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Introduction

Background

The Cancer Central Clinical Participant Registry (C3PR) is a web-based application used for end-to-end registration of patients to clinical trials. This includes capturing information related to consent forms, eligibility, stratification, randomization, and screening. Clinical workflows are enabled by both subject- and study-centric views into the registration process. C3PR can be run in a standalone mode where study definitions, investigators, study personnel, and sites are entered into the system, or C3PR can be run in an integrated mode with the caBIG Clinical Trials Suite. C3PR also enables multi-site clinical trials where registration information is entered locally at affiliate sites and the registration is completed by call-out to the coordinating site.

Throughout the development of C3PR, a number of elaborator and adopter sites are actively being engaged to help define requirements and test the application. Our primary elaborators include Duke, Wake Forest, Mayo, Westat, CALGB, CCR, and the Coalition of Cooperative Groups. Our primary adopters include Duke and Wake Forest with engagement of Georgetown and CCR.

C3PR release 1 was developed by Nortel Solutions and released in 2006. Release 2 was developed by Duke Cancer Center in collaboration with SemanticBits, LLC and was released in March, 2008. The current version, C3PR v2.9.1, was released on September 30, 2010 in conjunction with the caBIG Clinical Trials Suite v.2.2.

Document Conventions

The C3PR Release 2 project follows the iterative development of the Unified Framework Process. Thus, each document is a snapshot of a work-in-progress. The following conventions will be used throughout the document:

- will indicate new items that need to be addressed immediately in the next iteration by the developers.
- will indicate new items that need to be addressed in the next iteration by the elaborators.

Related Documentation

End User	Analysis	Technical	Management
C3PR Main Project Page	**Use Cases**	Architecture Guide	Vision and Scope
Tool Landing Page	Requirements Specification	Domain Analysis Model	Project Plan
End User Guide	Activity Diagrams	Implementation Model	Scrum Artifacts
Training Library	BRIDG Compliance Report	Multisite Deployment Guidelines	Adoption Plan
Installation Guide	BAM Compliance Report	Deployment Diagrams	Communications Plan
Configuration Guide	COPPA Gap Analysis	C3PR Multisite Deployment Pilot	Test Plan
Release Notes	C3PR 2.0 Silver Compatibility Package		Test Logs
			Test Script
			Arc Requests
			Lessons Learned

			C3PR caBIG License

Actors and Roles

The likely users of C3PR are people with the job responsibilities listed below. The role(s) granted to each user in the application will depend on the specific responsibilities of the person's job and other institutional rules under which they execute their responsibilities.

- Registrar
- Study Coordinator
- Site Coordinator
- System Administrator

The following table contains the different kinds of user groups:

System Administrator	• Is a "super-user" who manages the application • Grants users to a role within the application
Site Coordinator	• Manages studies across the site • Approves and manages user registration process • Grants users to a role within the application • Creates new studies in the system
Study Coordinator	• Enters Study definitions in the system • Reviews completed Study definitions to determine if they are complete and correct
Registrar	• Enrolls Participants to Studies for which approval has been granted

Manage Subjects

Create Subject

Use Case Model

Brief Description	Existence of the subjects within the C3PR system is required for several use cases. In this use subject is created in the C3PR system.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged into the system with a user account that has role authority to creat Subject. 2. The Subject doesn't already exist.
Basic Flow of Events	1. The user selects Create Subject 2. The user is presented with a screen where details about the Subject are entered. 3. The user enters the Subject data elements in the fields. 4. The user submits the data 5. If a subject with duplicate information is found in the system an alternate flow is intr 6. The system displays the result page confirming the successful creation of a Subject.
Post Conditions	1. Subject data is stored in the system. 2. The user is presented with a conformation of Subject creation.
Alternate Flow	1. The system shows an error for Subjects with a duplicate identifier. 2. The user cancels the creation of the subject. 3. The user changes the identifier value for a given system and creates the subject. 4. The system displays the result page confirming the successful creation of the subject.

