

## caTissue Suite v 2.0

### Requirements and Use Cases

Version 1.5

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## Revision History

Date	Version	Description	Author	Reviewed by
2/4/2011	1.0	Initial version	caTissue Development Team	caTissue Development Team
3/9/2011	1.1	Added DE API and CBM Requirements. Also incorporated feedback on version 1.0	caTissue Development Team	caTissue Development Team
6/6/2011	1.2	Final version of the requirements	caTissue Development Team	caTissue Development Team
11/21/2011	1.3	Revisions based on final review	caTissue Development Team	caTissue Development Team
2/23/2012	1.4	Updated requirements ids	caTissue Development Team	caTissue Development Team
7/23/2012	1.5	Final version	caTissue Development Team	CaTissue Development Team

Foswiki > Catissue Web > CaTissue > V20 > RequirementDocuments (12 Dec 2011, DenisKrylov?)

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## Introduction

This document describes the requirements and use cases for the caTissue v2.0 release. This release will contain the following new features:

1. Integration with other caBIG applications ([C3PR](#) and [caArray](#))
2. Integration with caGrid Security Infrastructure
3. Specimen Processing Procedures (SPP) for biospecimen collection
4. BDAfication of caTissue code projects
5. Technical stack upgrade
6. Enhancements in Bulk Operations (BO)
7. Enhancements in Ordering and API demo program
8. Age at participant collection
9. Legacy bug fixes
10. Unified DE and Static caCORE API exposed through unified writable caGrid service.

This document describes these features in more detail.

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## caGrid User Authentication

To support caBIG enterprise use cases, caTissue must reconcile local caTissue users with caGrid users and be able to operate at the caGrid level to support add/edit and query use cases, both those specific to caTissue and those related to complex workflows involving other caBIG® tools. This document describes the use cases and requirements to adopt the caGrid security infrastructure fully to support both user and group fine-grained authorization policies at the caGrid level.

The goal is that caTissue should be deployable in one of two modes – local authentication or caGrid authentication mode. In caTissue v1.2, a caTissue instance can be configured to either use a local CSM or any local Identity Providers ([IdPs](#)). Thus in Local mode, CSM or one or more institution [IdPs](#) will be used for authentication and authorization will be performed by caTissue's CSM. In caGrid mode, NCI dorian or any other configured Dorian/s will be used as the Identity Federation Service (IFS) that will determine the list of valid [IdPs](#).

### Use Cases at high level:

#### Authentication

- To be able to sign up in caTissue using a particular [IdP](#) registered to a caGrid Dorian for authentication
- To be able to migrate an existing user to a caGrid Dorian-approved [IdP](#) for authentication
- Allow administrators (superadmin or site admin) to provision a user by selecting any of the caGrid [IdPs](#) the user belongs to and to set that [IdP](#) for authentication for that user

#### Authorization

- To be able to propagate collection protocol privileges to caGrid users and groups

## Requirements

### Deployment

In order to support provisioning caGrid users within a local caTissue instance, there are some deployment related enhancements that need to be supported as described below. Currently local [IdPs](#) at an instance can be configured. In a similar manner, it should be possible to configure caGrid [IdPs](#).

Requirement ID	Requirement
caTissue-v20-01	Deployment administrators should be able to configure URL of caBIG Dorian and/or NCI LDAP to provision caGrid users.
caTissue-v20-05	Deployment administrator should be able to configure URL of authentication services within particular Dorian IdP.

### caGrid User Sign-up

Similar to user sign up using the local CSM, existing caGrid users should be able to sign up to a caTissue instance. In order to do this, the users should be able to select an appropriate caGrid IdP against which s/he authenticates.

Figure 1: Sign Up page with caGrid IdPs

Requirement ID	Requirement
caTissue-v20-10	caGrid users should be able to sign up within caTissue by selecting particular caGrid IdP(as configured by deployment administrators of the local caTissue instance).
caTissue-v20-12	User should be authenticated against the selected caGrid IdP and error message should be displayed in case of invalid caGrid user.
caTissue-v20-13	Based on caGrid login name, the user details that can be fetched from caGrid should be populated on the sign up page - last name, first name, address, email, phone
caTissue-v20-14	User having user provisioning privilege should be able to approve caGrid user sign up requests.

### Login Migration:

Existing users should be able to migrate their local CSM account to their corresponding caGrid user account for authentication. The user will then be authenticated using caGrid approved IdP (i.e. registered at a caGrid Dorian) and authorized based on caGrid user using caTissue's local CSM. Currently caTissue supports this for local IdPs (See Figure 2 below).

Figure 2: Login migration to different IdP

Requirement ID	Requirement
caTissue-v20-15	There should be a provision for migrating authentication from the local CSM to any IdP (local or caGrid) after the user logs in if not already migrated.
caTissue-v20-17	User should be able to enter the login, password and IdP to which the user wants to migrate. The list of IdPs should come from the local deployment configuration.

### Provision caGrid User

Similar to how administrator can provision local CSM users, it should be possible to provision caGrid users into local caTissue instance.

**Add User**

**Identity Provider Details**

- \* Please select the system where you have a current login and password.
- \* Login Name

**User Details**

* E-mail Address <input type="text"/>	* Confirm E-mail Address <input type="text"/>
* Last Name <input type="text"/>	* First Name <input type="text"/>
Street <input type="text"/>	* City <input type="text"/>
* State <input type="text"/>	* Zip Code <input type="text"/>
* Country <input type="text" value="United States"/>	* Phone Number <input type="text"/>
Fax Number <input type="text"/>	* Institution <input type="text"/>
* Department <input type="text"/>	* Cancer Research Group <input type="text"/>

Figure 3: Add User page allowing provisioning users of particular IdP

Requirement ID	Requirement
caTissue-v20-32	System should check if the login name exists within the IdP selected.
caTissue-v20-35	Based on caGrid login name, the user details that can be fetched from caGrid should be populated on the user creation page - last name, first name, address, email, phone

#### CP Privileges to caGrid Users/Groups

Similar to how an administrator can currently give local users privileges at a collection protocol level, it should be possible to assign the privileges to caGrid users and/or groups.

**1. Users**  
Site1  
Site2

**2. Select Users**  
caGrid User1  
caGrid User2  
Site User1  
Site User 2

**3. Role**  
Supervisor

**4. Privileges**  
Register  
Specimen Processing

Figure 4: Mock screenshot for assigning CP privileges to caGrid users

**1. caGrid Groups**  
Site1  
Site2

**2. caGrid Group**  
caGrid Group1

**3. Role**  
Supervisor

**4. Privileges**  
Register  
Specimen Processing

Figure 5: Mock screenshot for assigning CP privileges to caGrid groups

Requirement ID	Requirement
caTissue-v20-45	It should be possible to make caGrid user PI or Coordinator of a CP.
caTissue-v20-50	At the Collection Protocol level, a super or site administrator should be able to assign roles and privileges to individual caGrid user or Group based on repository sites.
caTissue-v20-51	An active user should be created in caTissue for every user belonging to caGrid group provisioned in caTissue. This user should not have any role or privileges at individual user level unless manually provided.
caTissue-v20-52	By default, users of caGrid groups should not have access to any data including de-identified data across all collection protocols.
caTissue-v20-53	Any operation done by the grid user should be audited, similar to a CSM user.
caTissue-v2-55	Any operation done by a grid user provisioned via a Group should be audited against the user.

#### Authenticate and authorize caGrid Group

Once an administrator has provided a caGrid group access to CP(s) as described in the above sections, all users in that group will automatically get the CP privileges assigned. This way there is no need to provision all users of a group into caTissue. The below requirements describe how the authentication and authorization of such users should be handled.

Requirement ID	Requirement
caTissue-v20-60	When a user of a group logs in, the user should be authenticated against caGrid if the caGrid IdP is selected by the user along with login credentials.
caTissue-v20-63	<p>After login check should be made if user is authentic user of the selected caGrid IdP in following sequence.</p> <ul style="list-style-type: none"> <li>• Error message should be shown if user is not valid caGrid user</li> <li>• If valid caGrid user, check if the user is registered in caTissue and check the privileges</li> <li>• If valid caGrid user and is NOT registered in caTissue, then get the list of caGrid groups and check if any of the user's groups are linked with any CP in caTissue. If the group is not linked to any CP, throw appropriate error message (i.e. you do not have any privileges to perform any functions in this system).</li> <li>• Even if the user is registered in caTissue and selected IdP is a caGrid IdP, get the list of groups the user is part of because in some CPs privileges might be assigned to the group instead of individual user. This is because privileges of user are combination of individual's privilege plus the privileges of the caGrid group to which the user belongs to.</li> <li>• If user is valid caGrid user, but not registered in caTissue and not part of any caGrid group, then throw error (i.e. you do not have any privileges to perform any functions in this system).</li> </ul>

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## caGrid User Authorization?

### 1.1 Overview

Grid Grouper Integration is a part of a major development effort to enable federation of caTissue user authentication and authorization across multiple institutions. At this point, caTissue Grid Authentication component has already been implemented and covers both grid user authentication and local-to-grid user migration tasks. The main goal of Grid Grouper Integration is to allow centralized management of a caTissue user's group membership information that can span more than a single institution or organization. Thus, for example, different authorization policies can be applied to a single user at different institutions running caTissue and without requiring separate provisioning steps at each individual institution.

### 1.2 Grid Grouper

The best place to obtain information about Grid Grouper is the [caGrid website](#).

