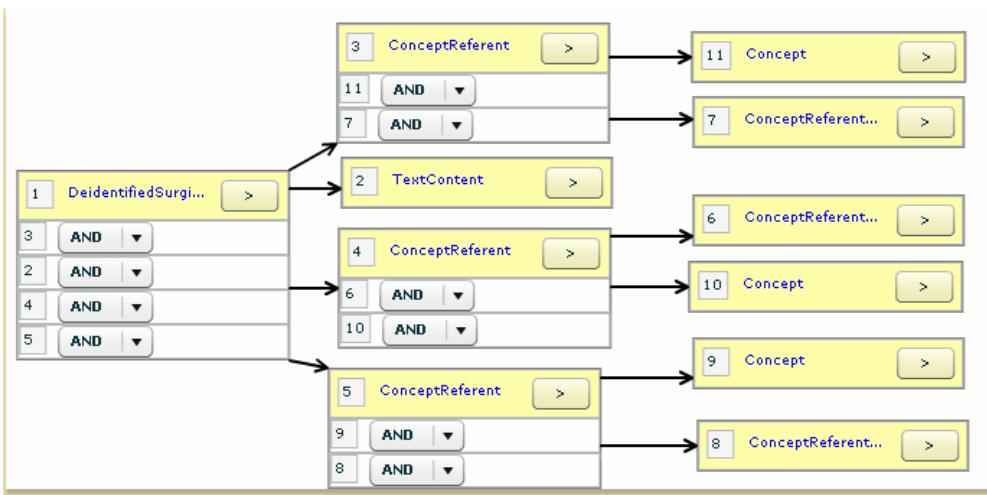


Figure 158: Diagrammatic representation for case R

## Queries on Annotations

- S. Find all the patients who have a smoking history of 3 or more packs per day.



For this query the smoking history annotation is required, since the packs per day attribute is available under the Smoking Health Annotation.

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
2	Smoking Health Annotation	Packs per day	Greater than or Equal to	3

After adding the classes in the Diagrammatic View, connect the Participant node to Smoking Health Annotation node. Click the Search button. The result will display all the participants who have a smoking history of 3 or more packs per day.

The following figure shows how the diagram will look like.

## Appendix 3: Complex Querying



**Figure 159: Diagrammatic representation for case S**

- T. Find all Specimen Collection Groups under which fresh breast tissue specimens have been collected which show Microcalcification in invasive carcinoma. Also Lymph node sampling has been done for the Sentinel Lymph Nodes only.

	For this query the breast pathology annotation is required, since the pathological data is available under the “Breast Pathology Annotation”.
---	---

For this query, add the classes in the Diagrammatic View with conditions on the attribute as shown in the following table:

No	Class	Attribute	Operator	Condition
1	SpecimenCollectionGroup	Id		Is Not Null
2	Specimen	Type	In	Fresh Tissue
3	SpecimenCharacteristics	Tissue Site	In	Breast NOS
4	BreastPathologyAnnotation	Lymph Node Sampling	In	Sentinel lymph node(s) only
5	Microcalcification	Value	In	Present in invasive carcinoma

After adding the classes in the Diagrammatic View, connect the following classes:

1. SpecimenCollectionGroup to Specimen.
2. Specimen to SpecimenCharacteristics.
3. SpecimenCollectionGroup to BreastPathologyAnnotation.
4. BreastPathologyAnnotation to Microcalcification.

The following figure shows how the diagram will look like.

Click the Search button. The result will display all the specimen collection groups under which fresh breast tissue specimens have been collected, which show Microcalcification in invasive carcinoma. Also Lymph node sampling has been done for the Sentinel Lymph Nodes only.

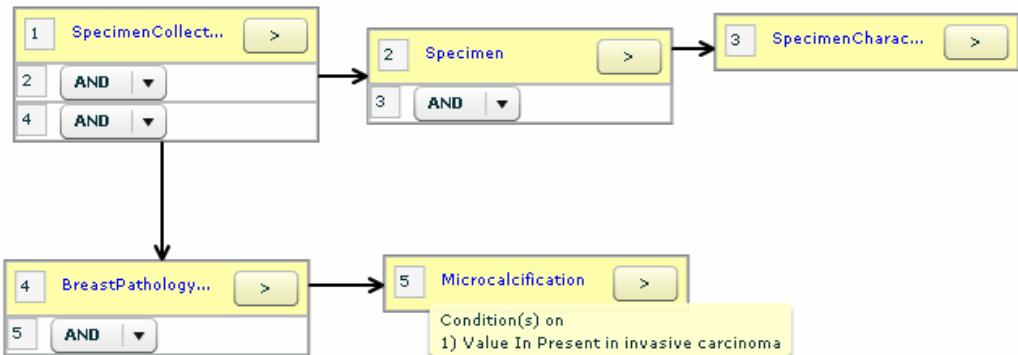


Figure 160: Diagrammatic representation for case T

## Appendix 4: Error Messages

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This section outlines the common error messages you may encounter while using the caTissue Suite. The error messages in this appendix are categorized as:

- Administrative Data tab errors
- Biospecimen Data tab errors

### Administrative Data Tab Errors

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This section outlines the common errors found on the Administrative Data tab.