Special Requirements

Data Item	Notes/Validation Rule
Subject Identfier	At least one is required. The system will allow for any number of these to be specified and will capture t the identifier, the issuer of the identifier, and its value. This ID is uniquie to the Subject independent of t Subject's participation in a clinical trial.
First Name	Required
Middle Name	Not Required
Maiden Name	Not Required
Last Name	Required
Date of Birth	mm/dd/yyyy, forced format, Required
Gender	Coded, Required (Valid values include "unknown" and "not reported")
Race	Coded, Required (Valid values include "unknown" and "not reported")
Ethnicity	Coded, Required (Valid values include "unknown" and "not reported")

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Search for a Subject

Use Case Model

Brief Description	This use-case deals with searching for a subject. Reasons for searching for a subject include:

	• Looking for duplicate subjects • Begin subject registration in create registration workflow • View registration details • Update subject information • Update registration
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	The user is logged in to the system with a user account that has role authority to search for a su
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a subject. 2. The user selects the search basis on which he/she wants to perform the search. 3. The user enters the search criteria for the subject and submits the information to the sy 4. The system displays search results for subjects depending on the search criteria. 5. If no result is displayed use the alternate flow.
Post Conditions	The resulting subject is in a state that the user can use to perform registration in create registra or simply to view subject details or to update subject details.
Alternate Flow	#The use changes the search criteria. 1. The user submits the search critera.

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View a Subject

Use Case Model

Brief Description	This use case allows the user to view Subject's record.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	The subject already exists.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a subject. 2. The user enters the search criteria for the subject and submits the information to system. 3. The system displays 0, 1 or multiple subjects depending on the search criteria. 4. The user selects a subject. 5. The user views the subject details
Post Conditions	1. The subject details are displayed. 2. The user can transition to Edit Use Case.

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Update Subject Details

Use Case Model

Brief Description	This use case allows the user to update Subject's record.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	The subject record already exists.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a subject. 2. The user enters the search criteria for the subject and submits the information t system. 3. The system displays 0, 1 or multiple subjects depending on the search criteria. 4. The user selects a subject. 5. The user views the subject details. 6. The user selects the edit option for the displayed subject details. 7. The user updates the subject detais.
Post Conditions	1. The subject record is updated.
Special Requirements	None.

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Manage Study

High Level Study Diagram

Use Case Model

Brief Description	Study Management is not the primary function of C3PR. However, Study Management is critica independent functioning of C3PR because registration is driven by the structure of the study. Th is included as a primary use case.
Primary Actor(s)	TBD
Secondary Actor(s)	TBD
Preconditions	TBD
Basic Flow of Events	TBD
Post Conditions	TBD
Alternate Flow	TBD

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Data Capture Diagram

Use Case Model

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Brief Description	TBD
Primary Actor(s)	TBD
Secondary Actor(s)	TBD
Preconditions	TBD
Basic Flow of Events	TBD
Post Conditions	TBD
Alternate Flow	TBD

Create Study Definition Manually

Use Case Model

Brief Description	This use-case deals with the manual creation of a study by entering each data element of the st
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to create 2. The study has not already been entered.
Basic Flow of Events	1. The user indicates to the system that he/she wants to create a new study definition. 2. The system displays the screen that gives the user the option of entering the study info manually. 3. The user enters the study data elements in the fields. 4. The user indicates to the system that the required study information has been entered creation of a new study through a confirmation window with all of the study data item
Extension	1. If this is a multi-site study that is shared across more than one organization, the user in the system that the information must be broadcast to all participating organization site
Post Conditions	1. The study is created in the system. 2. The study is created and defined as being in either "Pending" or "Active" status.
Alternate Flow	1. If a duplicate study is found then the user has to fix the details before it can be saved i
Special Requirements	None.

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Search for Studies

Use Case Model

Brief Description	This use-case deals with searching for a study. Reasons for searching for a study include: • Looking for duplicate studies • Begin subject registration • Check for eligibility requirements • Check study status • Modify a study
Primary Actor(s)	Database Manager, Site Coordinator, Registrar or any other user of C3PR with role authority to s a study.
Secondary Actor(s)	None
Preconditions	The user is logged in to the system with a user account that has role authority to search for a stud
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study definition. 2. The user enters the search criteria for the study and submits the information to the systen 3. The system displays 0, 1 or multiple study definitions depending on the search criteria.
Post Conditions	The resulting study list is in a state that the user can transition to any of the manage study or regi subject use cases. This means sufficient detail is presented to the user in order to determine whic transition to. These details will be determined in later iterations.

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View Study

Use Case Model

Brief Description	This use-case deals with viewing a study.
Primary Actor(s)	Study Coordinator, Site Coordinator and Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has a role authori a study definition.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study 2. The user enters the search criteria for the study and submits the information t system. 3. The system displays 0, 1 or multiple study definitions depending on the searc 4. The user selects a study. 5. All data items from the study are displayed
Post Conditions	The user can transition either to edit the use case or export the study use case.
====Special Requirements	None

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Update Study

Use Case Model

Brief Description	This use-case deals with updating a study entry through the user interface. Note that this is diff a study amendment, which is a metadata item about an official change to a study.
Primary Actor(s)	Study Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to updat definition.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study definitio 2. The user enters the search criteria for the study and submits the information to the syst 3. The system displays 0, 1 or multiple study definitions depending on the search criteria 4. The user selects a study and views that study. 5. The user updates the necessary fields. 6. The user saves the updated study information to the system.
Post Conditions	1. If the user is logged in to the system with a user account that has role authority to upda the study stands updated.
Special Requirements	The "Blinded" and "Multi-Institutional" data fields cannot be updated.