### 1.3 Storyboard

To see potential benefits of Grid Group Integration, let's consider the following scenario.

Two instances of caTissue are deployed at Duke University Medical Center (DUMC) and at Wake Forest University Baptist Medical Center (WFUBMC). Both institutions are participating in a single clinical study with a collection protocol and thus are interested in collaborating with each other. Jane Doe is a supervisor at DUMC and has unrestricted access to a local caTissue instance. Since the study is being conducted at two institutions, Jane Doe also needs to access tissue information at WFUBMC; however, her access to caTissue at WFUBMC needs to be limited, because she is not an employee at that institution.

The following steps can be followed to realize this use case:

- Jane gets a grid account to represent her identity.
- Jane receives a membership in Grid Grouper that assigns her to "Supervisors" group under "DUMC" stem and to "Scientists" group under "WFUBMC" stem.

- Jane registers in both instances of caTissue.
- Jane's membership information is retrieved from Grid Grouper by caTissue instances, and her local caTissue accounts are assigned corresponding privileges automatically.
- Jane is now able to log into each caTissue instance using a single set of grid credentials, and her privileges in each instance correspond to her group membership in Grid Grouper.
- Jane gets her access restrictions at WFUMBC lifted. She gets re-assigned to "Supervisors" group under "WFUBMC" stem in Grid Grouper.
- Her new role change is reflected in caTissue instance at WFUBMC seamlessly and automatically. A wider set of access privileges is granted.

## 1.4 Requirements

Requirement ID	Requirement
caTissue-v20-100	caTissue MUST retrieve group membership information from Grid Grouper for a) every newly provisioned user, whose target identify provider is on the grid (Dorian), b) every local user that has been migrated to the grid.
caTissue-v20-101	caTissue SHOULD store group membership information obtained from Grid Grouper in a local CSM data store.
caTissue-v20-102	caTissue MUST enforce authorization of grid users using their group membership information retrieved from or synced with Grid Grouper.
caTissue-v20-103	caTissue SHOULD map Grid Grouper groups to local CSM groups.
caTissue-v20-106	caTissue MUST sync its local CSM with Grid Grouper periodically to ensure that group and group membership information is up-to-date.
caTissue-v20-110	caTissue MUST notify administrators of issues synchronizing.
caTissue-v20-111	caTissue MUST notify administrators of synchronizing conflicts.
caTissue-v20-112	caTissue MUST NOT assign privileges to users automatically from Grid Grouper unless explicitly configured to do so.
caTissue-v20-113	Grid Grouper integration MUST be configurable, including whether the functionality is enabled, grid endpoints, and synchronization interval.
caTissue-v20-114	Integration with Grid Grouper MUST NOT interfere with normal security provisioning within caTissue.

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## caTissue writable API

### 1.1 Overview

caTissue provides Client API layer that allows invoking operations on caTissue domain objects remotely across networks. Examples of such operations include creation of institutions, users, and collection protocols. The Client API layer has been developed with caCORE framework; its main shortcoming is that it is not aligned with caGrid Integration effort having been undertaken by the caTissue development team. Specifically, the API is not compatible with grid API and does not utilize the grid security model.

The purpose of this effort is to grid-enable all operations that are currently available only through caCORE-based Client API.

### 1.2 Requirements

Requirement ID	Requirement
caTissue-v20-200	caTissue MUST expose a set of one or more grid services that provide the same level of functionality that is currently available via the Client API layer.
caTissue-v20-201	caTissue MUST follow the standard grid security model for controlling access to the aforementioned grid services.
caTissue-v20-202	caTissue WILL NOT develop the services as ECCF-based NES services.
caTissue-v20-203	caTissue WILL NOT harmonize the data model at the service interface with any Domain Analysis Model (DAM) such as BRIDG or LS-DAM beyond any existing caTissue harmonization.
caTissue-v20-204	The exposed grid API MUST mimic the existing caTissue caCORE SDK Java API.
caTissue-v20-205	The exposed grid API WILL NOT expose any additional operations that are not already exposed by existing caTissue caCORE SDK Java API.
caTissue-v20-206	The exposed grid API WILL NOT be tested for performance or scalability.

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## Ordering Services

### Biospecimen Requisition Service

In order to integrate biospecimen requisition with other research applications there needs to be a way to submit, track and fulfill requests programmatically. This should facilitate real time integration with other applications which want to submit and track orders in caTissue.

This should be possible to perform the following operations using API:

1. Add a new Order

2. Distribute an existing Order
  3. Get the status of an Order

It should be possible to do the above using caTissue caCORE APIs and the caTissue caGrid services.

## Requirements

Requirement ID	Description
caTissue-v20-Ordering-01	It should be possible to place an Order using caTissue caCORE API
caTissue-v20-Ordering-05	It should be possible to distribute an Order using caTissue caCORE API
caTissue-v20-Ordering-10	It should be possible to get the status of an Order using caTissue caCORE API
caTissue-v20-Ordering-15	There should be test programs available with the installable to demonstrate the above functionality.

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# SPP Integration

## Tracking Specimen Processing Procedure(SPPs) for Biospecimen Processing

Specimen Processing Procedure (SPPs) are a series of defined steps that dictate how to procure or process biospecimens. As a result of performing an SPP, a biospecimen experiences "events" in its "lifecycle". Examples of SPPs are surgical procedures used to obtain a biopsy or tissue resection, including anesthetic components administered throughout the operation, and protocols to isolate DNA or RNA from primary biospecimens. The accurate capture of SPPs and potential deviations that are used to procure and process biospecimens are vital to documenting the specimen life cycle.

Therefore, it is vital that caTissue be able to manage and represent SPPs associated with individual collection protocols.

## Rationale

- caTissue currently uses the 'Specimen Events' class to allow users to manually record a set of defined events (e.g. freezing, fixation, centrifugation) that happen to a specimen.
  - Current limitations of this functionality include:
    - Laborious, manually entry of events
    - Events limited to a pre-defined set of processes

## Use Cases

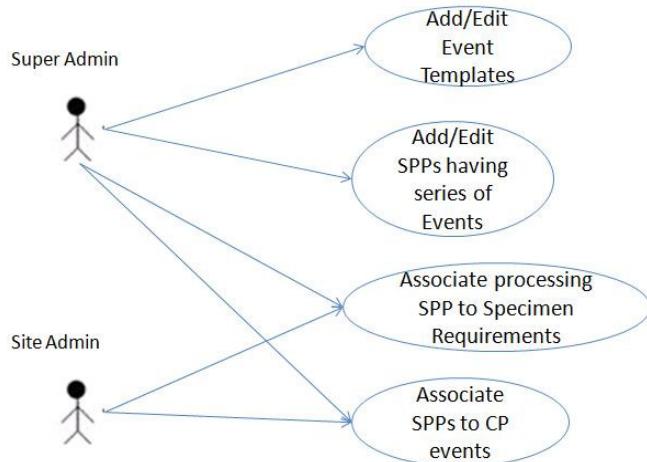


Figure 1: Admin SPP use cases

- Create SPP
    - Manage and represent SPPs associated with Collection Protocols
    - Underlying assumption is that all specimens of a specific class/type collected within a CP are processed identically since each CP is usually associated with a specific set of SPP(s).

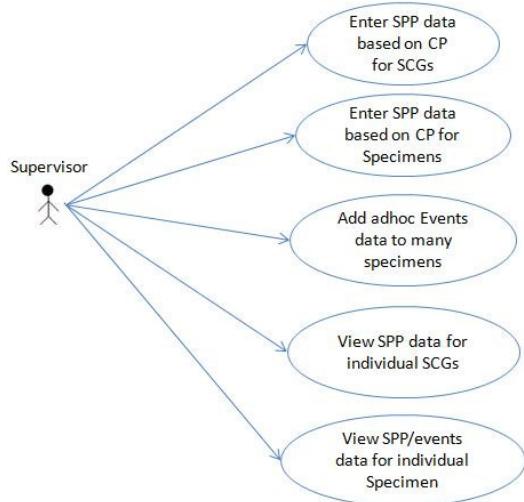


Figure 2: Supervisor SPP use cases

- Utilize SPP
  - During collection, record SPP details and any deviations either to the variables within defined events that are part of the SPP, or modifications to the SPP itself (e.g. an entire step or event was not performed).

## Requirements

### Defining Events

A user should be able to dynamically add new specimen events which are defined as a single action composed of a set of variables that pertain to that action being performed on a specimen. For example, a Freeze Event may contain the medium (e.g. iSPPentane), temperature of the medium (e.g. -20 C), and duration in medium (e.g. 15 minutes). The dynamic creation of events should be possible using the existing Dynamic Extensions XMI import feature or the UI form builder(Add Annotation). User should be able to use existing commands to:

- Import XMI file for the model defining the new event
- Import permissible value files for the enumerated fields

Requirement ID	Requirement
caTissue-v20-150	System administrator should be able to create new specimen events containing any number of event parameters via current dynamic extensions XMI import feature or form builder.
caTissue-v20-155	It should be possible to specify defaults to attributes within the event being defined.
caTissue-v20-160	System administrator should be able to edit existing specimen events: <ol style="list-style-type: none"> <li>Add new event attributes</li> <li>Edit existing attributes' permissible values</li> <li>Edit default values</li> </ol> These changes will be applicable only to future SPPs. If user wants to modify/delete existing attributes, they have to add new event.

