



caTISSUE - Core

Use Case Document

v2.0

Washington University

DOCUMENT REVISION HISTORY

Version Number	Date	Contributor	Description
1.0	12/20/2004	Janet Stone	Initial presentation
1.1	12/28/2004	Janet Stone	Incorporated comments from Rakesh Nagarajan and Srikanth Adiga
1.2	01/07/2005	Janet Stone	Changed format, removed data elements, Array and Pathology data.
1.3	01/24/2005	Janet Stone	Integrated comments from Mark Watson. Changed format to reflect alternate flows when adding like information from different pages. Deleted all reject/approve, edits, and data for existing/new scenarios per our meeting held on 1/20/2005.
1.4	2/23/2005	Janet Stone	Final data review before draft presentation. Entered data dictionary, updated schematics and checked grammar and punctuation.
1.5	2/28/2005	Janet Stone	Integrated comments received from Rakesh Nagarajan, and added Process Model.
1.6	3/2/2005	Rakesh Nagarajan	Minor changes
1.7	3/3/2005	Rakesh Nagarajan	Comments incorporated from internal reviewers
1.8	3/10/2005	Janet Stone	Incorporated comments received from development. Added "shopping cart" functionality use cases.
1.9	3/18/2005	Rakesh Nagarajan	Final edits – Delivered to Adopters
2.0	3/24/2005	Janet Stone	Entered Use Case IDs. Changed "Activate User" use case to "Add/Edit User" – with information describing the process taken when existing users want to edit their personal profile.



Background/Summary

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 the functionality to track multiple specimens from the same participant, track refined materials (RNA, DNA, Protein) that are used for molecular analysis, and annotate biospecimens with accumulating experimental data, as they are successively used for clinical correlative studies.

Existing tissue banking systems have some of the features, however no single system currently provides all the features described. Some do tracking, some do financial, some have automated pathology and clinical annotation, some may have experimental data associated with specimens, but no one system has it all.

Therefore, caTISSUE Core will be developed to be the central repository for all the data indicated above. This application will be capable of detailed biospecimen tracking and will integrate data from all three Tissue Banks & Pathology Tools applications (caTIES, caTISSUE Core, and caTISSUE Clinical Annotation).



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1 Introduction

1.1 Overview

Principle features of the caTISSUE Core system will include –

- Open source architecture and adherence to controlled vocabularies, common data elements, and “caBIG compatibility” guidelines with regard to architecture. caTISSUE Core will be “Silver Level” compliant and eventually, “Gold Level” compliant, once grid architecture is integrated into the design.
- Utilization of current specimen banking systems as a model for caTISSUE Core design. This will ensure that the design process does not “reinvent the wheel” and that caTISSUE Core will handle all basic functionalities associated with the operation of diverse biospecimen resources.
- Modular design. It is recognized that all desired functionality can not be built immediately into caTISSUE (hence the designation for this project, caTISSUE Core). However, caTISSUE Core will be designed so that additional functionality (e.g. Clinical Annotation Module, Biological Annotation Module, Billing and Financial Module, Specimen Request Module) can be added to the Core system without redesigning any of the core architecture.
- Rapid deployment to institutions with little or no specimen banking informatics. The first iteration of caTISSUE will be developed quickly and deployed to sites who are currently without an established system, utilizing spreadsheets, or highly customized databases (Access, FoxPro, File Maker) for tracking biospecimens. Rapid adoption of caTISSUE Core will allow these institutions to expand their system with additional caBIG compliant modules over time.
- Objects and data elements can be mapped from a legacy biospecimen informatics system. It is clearly recognized that not all sites can or will adopt caTISSUE Core as their sole solution for specimen banking informatics. Although not within the scope of this proposal, adopters will have the ability to map data from their own systems to objects and data elements in caTISSUE Core, so that they can maintain their existing systems while participating in caBIG.

1.2 Related Documents

Document Name	Version	Location
caTISSUE Core Initial Vision and Scope	1.5	http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/catissuecore/Vision%20and%20Scope/Initial_Vision_and_%20Scope_v1.5.doc
Data elements for caTISSUE Use cases	1.0	



2 Actors and Goals

Actors are defined based on their roles assigned. Each role has different access rights to the various data classes, with each actor assigned a role based on the following criteria:

- Involvement in the process flow
- Interaction with the system

Valid roles in the caTISSUE Core system include:

Administrator:

- Is a "super-user" who manages the caTISSUE system
- Has privileges to submit, edit, disable, and query all types of data in the system
- Approves and manages user submission process

Clinician:

- User role assigned to an individual responsible for supervising the protocol that results in biospecimen collection
- Has privileges to submit/edit Participant, Accession, Study, Site, and Protocol data
- Has privileges to query all available data (identified and de-identified)

Scientist:

- User role assigned to an individual who does not have any specific studies submitted in caTISSUE, but has general research interest
- Has privileges to query de-identified data
- Can not view identified data
- Can have ownership of a Study, but not a protocol

Technician:

- User role assigned to an individual responsible for the curation and storage of one or more biospecimens in a tissue bank
- Has privileges to submit any biospecimen
- Handles distribution of biospecimens to different studies

Collector:

- User role assigned to an individual responsible for the physical collection of biospecimens.
- Is not expected to use the caTISSUE system and does not have access privileges.

Public:

- Has read-only access to aggregate data



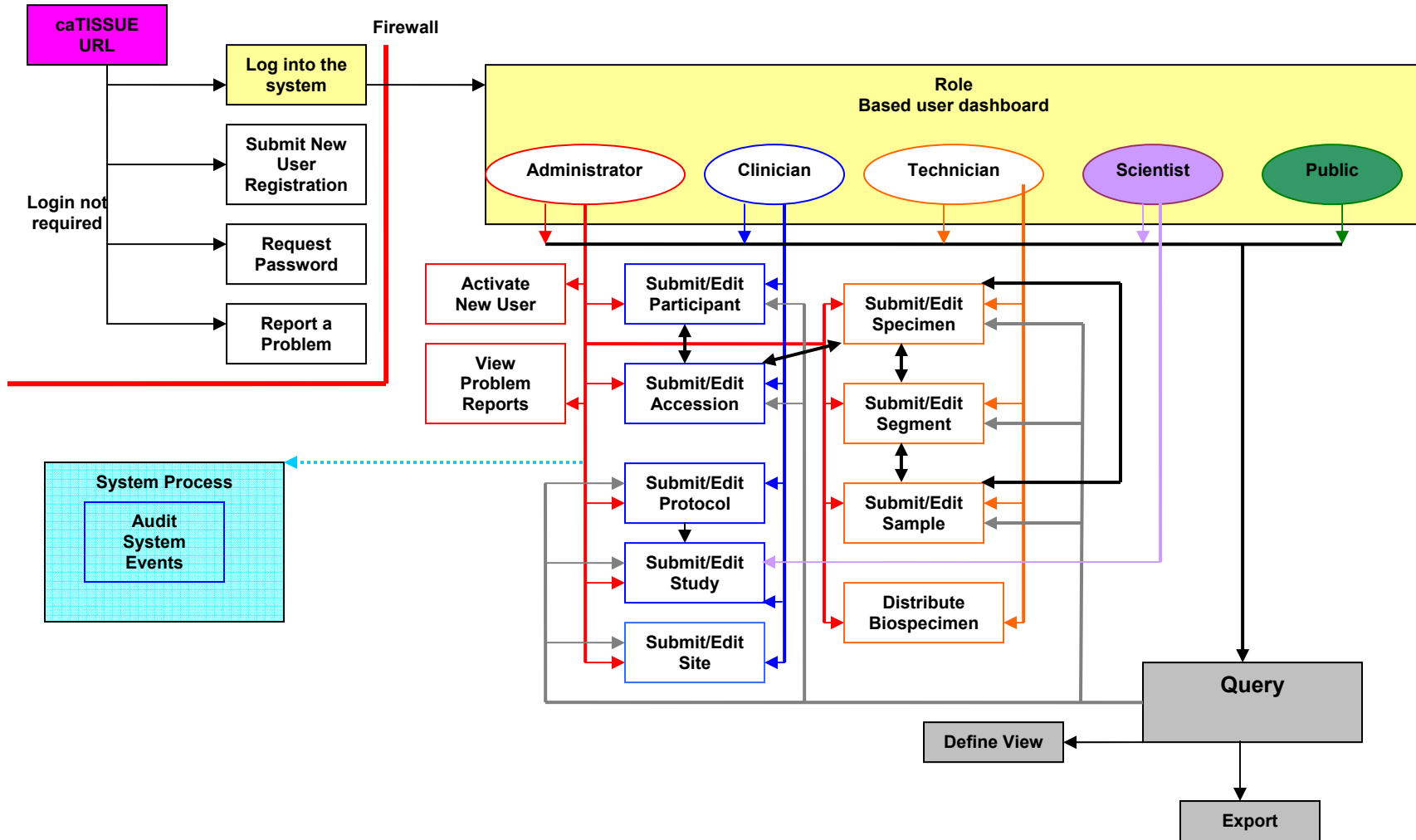
Each role has access privileges for the different data classes as defined in the table below.

Data Class Access	Description
Identified	A piece of data that directly or indirectly identifies the participant. This includes all HIPAA defined identifiers.
Anonymous Data	Identifiers have been stripped from the data displayed with no link to participant information in the database.
De-Identified Data	Identifiers have been stripped from the data displayed, with data still being linked to patient information in the database.
Aggregate	A piece of calculated data that pertains only to a group of participants

Data Privilege- Defines the *action* that the actor may perform on the data

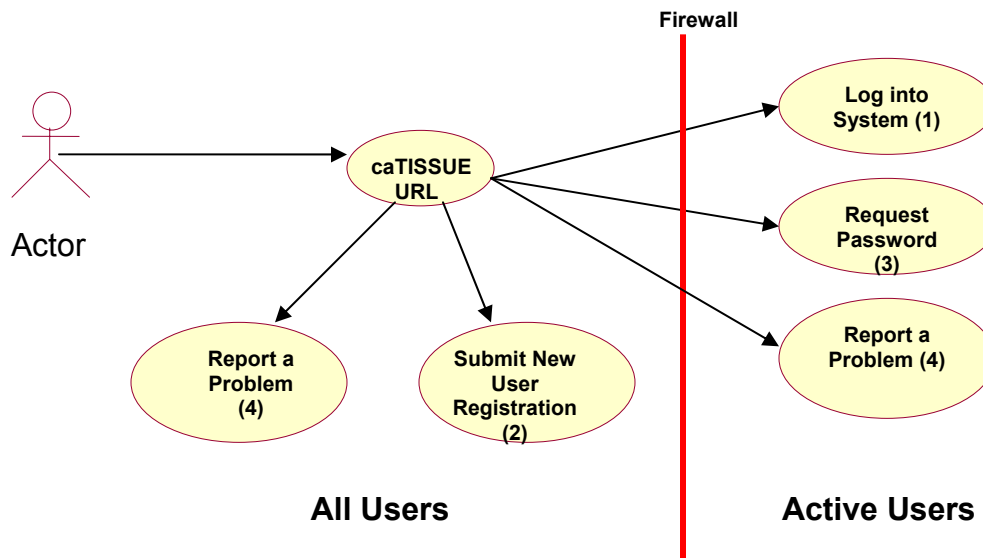
- Add: Submit new data into the system
- Edit: Update existing data
- Read: View only
- Disable: Record with associated data can no longer be viewed in the system.