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Associate Study Personnel Study

Use Case Model

Brief Description	A study, depending on whether it is multi-site study or not can have multiple sites associated wit site can have one or more personnel (Research Staff) involved in conducting the study. This use with associating such staff with a Study. Site Coordinator, during the creation of a study definitio able to add one or many of the study personnel for the study.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an administrative account that has role authority study personnel to the study organization. 2. The organization already exists. 3. The study exists. 4. The intended research staff member already exists at that organization and has an "Activ for that organization.
Basic Flow of Events	1. The user locates the study of interest 2. The user indicates that he/she wants to associate study personnel. 3. The user selects the desired organization for which the association should take place. 4. The user chooses from the list of research staff existing at this organization to be assigne personnel 5. The user chooses other relevant info for the association 6. The user may select more research staff repeating the steps 1-4

Post Conditions	None.
Special Requirements	None.

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Add Notifications to Study

Brief Description	A study can have multiple notifications associated with it. Every notification has a Threshold val associated with it. A notification email is sent when the number of registered participants reach th threshold value. These notifications can be either Email based or Role based. Email based notific take an email address as input and Role based notificatinos send emails to all the email addresses role for that study.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an administrative account that has role authority study personnel to the study organization. 2. The study already exists. 3. The intended roles and e-mail addresses for those roles that already exist in the C3PR sys
Basic Flow of Events	1. The user locates the study of interest 2. The user indicates that he/she wants to add notifications. 3. The user clicks on Add Notifications. 4. The user enters a threshold value for which he wants the notification to be sent. 5. The user enters an email address by clicking the Add email or selects a role by clicking o AddRole. 6. The user may repeat the steps 1-5 as many times as desired.
Post Conditions	The notifications are set up such that when the registered participants reach the threshold value th corresponding email addresses/roles are notified.
Special Requirements	None.

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Add Stratification

Use Case Model

Brief Description	Studies can have one or more stratification factors. Each stratification factor consists of a and two or more discreet answers. The answers for a particular Subject on a Study determ stratum group for the Study Subject. The stratum group can be used to help determine the during randomization.
Primary Actor(s)	Study Coordinator: defines the stratification when defining the study.
Secondary Actor(s)	Admin
Preconditions	1. The user is in the study creation or update workflow
Basic Flow of Events: Study Definition	1. The user enters the stratification portion of the study definition workflow 2. The user adds zero or more stratification factors 3. The user defines the question text for each stratification factor 4. The user defines one or more discreet answers for each stratification factor 5. The system saves the stratification factors
Basic Flow of Events: Subject Registration	1. The user enters the registration workflow 2. The user navigates to the stratification tab 3. The user answers each stratification factor question via drop-down menus 4. The stratum group is displayed when then final stratification factor is answered 5. The system saves the stratum group
Post Conditions	The system is ready to create a stratum group now.
Special Requirements	None.

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Add Randomization

Use Case Model

Brief Description	A study may use randomization as a method of assigning subjects to arms. There are several randomization commonly used in clinical trials.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is in the study creation or update workflow. 2. The user has indicated that the study uses randomization. 3. The user has defined what type of randomization is to be used for the study.
Basic Flow of Events	1. The user enters the randomization portion of the study definition workflow. 2. The user adds randomization information for each epoch that uses randomization for assignment.
Post Conditions	The system is ready to assign subjects to arms using randomization for the study.
Special Requirements	None.

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Disable a Stratum Group

Use Case Model

Brief Description	Studies can have one or more stratification factors. Each stratification factor consists of a qu and two or more discreet answers. The different combinations of all the questions along wit possible answers constitute the stratum groups. All stratum groups may not be important or the study. This use case deals with disabling an invalid group.
Primary Actor(s)	Study Coordinator and Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is in the study creation or update workflow. 2. The study is either newly created or is in pending status.
Basic Flow of Events: Study Definition	1. The user enters the stratification portion of the study definition workflow 2. The user adds one or more stratification factors if they do not already exist. 3. The user defines the question text for each stratification factor. 4. The user defines one or more discreet answers for each stratification factor 5. The user indicates to the system to generate the stratum groups if they do not alread if he/she updates any stratification questions and/or answers. 6. The user deletes the desired stratum group. 7. The user indicates to the system to update/save the study.
Post Conditions	1. The stratum group will be deleted. 2. If the study has book randomization, the book randomization entries have to be upd remove the entries for the deleted stratum group.