### Defining SPPs

A user should be able to create an SPP including series of events and/or other SPPs. This should be possible by uploading an XML which will define all the event and SPP names that is included as part of the SPP being defined. User should also be able to specify defaults for the event parameters specific to the SPP. In caTissue Suite 1.2, there exists static specimen events which can be added under any specimen. These should be available in caTissue Suite 2.0 for inclusion in any SPP.

The screenshot shows the caTissue Suite application interface. At the top, there is a navigation bar with links for Home, Administrative Data, Biospecimen Data, Search, and Bulk Operations. Below the navigation bar, there is a "Quick Links" sidebar with links to caBIG Home, NCI-CBIIT Home, Privacy Notice, Disclaimer, and Accessibility.

The main content area displays a hierarchical menu under "Administrative Data". The path shown is: Home > Administrative Data > Biospecimen Data. A yellow circle highlights the "Biospecimens" link in the menu. A red oval highlights the "Specimen Processing Procedures" link, which has a tooltip "Add SPP" and "Edit SPP" displayed below it. Other menu items include User, Institution, Department, Cancer Research Group, Site, Storage Type, Storage Container, Specimen Array Type, Biohazard, Collection Protocol, Distribution Protocol, Local Extensions, Clinical Integration, Reported Problems, and Conflicting SPRs.

Figure 4: Menu for SPP management

Specimen Processing Procedures

Add Edit

Add Specimen Processing Procedure

\* SPP Name: PreOophorectomyEvents

SPP Barcode:

\* Upload XML file: C:\Poornima\caTissue\2.0\demo\PreC

Figure 5: Creating SPP mock screen

Set SOP Defaults

\* Spin Event\*

Speed: 3000 rpm Duration In Minutes: 5

Temperature: 4 °C Equipment: TOMY micro centrifuge

\* Remove Supernatant Event\*

Description: Completely remove supernatant from cell pellet with a micropipette.  
Do not disturb cell pellet.

\* Snap Freeze Event\*

Method: Liquid Nitrogen / Isopentane Duration in Minutes: 15

Temperature: -20 °C

Description: Submerge only the bottom half of the tube in liquid nitrogen.  
DO NOT COMPLETELY IMMERSE THE TUBE.

\* Frozen Event\*

Method: Liquid Nitrogen / Isopentane Temperature: -20 °C

Figure 6: Setting defaults for events during SPP creation.

Requirement ID	Requirement
caTissue-v20-165	Super administrator should be able to create SPPs containing a series of events and/or other SPPs by uploading the definition via XML.
caTissue-v20-170	This action should be possible through UI as a separate menu under administrative data.
caTissue-v20-175	It should be possible to set default values of event parameters under an SPP when the SPP is defined. If defaults are set at events level, then it should be shown during SPP creation. SPP level defaults overrides event level defaults.
caTissue-v20-180	Anything can be edited for an SPP only if it's not associated to SCG/specimen  Once associated with SCG/specimen SOPApplication <ul style="list-style-type: none"> <li>• Add new events - should be possible</li> <li>• Edit default values - should be possible</li> <li>• Edit/delete of existing events within the SPP should not be allowed</li> </ul> For other edits user has to create new SPP. This is similar to current CP edit restrictions.  During edit, the user should be able to download existing SPP XML.
caTissue-v20-185	It should be possible to include caTissue Suite 1.2 static specimen events(except transfer and dispose) as part of any SPP.
caTissue-v20-188	It should be possible to specify the order of events within the SPP XML.
caTissue-v20-190	Error handling should be in place if user specifies invalid event name or order.

#### Associating an SPP to Collection Protocol Event and Specimen Requirement of a Collection Protocol

At collection protocol event level it should be possible to associate one or more SPPs, which will describe how and under what conditions should the parent specimens be collected during a participant visit. At specimen requirement level, user should be able to define what is the event that created that specimen and what SPP should be followed to process it further. The

creation event for the root specimens will be one of the events in the SPP defined at collection protocol event level. For other specimens, the creation event will be part of the processing SPP of its immediate parent.

Below diagram depicts how the SPPs can be associated within the protocol for a SPP example.

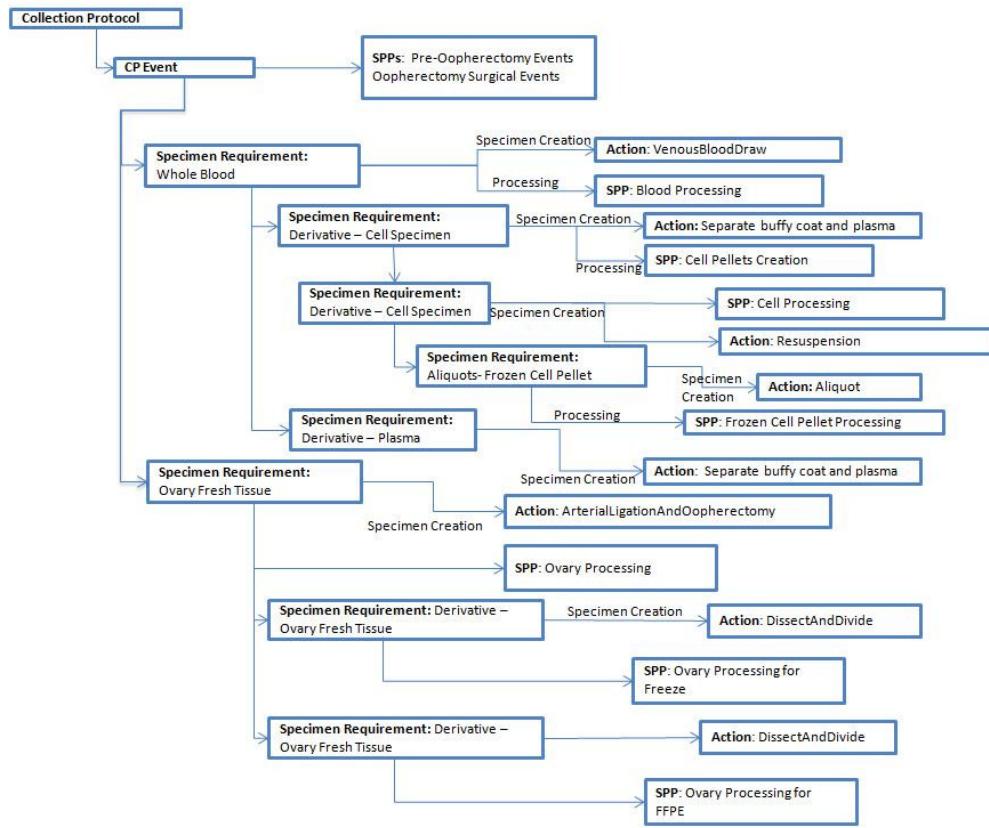


Figure 7: Events and SPPs associated within CP for Blood Processing SPP example

The screenshot shows the 'Collection Protocol' interface with the following details:

- Collection Protocol Details:** Ovary Cancer Protocol
- Event Details:**
  - Study Calendar Event Point: 0.0 Days
  - Collection Point Label: Event
  - Clinical Diagnosis: Not Specified
  - Clinical Status: Not Specified
- Specimen Processing Procedure:** PreOophorectomyEvents  
OophorectomyEvents
- Buttons:** Add, Edit, Submit, Add Specimen Requirements, Add Events >>, Save Collection Protocol

Figure 8: Associating SPPs at collection protocol event level and being able to preview the SPP details. These are the SPPs that will be expected to be performed on specimens collected at this time point in the CP. User can set all SPPs that result in creation of any specimen (or specimen requirement) collected under this CPE/SCG.

The screenshot shows the 'Collection Protocol' interface. In the 'Collection Protocol Details' tree, '0.0 Blood Collection' is expanded, showing 'Specimen\_E1'. Under 'Specimen Requirement', a 'Specimen Creation Event' is set to 'Blood Collection' and a 'Processing SOP' is listed as 'PBL+Plasma SOP'. A note states: 'Event under an SPP used to create the specimen' and 'SOP for additional processing steps that creates derivatives'. Below this, 'Derive Specimen(s)' is shown with a table for 'Specimen Creation Event' and 'Processing SOP'.

Figure 9: Processing SPPs and creation events association at specimen requirement level in CP

The screenshot shows the 'Collection Protocol' interface. In the 'Collection Protocol Details' tree, '0.0 Blood Collection' is expanded, showing 'Specimen\_E1'. Under 'Specimen Requirement', 'Aliquot(s)' is selected. The 'Aliquot(s)' section contains fields for 'Aliquot Count' (10), 'Quantity per Aliquot' (10000), 'Storage location' (Auto), 'Specimen Creation Event' (Aliquot Event), and 'Processing SOP' (Frozen Cell Pellet Processing). A note states: 'Aliquot count and quantity per aliquot are required'.

Figure 10: Associating creation event and processing event at aliquots level

Requirement ID	Requirement
caTissue-v20-195	It should be possible to associate multiple SPPs at collection protocol event level.
caTissue-v20-200	It should be possible to associate a SPP at specimen requirement level to specify how the specimen is further processed. This can be any SPP created in the system.
caTissue-v20-202	It should not be possible to set collection and received event defaults directly under specimen requirement. It has to be via SPP.
caTissue-v20-205	It should be possible to associate a creation event at specimen requirement level. The list of events should be populated from the SPP defined at collection protocol event level for root specimens and for other specimens, the list should be from the processing SPP defined at immediate parent level.
caTissue-v20-210	If association of a specimen creation event or an SPP within CP is edited after it has been utilized, it results in event or SPP being applied to future specimens collected under the associated specimen requirement. Specimens already collected continue to have the parameters and values of events and SPPs as defined prior to the edit.