3 caTISSUE Core Process Model





4 General Functions

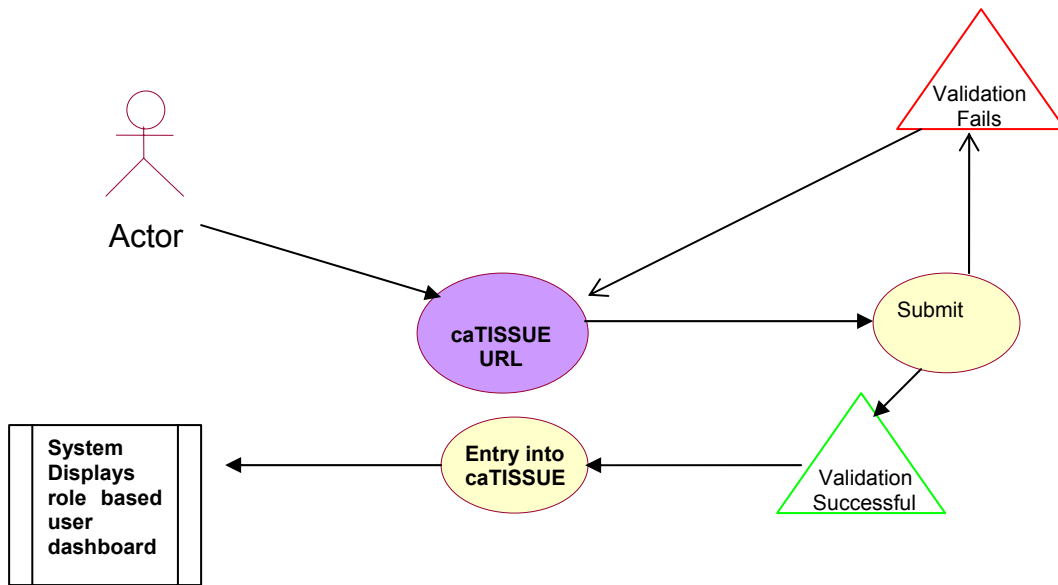


The first page displayed upon successful navigation to the caTISSUE URL, presents the actor with four options:

1. The actor can log into caTISSUE by entering their log in information.
2. The actor can select to become a user of the system by submitting a New User Registration Request.
3. The actor can request that their password be retrieved and sent to them via email.
4. The actor can select to report a problem (user can report a problem without signing in or can report a problem anytime once they have entered the system)



4.1 Log into the system



Use Case Name	Log Into the System
Use Case ID	caTISSUE_Core-UC-01
Primary Actor	All Users
Brief Description	Existing actors must log into the system entering an approved user ID (Identifier) and password. Once the system validates the ID and password entered, the user is granted access to the system and a user dashboard is displayed according to the actor's assigned role.
Trigger	Actor navigates to the caTISSUE URL
Pre-conditions	Successful navigation to the caTISSUE URL Actor has been approved and has access privileges to enter the system
Flow of Events	<ol style="list-style-type: none"> 1. The system presents entry fields for login data. 2. The actor <ol style="list-style-type: none"> a. Enters log-in information b. Selects the "Login" button 3. The system <ol style="list-style-type: none"> a. Validates login information b. If no errors are encountered, the system allows the user access to the caTISSUE Core system and displays user dashboard of menu options based on the users assigned role. [Branch Point - Invalid User, Invalid Password, System Error]
Post Conditions	Success Condition: User is granted entry. System displays appropriate user dashboard. Error Condition: Invalid User Error Condition: Invalid Password Error Condition: System Error



<p>Branch Point – Invalid User Invalid Password System Error</p>	<p>If a validation error occurs, the system throws an exception, displays an error message and re-displays page for data entry.</p> <ul style="list-style-type: none"> a. Invalid user (use case Submit New User Registration) b. Invalid password <ul style="list-style-type: none"> - Retype password (Return to step 2a) - (use case Request Password) c. System Error. User enters valid password, but is still unable to login (see use case Report a Problem)
<p>Related Use Cases</p>	<p>Submit New User Registration Request Password Report a Problem</p>

An actor with the role of “Administrator” will be presented with a user dashboard consisting of options to:

- View User Registrations
- View Problem Reports
- Add Protocol
- Add Site
- Add Study
- Add Participant
- Add Accession
- Add Specimen
- Add Segment
- Add Sample
- Query (Identified and de-identified data)
- View Stored Queries
- View Shopping Cart
- Edit Profile

An actor with the role of “Clinician” will be presented with a user dashboard consisting of options to:

- Add Participant
- Add Protocol
- Add Study
- Add Site
- Query (Identified and De-identified data)
- View Stored Queries
- Report a Problem
- View Shopping Cart
- Edit Profile

An actor with the role of “Scientist” will be presented with a user dashboard consisting of options to:

- Query (de-identified data only)
- Add Study
- Report a Problem
- View Shopping Cart
- Edit Profile

An actor with the role of “Technician” will be presented with a user dashboard consisting of options to:

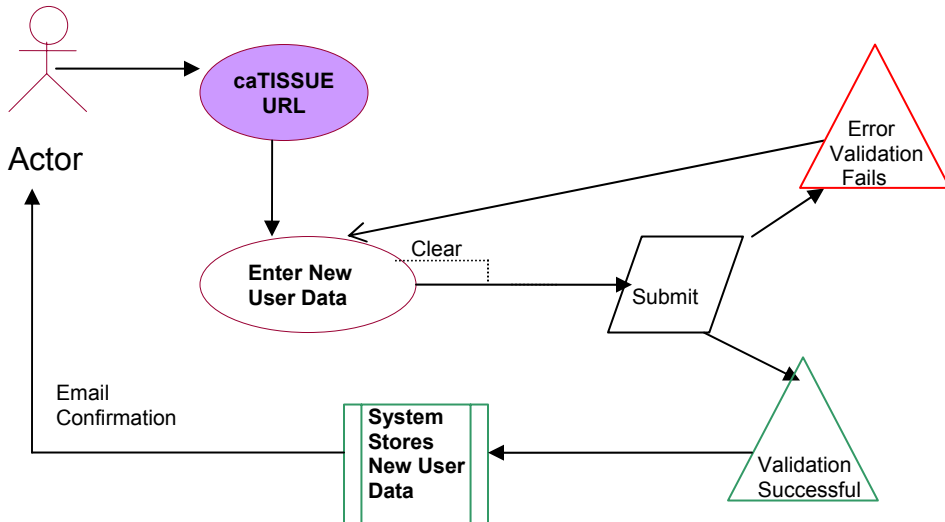
- Add Accession
- Add Specimen
- Add Sample
- Add Segment
- View Accessions to be received
- Distribute Biospecimen
- Report a Problem
- Edit Profile



An actor with the role of “Public” user will be presented with a user dashboard with the option to:

- Query (aggregate data only)
- Report a Problem
- Edit Profile

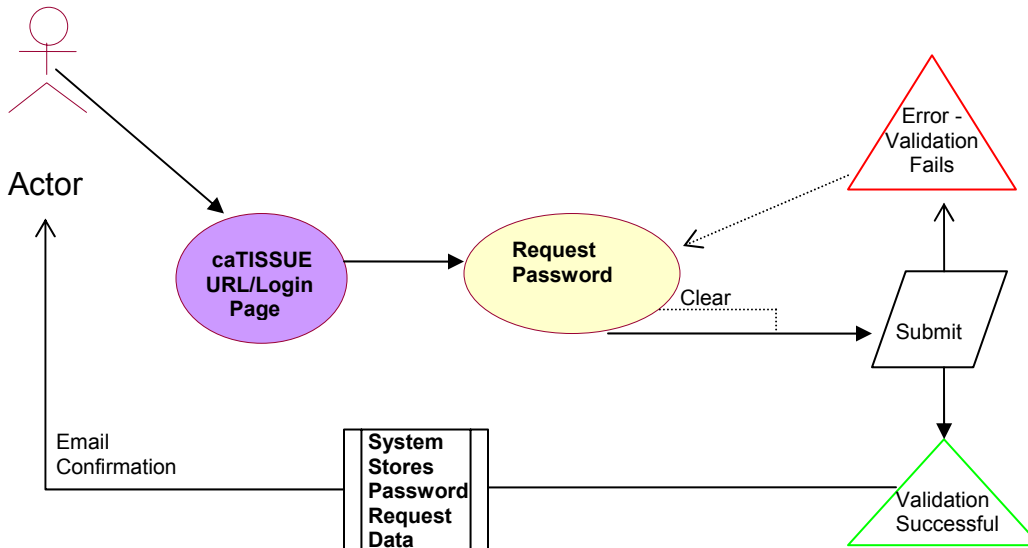
4.2 Submit New User Request



Use Case Name	Submit New User Registration
Use Case ID	caTISSUE_Core-UC-05
Primary Actor	Administrator Potential User
Brief Description	All users wishing to use the system must complete and submit a registration request.
Trigger	The Actor selects the Register A New User option on the log-in page.
Pre-conditions	Successful navigation to the caTISSUE URL Actor does not exist in the system
Flow of Events	<ol style="list-style-type: none"> The system provides entry fields for New User Information. The actor <ol style="list-style-type: none"> Enters New User information into the fields provided. Selects the “Submit” option. [Branch Point – Clear] The system <ol style="list-style-type: none"> Validates required data elements. If no exceptions are encountered, the system stores registration data. [Branch Point – Invalid Data, Incomplete Date, User exists]
Post Conditions	Success Condition: New User Registration is successfully stored in the system. Error Condition: Invalid Data Error Condition: Incomplete Data Error Condition: User exists (use case Log into the system)
Branch Point – Clear	The actor selects the “Clear” option. The system deletes all data entered onto the page. [Return to step 2a]
Branch Point – Invalid Data Incomplete Data User Exists	The System displays appropriate error, and redisplay page. The Actor has the option to <ol style="list-style-type: none"> add additional data or change entered data (return to step 2a) terminate the process
Related Use Cases	Log into the system



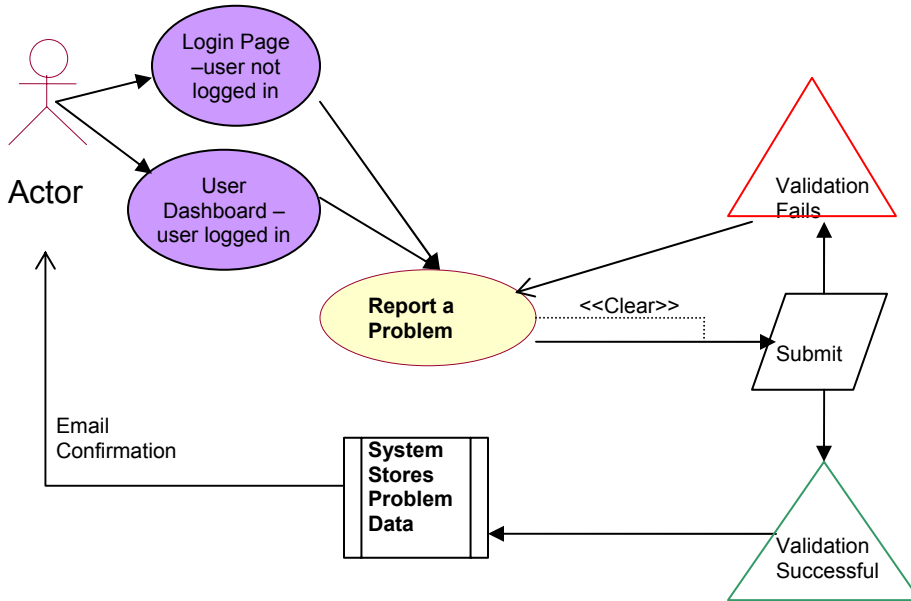
4.3 Request Password



Use Case Name	Request Password
Use Case ID	caTISSUE_Core-UC-10
Primary Actor	Active user
Brief Description	This option assists authorized users of the system who may have forgotten their password and can not proceed with the login process.
Trigger	The Actor selects the Forgot Password? Option on the login page.
Pre-conditions	Successful navigation to the caTISSUE URL. Actor must be an approved user
Flow of Events	1. The system displays page with entry fields for password request information. 2. The actor a. Enters requested password information into the fields provided. b. Selects the "Submit" option. [Branch Point – Clear] 3. The System validates information entered. If no exceptions are encountered, the system sends the password to the users email account. [Branch Point – Invalid User, Invalid Password, System Error]
Post Conditions	Success condition: Password is sent to the Email account of the actor placing the request and the system returns to the login page. Error Condition: Invalid User Error Condition: Invalid Password Error Condition: System Error
Branch Point – Clear	The actor selects the "Clear" option. The system deletes all data entered onto the page. (return to step 2a)
Branch Point – Invalid User Invalid Password System Error	The System displays appropriate error, and redisplay page. The Actor has the option to a. change data entered (return to step 2a) b. submit New User Registration (see use case Submit New User) b. Report a Problem (see use case Report a Problem) c. Terminate the process
Related Use Cases	Submit New User Report a Problem