**Table 70: Error Messages on the Administrative Data Tab**

Error Message	Why does it occur?	How to resolve?
Incorrect Email Address or Password	Wrong email address or password is entered in the provided field on the home page of the application.	Enter the correct email address and password. You can use the Forgot your Password? link to retrieve the password.
New password must include at least one upper case letter, one lower case letter and a number. The password can not contain spaces.	The new password does not fulfill the specified password requirements.	Add the password as per the specified requirements.
Record Id is required Group/User is required	A Record ID or Group/User is not entered while assigning a privilege.	You need to select the appropriate ID, and Group or User to assign privilege(s).
Unable to update, Only Consents can be added under this Collection protocol	The CP details other than consents are edited and the CP is saved.	Edit only the Consents in the CP once a participant is registered to the CP.
At least one event is required to create Collection Protocol	A single specimen event is not added to the CP.	Add a Specimen Event to save the CP.
Please enter valid values*	An incorrect value is added. For example: In the Temperature field you are required to enter a numeric value. If you add a string value, an error message is displayed.	Enter the correct alphabetical, numerical, or alphanumerical value.
Field Name# is required	A value is not entered in the selected field.	Enter a value in the selected field.

\* For example: alphabetical, numerical, or alphanumerical value

# For example: Site name, Specimen type, class, and so on.

## Biospecimen Data Tab Errors

---

This section outlines the common errors found on the Biospecimen Data tab.

**Table 71: Biospecimen Data Tab Error Messages**

Error Message	Why does it occur?	How to resolve?
Duplicate collection protocol selected	A participant is registered twice to the same protocol.	Register the participant to another protocol.
Either Site or Medical Record Number is missing in Medical Identifier	Source or Medical Record Number under the Medical Identifiers on Participant page is not added.	Add both the Source and Medical Record Number under the Medical Identifiers field.
Submission failed since a Collection Protocol Registration with the same COLLECTION_PROTOCOL_ID, PROTOCOL_PARTICIPANT_ID already exists.	A new participant is registered with the PPI same as that of an already existing participant under the same collection protocol.	The combination of PPI and CP should be unique. No two participants registered under a CP can have the same PPI. Enter a different PPI for the other participant to avoid this error.
Submit was not successful because some matching participants found.	Participant details are entered that are similar to an existing participant.	Ignore matches to create new participant or add more details. Perform another lookup once this is done. For more information, refer to the paragraph on participant duplicate check under Registering a Participant to a Collection Protocol.
Collection Site is invalid	An incorrect site name is entered or the Collection Site field is left blank on the SCG page	Select the required site from the Collection Site drop down or enter the correct site name.
Number of Specimens should be greater than zero	The Number of Specimen(s) is entered as zero on the edit SCG page and the Add Multiple Specimens button is clicked.	Enter a number greater than zero to add multiple specimen(s).
Please enter valid Aliquot Count	An invalid value is entered during the creation of aliquots or the Aliquot Count field is left blank.	Enter a valid aliquot count to create aliquots.
Cannot perform operation :Specimen not available	An action is performed on a specimen that is unavailable. It means the Is Available check box is not selected.	If the specimen is available, check the Is Available check box and then perform an action on the specimen.

## Appendix 4: Error Messages

Error Message	Why does it occur?	How to resolve?
Unable to disable Specimen Collection Group: Before disabling it, dispose all the associated Specimens.	A SCG that has specimens is disabled.	Disable all the specimens under the SCG and then the SCG.
Available Quantity cannot be greater than Initial Quantity	The Available Quantity entered is more than the initial quantity on the Specimen Details page.	Both quantities should be same or the available quantity should be less if the specimen is previously used.
Can not disable specimen. Specimen contains sub-specimen.	A parent specimen that has child specimens (aliquots or derivatives) is disabled.	Disable the child specimens first and then the parent specimen.
System can not distribute available quantity among the aliquots due to insufficient amount.	The aliquot quantity entered is more than the parent specimen's available quantity.	The sum of quantity per aliquot for each aliquot should be less than or equal to the available quantity of parent specimen.
Please add compatible specimens to specimen array (belong to same specimen class & specimen types of Array).	Specimen of class and type are added that are different from the specimen array type. For example: adding cryopreserved cells to a DNA array.	Add specimens of the same class and type as that of the specimen array type.
Please enter at least one condition to add a limit to limit set.	The Add Limits button is clicked without entering conditions on the attributes.	Add one condition and then click the Add Limits button to register the class in the DAG view.
Expression graph should be a connected graph.	Two or more classes in the DAG view are not connected and the Search button is clicked.	Connect all the classes before performing search.
List is empty	No items are added to My List.	Add items to My List before performing bulk operations or ordering.
Can not add in to List as view of List is different.	Items are added to My List when My List contains items that have a different view. For example: adding specimens to My List when My List already contains specimen arrays.	Delete the existing items in My List and add new items. You can also define a view of the items on the advanced query results page to match the view of the existing items in My List.
Please verify Consents for Specimen(s)	Order View >> Order Details page: The consent responses before distributing the specimen(s) are not verified.	Select the View link under Consent for Specimen. The Consent Form page is displayed. Verify the consents by selecting the check box and then click the Done button.