### Utilize SPPs

As biospecimens are procured, biorepository personnel should be able to specify that biospecimens collected under that protocol were procured as per all of the events and their parameters defined under the SPP with the option to edit values for one or more parameters for a single specimen or set of specimens (e.g. The length of incubation time in a fixative may be 30 minutes but was 60 minutes for four of the specimens in a batch). In the process of performing an SPP on a specimen, a new (derivative) specimen may be created. Some events or SPPs may occur on a 'specimen' before it is instantiated in the system. A specimen may also experience events that are completely unanticipated.

At the level of the specimen collection group, an SPP may define how one or more primary parent specimens are collected and/or any events which are applicable to the participant.

The screenshot shows a table with columns: CP Title, PPI, Participant Name, SCG Name, and Collection Time Point. The data includes:

SOP	Blood Isolation	CP Title	PPI	Participant Name	SCG Name	Collection Time Point
<input checked="" type="checkbox"/>	CP1	123	Smith, John	CP1_SCG1	Initial Diagnosis	
<input checked="" type="checkbox"/>	CP1	124	Smith, Harry	CP1_SCG2	Initial Diagnosis	
<input checked="" type="checkbox"/>	CP1	125	Doe, John	CP1_SCG3	Initial Diagnosis	

Buttons at the bottom include "Check All On This Page", "Check All", "Enter SOP Data", and page navigation links "1 - 100 of 217" and "1 2".

Figure 11: In this view, user selects a specific SPP and then can apply / enter all specimen event data for instantiated specimens associated with that SPP, across any CP, at the level of the SCG

The screenshot shows a table with columns: CP Title, PPI, Participant Name, SCG Name, Collection Time Point, Specimen Label, and Specimen Type. The data includes:

SOP	Frozen Cell Pellet Processing	CP Title	PPI	Participant Name	SCG Name	Collection Time Point	Specimen Label	Specimen Type
<input checked="" type="checkbox"/>	CP1	123	Smith, John	CP1_SCG1	Initial Diagnosis	101231_1	Frozen Cell Pellet	
<input checked="" type="checkbox"/>	CP1	123	Smith, John	CP1_SCG1	Initial Diagnosis	101231_2	Frozen Cell Pellet	
<input checked="" type="checkbox"/>	CP1	123	Smith, John	CP1_SCG1	Initial Diagnosis	101231_3	Frozen Cell Pellet	
<input checked="" type="checkbox"/>	CP2	123	Smith, John	CP1_SCG1	Initial Diagnosis	101232_1	Frozen Cell Pellet	

Buttons at the bottom include "Check All On This Page", "Check All", "Enter SOP Data", and page navigation links "1 - 100 of 217" and "1 2".

Figure 12: In this view, user selects a specific SPP and then can apply / enter all specimen event data for instantiated specimens associated with that SPP, across any CP, at the level of the individual specimen

The screenshot shows a form for entering event data. The top section is titled "SOP Label: Frozen Cell Pellet Processing". Below it is a "Reason for Deviation" text area.

The main area contains four expandable sections for different events:

- Event performed:**
  - "Spun Event": User admin\_1, admin\_1, Date 02-16-2011, Time 5 Min., Speed 3000 rpm, Duration In Minutes 5, Temperature 4 °C, Equipment TOMY micro centrifuge.
  - "Remove Supernant Event": User admin\_1, admin\_1, Date 02-16-2011, Time 5 Min., Description Completely remove supernatant from cell pellet with a micropipette. Do not disturb cell pellet.
  - "Snap Freeze Event": User admin\_1, admin\_1, Date 02-16-2011, Time 15 Min., Method Liquid Nitrogen / Isopentane, Duration in Minutes 15, Temperature -20 °C, Description Submerge only the bottom half of the tube in liquid nitrogen. DO NOT COMPLETELY IMMERSE THE TUBE.
  - "Frozen Event": User admin\_1, admin\_1, Date 02-16-2011, Time 5 Min., Method Liquid Nitrogen / Isopentane, Temperature -20 °C.

At the bottom are "Save" and "Back to Dashboard" buttons.

Figure 13: Event data entry screen

The screenshot shows a software interface for managing specimen events. At the top, there's a header with tabs for 'Specimen' (selected), 'SOP', 'Event', and 'Spun Event'. Below this is a section titled 'Event performed' containing a form for a 'Spun Event'. The form includes fields for User (admin\_1, admin\_2), Date (02-16-2011), Speed (3000 rpm), Temperature (4 °C), Time (5 min.), Equipment (TOMY micro centrifuge), and Reason for Deviation. A 'Save' button is at the bottom.

Figure 14: Adhoc events data entry for specimens

This screenshot shows a more complex interface for managing multiple events across a group of specimens. The top part displays a list of specimens (45678900, 45679041, 45679041\_2, 45679041\_3, 45679041\_5, 45679041\_6, 45679041\_7). Below this, there are sections for 'Event performed' (Spun Event), 'Remove Supernatant Event', 'Snap Freeze Event', and 'Frozen Event'. Each section contains a form with fields like User, Date, Speed, Temperature, Method, Duration, and Description. A red annotation on the right side states: 'Use can add a series of defined events (SOP) or individual events to a group of specimens'. Another red annotation below it states: 'Attributes of the single event or (in this case) series of events (SOP) are applied to all specimens in the list'.

Figure 15: Adhoc events data entry for specimens

This screenshot compares two pages: 'Edit Specimen Collection Group' and 'New Specimen'. The left panel (SCG) shows a 'Events' section with 'Collected' and 'Received' tabs, both of which are highlighted with a red border. The right panel (Specimen) also has a 'Events' section with similar tabs. Red annotations on both panels state: 'Remove collected or received event section on the SCG main page' and 'Remove collected or received event section on the Specimen main page'.

Figure 16: Remove collected and received event at SCG and Specimen pages

Blood Isolation SOP

**Collection Event**

- Collector: admin\_1, admin\_1
- Date: 01-21-2011 [MM-DD-YYYY]
- Time: 4 Hr. 17 Min.
- Procedure: Indwelling Catheter
- Container: ACD Vacutainer
- Comments:

Add SOP (SOP3)

Figure 17: SPP events data tab at individual SCG level. By default this page will show one or more SPPs set at collection protocol event level.

**SOP**

**\*Spec Event\***

User: admin\_1, admin\_1 Date: 01-20-2011 Time: 2005 IPM Duration In Minutes: 3

**Remove Supernatant Event\***

User: admin\_1, admin\_1 Date: 01-20-2011 Time: 2005 IPM Duration In Minutes: 3

Description: Computer remove supernatant from osmolar with a micropipette. Do not disturb cell pellet.

Reason for Deviation:

**Snap Freeze Event\***

User: admin\_1, admin\_1 Date: 01-20-2011 Time: 2005 IPM Duration In Minutes: 15

Method: Liquid Nitrogen / Isopentane

Temperature: <20 °C

Description: Submerge only the bottom half of the tube in liquid nitrogen. DO NOT COMPLETELY IMMERSIVE THE TUBE.

Reason for Deviation:

**\*Frozen Event\***

User: admin\_1, admin\_1 Date: 01-20-2011 Time: 2005 IPM Temperature: <20 °C

Method: Liquid Nitrogen / Isopentane

Reason for Deviation:

Save

Figure 18: SPP event data tab at individual specimen level, this will show the SPP events set at CP specimen requirement level.

Identifier	Event Parameter	User	Date / Time
3791	Creation Event	admin_1 admin_1	01-20-2011 00:19
3792	Received Event	admin_1 admin_1	01-20-2011 00:19
3793	Spun Event	admin_1 admin_1	01-20-2011 00:19

Select Specimen Event To Add

-- Select --

- Select --
- Cell Specimen Review
- Check In Check Out
- Collection
- Disposal
- Embedded
- Fixed
- Fluid Specimen Review
- Frozen
- Incubation
- Molecular Specimen Review
- Procedure
- Received
- Resuspension
- Spun
- Thaw
- Tissue Specimen Review
- Transfer

Figure 19: Event data tab at specimen level, user can add adhoc events from list of all events present in the system. This list will contain current 1.2 events plus any additional events that will be added dynamically by the administrator (like Isolation and Resuspension in this example)

Requirement ID	Requirement
caTissue-v20-220	User should be able to record SPP data for multiple SCGs at once as per what is defined in CP's corresponding collection protocol event.
caTissue-v20-225	User should be able to easily record SPP data for group of specimens processed together as per what is defined at specimen requirement level.
caTissue-v20-230	User should also be able to add any adhoc events data to multiple specimens at once.
caTissue-v20-235	User should be able to view/add/edit SPP and event data at individual specimen level.
caTissue-v20-240	User should be able to view/add/edit SPP data at individual specimen collection group level.
caTissue-v20-243	All events that led to the creation of the specimen and all of its processing events must be shown in the events tab. This includes the first event from the SCG to its creation (creation is marked by the 'specimen creation event' field which is set during cp definition). Order of events shown should be based on event timestamp and will list below events: <ol style="list-style-type: none"> <li>1. Events in the parent hierarchy</li> <li>2. Its creation event</li> <li>3. Its processing SPP events</li> <li>4. Adhoc events</li> </ol>
caTissue-v20-245	A user should be able to indicate if there were any deviations from the SPP by changing values for one or more parameters of events under the associated SPP event and should be able to add a description for the deviation.
caTissue-v20-250	A user should be able to indicate if an entire event was skipped
caTissue-v20-255	Specifying whether specimens were collected based on their associated SPP or not should be possible through bulk operations.
caTissue-v20-260	User should be able to capture information about who performed the event and the timestamp when it was performed.
caTissue-v20-265	None of the events created on a parent specimen should be copied to child specimens when derived or aliquoted.
caTissue-v20-270	Collected and received events should no more be created by default when specimens are collected and these needs to be removed from SCG,single specimen and multiple specimen pages.
caTissue-v20-275	A user should be able to query any specimen's or SCG's associated specimen events that comprise its associated SPP via the UI, API or the caGrid.
caTissue-v20-276	Collection data and time should be part of the SCG page. The default date shown on add and pending SCG page should be registration date + study calendar event point. This date should appear on the SCG tree of CP based view too. The SCGs in the tree should be sorted based on this date in ascending order. The SCG with blank date should appear at the end.
caTissue-v20-278	The collection date of SCG should be propagated to created on date of all parent specimens.