4.4 Report a Problem

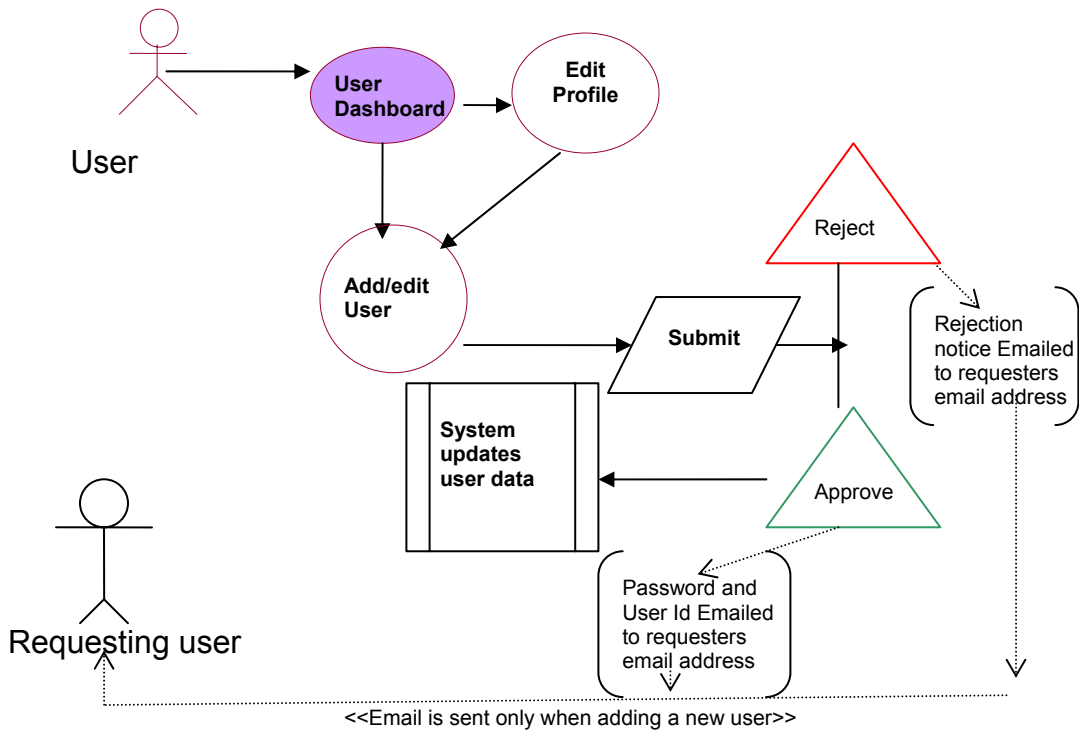


Use Case Name	Report a Problem
Use Case ID	caTISSUE_Core-UC-15
Primary Actor	All Users
Brief Description	This option allows a user to report a problem to an administrator directly. Once the submission is successful, a confirmation email is sent to the email address entered.
Trigger	The Actor selects the “Report a Problem” option on the Login page. (option before logging into the system) Or The Actor selects the “Contact Us” option on their user dashboard. (option after logging into the system)
Pre-conditions	Navigation to the caTISSUE Login page
Flow of Events	1. The system displays page with entry fields for writing a problem report. 2. The actor a. Enters information into the fields provided. b. Selects the “Submit” option. [Branch Point – Clear] 3. The system validates information entered. a. If no exceptions are encountered, the system stores problem information. [Branch Point – validation fails]
Post Conditions	Success Condition: Problem report is successfully Submitted. Error Condition: Submission failed
Branch Point – Clear	The actor selects the “Clear” option. The system deletes all data entered onto the page. (return to step 2a)
Branch Point – Validation fails	If a validation error occurs due to required data not provided, the system a. throws an exception and displays an error message b. displays page for re-entry of password information. (Return to step 2a)
Related Use Cases	If a problem is encountered in any of the use case flows, an actor can select the “Contact Us” option on their user dashboard and report a problem.



5 Submit/Edit Administrative Data

5.1 Add/Edit User



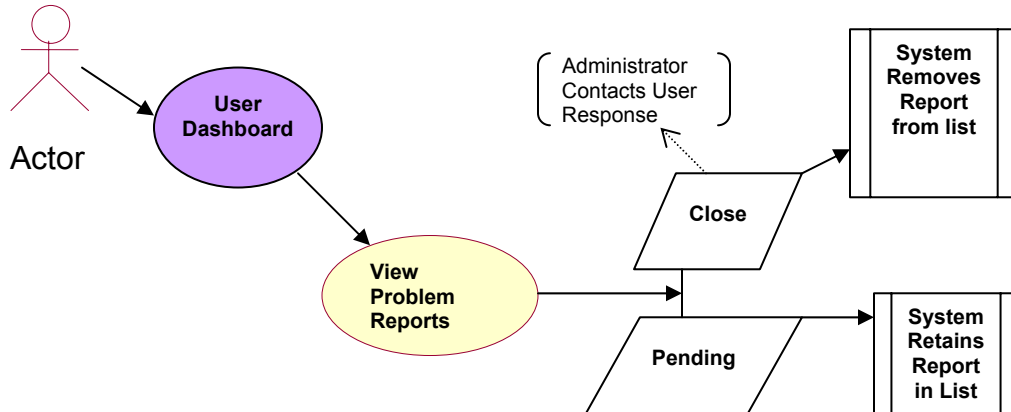
Use Case Name	Add/Edit User
Use Case ID	caTISSUE_Core-UC-20
Primary Actors	Administrator – Add User Clinician – Edit User Profile Technician – Edit User Profile Scientist – Edit User Profile Public – Edit User Profile
Brief Description	Before a new user can gain access to the caTISSUE Core system, they must fill out and submit an online registration. An administrator can then view all new submitted registration requests with the option to approve, reject or take no action on each request. A registration request must have the status of “approve” in order to be added into the system. Once a user has access to the system, they can edit their personal information by selecting the “Edit Profile” option on their user.
Trigger	Administrator selects the option to view all new registration requests from their user dashboard. Or Active user selects the Edit Profile option on their user dashboard.
Pre-conditions	Actor must have privileges to approve/reject new users. There should be at least 1 new user registration.
Flow of Events	For Existing Users: [Branch Point – Edit Profile] For New Users: 1. The system displays all new user registration requests



	<p>2a. The Administrator selects to change the status to “Approve” The system activates new user information in the system, and sends Login ID and password via email to the address listed on the registration.</p> <p>2b. The Administrator selects to change the status to “Reject” The system marks the request as rejected and sends rejection email to the address listed in the registration.</p> <p>2c. The Administrator selects to take no action. The system retains registration request with no change in status</p>
Post Conditions	<p><u>For New Users:</u> New User Registration status is changed and an email message is sent to the email address listed on the registration.</p> <p><u>For Existing Users:</u> The existing user profile is updated and saved in the system.</p>
Branch Point – Edit Profile	<p>The Actor selects the “Edit Profile” option on their user dashboard.</p> <p>The System retrieves the logged in user’s profile.</p> <p>The Actor enters updated data and selects to “Submit”.</p> <p>The System updates the current users profile.</p>
Related Use Cases	<p>Submit New User Request</p>



5.2 View Problem Reports

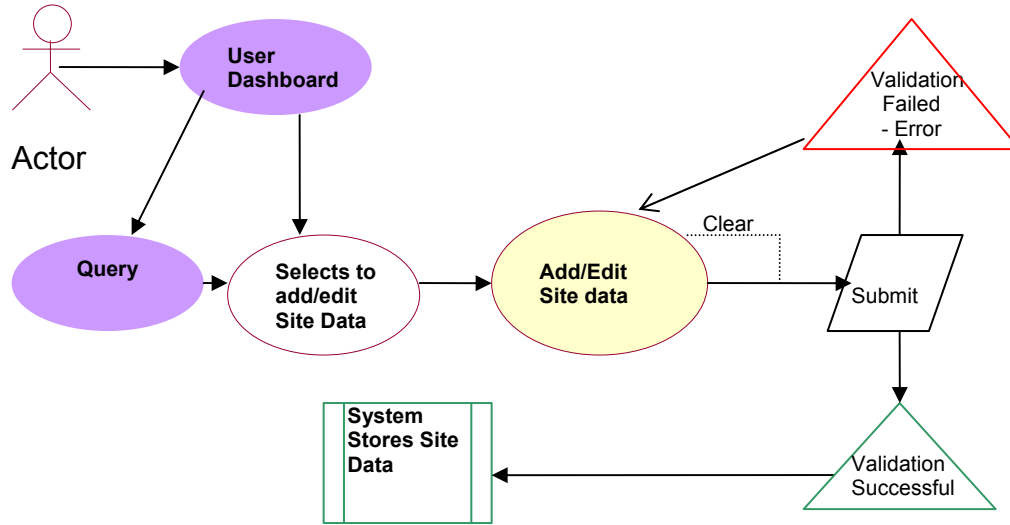


Use Case Name	View Problem Reports
Use Case ID	caTISSUE_Core-UC-25
Primary Actor	Administrator
Brief Description	The administrator selects to view all problem reports. The administrator can respond to the report via phone, fax, email etc.
Trigger	The Actor selects the "View Problem Reports" option from their user dashboard.
Pre-conditions	The actor must be assigned the role of "Administrator".
Flow of Events	<ol style="list-style-type: none"> 1. The system displays a list of all problem reports submitted. 2. The actor selects a report from the list presented. 3. If a problem is resolved, the Administrator can change the Problem Report Status to "Close" [Branch Point – "Pending"] 4. The system marks the Problem Report as closed and removes the problem report from the Problem Report list. 5. The Administrator must then manually contact the reporting user with a response.
Post Conditions	Success Condition: Problem report is successfully Submitted.
Branch Point – Pending	The system marks the Problem Report Status to Pending and retains the problem report in the problem report list.
Related Use Cases	Report a Problem



5.3 Add/Edit Site Data

A Site is defined as a location where a specimen is collected or to where specimens/segments/samples are stored or distributed.