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## Appendix 6: Glossary

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Term	Definition
Administrative Data	One of the three different data types in which caTissue Core data can be categorized. Collection protocol, Distribution protocol, Biohazards, Site, Storage container, User, Department, Institution, Cancer Research Group.
Administrator	The Administrator registers new users, sites, containers, and collection and distribution protocols into the system. See Chapter 3 (User Roles) for definition.
Aggregate data	Data collected and reported.
Aliquot	Pertaining to a portion of the whole; any one of two or more samples of something, of the same volume or weight.
API	Application Programming Interface.
Array	An orderly arrangement of biospecimens.
Biohazards	An attribute of a Specimen that renders it potentially harmful to a User.
Cancer Research Group	A collection of Scientist or clinician users with a common research objective related to biospecimen collection and utilization.
cardinality	Cardinality describes the minimum and maximum number of associated objects within a set.
Cell Specimens	A biospecimen composed of purified single cells not in the context of a tissue or other biospecimen fluid. These are discrete in nature and so will always be measured in cell count in the system.
Check-in/Check-out Event	Event that refers to temporary movement of specimens from stored location.
Clinical Report	A clinical report associated with the participant at the time of specimen collection event (also referred to as Clinical Annotation).
Collection Event	Event that refers to collection of a specimen from participant under a collection protocol.
Collection Protocol	A set of written procedures that describe how a biospecimen is collected.
Collection Protocol Registration	A registration of a Participant to a Collection Protocol.
De-identified data	De-identified information excludes all patient-identifiable information but can include biospecimen identifiers.
Department	A department to which a User belongs.
Disposal Event	Event that refers disposing/rejecting a specimen.
Distribution	The act of distributing or spreading or apportioning.
Distribution Protocol	An abbreviated set of written procedures that describe what, how many, and how much of a biospecimen or biospecimens will be utilized for research. Biospecimens may be collected under one collection protocol and then later utilized by single or multiple studies.
Embedded Event	Event that refers to embedding a specimen in paraffin or plastic material.
Fixed Event	Event that refers to fixing a specimen.

<b>Term</b>	<b>Definition</b>
Fluid Specimens	A single unit of bodily fluid that is collected from a participant or created from another specimen. These are fluid in nature and so will always be measured $\mu\text{l}$ (microliter) in the system.
Frozen Event	Event that refers freezing a specimen at certain temperature.
HIPPA	Health Insurance Portability and Accountability Act.
Identified Distribution	Identified information can be disclosed to the receiver of the biospecimens. This type of distribution can be done only if the receiver of the biospecimens is a PI or coordinator of the collection protocol under which the biospecimen is collected.
Institution	An institution to which a user belongs.
Hook Entity	It is a static class in caTissue Suite to which the dynamically created annotation form is linked. A hook entity can be Participant, Specimen Collection Group, or Specimen.
Molecular Specimen	A molecular derivative (that is RNA or DNA or PROTEIN) created from a specimen. This is also known as sample. These can be fluid in nature but it will always be measured in micrograms, and concentration of molecular specimen will determine its volume.
Participant	An individual from which a biospecimen is collected.
Participant data	One of the three different data types in which caTissue Core data can be categorized. Participant, Participant's medical identifiers, Collection protocol registration, Specimen collection group, Clinical report.
Participant Medical Identifier	A medical record identification number that refers to a Participant.
Procedure Event	Event that refers customized procedure that is applied on a specimen to process it.
Received Event	Event that refers to receiving a specimen in the tissue bank.
Review Event	Event that refers to performing quality assurance actions on a specimen.
Scientist	A Scientist performs a query and adds specimens, pathology cases or arrays of interest to My List. See Chapter 3 (User Roles) for definition.
Site	A physical location involved in biospecimen collection, storage, processing, or utilization.
Specimen	A single unit of tissue or body fluid collected from a participant as part of a specimen collection event. A new specimen can be created as a derivative of an existing specimen or by dividing it into small pieces.
Specimen Collection Group	An event that results in the collection of one or more biospecimens from a participant.
Specimen Distribution	An event that results in transfer of a specimen from a Repository to a Laboratory
Specimen Events	Specimen events are actions that can be performed on specimen in a tissue bank. For example: collected, received, frozen, fixed, reviewed, and so on.
Specimen External Identifier	A pre-existing, externally defined identifier associated with a specimen.
Spun Event	Event that refers to spinning the specimen.

## Appendix 6: Glossary

Term	Definition
Surgical Pathology Report	Detailed findings based on surgical accession and examination of biospecimens.
Technician	See Chapter 4 (User Roles) for definition.
Thaw Event	Event that refers defrosting a specimen.
Tissue Specimens	A single unit of tissue that is collected from a Participant or created from another specimen. These are solid in nature and so will always be measured in grams in the system.
Transfer Event	Event that refers to moving specimen from one storage location to another storage location.