**Migration Requirements**

Requirement ID	Requirement
caTissue-v20-280	During upgrade of 1.2 to 2.0 version of caTissue, all the events added under existing specimens in 1.2 should be migrated to the new events model. Transfer and dispose events should remain as part of static model.
caTissue-v20-285	Migrate all data under old static event classes(excluding transfer and dispose) to their new DE-based event classes.
caTissue-v20-290	To migrate CPs, create a distinct SPP for each Collected-Received parameter set and associate with CP(s) using those default parameters. This should be set as processing SPP at requirement level. This will then be used for future data entry of Specimens under that CP. Name of the default SPP should be Procedure-Container-Quality.
caTissue-v20-300	Clean up event propagation-Compare each parent-child specimen event and disable each child event where all params are identical between events.

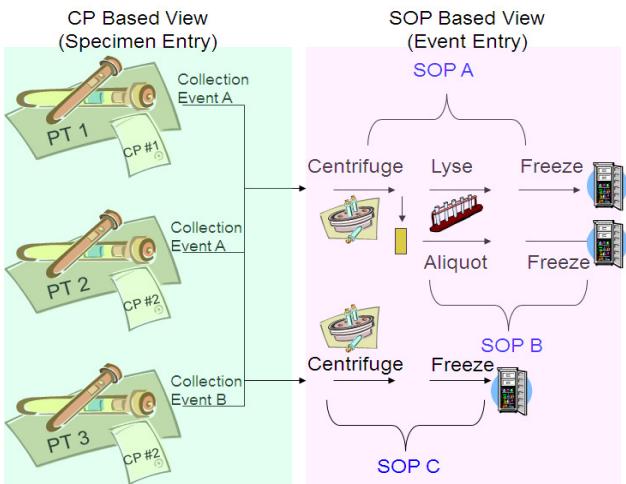


Figure 20: Representation of the lab Implementation workflow

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## MAGE-TAB Integration

The sharing of microarray data within the research community is facilitated by the use of a common data format. MAGE-TAB is a simple tab-delimited spreadsheet based format that is part of the MAGE microarray data standard. It can be used for annotating and communicating microarray data. The purpose of this document is to address the requirements for integrating MAGE-TAB exchange capabilities with the caTissue software product.

### Scope

MAGE-TAB is a tab-delimited format that is meant to serve as an alternative format to the more complicated MAGE-ML format that is based on XML. MAGE-TAB consists of a categorization of different formats:

1. Investigation Design Format (IDF)
2. Array Design Format (ADF)
3. Sample and Data Relationship Format (SDRF)
4. Data Files

The scope of this project is to allow users to export MAGE-TAB formatted files using information derived from biospecimen data stored in caTissue. The MAGE-TAB files may include information such as biospecimen global identifiers, material type, pathology/clinical status, and associated annotations such as tumor grade and stage.

caTissue users can use the Query Results page to select specimens that they would like to include in an exported MAGE-TAB formatted file.

### Out of Scope

The following identified requirements will be out of scope for this project:

- Integration of caTissue and caArray data sets using shared/common data elements.
- Pushing identifiers and annotations of interest from caTissue into an existing or new caArray experiment (as opposed to the proposed "pull only" approach).
- The ability to navigate directly from caArray to caTissue in order to view more detailed information about a sample that has been profiled and whose data has been stored in caArray.
- Import MAGE-TAB formatted files into caTissue.

## Use Cases

### MAGE-TAB Specimen Export:

<b>Brief Description</b>	Select a specimen and export MAGE-TAB that includes specimen identifiers and selected annotations (specifically, Sample and Data Relationship Format (SDRF)) and the Investigative Design Format (IDF). The SDRF file will include caTissue data such as specimen global identifier/label/barcode, material type, pathology/clinical status, and associated annotations.
<b>Primary Actor(s)</b>	Investigator: A PI who owns the experiment under discussion or a scientist who enters data on the PI's behalf.
<b>Secondary Actor(s)</b>	
<b>Preconditions</b>	The investigator has logged into the caTissue system. A Specimen exists within the system and is selected by the user.
<b>Basic Flow of Events</b>	<ol style="list-style-type: none"> <li>1. Investigator obtains a list of specimens via Search screens, My List screen, or via Relocation Event. Alternatively, Investigator may pick a specimen distribution for export.</li> <li>2. Investigator picks specimens to export or marks an entire distribution for export.</li> <li>3. Investigator chooses whether the extracts are RNA or DNA, if extract's type cannot be determined automatically.</li> <li>4. Investigator selects the source and samples for the selected specimens.</li> <li>5. Investigator selects attributes of the annotations of interest that he/she wants to export.</li> <li>6. Investigator exports the specimens (with unique IDs and selected annotations) into MAGE-TAB v1.0 set of files.</li> </ol>
<b>Post Conditions</b>	A MAGE-TAB formatted set of files is exported for the selected user. Details of the mapping of caTissue domain model are located in the mapping section of this document.
<b>Alternate Flow</b>	None.
<b>Special Requirements</b>	None.

### MAGE-TAB Export UI

#### MAGE-TAB Specimen Export UI

MAGE-TAB export is accessible from the "MyList" view. Clicking on the MAGE-TAB Export button triggers the export wizard.

The screenshot shows a web-based application interface for managing biospecimen data. At the top, there is a navigation bar with links for Home, Administrative Data, Biospecimen Data, Search, Bulk Operations, Help, Keyword Search, Report Problems, Contact Us, Summary, and Logout. Below the navigation bar, there are two tabs: 'Define Results Views' (circled in yellow) and 'View Results' (also circled in yellow).

The 'View Results' tab is active, displaying a search results table. The table has the following columns: Specimen : Comment, Specimen : Activity Status, Specimen : Label, Specimen : Created On, Specimen : Barcode, Specimen : Is Available, and Specimen : Collection Status. There are four rows of data in the table, each corresponding to a specimen labeled WU\_11234\_2010\_1 through WU\_11234\_2010\_1\_3. The 'Specimen : Is Available' column shows values false, false, false, and true respectively. The 'Specimen : Collection Status' column shows values Collected, Collected, Collected, and Collected.

At the bottom of the table, there are several buttons: 'Check All On This Page', 'Check All', 'MAGE-TAB', 'Add To My List', 'Export', 'Define View', and 'Redefine Query'.

Or alternatively in the My List View:

**My List View**

Check All

	Specimen : Comment	Specimen : Activity Status	Specimen : Label	Specimen : Created On	Specimen : Barcode	Specimen : Is Available	Specimen : Collection Status
<input checked="" type="checkbox"/>		Active	5		5	true	Collected
<input checked="" type="checkbox"/>		Active	15		15	true	Collected

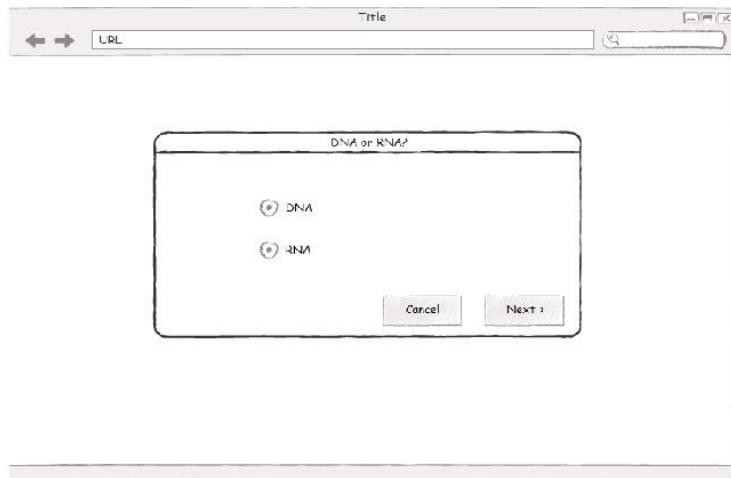
[Delete](#) [Export](#) [MAGE TAB Export](#)

Select the operation to be performed on the selected specimens and click 'Submit'

Order Biospecimens       Multiple Specimen Page       Specimen Event      Transfer 
  
 Request Shipment       Create New Shipment       Distribute       Print Labels

[Submit](#)

When the user clicks on the "MAGE-TAB Export" button, the UI will ask the user if all the specimens are DNA- or RNA-export:



This dialog will not appear if all the specimens are already listed in one of the sets.

On selection, a spreadsheet will be shown for each of the selected specimens. Dropdowns will be provided for the user to select the source and samples. The dropdowns will be dynamic, if a source is selected; only the valid samples (i.e. specimens that are children of the source) will appear in the dropdown menu.