Use Case Name	Add/Edit Site Data
Use Case ID	caTISSUE_Core-UC-30
Primary Actor	Administrator Clinician
Brief Description	This use case process deals with entering Site information into the caTISSUE system.
Trigger	The Actor selects the option from their use dashboard to add Site data. Or The Actor selects a Site from the query result set.
Pre-conditions	Actor has access privileges to enter Site information into the system. For new sites, the site entered can not already exist in the system. For an existing site, a query must be conducted to locate the site for which new information is being entered.
Flow of Events	For submission of New Site Data (proceed to step 4a) For existing Sites: 1. The actor conducts a query (use case Query Data). 2. Selects Site from result set that is to be edited 3. System populates page with existing site data and allows editing of existing data or entry of new data. 4. The Actor a. Enters Site data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear] 5. The System validates Site data for required content. [Branch Point – Invalid Data, Incomplete Data, Site Exists] 6. New Site information is saved into the caTISSUE Core system.
Post Conditions	Success Condition: Site data entered is successfully submitted. Error Condition: Submission failed - Site already exists (When entering new Site) Error Condition: Submission failed - All mandatory fields are not populated. Error Condition: Submission failed - Invalid data entered (strings in place of numbers)
Branch Point – Clear	The Actor selects the “Clear” option. The System deletes all data entered into the form. (Return to step 4a)

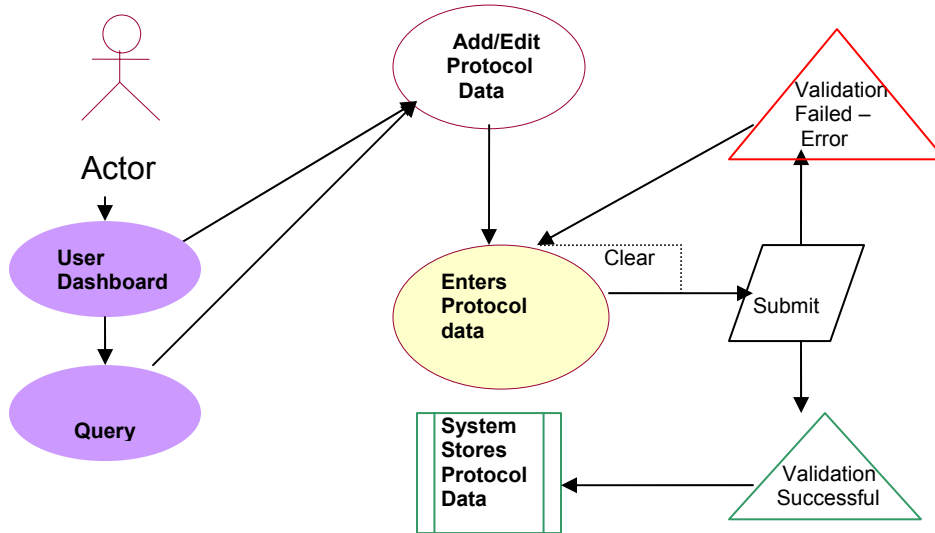


Branch Point – -Invalid Data -Incomplete Data -Site Exists	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)
Related Use Cases	Query Data Report a Problem



5.4 Add /Edit Protocol Data

A protocol is defined as a set of guidelines and procedures that dictate how and what biospecimens are to be collected from a participant.



Use Case Name	Add/Edit Protocol Data
Use Case ID	caTISSUE_Core-UC-35
Primary Actor	Administrator Clinician
Brief Description	This use case process deals with entering protocol data into the caTISSUE system.
Trigger	The Actor selects from their user dashboard to add protocol data into the system. Or The Actor selects a Protocol from query result set.
Pre-conditions	Actor has access privileges to enter Protocol information into the system. For new Protocols, the Protocol entered can not already exist in the system. For existing Protocols, a query must be conducted to locate the Protocol for which new information is being entered.
Flow of Events	<p><u>For submission of New Protocol Data</u> (proceed to step 4a) <u>For existing Protocol:</u></p> <ol style="list-style-type: none"> 1. The actor conducts a query (use case Query Data). 2. Selects Protocol from result set that is to be edited. 3. System populates page with existing Protocol data and allows editing of existing data or entry of new data. 4. The Actor <ol style="list-style-type: none"> a. Enters Protocol data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear] 5. The System <ol style="list-style-type: none"> a. validates Protocol data for required content. b. If no errors are encountered, the system stores new Protocol data. [Branch Point – Invalid Data, Incomplete Data, Protocol Exists] 6. Protocol data is saved into the caTISSUE Core system. 7. The Actor has the option to add study data for the protocol entered (use case Add/Edit Study)

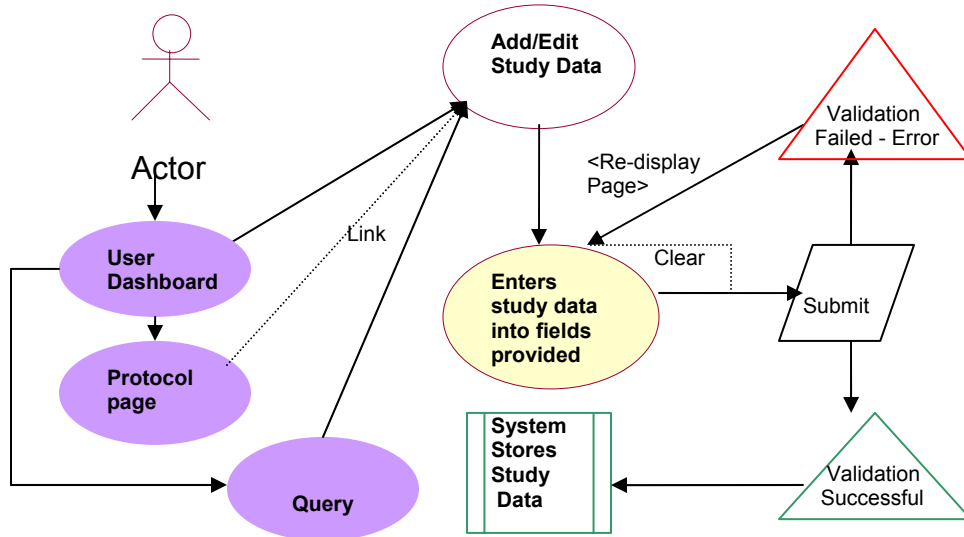


Post Conditions	Success Condition: New Protocol information is stored in the system. Error Condition: Submission failed – Protocol already exists (when entering new protocol data) Error Condition: Submission failed - - Invalid data entered (strings in place of numbers) Error Condition: Submission failed – Incomplete Data
Branch Point – Clear	The Actor selects the Clear option. The System deletes all data entered into the form. (Return to step 4a)
Branch Point – -Invalid Data -Incomplete Data -Protocol Exists	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)
Related Use Cases	Query Data Add/Edit Study Report a Problem



5.5 Add/Edit Study Data

A study is defined as a set of guidelines that dictates what, how much, and how many specimens, segments, or samples will be used for experimental purposes.



Use Case Name	Add/Edit Study Data
Use Case ID	caTISSUE_Core-UC-40
Primary Actor	Administrator Clinician Scientist
Brief Description	This use case process deals with entering Study information into the caTISSUE system.
Trigger	The Actor selects the option from their use dashboard to add Study data. Or The Actor selects the Add Study link on the Protocol page. (use case Add/Edit Protocol) Or The Actor selects Study from query result set.
Pre-conditions	Actor has access privileges to enter Study information into the system. For new Studies, the Study entered can not already exist in the system. For an existing Study, a query must be conducted to locate the Study for which new information is being entered.
Flow of Events	<p><u>For submission of New Study Data (proceed to step 4a)</u></p> <p><u>For existing Study:</u></p> <ol style="list-style-type: none"> 1. The actor conducts a query (use case Query Data). 2. Selects Study from result set that is to be edited. 3. System populates page with existing Study data and allows editing of existing data or entry of new data. 4. The Actor <ol style="list-style-type: none"> a. Enters Study data into the fields provided. b. Selects the "Submit" button [Branch Point – Clear] 5. The System validates Study data for required content. [Branch Point – Invalid Data, Incomplete Data, Study Exists] 6. New Study information is saved into the caTISSUE Core system.



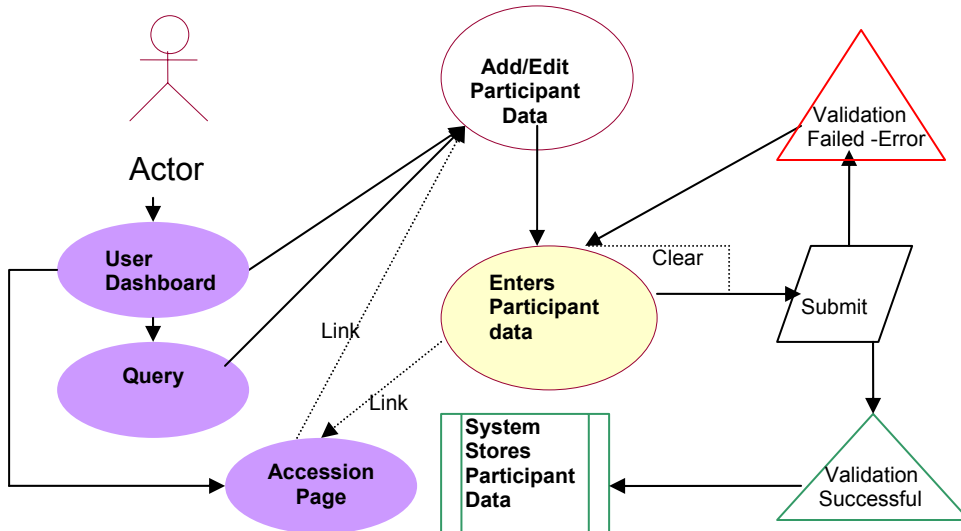
Post Conditions	Success Condition: Study data entered is successfully submitted. Error Condition: Submission failed - Study already exists (when submitting a New Study) Error Condition: Submission failed - All mandatory fields are not populated. Error Condition: Submission failed - Invalid data entered (strings in place of numbers) Error Condition: Submission failed – System Error
Branch Point – Clear	The Actor selects the “Clear” option. The System deletes all data entered. (Return to step 4a)
Branch Point – -Invalid Data -Incomplete Data -Study Exists	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)
Related Use Cases	Add/Edit Protocol Query Data Report a Problem



6 Submit/Edit Biospecimen and Participant Data

6.1 Add /Edit Participant Data

A participant is defined as an individual from whom a biospecimen is collected.



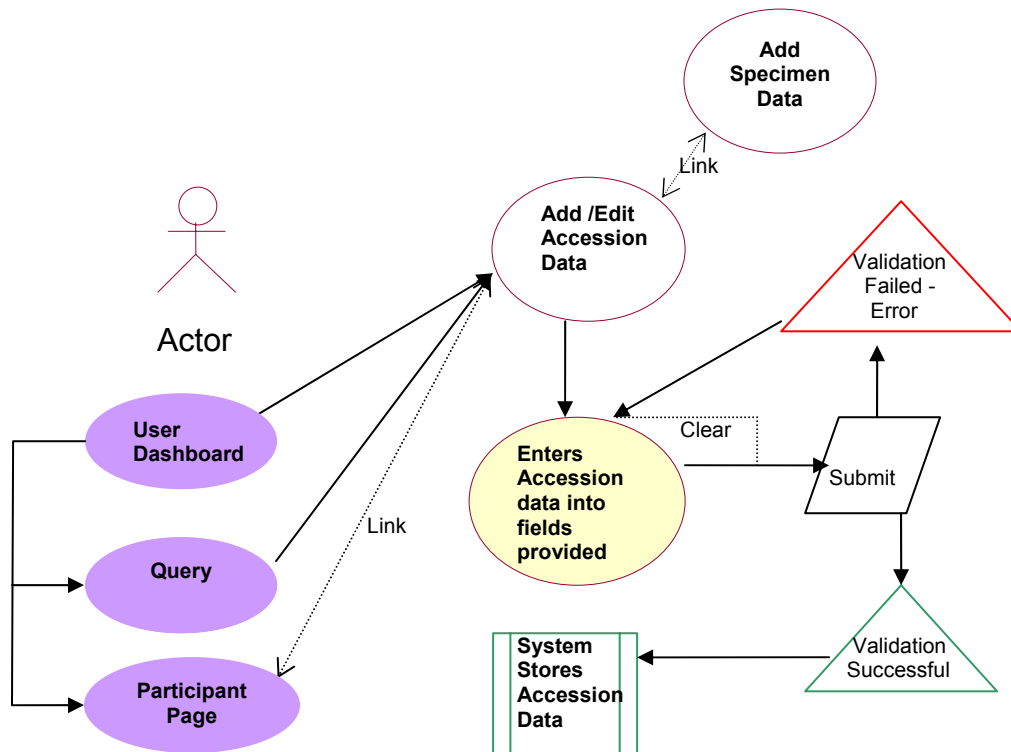
Use Case Name	Add/Edit Participant Data
Use Case ID	caTISSUE_Core-UC-45
Primary Actors	Administrator Technician
Brief Description	This use case process deals with entering new participant data into the caTISSUE system.
Trigger	The Actor selects the add Participant option from their user dashboard Or The Actor selects the add participant Link on the Accession page (use case Add/Edit Accession) Or The Actor selects Protocol from query result set.
Pre-conditions	Actor has access privileges to enter Participant information into the system. For new Participant, the Participant entered can not already exist in the system. For existing Participants, a query must be conducted to locate the Participant for which new information is being entered.
Flow of Events	<u>For submission of New Participant Data</u> (proceed to step 4a) <u>For existing Participant:</u> 1. The actor conducts a query (use case Query Data). 2. Selects Participant from result set that is to be edited. 3. System populates page with existing Participant data and allows editing of existing data or entry of new data. 4. The Actor a. Enters Participant data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear] 5. The System a. validates Participant data for required content. b. If no errors are encountered, the system stores new Participant data. [Branch Point – Invalid Data, Incomplete Data, Participant Exists]