Special Requirements	None.

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Add Eligibility Criteria

Use Case Model

Brief Description	Studies can have one or more Eligibility Criterion. These are further classified as Inclusion Exclusion Eligibility criteria. The user can add new eligibility criteria to any treatment epoc use case helps add new eligibility criteria in 3 different ways depending on the business req
Primary Actor(s)	Study Coordinator and Site Coordinator

Secondary Actor(s)	Admin
Preconditions	1. The user is in the study creation or update workflow
Basic Flow of Events: Create Study	1. The user enters the eligibility portion of the study definition workflow. 2. The user identifies the treatment epoch for which eligibility criteria needs be added 3. The user adds one or more inclusion or/and exclusion criterion. 4. The user updates the study to save the newly added eligibility questions.
Alternate Flow (Load caDSR):	1. The user enters the eligibility portion of the study definition workflow. 2. The user selects the treatment epoch for which eligibility criteria needs be added fr dropdown. 3. The user adds clicks on the browse button and selects the file to be uploaded. 4. The user clicks the upload button. 5. The user can now add to or modify the uploaded contents.
Basic Flow of Events: Edit Study	1. If the desired study is saved in a pending status, the user enters the search criteria a searches for the desired study. 2. The user selects the desired study and enters the edit workflow. 3. The user enters the eligibility portion of the study. 4. The user identifies the treatment epoch for which eligibility criteria needs to be add 5. The user adds one or more inclusion/exclusion eligibility criterion. 6. The user updates the study to saves the newly added eligibility questions.
Basic Flow of Events: Amend Study	1. If the desired study is saved in an active status, the user enters the search criteria ar searches for the desired study. 2. The user selects the desired study and enters the amend study workflow. 3. The user indicates that treatment epoch and eligibility change as a result of the ame 4. The user enters the eligibility portion of the study. 5. The user identifies the treatment epoch for which eligibility criteria needs to be add 6. The user adds one or more inclusion/exclusion eligibility criterion. 7. The user updates the study to saves the newly added eligibility questions.
Post Conditions	New eligibility criteria is added to the study.
Special Requirements	None.

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Add Diseases

Use Case Model

Registration Flow

Brief Description	Studies can have one or more diseases associated with them. These diseases are used durin Registration to allow the user to select a disease for a Study Subject. The user will also be a select a primary disease site for the Study Subject. There are a number of different disease disease site nomenclatures used in the community. C3PR will initally provide the CTEP dis

	disease sites.
Primary Actor(s)	Study Coordinator: defines the disease sites when defining the study Registrar: registers a subject to a study and, in doing so, defines the disease and disease site subject.
Secondary Actor(s)	None
Preconditions	None
Basic Flow of Events	1. The user enters the disease portion of the study definition workflow. 2. The user adds one or more diseases.
Basic Flow of Events: Subject Registration	1. The user enters the registration workflow. 2. The user navigates to the disease tab. 3. The user selects a disease or enters a free-text disease. 4. The user selects a disease site or enters a free-text disease site.
Post Conditions	1. A new disease and disease site are associated with the study.
Alternate Flow	None
Special Requirements	None

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Change Status from Pending to Open

Use Case Model

Brief Description	A new study entered into c3pr using the User Interface can be saved in a pending status. All the s need at least one study site and one enrolling epoch and other basic data to be considered as data complete (which is system derived). The study has to go through a curation phase or a quality an check before the study coordinator or site coordinator reviews and can set the study status to ope case deals with this scenario.
Primary Actor(s)	Study Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to update s status from Pending to Open. 2. The study is in a Pending status.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study definition. 2. The user enters the search criteria for the study and submits the information to the systen 3. The system displays 0, 1 or multiple study definitions depending on the search criteria. 4. The user selects a study and views its summary. 5. The user updates the study definition or any part of the study in the edit flow if required. 6. The user updates the study status from Pending to Open.
Post Conditions	1. If the user is logged in to the system with a user account that has role authority to update status, the study status is updated from Pending to Open.

Special Requirements	1. The system requires at least one study site. 2. The system requires at least one enrolling epoch.

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Change Status from Amendment Pending to Open

Use Case Model

Brief Description	A study in an open status can be modified through an amendment. Once an amendment is anticipa initiated, the user captures the study amendment information. However, at this stage the user may sufficient information to completely capture all the required information or the amendment may n IRB approval yet. At this stage the system automatically puts the study in an Amendment Pending The study has to go through a quality analysis check before the study coordinator or site coordina reviews and can update the study status from Amendment Pending to Open. This use case deals w scenario.
Primary Actor(s)	Study Coordinator, Site coordinator or any other user of C3PR with role authority to update the st study to Open.
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with a user account that has role authority to update st from Amendment Pending to Open.