Title

URL

Select Sources and Samples

Source	Sample	Extract
Data 1	Data 2	Data 3
Data 1	Data 2	Data 3
Source Data 1	▼ Sample Data 1 ▼	Data 3
Data 1	Data 2	Data 3
Data 1	Data 2	Data 3
Data 1	Data 2	Data 3

On selecting the 'Next' button, the following view will be shown:

The screenshot shows the 'MAGE-TAB Export Wizard (1 of 1)' window. It contains three main sections:

- Source Annotation Attributes:** Contains three items: 'Attribute 1', 'Attribute 2', and 'Annotation 3 / Attribute 1'. A vertical scroll bar is visible on the right.
- Sample Annotation Attributes:** Contains three items: 'Attribute 3', 'Attribute 4', and 'Annotation 1 / Attribute 2'. A vertical scroll bar is visible on the right.
- Extract Annotation Attributes:** Contains one item: 'Annotation 7 / Attribute 12'. A vertical scroll bar is visible on the right.

A 'Finish' button is located at the bottom right of the wizard window.

Annotations from the static model will be shown. These are specifically:

**Participant:**

- Race
  - Ethnicity
  - Gender
  - Date of birth (Age is a calculated value that will go into MAGE-TAB export file)
  - Patient protocol ID

**Specimen Collection Group:**

- Clinical diagnosis
  - Clinical status
  - Study calendar event point
  - Collection protocol name

Specimen:

- Specimen type
- Tissue site
- Pathological status
- GSID

This view allows the user to select the annotations to appear in the MAGE-TAB file. Clicking the "Back" button moves the user to the previous wizard screen.

Requirement ID	Requirement
caTissue_v20_MageTab	caTissue should implement the MAGE-TAB Specimen Export use case.

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## CTRP Integration

CTRP is a source for records of Persons, Organizations, Protocol Abstractions, and the Correlations between these entities. caTissue will be enhanced to allow users to search for these entities, pull them into caTissue, and refer to them when performing activities within caTissue. The latest data will be fetched from CTRP NCI Enterprise Services (NES) whenever appropriate for business workflows. At a high level the mappings from CTRP to caTissue are:

CTRP	caTissue
Persons	Users
Organizations	Institutions
Protocol Abstractions	Collection Protocols

The following sections describe the use cases and requirements for CTRP integration in more detail.

### Use Cases

#### Save Remotely Managed Entities

Data from remote entities will be cached in the local caTissue instance with a reference to the remote entity. Whenever that entity is displayed in the caTissue application, the locally cached data will be displayed. The data will be updated on a per-case basis depending on whether display of the latest data is of critical importance to the current workflow.

#### Edit Remotely Managed Entities

Remotely managed entities cannot be edited by regular users of the system. Fields that are managed remotely will be grayed out and the caTissue client API will not allow the editing of these fields by regular users. However, because the functioning of caTissue is mission critical to users, caTissue administrators will be allowed to edit the local cache. The data will be flagged as "dirty" and cannot be overridden by local cache refreshes until the administrator releases his changes by toggling the dirty flag.

#### Synchronize with CTRP

caTissue is an operational system with production data. An option will be provided for Users, Institutions, and Collection Protocols to synchronize with the CTRP NES. A search will be made against CTRP for existing data, and the results will be displayed to the user. The user will have the option of selecting a remote entity to overwrite the locally managed entity. Once overwritten, the local entity will become a remotely managed entity and will follow all of the business logic described above.

## Requirements

ID	Requirement
caTissue-v20-ctrp-1	caTissue MUST support integration with CTRP.
caTissue-v20-ctrp-2	caTissue MUST support reading of data from CTRP.
caTissue-v20-ctrp-3	caTissue MAY support writing of data to CTRP.
caTissue-v20-ctrp-4	caTissue MUST leverage CTRP NES.
caTissue-v20-ctrp-5	caTissue MUST search CTRP for remote entities.
caTissue-v20-ctrp-7	caTissue MUST clearly indicate to users the entities that are remotely managed.
caTissue-v20-ctrp-8	caTissue MUST show the latest data from CTRP NES during critical business workflows.
caTissue-v20-ctrp-9	caTissue MAY show stale, cached data from CTRP NES on non-critical pages.
caTissue-v20-ctrp-10	caTissue MUST NOT allow regular users to edit remotely managed entities.
caTissue-v20-ctrp-11	caTissue SHOULD allow administrators to edit remotely managed entities.
caTissue-v20-ctrp-12	caTissue MUST NOT overwrite locally edited and remotely managed entities unless given express permission by the administrator.
caTissue-v20-ctrp-13	caTissue SHOULD allow administrators to mark a locally edited remote entity for automatic refreshing (per caTissue-v20-ctrp-8)
caTissue-v20-ctrp-14	caTissue SHOULD allow locally managed entities to be marked as remotely managed.
caTissue-v20-ctrp-15	caTissue SHOULD convert locally managed entities marked as remotely managed completely to remotely managed to be updated automatically (per caTissue-v20-ctrp-8).

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## C3PR Integration

caTissue needs to collaborate with [C3PR](#) in a number of different scenarios. caTissue needs to:

1. Become aware of certain events initiated by [C3PR](#)
2. Obtain data related to the aforementioned events
3. Execute own workflow on the data obtained.

[C3PR](#) is a caBIG application which supports Subject registration to clinical studies. After integration, a Subject registered in [C3PR](#) should automatically get registered the corresponding Collection Protocol in caTissue. In the [C3PR](#) integration, subjects are registered to studies through the [C3PR](#) web interface and [C3PR](#) broadcasts, a registration notification that includes key identifiers of the subject. For clinical trials that contain a biospecimen collection component, studies in [C3PR](#) will be linked to collection protocols in caTissue through COPPA services. When subjects are registered in [C3PR](#), the registration notification will be broadcasted to caTissue and this participant will be registered to the associated collection protocol. When a Patient is registered to a study, the message should convey the consent, signature date, and registration date.

## Register Subject

Brief Description	<p>The new patient must be registered to a study. The Clinical Research Associate (CRA) verifies that the subject meets the eligibility criteria, enters the required information into the Suite via the Patient Registry application, and stores in the database. Once the patient has been assigned to an epoch, the CRA initiates Register Subject message, including epoch start date and name to the other Suite applications that record the participant information and epoch. The message to the Study Calendar automatically triggers the generation of the study calendar for that subject. The CRA reviews the schedule of upcoming visits and the associated activities for that subject.</p>										
Primary Actor(s)	<i>Application</i>	<i>Role</i>									
	C3PR	Registrar									
Secondary Actor(s)	Admin										
Preconditions	<p>Before subject's registration can be successfully broadcasted from <a href="#">C3PR</a> to the other other applications in the suite, a number of prerequisites must be met. These include the following:</p> <ol style="list-style-type: none"> <li>1. The study must already be created in each module.</li> <li>2. In PSC, the study template must be created and released. The user registering the subject must be authorized to assign subjects to the study.</li> </ol>										
Basic Flow of Events	<ol style="list-style-type: none"> <li>1. The user registers the subject to the study.</li> <li>2. The user completes data entry and saves the data in the Participant Registry.</li> <li>3. The subject is enrolled in the study.</li> <li>4. Replication of the subject's registration to the other applications is performed.</li> </ol>										
Post Conditions	<p>The status message of the broadcast will be updated. If the message does not change, click the refresh button to check on the status. The following status messages may appear:</p> <table border="1"> <thead> <tr> <th>Status</th><th>Meaning</th></tr> </thead> <tbody> <tr> <td>Message Send</td><td>The registration message has been sent to the other modules. Confirmation not yet received.</td></tr> <tr> <td>Message Send Confirmed</td><td>The registration message has been sent and confirmed. The registration has been processed in each module.</td></tr> <tr> <td>Message Send Failed</td><td>The message failed. The registration was not completed in any of the other modules.</td></tr> </tbody> </table>			Status	Meaning	Message Send	The registration message has been sent to the other modules. Confirmation not yet received.	Message Send Confirmed	The registration message has been sent and confirmed. The registration has been processed in each module.	Message Send Failed	The message failed. The registration was not completed in any of the other modules.
Status	Meaning										
Message Send	The registration message has been sent to the other modules. Confirmation not yet received.										
Message Send Confirmed	The registration message has been sent and confirmed. The registration has been processed in each module.										
Message Send Failed	The message failed. The registration was not completed in any of the other modules.										
None.											
None.											

## Behavior

On receipt of a Subject Registration

- caTissue will queue this message.

An Administrator will retrieve the queued messages and select the messages to create a new [ProtocolRegistration?](#).

- caTissue will lookup [CollectionProtocol?](#) from Internal or NCI CTRP.
- caTissue will lookup up the Participant, if none is found create a new Participant.
- caTissue will create a new [ProtocolRegistration?](#).
- caTissue will assign the Participant to the [ProtocolRegistration?](#).
- caTissue will assign the [ProtocolRegistration?](#) to the [CollectionProtocol?](#).

ID	Requirements
caTissue-v20-c3pr-1	Registrations made in <a href="#">C3PR</a> must be propagated to caTissue.
caTissue-v20-c3pr-2	Registrations made in caTissue must be propagated to <a href="#">C3PR</a> .
caTissue-v20-c3pr-3	caTissue must use the <a href="#">ParticipantRegistration?</a> service interface, not <a href="#">C3PR</a> -specific APIs.
caTissue-v20-c3pr-4	<a href="#">C3PR</a> integration must be able to be turned off.
caTissue-v20-c3pr-5	The <a href="#">ParticipantRegistration?</a> service endpoint must be configurable at installation time.
caTissue-v20-c3pr-6	caTissue must provide a way to resolve participant registration conflicts.