	6. The Actor may select to enter accession data for the participant entered. (use case Add/Edit Accession)
Post Conditions	Success Condition: New Participant information is stored in the system. Error Condition: Submission failed - - Invalid data entered (strings in place of numbers) Error Condition: Submission failed – Participant already exists (when entering New Participant data)
Branch Point – Clear	The Actor selects the Clear option. The System deletes all data entered into the form. (Return to step 4a)
Branch Point – -Invalid Data -Incomplete Data -Participant Exists	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)
Related Use Cases	Query Data Add/Edit Accession Report a Problem

6.2 Add/Edit Accession Data

As accession is defined as a single event in time that results in the collection of one or more biospecimens from a Participant.





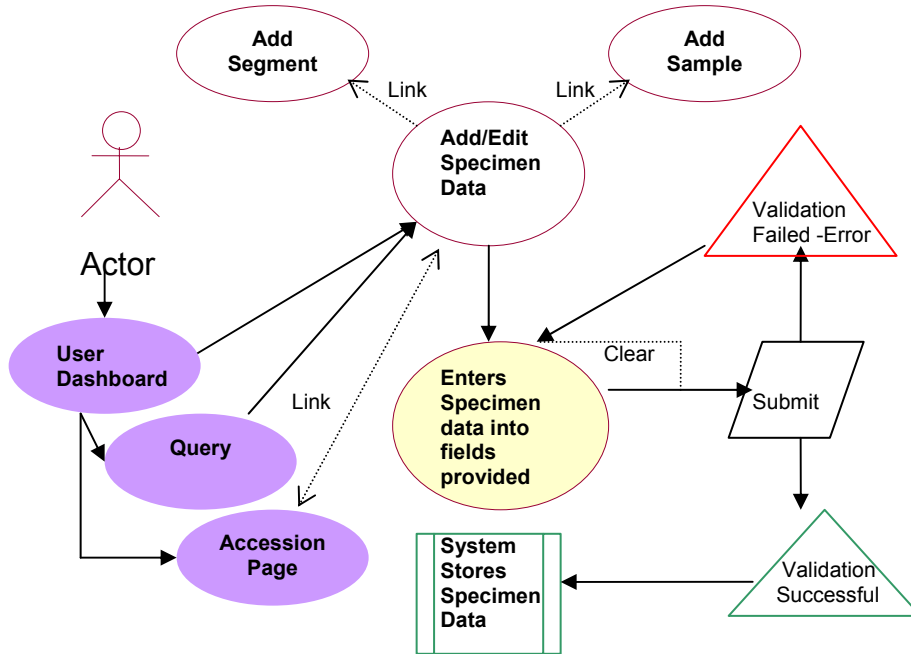
Use Case Name	Add/Edit Accession Data
Use Case ID	caTISSUE_Core-UC-50
Primary Actors	Administrator Technician
Brief Description	This use case process deals with entering new data or edit existing accession data into the caTISSUE system.
Trigger	The Actor selects the add Accession option from their user dashboard Or The Actor selects the add Accession Link on the Participant page (use case Add/Edit Participant) Or The Actor selects the add Accession Link on the Specimen page (use case Add/Edit Specimen) The Actor selects Accession from query result set.
Pre-conditions	Actor has access privileges to enter Accession information into the system. For new Accessions: The Accession entered can not already exist in the system. For existing Accessions: A query must be conducted to locate the Accession for which new information is being entered. For new Accessions the corresponding PARTICIPANT must be registered to the PROTOCOL (see use case Add/Edit Participant)
Flow of Events	For submission of New Accession Data (proceed to step 4a) For existing Accession: 1. The actor conducts a query (use case Query Data). 2. Selects Accession from result set that is to be edited. 3. System populates page with existing Accession data and allows editing of existing data or entry of new data. 4. The Actor a. Enters Accession data into the fields provided. b. Selects the "Submit" button [Branch Point – Clear] 5. The System a. validates Accession data for required content. [Branch Point – Invalid Data, Incomplete Data, Accession Exists] b. If no errors are encountered, the system stores new Accession data.
	6. The Actor may a. select to enter Specimen data for the Accession entered. (use case Add/Edit Specimen) b. select to enter Participant data for the Accession entered. (use case Add/Edit Participant)
Post Conditions	Success Condition: New Accession information is stored in the system. Error Condition: Submission failed – Accession already exists (when entering new Accession data) Error Condition: Submission failed - Invalid data (strings in place of numbers) or Error Condition: Submission failed -Incomplete data
Branch Point – Clear	The Actor selects the Clear option. The System deletes all data entered into the form. (Return to step 4a)
Branch Point – -Accession Exists -Invalid Data -Incomplete Data	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)



Related Use Cases	Add/Edit Participant Add/Edit Specimen Query Data Report a Problem
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6.3 Add/Edit Specimen Data

A single unit of tissue or body fluid collected from a participant as part of an accession event.



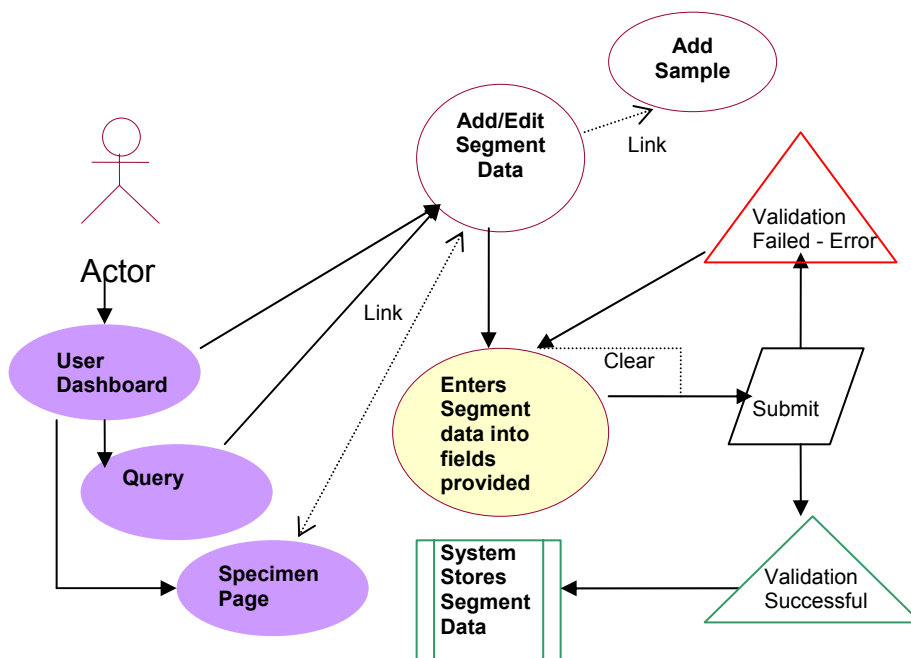
Use Case Name	Add/Edit Specimen Data
Use Case ID	caTISSUE_Core-UC-55
Primary Actors	Administrator Technician
Brief Description	This use case process deals with entering Specimen data into the caTISSUE system.
Trigger	The Actor selects from their user dashboard the option to add Specimen data into the system. Or The Actor selects the add Specimen link on the Accession page (use case Add/Edit Accession) Or The Actor selects Specimen from query result set.
Pre-conditions	Actor has access privileges to enter Specimen information into the system. <u>For new Specimens:</u> The Specimen entered can not already exist in the system, however a corresponding ACCESSION event must already exist. <u>For existing Specimens:</u> A query must be conducted to locate the Specimen for which new information is being entered.
Flow of Events	<u>For submission of New Specimen Data (proceed to step 4a)</u> <u>For existing Specimen:</u> 1. The actor conducts a query (use case Query Data). 2. Selects Specimen from result set that is to be edited. 3. System populates page with existing Specimen data and allows editing of existing data or entry of new data. 4. The Actor



	<p>a. Enters Specimen data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear]</p> <p>5. The System a. validates Specimen data for required content. [Branch Point – Specimen Exists, Invalid Data, Incomplete Data, no associated Accession] b. If no errors are encountered, the system stores new Specimen data.</p> <p>6. The Actor may choose to a. add a Segment for the Specimen entered (use case Add/Edit Segment) b. add a Sample for the Specimen entered (use case Add/Edit Sample)</p>
Post Conditions	<p>Success Condition: New Specimen information is stored in the system. Error Condition: Submission failed – Specimen already exists (when entering new Specimen data) Error Condition: Submission failed - Invalid data (strings in place of numbers) or incomplete data entered Error Condition: Submission failed – Incomplete data Error Condition: No associated Accession</p>
Branch Point – -Specimen Exists -Invalid Data -Incomplete Data -No associated Accession	<p>The System displays appropriate error, and redisplay page. The Actor has the option to a. add Accession for the specimen being entered (use case Add/Edit Accession) b. add additional data or change entered data (return to step 2a) c. terminate the process with no further action taken d. report a problem (use case Report a Problem)</p>
Related Use Cases	<p>Add/Edit Accession Add/Edit Segment Add/Edit Sample Query Data Report a Problem</p>

6.4 Add/Edit Segment Data

A homogeneous subdivision of a specimen into multiple parts. In the system, segments from the same specimen are indistinguishable.