	2. The study is in an Amendment Pending status.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study definition. 2. The user enters the search criteria for the study and submits the information to the system 3. The system displays 0, 1 or multiple study definitions depending on the search criteria. 4. The user selects a study and views its summary. 5. The user goes through the amendment workflow and updates any information if required. 6. The user updates the study status from Amending Pending to Active
Post Conditions	1. If the user is logged in to the system with a user account that has role authority to update status, the study status is updated to Open.
Extension	1. If this is a multi-site study that is shared across more than one organization, the user indic system that the modified information must be broadcast to all participating organization s
Special Requirements	None

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Update Study Definition

Use Case Model

Brief Description	This use-case deals with amending a current study definition.

Primary Actor(s)	Study Coordinator
Secondary Actor(s)	None.
Preconditions	1. The user is logged into the system with a user account that has role authority to ar study definition. 2. The study is in an active status.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study defi 2. The user enters the search criteria for the study and submits the information to the 3. The system displays 0, 1 or multiple study definitions depending on the search cri 4. The user selects the study definition for which he/she wants to amend. 5. The user indicates to the system that he/she wants to make an amendment. 6. The user enters the amendment data items
Post Conditions	The study definition has been amended.
Alternate Flow	None.
Special Requirements	None.

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Create Stand-alone Companion Study

Brief Description	This use case describes the creation of a stand-alone companion study. A stand-alone compani without any association to another study.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	
Preconditions	1. The user is logged into C3PR with role authority to create a study. 2. The companion study has not been entered.

Basic Flow of Events	1. The user indicates to the system that he/she wants to create a new stand-alone compan definition. 2. The system displays the screen that gives the user the option of entering the companio 3. The user enters the study data elements in the fields. 4. The user indicates to the system that the required companion study information has be 5. The system displays a confirmation page with a summary of the newly entered compa information.
Extension	1. If this is a multi-site study that is shared across more than one organization, the user i the system that the information must be broadcast to all participating organization site
Post Conditions	1. The study is created in the system. 2. The study is created and defined as being of "Pending" or "Open" status.
Alternate Flow	
Special Requirements	

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Create Embedded Companion Study

Use Case Model

Brief Description	This use case describes the creation of an embedded companion study. An embedded compani only with an association to another study that is referred to as the parent study.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	
Preconditions	1. The user is logged into C3PR with role authority to create a study.

	2. The user has begun entering parent study data into the system 3. The companion study has not been entered.
Basic Flow of Events	1. During entry of a study into the system, the user indicates that he/she wants to create a embedded companion study definition. 2. The system displays the screen that gives the user the option of entering the companio 3. The user enters the study data elements in the fields. 4. The user indicates to the system that the required companion study information has be 5. The system displays a confirmation page with a summary of the newly entered compa information. 6. The user completes entry of the parent study information.
Extension	1. If this is a multi-site study that is shared across more than one organization, the user i the system that the information must be broadcast to all participating organization site 2. The embedded companion may be considered to be mandatory or not with respect to registration.
Post Conditions	1. The study is created in the system. 2. The study is created and defined as being of "Pending" or "Open" status.
Alternate Flow	
Special Requirements	

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Update Study Protocol Version

Use Case Model

Brief Description	The study protocol version can be updated by amending a study with an open status. Once an upda study site protocol version is anticipated or initiated, the user captures the information needed to u protocol version. However, at this stage the user may not have completely captured all the required information or the update to the protocol version may not have IRB approval yet. At this stage the automatically puts the update to the study in an Amendment Pending status. The update to the prot version has to go through a quality analysis check before the study coordinator or site coordinator the study protocol version. This use case deals with this scenario.
Primary Actor(s)	Study Coordinator, Site coordinator or any other user of C3PR with role authority to update the sta study.
Secondary Actor(s)	None.
Preconditions	

	1. The user is logged in to the system with a user account that has role authority to update stu from Amendment Pending to Open.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a given study definition. 2. The user enters the search criteria for the study and submits the information to the system. 3. The system displays 0, 1 or multiple study definitions depending on the search criteria. 4. The user selects a study and views its summary. 5. The user goes through the amendment workflow and updates information for the protocol update. 6. After a quality analysis check of the protocol version update has been performed and IRB has been received, the user updates the study status from Amending Pending to Open.
Post Conditions	1. If the user is logged in to the system with a user account that has role authority to update st status, the study protocol version is updated.
Extension	1. If this is a multi-site study that is shared across more than one organization, the user indica system that the modified information must be broadcast to all participating organization sit

