4.7 - Introduction to Clinical Annotations v2.0

This section provides descriptions and instructions to use Clinical Annotations (CA). Clinical Annotations allows you to collect additional clinical and pathological information of the participant, accession, and biospecimens. Clinical Annotations is divided into pathology information and clinical and health information.

This section includes the following topics.

- Pathology Information
- Clinical and Health Information
  - Features of Clinical Annotations (CA)
  - Clinical Annotations Workflow
  - Assigning Annotations to a Collection Protocol
  - Adding Clinical and Pathological Data to an Annotation
  - Querying on Annotations

Pathology Information

This section outlines CAP-based (College of American Pathologists) pathology annotations. It involves a 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 include the following:

- Prostate
- Pancreas
- Kidney
- Lung
- Blood/Bone Marrow (labeled as Heme in caTissue Suite)
- CNS
- Colon and Rectum
- Breast
- Skin (labeled as Melanoma in caTissue Suite)

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

Clinical and Health Information

Clinical and health information comprises 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>
<thead>
<tr>
<th>Participant</th>
<th>Specimen Collection Group</th>
<th>Specimen</th>
</tr>
</thead>
</table>


Features of Clinical Annotations (CA)

Clinical Annotations provides the following features:

1. Assign a Clinical Annotation 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. A Super Administrator associates annotations to one or more than one relevant collection protocols.
2. An Administrator, Supervisor, or Technician enters clinical data or pathological data for the annotations under the site and collection protocol to which they have access. The Registration or Specimen Processing privilege is required for this operation too.
3. An 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. 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

1. Click the Administrative Data tab.
2. Click Local Extensions > Edit.
   A warning message opens. It warns about the possible alterations to the database tables while creating or editing the dynamic extensions.
3. Click Next and the Assign Clinical Annotations – Warning page opens with the message, Please note that creating or editing a dynamic extension will create or alter tables in caTissue database. As a good data administration practice, we suggest that you take a backup of the database before creating any new Dynamic Extensions or editing the existing Dynamic Extensions.
4. On the Build Annotation Form page, select the required Clinical Annotation Group – Warning page opens with the message, Please note that creating or editing a dynamic extension will create or alter tables in caTissue database. As a good data administration practice, we suggest that you take a backup of the database before creating any new Dynamic Extensions or editing the existing Dynamic Extensions.
5. Click the Edit link under Conditions for the annotation on which the collection protocol restrictions are to be assigned. For example, if you select the pathology_specimen group, all the Clinical Annotation forms created under this group are displayed under Form Title. For example, if you select the pathology_specimen group, all the Clinical Annotation forms created under this group are displayed under Form Title. For example, if you select the pathology_specimen group, all the Clinical Annotation forms created under this group are displayed under Form Title. For example, if you select the pathology_specimen group, all the Clinical Annotation forms created under this group are displayed under Form Title.
6. To set restrictions on the availability of that annotation, select or update the required collection protocol in the Title list box, such as, C_C_P (Colon Cancer Protocol) as shown in the following figure.

![Image of annotation form]

7. Click Submit to save the changes. Click Cancel to ignore the changes made to the collection protocol restrictions.

8. You can continue assigning annotations to specific collection protocols, or you can select multiple collection protocols. Select the required collection protocol, press the <Ctrl> key, and select another collection protocol.

Adding Clinical and Pathological Data to an Annotation

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

To add data to the associated clinical annotation:

1. Click the Biospecimen Data tab.
2. Select the Collection Protocol Based View.
3. In the Collection Protocol box, type or select the collection protocol to which your annotation is restricted.
4. From the following list, select a hook entity that the Collection Protocol is associated with:
   - Participant
   - Specimen Collection Group
   - Specimen
5. Click the View Annotation tab on the right pane.
   All the annotations associated with the collection protocol are displayed in a tabular format:
   - The Group column displays the entity group name.
   - The Form column displays the annotation name.
   - The Count column displays the number of records added to the annotations.
   - The Action column displays the Add or Edit options for adding a record to an annotation or editing an existing record.
6. To add a new annotation:
   a. Click Add for the annotation to which you want to add data.
      The form opens for data entry.
b. **Type or select the clinical and pathological data.**

The View Annotation page opens with the count for the updated annotation increases by one.

7. To edit the annotation:
   
a. Click the **Edit** link on the Action column.
   
   Under **Update Records**, records added to the entity group are displayed in a tabular format:
   
   - The **Record Id** column displays the record Id of the added annotations.
   - The **Updated By** column displays the name of the user who inserted the record.
   - The **Action** column contains the **Edit** link.

b. Click **Edit** in the row for the annotation you want to edit.

   The Annotation details are displayed.

c. Edit the existing details that you want to change, and click **Submit**.

   caTissue Suite navigates back to records page.

For more information on default annotations in caTissue Suite, refer to **Data Entry for Clinical Information Annotation**.

**Querying on Annotations**

Once you enter data in the annotations, you can search for the required annotations under specific collection protocols. For more information on advanced querying, refer to **Using the Advanced Query Wizard**. For more information on querying clinical annotations and viewing related examples, refer to **Complex Querying**.