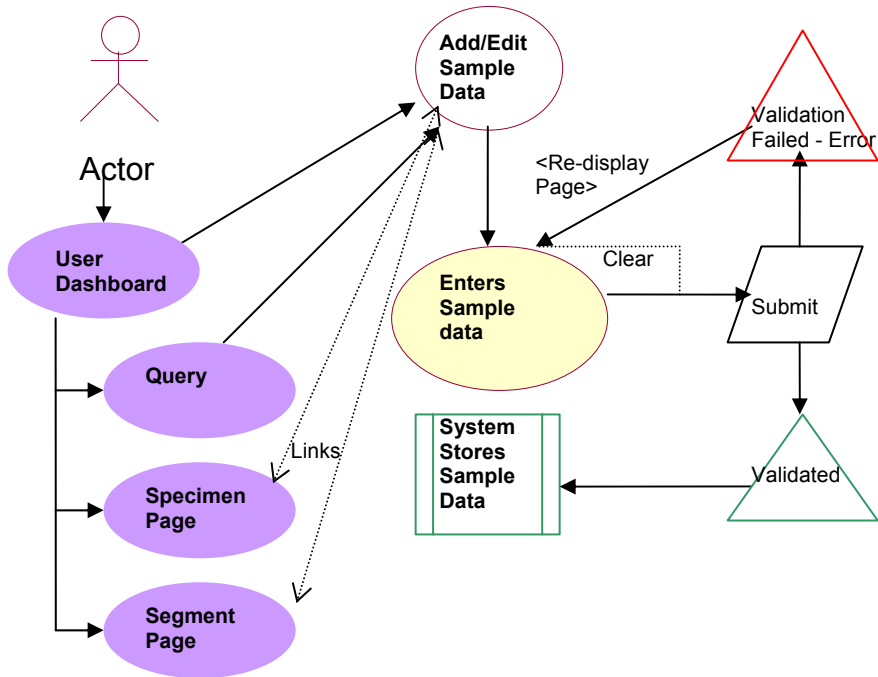
Use Case Name	Add/Edit Segment Data
Use Case ID	caTISSUE_Core-UC-60
Primary Actors	Administrator Technician
Brief Description	This use case process deals with entering new Segment data into the caTISSUE system.
Trigger	The Actor selects from their user dashboard the option to add Segment data into the system. Or The Actor selects the add Segment link on the Specimen Page (use case Add/Edit Specimen) Or The Actor selects Segment from the query result set.
Pre-conditions	Actor has access privileges to enter Segment information into the system. For a new Segment: The Segment entered can not already exist in the system. For an existing Segment: A query must be conducted to locate the Segment for which new information is being entered. For a new SEGMENT, the parent SPECIMEN must exist.
Flow of Events	<u>For submission of New Segment Data</u> (proceed to step 4a) <u>For an existing Segment:</u> 1. The actor conducts a query (use case Query Data). 2. Selects Segment from result set that is to be edited. 3. System populates page with existing Segment data and allows editing of existing data or entry of new data. 4. The Actor a. Enters Segment data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear] 5. The System a. validates Segment data for required content. [Branch Point – Segment Exists, Invalid Data, Incomplete Data, no associated parent specimen] b. If no errors are encountered, the system stores new Segment data. 6. The Actor may choose to add a Sample for the Segment entered (use case Add/Edit Sample)
Branch Point – Clear	The Actor selects the Clear option. The System deletes all data entered into the form. (Return to step 4a)
Post Conditions	Success Condition: New Segment information is stored in the system. Error Condition: Submission failed – Segment already exists (when entering new Specimen data) Error Condition: Submission failed - Invalid data (strings in place of numbers) or incomplete data entered Error Condition: Submission failed – Incomplete data
Branch Point – -Segment Exists -Invalid Data -Incomplete Data -No associated parent specimen	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. enter parent Specimen data (use case Add/Edit Specimen) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)



Related Use Cases	Add/Edit Specimen Add/Edit Sample Query Data Report a Problem
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6.5 Add/Edit Sample Data

A molecular derivative (i.e. RNA / DNA/ protein) obtained from a specimen or segment.





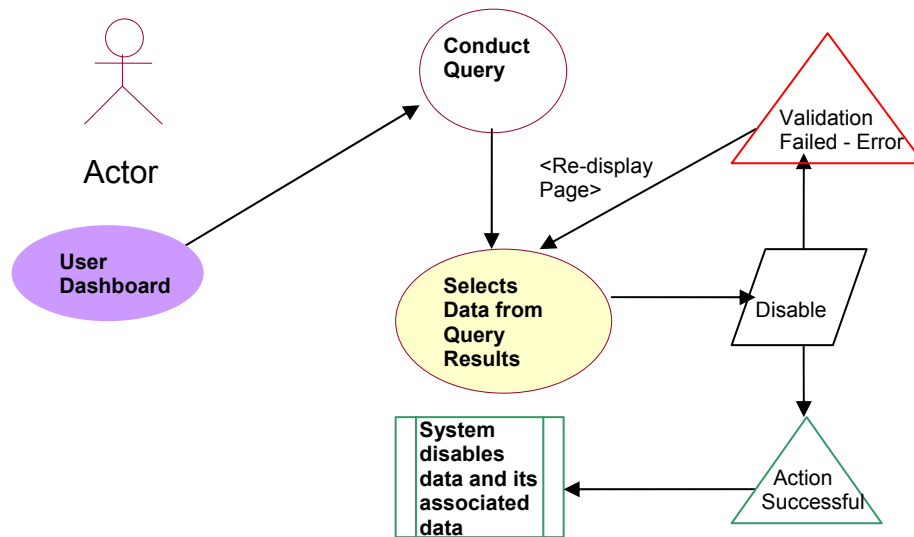
Use Case Name	Add/Edit Sample Data
Use Case ID	caTISSUE_Core-UC-65
Primary Actors	Administrator Technician
Brief Description	This use case process deals with entering new Sample data into the caTISSUE system.
Trigger	The Actor selects the add Sample option on their user dashboard. Or The Actor selects the add Sample link on the Specimen page (use case Add/Edit Specimen) Or The Actor selects the add Sample link on the Segment page (use case Add/Edit Segment) Or The Actor selects a Sample from a query result set.
Pre-conditions	Actor has access privileges to enter Sample information into the system. <u>For a new Sample:</u> The Sample entered can not already exist in the system. <u>For an existing Sample:</u> A query must be conducted to locate the Sample for which new information is being entered.
Flow of Events	<u>For submission of New Sample Data</u> (proceed to step 4a) <u>For an existing Sample:</u> 1. The actor conducts a query (use case Query Data). 2. Selects Sample from result set that is to be edited. 3. System populates page with existing Sample data and allows editing of existing data or entry of new data. 4. The Actor a. Enters Sample data into the fields provided. b. Selects the “Submit” button [Branch Point – Clear] 5. The System a. validates Sample data for required content. [Branch Point – Sample Exists, Invalid Data, Incomplete Data] b. If no errors are encountered, the system stores new Sample data.
Branch Point – Clear	The Actor selects the Clear option. The System deletes all data entered. (Return to step 4a)
Post Conditions	Success Condition: New Sample information is stored in the system. Error Condition: Submission failed – Sample already exists (when entering new Sample data) Error Condition: Submission failed - Invalid data (strings in place of numbers) or incomplete data entered Error Condition: Submission failed – Incomplete data
Branch Point – -Sample Exists -Invalid Data -Incomplete Data	The System displays appropriate error, and redisplay page. The Actor has the option to: a. add additional data or change entered data (return to step 4a) b. add parent specimen (use case Add/Edit Specimen) b. terminate the process with no further action taken c. report a problem (use case Report a Problem)
Related Use Cases	Query Data Report a Problem



6.6 Disable Data

Disabling administrative data is another form of edit data which will result in making that data invisible to the end users. Once data is disabled, it cannot be used, referenced, or queried in the future. Additionally, all objects that are associated with the data should also be disabled.

E.g. If a protocol is disabled, then all accessions, and associated specimens, samples and segments should also be disabled from view or future use.



Use Case Name	Disable Administrative Data
Use Case ID	caTISSUE_Core-UC-70
Primary Actors	Administrator User with appropriate access privileges
Brief Description	Disabling data involves conducting a query for the data and then selecting to disable. Disabling a data item will also disable all associated data (see table below)
Trigger	The Actor selects the option to disable specified data.
Pre-conditions	The Actor must have access privileges to submit the type of data being disabled. Query must be conducted to find data to be disabled (see use case Query Data).
Flow of Events	<ol style="list-style-type: none"> 1. The Actor <ol style="list-style-type: none"> a. verifies that the data displayed in the query results is the data to be disabled. b. selects the option to "Disable" 2. The system verifies that the Actor has privileges to disable data. <ul style="list-style-type: none"> -If "Yes" the system disables all data displayed along with its associated data. -If "No" the system displays an error and re-displays page [Branch Point – Unauthorized action]
Post Conditions	Success condition: Data and all associated data is disabled and can no longer be viewable in the system. Error condition: Unauthorized action
Branch Point – Unauthorized action	The Actor <ul style="list-style-type: none"> - can conduct another query for different data - can terminate the process with no further action taken
Related Use Cases	Query Data



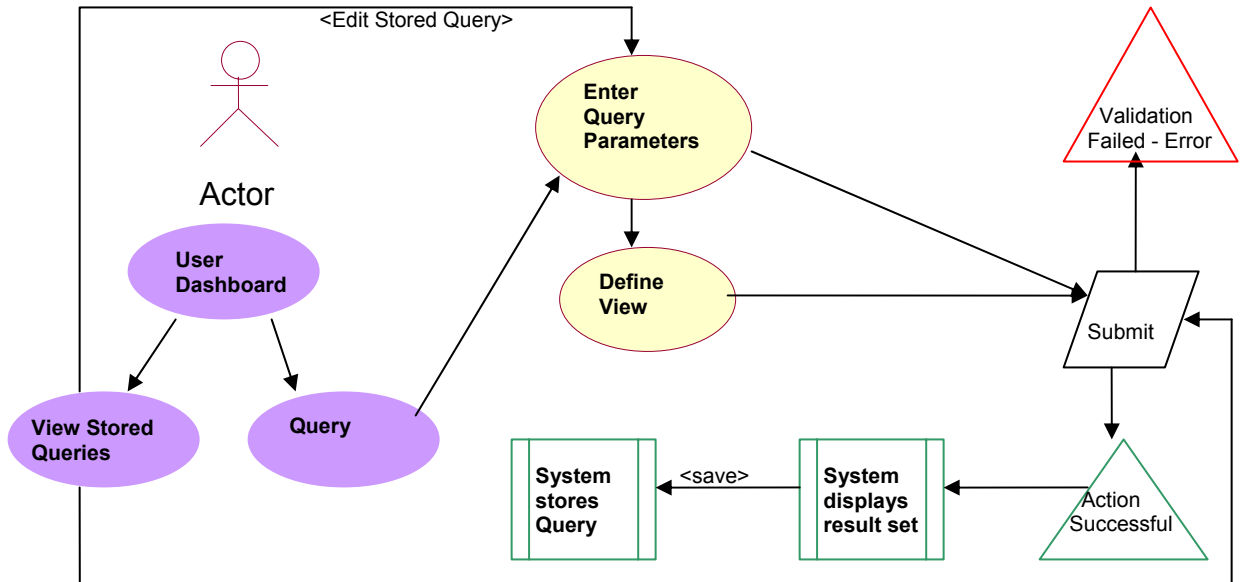
The following table displays the cascade effect when disabling an object:

Object	Description
PROTOCOL	<ul style="list-style-type: none">• No more accessions should be accepted under the disabled protocol• The current accessions and biospecimens should be marked as disabled and should be disabled from querying and distribution.• The status of the accessions and biospecimens which were already distributed should not be altered.
PARTICIPANT	<ul style="list-style-type: none">• A participant can revoke consent from a particular protocol after certain accessions are performed. In such cases:• No more accessions should be accepted under that protocol• All biospecimens of that participant for that protocol should be disabled from being queried or distributed.
ACCESSION	<ul style="list-style-type: none">• If an accession is disabled, then all the specimens, samples, segments related to the accession should also be disabled from being queried or distributed.
SPECIMEN	<ul style="list-style-type: none">• If a specimen is disabled, then all the segments and samples related to the specimen should also be disabled from being queried or distributed.
SEGMENT	<ul style="list-style-type: none">• If a segment is disabled, then all the samples related to that segment should also be disabled from being queried or distributed.
SAMPLE	<ul style="list-style-type: none">• The sample should be disabled from being queried or distributed.