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View Registrations for a Study

Use Case Model

Brief Description	This use case allows for viewing subjects that have been registered to a study in the syster
Primary Actor(s)	Study Coordinator, Site Coordinator, Registrar
Secondary Actor(s)	None.
Preconditions	1. The study exists in the system. 2. Subjects have been registered to the study.
Basic Flow of Events	1. The user locates and accesses the desired study. 2. The user views the portion of the study record that shows a list of subjects registe study.
Post Conditions	1. Nothing has been changed in the system.
Extension	none

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Manage Registration

Register a New Subject

Use Case Model

Brief Description	This use case will allow the user to register a subject not currently in the C3PR system to a stu user will be required to enter subject information before completing the registration.
Primary Actor(s)	Registrar or any other designated user of C3PR with role authority to register a Subject.
Secondary Actor(s)	None.
Preconditions	1. The Study already exists. 2. Any hard accrual limits are not exceeded. 3. The Study is in Active status. 4. The study has an enrolling epoch. 5. The subject does not already exist in the system. 6. The subject meets the eligibility criteria for the enrolling epoch.
Basic Flow of Events	1. The user enters create registration workflow 2. The user creates a new subject. 3. The user searches and selects the desired study 4. The user selects a study site 5. The user selects an enrolling epoch from the selected study. 6. The system alerts the user of any soft accrual limits. 7. The system alerts the user if the subject is already registered to the same study. 8. The user fills out the enrollment details completely. 9. If the study involves Randomization, the user indicates to the system that he/she want randomize
Post Conditions	1. If the enrolling epoch involves randomization, an arm is successfully obtained. 2. If the user was logged in to the system with a role authority to register a subject, the su

	registered to the study.
Alternate Flow	None.
Special Requirements	None.

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Register Subject to Multi-site Study

Use Case Model

Brief Description	The user must first create a registration in the appropriate study site before they can enroll a subje use case will explain how the user can create a registration in a study site in a multi-site study. In register a subject to a study site of a multi-site study the study must already exist the system and Open status. Once the registration has been created go to the Enroll Subject to Study Site use cas

	follow the steps to complete the registration of a subject.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to register a 2. The Study already exists. 3. Any hard accrual limits are not exceeded. 4. The Study is in Active status. 5. The study has an enrolling epoch. 6. The subject meets the eligibility criteria for the enrolling epoch.
Basic Flow of Events	1. The user enters create registration workflow 2. The user searches and selects the desired multi-site study 3. The user selects the desired study site 4. The user selects an enrolling epoch from the selected study. 5. The system alerts the user of any soft accrual limits. 6. The system alerts the user if the subject is already registered to the same study. 7. The user fills out the enrollment details completely. 8. The system sends the registration notification fo the ESB. 9. The ESB sends the registration notification to the coordinating center for approval. 10. The system gets back either an approval or a disapproved message back from the coordin center.
Post Conditions	1. If the subject meets eligibility criteria, he/she is successfully registered. 2. If the enrolling epoch involves randomization, an arm is obtained.
Alternate Flow	None.
Special Requirements	None.

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Enroll Subject to a Study Site

Use Case Model

Brief Description	This use case will explain how the user can enroll a subject to a study site in a multi-site study af have created the registration. The user must first create a registration in the appropriate study site they can enroll a subject. Once the steps in the Register Subject to Multi-site Study use case have completed the user can follow the steps in this use case to enroll a subject in the registration of a
Primary Actor(s)	Registrar or any other designated user of C3PR with role authority to register a Subject.
Secondary Actor(s)	None
Preconditions	1. Registration is pending 2. Randomization of study subjects is complete
Basic Flow of Events	1. The user searches and selects the desired study 2. The user enters create registration workflow and broadcasts the registration 3. The user changes the status of an existing subject. 4. The user selects an enrolling epoch from the selected study. 5. The system alerts the user of any soft accrual limits. 6. The system alerts the user if the subject is already registered to the same study. 7. The user fills out the enrollment details completely.
Post Conditions	1. If the user was logged in to the system with a role authority to register a subject, the subj registered to the study.
Alternate Flow	None.
Special Requirements	None.

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Transfer Epoch to Study Site of Multi-site Study

Use Case Model

Brief Description	Before you can transfer subjects from one epoch to another you must first transfer the epoch to appropriate study site in the multi-site study. In this use case an epoch is changed in the system stored in a study site.
Primary Actor(s)	Study Coordinator
Secondary Actor(s)	Admin
Preconditions	

	1. The user is logged in to the system with a user account that has role authority to registe Subject.
Basic Flow of Events	1. The user searches for the appropriate study 2. The user selects the study to edit it 3. The user selects or adds the appropriate epoch 4. The user broadcasts the epoch to study sites
Post Conditions	1. The epoch is now stored in the appropriate study site of the multi-site study.
Alternate Flow	None.
Special Requirements	None.