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## PSC Integration (Out of Scope)

**Note: We made a decision not to implement PSC integration with caTissue due to technical issues with PSC services and decided to implement this in a future Release.**

For calendar events that have an associated biospecimen collection, PSC will broadcast notifications to caTissue. These notifications will include a call-back to the calendar service. The call-back will synchronize caTissue CollectionProtocolEvent? and the caTissue CollectionProtocolEvents? that are associated with the CollectionProtocol? are synchronized with the PSC PlannedCalendar?. Also, caTissue CollectionProtocolRegistration? and SpecimenCollectionGroup? are synchronized with the PSC ScheduledActivity?.

A notification message will be sent by PSC about changes in the ScheduledCalendar?. The calendar service will provide a query that returns all ScheduledActivity? objects within a specified time period. With the ScheduledActivity? at the root, it is expected that the PlannedCalendar? and its referenced study are accessible.

### Create Calendar for Subject

Use Case Description: after a subject coordinator assigns a subject to a study, s/he creates a calendar of activities by scheduling segments.

Use Case Name	Create Calendar for Subject
Use Case ID	PSC_UC_012
Primary Actor	Subject Coordinator (SubC?)
Secondary Actor	None
Brief Description	SubC creates a calendar of activities by scheduling segments.
Trigger	Subject assigned to a study.
Preconditions	Must know when the subject will begin in the study and which segment he or she will be on in the first epoch (if applicable).
Flow of Events	<ol style="list-style-type: none"> <li>1. Subject is assigned to study.</li> <li>2. The SubC? selects a segment and enters a start date for that segment.</li> <li>3. If the next segment is known, the SubC? selects the next segment and enters the start date for it and noting whether the change is "immediate" or "per protocol."</li> <li>4. Repeat step 3 for all known segments.</li> <li>5. The calendar is automatically (re)generated with each segment assignment.</li> <li>6. The system shall broadcast a ScheduledActivity? Change for the subject into the ESB.</li> </ol>
Post Conditions	The subject has personalized schedule for his or her involvement in the study.
Branch Point <error handling>	None
Quality Use Case	None
Related Use Cases	PSC_UC_010, PSC_UC_021
Business Rules	None

### Manage Scheduled Activities for a Subject

Use Case Description: subject coordinator accesses a subject's calendar and is able to record information about the scheduled activities. Specifically, the activities can be rescheduled, marked as having occurred, been missed or been canceled. The PC may also make notes about the activities.

Use Case Name	Create Calendar for Subject
Use Case ID	PSC_UC_021
Primary Actor	Subject Coordinator (SubC?)
Secondary Actor	None
Brief Description	Manage the scheduled activities in a subject's calendar.
Trigger	SubC accesses the calendar of a subject.
Preconditions	<ol style="list-style-type: none"> <li>1. Subject assigned to study.</li> <li>2. Calendar generated for subject.</li> </ol>
Flow of Events	<ol style="list-style-type: none"> <li>1. The SubC? accesses a subject's calendar.</li> <li>2. The SubC? selects a scheduled activity.</li> <li>3. The SubC? reschedules the activity or marks it as canceled, missed, or occurred.</li> <li>4. The SubC? makes notes about the activity.</li> <li>5. The system shall broadcast the ScheduledActivity? for the subject into the ESB.</li> </ol>
Post Conditions	The subject's schedule has been updated.
Branch Point < error handling>	None
Quality Use Case	None
Related Use Cases	PSC_UC_010, PSC_UC_012, PSC_UC_022.
Business Rules	None

### Behavior

On reception of a [ScheduledActivity?](#) Change from PSC

- CaTissue will queue this message.

An Administration user will select entries from the Queue to update a [CollectionProtocolRegistration?](#).

- caTissue will locate the [ScheduledActivity?](#) using the calendar Service.
- The [ScheduledActivity?](#) with its associated [PlannedCalendar?](#) is retrieved.
- The [PlannedCalendar?](#) should have a reference to a study so that that a [CollectionProtocolRegistration?](#) can be identified. The PSC 'assignedIdentifier' attribute is used to locate the study.
- A lookup for the [CollectionProtocolRegistration?](#) object is done. If it is absent, a new one is created.
- SpecimenCollectionGroups? are created for the using the [CollectionProtocolRegistration?](#).

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## Tech Stack Upgrade and BDA

Prior versions of caTissue were using very old versions of some of its components(caCORE, acGrid, CSM etc.). In order to utilize additional features of these components and to make caTissue compliant with caBIG Tech Stack Migration, caTissue v2.0 will undergo tech stack upgrade in following areas:

Technology	Current Version	Upgraded Version	Benefits
CSM	3.2	4.2	Fully integrated within caCORE v4.2 providing in-built security to caCORE APIs.
caCORE	3.2	4.2	Removal of code customizations done for caCORE APIs in caTissue
caGrid	1.2	1.4	Provisioning Grid users on caTissue through caGrid provisioning APIS instead of provisioning as local CSM users. This requirement is thoroughly covered under <a href="#">caGrid Integration</a>
MySQL	5.0	5.1	Improved internal features of MySQL?
JBoss	4.2.2	5.1	Improved internal features of JBoss
JDK	1.5	1.6	Improved internal features of Java

### BDA'fication

caTissue v2.0 will undergo BDA'fication, a streamlined process defined by NCI BDA team for building & deploying software projects. [CaTissue](#) v2.0 will have benefits such as unified process to create consistent and repeatable build and deployment through high levels of automation with a single command or button click to produce working software.

caTissue v2.0 will undergo BDA'fication of following projects

No.	Project
1	Bulk Operations
2	Catissue Advanced Query
3	Catissue Dao
4	Catissue IDP Authentication Manager
5	Catissue Participant Manager
6	Catissue Security Manager
7	Catissue Simple query
8	Catissue CAS
9	Catissuecore
10	Dynamic Extensions
11	Keyword Search
12	Metadata Based Query
13	Wustl Common Package
14	Wustl Common Utilities

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## GSID Integration

The Global Specimen Identifier (GSID) provides a service that maintains the relationships between biospecimens across multiple applications to facilitate interoperability. The caTissue application is used for biospecimen inventory management, especially with tracking and annotation. The purpose of this document is to describe the integration of the caTissue application with the GSID service.

### Scope

The scope of this integration is:

- Modify the user interface (UI) to register and fetch GSID upon the creation of a biospecimen.
- Provide a configurable mechanism to specify if a caTissue application instance will make use of GSID integration or not.
- The Biospecimen class in caTissue will be amended to include a new Global Specimen Identifier attribute.
- The solution will support a user's search for GSIDs.
- The solution will provide a tool to upgrade a new caTissue installation by registering every specimen to the GSID service.

### Out of Scope

- Caching of GSIDs.
- A management user interface that will track errors when registering GSIDs.
- The registrations of GSIDs in a thread that is separate from the main UI thread.
- Selective registering of biospecimens to the GSID service.

## Requirements

Requirement ID	Requirement
caTissue-v20-GSID-1	The system will remotely register biospecimens with the GSID service automatically.
caTissue-v20-GSID-2	The UI will display the registered GSID for every biospecimen.
caTissue-v20-GSID-3	The UI will provide a mechanism for searching GSIDs.
caTissue-v20-GSID-4	The system will manage errors when registering GSIDs.
caTissue-v20-GSID-5	A caTissue instance will be configured with its unique GSID site information.

## System Flow

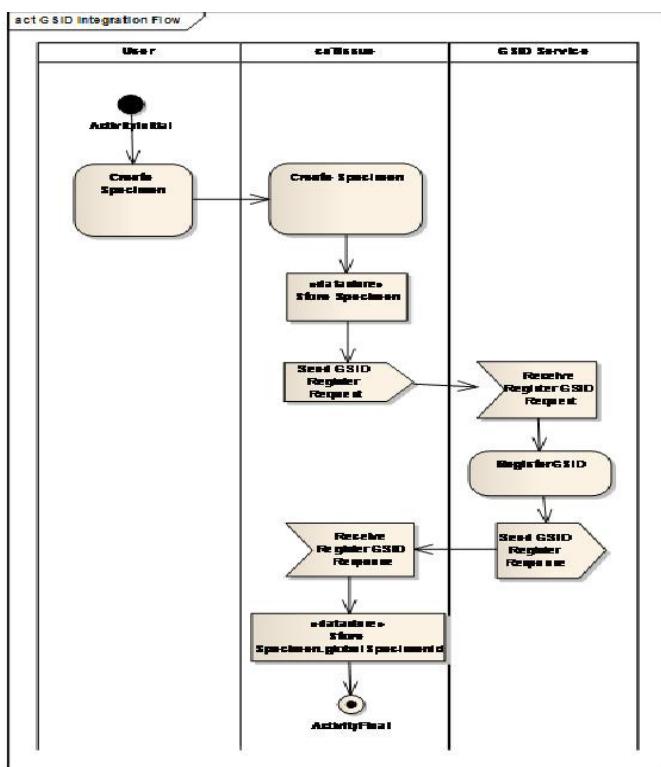


Figure 1. System flow of GSID registration.

In the figure above, a user creates a biospecimen within caTissue. After the user creates the specimen, caTissue will remotely invoke the GSID service to register a new specimen. Once the remote invocation returns, caTissue will store the newly assigned UUID to an attribute (i.e. globalSpecimenId) of the Biospecimen instance.