7 Queries

7.1 Query Data



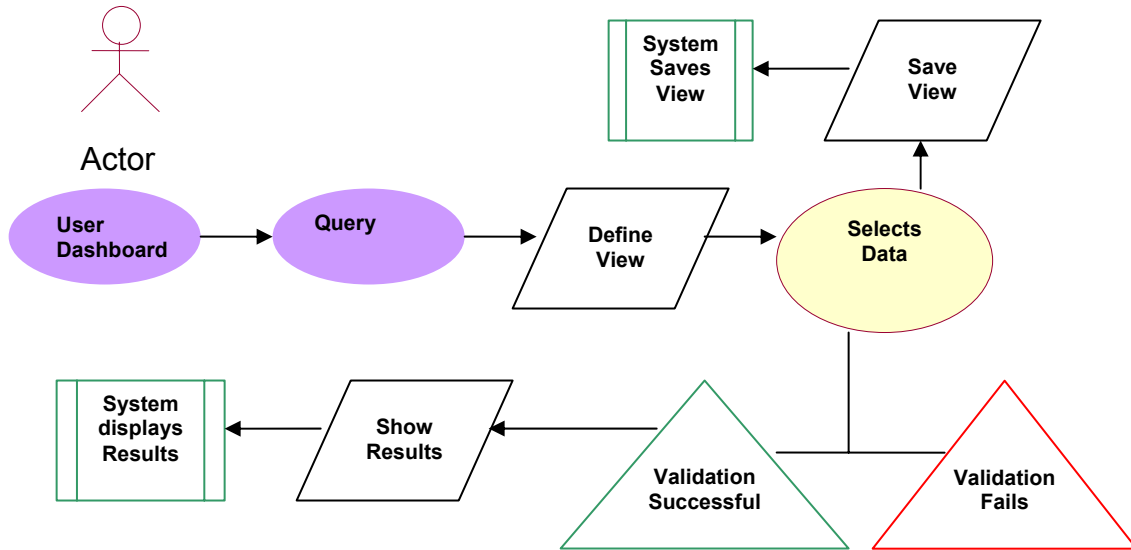
Use Case Name	Query Data
Use Case ID	caTISSUE_Core-UC-75
Primary Actors	All registered users
Brief Description	This use case process deals with the Actor entering query parameters (rules) and the system returning the matching result set. Once the result set is displayed, the Actor can continue to: <ol style="list-style-type: none"> 1. Refine query 2. Save query 3. View in spreadsheet mode 4. View in single object mode 5. Save results to file
Trigger	The Actor selects the option to Query data from their user dashboard. Or The Actor selects the View Stored Queries option on their user dashboard
Pre-conditions	The Actor must have privileges to view the data that they are querying for. (Example: A public user can not query identified data, since they cannot view identified data)
Flow of Events	<u>New Query</u> 1. The System presents entry fields for query parameters. (go to step 5a) <u>Stored Query</u> 1. The System displays list of stored queries 2. The Actor selects a query from the list presented 3. The System displays Query details 4. The Actor a. selects to edit the query (go to step 5a) b. selects to submit the query (go to step 5b)



	<p>5. The Actor</p> <p>a. Selects query parameters from the options presented</p> <p>b. Selects to Submit</p> <p>[Branch Point – Reset Query]</p> <p>[Branch Point – Define View]</p> <p>6. The System returns a result set (potentially an empty set) matching the parameters entered.</p> <p>7. The Actor selects a record from the result set</p> <p>8. The System displays data for the record selected.</p> <p>9. The Actor</p> <p>a. can refine the query by selecting the “Define View” option (see use case Define Query View)</p> <p>b. Save the result set for future use. [Branch point – Save Query]</p>
Post Conditions	<p>Success condition: Query is successful and result set is displayed</p> <p>Error condition: Unauthorized action</p>
Branch Point – Reset Query	<p>The Actor selects to Reset Query</p> <p>The System deletes all data entered into the page and redisplay page. (return to step 5a)</p>
Branch Point – Save Query	<p>The Actor selects to Save Query</p> <p>The System stores Query data.</p>
Branch Point – Unauthorized action	<p>The Actor</p> <ul style="list-style-type: none"> - can conduct another query (return to step 1 – New Query) - can terminate the process with no further action taken - can Report a Problem
Related Use Cases	<p>Define Query View</p> <p>Report a Problem</p>



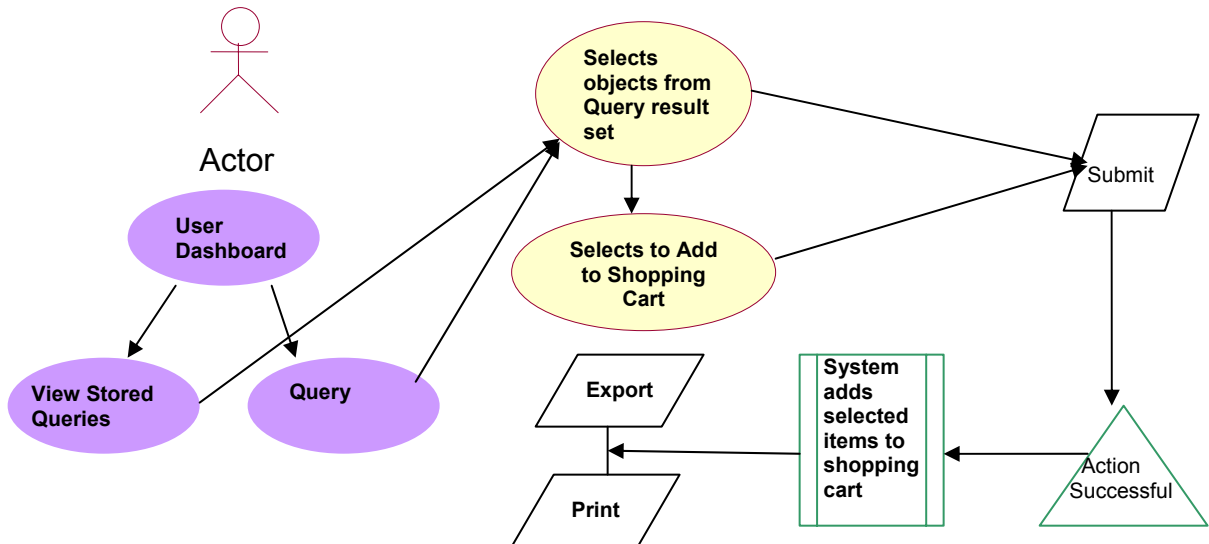
7.2 Define Query View



Use Case Name	Define Query View
Use Case ID	caTISSUE_Core-UC-80
Primary Actors	All registered users
Brief Description	When adding items to a shopping cart, a user can select to define the displayed view, which allows the user to customize the data they want to view.
Trigger	The Actor selects the Define View option when `.
Pre-conditions	The Actor has permissions to view the data items selected.
Flow of Events	<ol style="list-style-type: none"> 1. The System presents selection boxes for all objects. 2. The Actor selects desired data elements for each object and then clicks on the right arrow button to move the selected data elements to a data box that the system will use to construct the query. 3. The System displays all data matching the selected items. 4. The Actor can <ol style="list-style-type: none"> a. select the "Save View" option [Branch Point – Save View] b. select the "Show Results" option [Branch Point – Show Results] 5. If no errors are found, the system displays the selected data matching the query parameters. [Branch Point – Unauthorized Action]
Post Conditions	Success Condition: Query view is saved into the system. Success Condition: Query results are displayed Error Condition: Unauthorized Action
Branch Point – Save View	The System stores the view.
Branch Point – Show Results	The System displays result set matching the data elements selected.
Branch Point – Unauthorized action	The Actor - can conduct another query (return to step 2) - can terminate the process with no further action taken - can Report a Problem
Related Use Cases	Query Data Report a Problem



7.3 Compile Shopping Cart



Use Case Name	Compile Shopping Cart
Use Case ID	caTISSUE_Core-UC-85
Primary Actors	All registered users
Brief Description	This use case process deals with the Actor conducting a query and selecting items from the result set and saving them into their personal shopping cart. Additional items can be added or deleted until all desired items have been included. The user then has the option to export or print the list items
Trigger	The Actor selects items from a query result set and selects the “Add to Shopping Cart” feature.
Pre-conditions	The Actor must have role based privileges for the items being placed into their shopping cart.
Flow of Events	<ol style="list-style-type: none"> 1. The System adds selected items to the users shopping cart. 2. The Actor has the option to <ul style="list-style-type: none"> • Add items [Branch Point – Add Items] • Delete Items [Branch Point – Delete Items] 3. The system refreshes the shopping cart list to reflect additions and deletions. 4. The Actor has the option to <ul style="list-style-type: none"> • Export [Branch Point – Export] • Print [Branch Point – Print]
Post Conditions	Success condition: Items are sent to be printed Success condition: Items are prepared for export
Branch Point – Add Items	The Actor selects the option to “Add items” to their shopping cart. The System displays the Query page (see use case Query Data). The Actor repeats the query process and selects items to be added to their shopping cart (return to step 1).
Branch Point – Delete Items	The Actor marks items in their shopping cart and selects the “Delete Items” option. The System deletes selected items and redisplay the Shopping Cart.
Branch Point – Export	The Actor selects the option to “Export”. The System exports all listed items and redisplay the shopping cart (list should be vacant).
Branch Point – Print	The Actor selects the option to “Print”. They system sends all items contained in the shopping cart to the printer and redisplay shopping cart (list should be vacant).

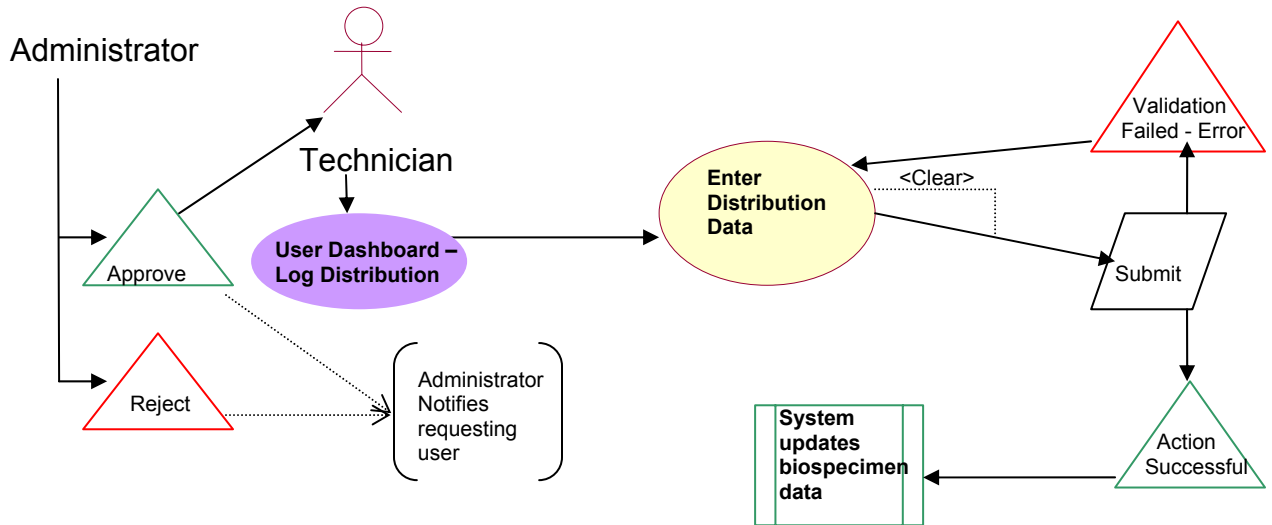


Related Use Cases	Query Data Report a Problem
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8 Distribution

8.1 Distribute Biospecimen



Use Case Name	Distribute Biospecimens
Use Case ID	caTISSUE_Core-UC-90
Primary Actors	Administrator Technician
Brief Description	The physical distribution of biospecimens takes place after an administrator is notified (by telephone, fax, email, postal service) from an authorized user regarding biospecimens desired as they correlate to an approved study. Once the request is approved it is handed to a technician who manually logs the distribution into the system. Once the distribution is logged into the system the technician will manually gather and package the biospecimens and send them to the requestor.
Trigger	Administrator receives list of biospecimens requested for distribution.
Pre-conditions	The Actor has conducted a query (use case Query Data) and generated a list of all biospecimens needed for a study and has transmitted the list (via phone, fax, email etc.) to an administrator for approval. Once the Administrator has reviewed and approved the request it is handed over to a technician for entry into the caTISSUE system.
Flow of Events	<ol style="list-style-type: none"> 1. The Administrator approves Distribution Request and sends the list to a technician to fill. [Branch Point – Reject] 2. The Actor selects the option to distribute Biospecimen from their user dashboard. 3. The System displays entry fields for entry of distribution data. 4. The Actor <ol style="list-style-type: none"> a. enters distribution data b. selects “Submit” [Branch Point – Clear] 5. If no errors are found the System makes adjustments to the status, and quantity of the biospecimens being distributed and stores the information into the system. [Branch Point – Incomplete Data, Invalid Data] 6. The Technician manually fills the request and mails it to the requesting user.