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Assign Subject to New Epoch in Study Site

Use Case Model

Brief Description	Subjects can be assigned to an epoch in a study site after the epoch has been transferred to the st a multi-site study. You will need to change the registration status of the subject and broadcast th information to the study sites associated with the multi-site study. In this use case a subject is ass an epoch in a study site of a multi-site study.
Primary Actor(s)	Study Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to register 2. If randomization is selected for the study then randomization of the subjects must be cor
Basic Flow of Events	1. The user searches for the appropriate study 2. The user selects the study to edit it 3. The user selects or adds the appropriate subject 4. The user broadcasts to study sites
Post Conditions	1. The subject is now assigned to the appropriate epoch of the multi-site study.
Alternate Flow	None.
Special Requirements	None.

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Register Existing Subject to a Study

Use Case Model

Brief Description	This use case will allow the user to register a subject not currently in the C3PR system to a stu user will be required to enter subject information before completing the registration.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to regist Subject. 2. The Study already exists. 3. Any hard accrual limits are not exceeded 4. The Study is in Active status. 5. The study has an enrolling epoch. 6. The subject already exists and meets the eligibility criteria required by the enrolling ep
Basic Flow of Events	1. The user enters create registration workflow 2. The user searches and selects the desired subject.

	3. The user searches and selects the desired study 4. The user selects a study site 5. The user selects an enrolling epoch from the selected study. 6. The system alerts the user of any soft accrual limits. 7. The system alerts the user if the subject is already registered to the same study. 8. The user fills out the enrollment details completely. 9. If the study involves Randomization, the user indicates to the system that he/she want randomize
Post Conditions	1. The randomization process successfully returns an arm. 2. If the user was logged in to the system with a role authority to register a subject, the su registered to the study.
Alternate Flow	None.
Special Requirements	None.

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Assign Kit Number for Blinded Study

Use Case Model

Brief Description	This use case will allow the user to register a subject to a blinded study and obtain a kit n
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to r subject. 2. The blinded Study already exists. 3. Any hard accrual limits are not exceeded 4. The Study is in Active status. 5. The study has an enrolling epoch. 6. The subject already exists and meets the eligibility criteria required by the enrolli
Basic Flow of Events	1. The user enters create registration workflow 2. The user searches and selects the desired subject. 3. The user searches and selects the desired blinded study 4. The user selects a study site 5. The user selects an enrolling epoch from the selected study. 6. The system alerts the user of any soft accrual limits. 7. The system alerts the user if the subject is already registered to the same study. 8. The user fills out the enrollment details completely. 9. The user indicates to the system that he/she wants to obtain a kit number.
Post Conditions	#If the subject is eligible and no hard accrual limits are exceeded, a kit number is obtaine
Alternate Flow	None.
Special Requirements	None.

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Save a Registration in Incomplete Status

Use Case Model

Brief Description	This use case allows the user to select a study and select a subject and without entering other det the information in an incomplete status. Users can then search for the registration and complete t information and the registration will either go on pending status if it requires some approval, if it site study or it can be accepted as a complete registration.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to register 2. The Study already exists. 3. Any hard accrual limits are not exceeded 4. The Study has an Active status. 5. The Subject is not already registered to the same Study.
Basic Flow of Events	1. The user enters create registration workflow 2. The user searches and selects the desires subject. 3. The user searches and selects the desired study 4. The user selects a study site 5. The user selects an epoch from the selected study. 6. The system alerts the user of any soft accrual limits. 7. The system alerts the user if the subject is already registered to the same study. 8. The user fills out the enrollment details incompletely i.e. either the treating physician is entered or eligibility is not met or Informed Consent Version or Date is not valid.
Post Conditions	

	1. The registration is saved in an incomplete status if no hard accrual limits are exceeded o subject is not already registered to the same study site.
Alternate Flow	None.
Special Requirements	None.