The implementation will also provide a batch interface independent of the caTissue UI that will allow the bulk registration of GSID registrations.

## Algorithms

The algorithm for registering a biospecimen is as follows:

Input: Specimen

Pre-Conditions: globalSpecimenIdentifier is null.

Post-Condition: Specimen with globalSpecimenIdentifier attribute assigned

Implementation:

Navigate to the parent of the input 'specimen'.

If the parent has a globalSpecimenIdentifier then store this in a variable 'parents'

Else recursively register the parent specimen with the GSID service.

Register the input specimen with the GSID service using the 'parents' variable for its parents.

Exceptional Condition:

If the registration fails, leave the globalSpecimenIdentifier attribute as null.

The algorithm for bulk registering a caTissue application is as follows:

Input: Collections of Specimen instances.

Pre-Condition: All the globalSpecimenIdentifiers of the Collection are null.

Post-Condition: All specimen in the collection will have their globalSpecimenIdentifier attribute assigned

Implementation: Loop through each value in the collection

For each value register and assign the global specimen identifier using the previous algorithm.

Exceptional Condition:

If the registration fails, leave the globalSpecimenIdentifier attribute as null

## Data Model

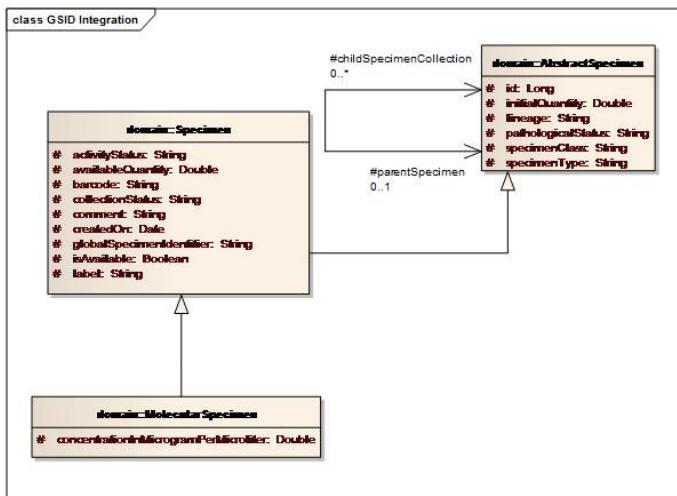


Figure 2: A data model that represents the modified Specimen class

To support this integration, a new attribute on the Specimen class of caTissue will be created.

## CaTissue UI Modifications

The following pages will be modified to include a field that shows the registered GSID.

- Single Specimen Page

- Multiple Specimen Flex Page
- Aliquots Page
- Derivatives Page
- Collection Protocol Summary Page

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## CBM Migration

The CBM UML model is defined by NCI to enable sharing data by any biobanking software applications on caGrid. More information about CBM can be found here: <https://cabig.nci.nih.gov/workspaces/TBPT/CBM/>. caTissue v2.0 should provide mechanism to migrate data from caTissue database to the latest CBM database.

**caTissue\_v20\_CBM\_01** There should be a ETL tool to migrate data from v20 database to CBM database.

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## Integrated API

### Overview

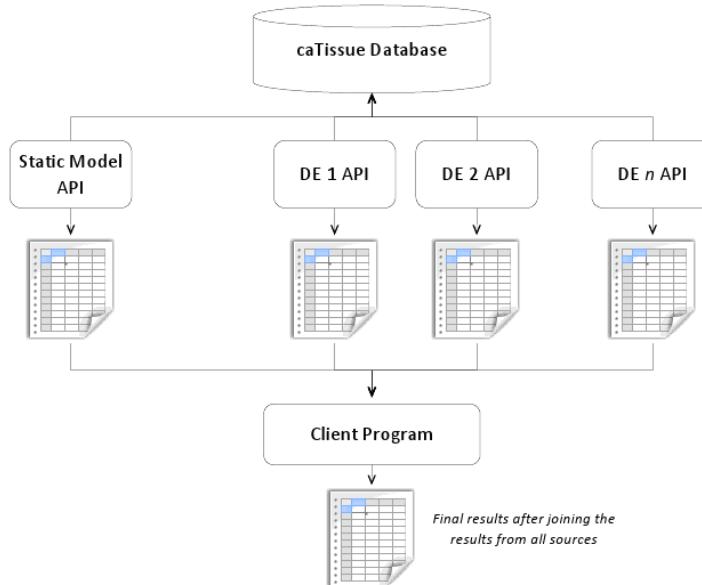
caTissue will provide a unified caCORE API and a unified caGrid API. The unified caCORE API will enable read and write of both static and DE model elements through a single API in a seamless fashion. The unified caGrid API will expose all the functionality of the caCORE API through a caGrid service interface, utilizing the caGrid security infrastructure.

### Background

The previous versions of caTissue has two or more APIs services. One for the static caTissue UML model and one service each for every Dynamic Extension (DE) available in that instance of caTissue. This approach has the following shortcomings:

1. Need to query multiple services to query across static and DE data
2. Data from different services will have to be joined by the client program leading to usability and performance issues
3. Role based and PHI data security restrictions will have to be managed at each service level

The below diagram demonstrates the current setup when using APIs of static and domain models.



To overcome these shortcomings, caTissue v20 should support an integrated API across all the static and DE services. The single API should support write and query of static and DE objects within a single call without using any intermediate tables or additional calls. It should be possible to seamlessly traverse between DE and static UML models.

### Requirements

This API should support the following requirements.

caTissue_v20_API_1	caTissue should support a single integrated read and write API across the static and DE APIs.
caTissue_v20_API_5	The API should filter records based on privileges of the user.
caTissue_v20_API_10	It should be possible to perform integrated queries over the caGrid.
caTissue_v20_API_15	There should not be any non-standard tasks to be performed when inserting or querying data across DE and static model, like fire any SQLs, query for any unregistered objects, or execute any additional DE APIs.
caTissue_v20_API_20	It should be possible to traverse from Participant, SpecimenCollectionGroup?, and Specimen to any DE class associated with them. For example, it should be possible to call Participant.getSmokingHistoryAnnotation().
caTissue_v20_API_25	It should not be needed to insert or read data into any intermediate tables when using the read or write APIs.

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## Bulk Operation Enhancements

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### Rerun after Error

Currently bulk operation generates a log file for every run. The log file contains all the records and two additional columns; one for success/failure and other for error message. In case of error messages, one will have to open the original file, delete the successful records, and fix the erroneous records, and rerun.

It should be possible to fix the errors in the error log file itself and upload the file back. BO should ignore the successful records and retry only the records with status "FAILURE".

ID	Requirement
caTissue2_0_BO_1	It should be possible to fix the FAILURE records in the BO report and upload it back.
caTissue2_0_BO_5	The report generated in the second run should retain all previous success records and update the FAILURE records' new status.

## XML cleanup

The current XML file has many superfluous attributes. A thorough review of the XML structure should be done and the XML structure should be simplified as much as possible. Since there are many BO templates already in use, v20 should be backward compatible i.e., the old XML and new XML should both work.

caTissue2_0_BO_10	The XML schema for template generation should be simplified.
caTissue2_0_BO_15	caTissue v20 should be backward compatible with both versions of XML.
caTissue2_0_BO_20	The XSD file should be published in the installable zip and should be downloadable from bulk operations page

## Multiple Object Support

Currently users can upload data for only one object type at a time using bulk operation. I.e., if someone wants to upload participant, registration, specimen collection group (SCG) and specimen, in the current setup one has to first upload the participant CSV, copy the participant ids to in the SCG CSV and upload it, copy the SCG ids to the Specimen CSV and upload the specimens.

Instead it should be possible to upload more than one object in a single BO operation for the biospecimen data.

caTissue2_0_BO_25	It should be possible to upload BO templates with the following combination:
	Participant, CPR
	Participant, CPR, SCG
	Participant, CPR, SCG, Specimen
	Participant, CPR, SCG, Specimen, SPP Events
	SCG, Specimen, SPP Events
	SCG, Specimen, SPP Events
	Specimen, SPP Events

caTissue2\_0\_BO\_30 All the objects in a single row should be inserted in a single transaction. E.g., if Participant and CPR objects are uploaded together and if the Participant object creation fails, then the CPR object also should not be created.

## BO Support for DE entities and Category

It should be possible to import DE entities and categories using Bulk Operation. The following requirements should be met.

ID	Description
caTissue_BO_35	BO should support uploading data for DE objects.

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## Participant Age at Collection

It should be possible to query for participant age at collection at the specimen collection group level. To achieve this, the following requirements should be met.

ID	Description
caTissue_v20_AgeColl_01	A new attribute should be added to store the age at collection in specimen collection group object.
caTissue_v20_AgeColl_03	SCG page should display collection data and timestamp for data entry. This attribute is already in the model.
caTissue_v20_AgeColl_05	In the SCG page, the age at collection should be automatically calculated if the participant's date of birth and SCG collection date is present in the database.
caTissue_v20_AgeColl_10	Entering age at collection should be optional.
caTissue_v20_AgeColl_15	Age at collection should be calculated during inserting SCG via API or BO.
caTissue_v20_AgeColl_20	During upgrade, age at collection should be updated based on participant date of birth and SCG collection date.
caTissue_v20_AgeColl_25	Age at collection should be available for query via UI and via caCORE and caGrid read and write APIs.

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