Post Conditions	Success condition: Distribution information is stored in the system. Error condition: Request denied - Distribution does not take place and is not entered into the system. Error condition: Incomplete Data Error condition: Invalid Data
Branch Point - Reject	If the distribution request is rejected, the Administrator notifies the requesting site, with no entry being made into the caTISSUE system.
Branch Point - Clear	The Actor selects "Clear" The System deletes all data entered into the form. (return to step 4a)
Branch Point – Incomplete Data Invalid Data	The System displays appropriate error, and redisplay page. The Actor has the option to a. add additional data or change entered data (return to step 4a) b. terminate the process with no further action taken c. report a problem (see use case Report a Problem)
Related Use Cases	Query Data Report a Problem



9 Audit

9.1 Audit System Events

Use Case Name	Audit System Events
Use Case ID	caTISSUE_Core-UC-95
Primary Actors	caTISSUE system
Brief Description	For every transaction, the system stores the event details in the database in an audit table. The audit table lists what event took place, the time the event was entered into the database, the user initiating the event, the object and element being altered, the type of change, as well as previous values and current values. To view event details a query must be conducted (see use case Query Data).
Trigger	Successful event completion that alters data stored in the database. Example: A new Participant is added to a Protocol.
Pre-conditions	None
Flow of Events	The system updates data tables to reflect the changes entered and makes an entry into the Audit table.
Post Conditions	Entry is made in the audit table
Related Use Cases	Query Data



10 Overall Requirements

10.1 Requirements Prioritization

Priority	Use Case Name	Supp Requirement Ref #
1	Log into the system	caTISSUE_Core-UC-01
1	Submit New User Request	caTISSUE_Core-UC-05
1	Add/Edit User	caTISSUE_Core-UC-20
1	Audit System Events	caTISSUE_Core-UC-95
1	Query Data	caTISSUE_Core-UC-75
1	Define Query View	caTISSUE_Core-UC-80
1	Distribute Biospecimen	caTISSUE_Core-UC-90
1	Add/Edit Site Data	caTISSUE_Core-UC-30
1	Add/Edit Protocol Data	caTISSUE_Core-UC-35
1	Add/Edit Study Data	caTISSUE_Core-UC-40
1	Add/Edit Participant Data	caTISSUE_Core-UC-45
1	Add/Edit Accession Data	caTISSUE_Core-UC-50
1	Add/Edit Specimen Data	caTISSUE_Core-UC-55
1	Add/Edit Segment Data	caTISSUE_Core-UC-60
1	Add/Edit Sample Data	caTISSUE_Core-UC-65
1	Compile Shopping Cart	caTISSUE_Core-UC-85
1	Disable Data	caTISSUE_Core-UC-70
1	Request Password	caTISSUE_Core-UC-10
1	Report a Problem	caTISSUE_Core-UC-15
1	View Problem Reports	caTISSUE_Core-UC-25



11 Data Definitions

Data Element	Definition
Accession ID	Accession identifier
Action	Status of the request.
Active	Indicates if the user still exists as a registered user.
Amount of Sample Available	Indicates the amount of sample that is available for use.
Are multiple sited involved in this protocol?	Indicates if multiple sites are involved for the protocol being entered.
Are specimens collected on this protocol?	Indicates if an accession of a specimen is part of the protocol being entered.
Are specimens utilized on this protocol?	Indicates if specimens will be utilized in the protocol being entered.
Box #	Indicates the box number where the specimen, segment or sample is held.
Cancer Type	Type of cancer
City	Name of the city where the mailing address is located.
Clinical Diagnosis	Diagnosis at the time of accession.
Clinical Status	Status at the time of accession.
Collected by	Name of the collector
Collection Date	Month, day and year the accession was collected.
Collection Site	Name of the physical location where the accession took place.
Collection Time	Time the accession was collected.
Collector	Initials of collecting pathologist.
Concentration	Concentration of sample (0 if unknown or not applicable)
Confirmation at TRCF	Pathologist who confirmed diagnosis of specimen received.
Country	Name of the country that the state belongs to.
Created By	Indicates the person who created the segment.
Creation Date	Indicates the date the segment was created. Or Date synthesized
Date Added to System	Date user was granted access.
Date Received	Date Specimen Received by TRCF.
Department	Name of the department inside the institution where the user is assigned. a.k.a – Department Affiliation
Disease Status	Describes the current status of the disease from which the specimen was collected.
Distributed by	Reference the user who entered the distribution
Distribution Date	Date Distributed
Distributed for	Reference STUDY that the distribution is intended for.
Distributed from	Reference SITE (=Repository) from which the distribution originated.
Distributed to	Reference SITE (=Laboratory) of the distribution destination.
Distribution ID	Distribution identifier



Distribution List	A dimension table that lists the material distributed. This includes: ITEM_TYPE, ITEM_ID, ITEM_QUANT, and ITEM QUANT_UNIT
Distribution Tracking Number	Tracking number of distribution shipment
DOB	Abbreviation for "Date of Birth". Month, Day, and Year the person indicated was born.
DX Date	Date of diagnosis
Email	Primary Email address for the user reporting the problem.
End Date	Month, day and year the protocol will end.
Family History of Diagnosis	Indicates if other members of the person's family have a history of the same diagnosis.
Family History of Other Malignancies	Family history of other malignancies
Fax	Fax number for the user being added.
First Name	Person's first name
Gel Number	Indicates the number of the gel which contains the sample
Gender	Indicates if the person named is a male or female.
Histological Quality	Histological quality of specimen
History of Other Malignancies	History of other malignancies
Hospital	Name of the Hospital utilized by the person indicated.
Institution	Name of the institution where the user is assigned.
IRB Id	Sponsoring IRB approval number
Is sample previously distributed?	Indicates if the sample has been previously distributed.
Lane Number	Indicates the lane number of the gel.
Last Name	Person's last name
Location (Box Number)	Specimen location box number.
Login ID	ID entered by user at time of registration.
Login Name	Name entered by user at time of registration.
Lymph	% Lymphocytic invasion in specimen.
Mailing Address	Primary street address of the registering user.
Middle Initial	1 st position alpha character in a person's middle name
MR_Number	
MR_Report	
Name	Name of the user requesting login approval.
Necrosis	% Necrosis in specimen.
Neoplastic Cellularity	% Neoplastic cellularity in specimen.
Number of anticipated subjects to accrue	Projected number of participants needed for the study being entered.
Notes	Miscellaneous support information not covered by entry fields.
Number of Participants anticipated	Number of participants expected for the protocol being entered.
Original Quantity of Segment	Indicates the original quantity of the segment.
Participant ID	Participant identifier
Participant Number (TRCF)	TRCF Participant Number
Password	Password generated by the system and sent to the new user via email upon approval.
Phone	Primary telephone number for the registering user.
Physical Location	Describes the actual physical location of Site being entered



Physician	Attending physician for the person indicated
Position in box	Indicates the position in the box where the segment is held.
Principal Investigator	Name of the principal investigator for the study being entered.
Problem Summary	Text of the problem being reported.
Process ID	Specimen processing description.
Protocol Coordinator	Name of the protocol coordinator for the protocol being entered.
Protocol ID	Protocol identifier
Protocol Investigator	Name of the primary protocol investigator
Protocol Number	Participant number in the protocol
Quantity	Indicates the quantity being entered for each specimen
Race	Ethnicity of the indicated person.
Rack #	Indicates the rack number where the segment is held.
Received by	Name of the person receiving the accession.
Received Date	Month, day, and year the accession was received.
Received Location	Hospital received from.
Received Quality	Quality of specimen received.
Received Site	Name of the site receiving the accession.
Received Time	Time the accession was received
Received_Track	
Restricted Access?	Indicates if the specimen has restricted access.
Role	Functional role as it pertains to access privileges in the system.
Sample Made?	Samples successfully made from this specimen.
Sample Type	Indicates type of sample
Select Unit	Indicates if the original quantity of the segment is in ml or g.
Shelf #	Indicates the shelf number where the segment is held.
Shipping Address	Address where the Site being entered can receive packages.
Short Title	Shortened title of the protocol being entered.
Site Coordinator	Name of the coordinator for the Site being entered.
Site Name	Legal name of the Site being entered.
Site Type	Describes the type of Site being entered.
Size	Size of specimen (g or ml)
Specimen	Identifies the specimen from which the segment is being created.
Specimen Available	Indicates if the specimen is still available for use.
Specimen Number	TRCF Specimen ID Number
SP_Report	Surgical-Pathology Report
Start Date	Month, day and year the protocol will start.
State	Name of the state where the city is located.
Storage	Indicates <i>how</i> specimen, segment or sample is stored.
Storage Class	Indicates the storage class of the segment
Storage Site	Indicates the physical location where the segment is stored.
Storage Unit	Indicates the storage unit where the segment is held.
Study Coordinator	Primary coordinator of the study being entered.
Study Number	Patient Study Number
Surgeon	Attending surgeon for the person indicated
Surgical Pathology Number	Surgical Pathology Number
Tissue Side	Side of tissue location.
Tissue Site	Tissue location of the specimen.
Tissue Type ID	Type of tissue specimen.
Title	Full Title of the Protocol
Total Cellularity %	% Total cellularity in specimen.
TRCF Patient #	TRCF Patient ID Number
TRCF Sample ID	TRCF Sample Number
TRCF Specimen ID	TRCF Specimen Number



Type	Indicates what type of specimen is being entered.
Type of Distribution	Details how the distribution was sent (by hand, courier, FedEx, UPS)
Unit	Indicates <i>where</i> the specimen, segment or sample is stored.
URL	Hyperlink to the protocol text
Zip Code	Postal code for the state entered.



12 Sign Off

12.1 Approval

<i>Workspace General Contractor Rep</i>	<i>Print Name</i>	<i>Date</i>
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<i>Architecture Workspace Rep</i>	<i>Print Name</i>	<i>Date</i>
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<i>VCDE Workspace Rep</i>	<i>Print Name</i>	<i>Date</i>
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<i>Workspace Working Group Rep</i>	<i>Print Name</i>	<i>Date</i>
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<i>NCICB Rep</i>	<i>Print Name</i>	<i>Date</i>
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