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Register Subject to Reservation Study

Use Case Model

Brief Description	1. In some Phase I studies, there are very small number of accrual slots. 2. It is important that someone can be registered to the study, get worked up, and then potentially be removed from the study. 3. This type of "reservation" allows the next candidate to take the originally registered 4. This differs from most studies, where the de-registered slot is "lost" - the next subje registered to the next slot.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin
Preconditions	

	1. The user is logged in to the system with a user account that has role authority to res spot on the study. 2. The Study already exists. 3. Any hard accrual limits are not exceeded 4. The Study is in Active status. 5. The study has a reserving or enrolling epoch. 6. The subject already exists.
Basic Flow of Events	1. The user enters create registration workflow 2. The user searches and selects the desired subject. 3. The user searches and selects the desired study. 4. The user selects a study site. 5. The user selects a reserving or an enrolling epoch from the selected study. 6. The system alerts the user of any soft accrual limits. 7. The system alerts the user if the subject is already registered to the same study. 8. The user fills out the enrollment details.
Post Conditions	1. The subject is reserved a spot on the study.
Alternate Flow	None.
Special Requirements	None.

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Search for Registrations

Use Case Model

Brief Description	This use-case deals with searching for registrations. Reasons for searching for registrations inclu • Looking for duplicate registrations • View registration history • Check for eligibility requirements • Check registration status • Modify a registration • To assign a subject to a randomized arm
Primary Actor(s)	Study Coordinator, Site Coordinator and Registrar
Secondary Actor(s)	Registrar
Preconditions	1. The user is logged in to the system with a user account that has role authority to search f registration.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for registrations. 2. The system displays a 2-step search process. The user first searches for a subject, study registration identifier based on subject search criteria, study search criteria or the registr identifier value respectively. 3. The user then searches for the registrations based on the selected subject, study or regist identifier

	4. The system displays 0, 1 or multiple registrations depending on the search criteria.
Post Conditions	1. The resulting registration list is in a state that the user can transition to any of the manag registration use cases like completing, updating eligibility, assigning to a randomized ar updating registration status etc. This means sufficient detail is presented to the user in or determine which registration to transition to.
Alternate Flow	None.
Special Requirements	None.

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View Subject Registration History

Use Case Model

Brief Description	This use case allows the user to view registration details of a subject.
Primary Actor(s)	Registrar, Site Coordinator, CRA or any other designated user of C3PR with role authority to registration.
Secondary Actor(s)	Registrar
Preconditions	1. The subject is already registered to a study at a particular healthcare site.

	2. The user is logged into the system with a user account that has role authority to view registration details.
Basic Flow of Events	1. The user searches for a given subject. 2. The user selects desired subject to view the subject details. 3. The user indicates that he/she wants to view the desired registration from a list of reg the subject is on. 4. The user can choose to view registration details, eligibility status, registration status, stratification factors, randomization arm, and registration identifiers.
Post Conditions	#The registration details have been viewed by the user.
Alternate Flow	None.
Special Requirements	None.

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Update Eligibility Status for Registration

Use Case Model

Brief Description	This use case allows the user to update eligibility status of a subject on a given registration.
Primary Actor(s)	Registrar
Secondary Actor(s)	Admin

Preconditions	1. The subject is already pre-registered to a study at a particular healthcare site. 2. The user is logged into the system with a user account that has role authority to upda eligibility status of a subject on a given study.
Basic Flow of Events	1. The user searches for a given subject. 2. The user selects desired subject to view the subject details. 3. The user indicates that he/she wants to view the desired registration details from a li registrations the subject is on. 4. The user indicates that he/she wants to view the eligibility of the subject on the give selecting the eligibility tab. 5. The user can change the eligibility of the subject and indicates to the system that he/ to save the new eligibility status.
Post Conditions	1. If the user had the role authority to update eligibility of the subject on the given stud registration status is updated if eligibility is met.
Alternate Flow	None.
Special Requirements	None.

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Randomize Subject

Use Case Model

Brief Description	This use case allows the user to assign a subject to an arm.
Primary Actor(s)	Registrar

Secondary Actor(s)	Admin
Preconditions	1. The subject is already registered to a study at a particular healthcare site. 2. The user is logged into the system with a user account that has role authority to assig subject to a randomized arm on a given study.
Basic Flow of Events	1. The user searches for a given subject. 2. The user selects desired subject to view the subject details. 3. The user indicates that he/she wants to view the desired registration details from a lis registrations the subject is on. 4. The user indicates that he/she wants to view the randomization information of the su the given study by selecting the randomization tab. 5. The user selects the desired arm to which the subject is to be assigned indicates to th that he/she wants to save the arm.
Post Conditions	1. If the user has the role authority to assign the subject to a randomized arm on the giv the subject is assigned to a randomized arm.
Alternate Flow	None.
Special Requirements	None.

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Take Subject Off Study

Use Case Model

Brief Description	This use case allows the user to update the registration status of a subject on a given study.
Primary Actor(s)	Site Coordinator, CRA, or any other designated user of C3PR with role authority to update th registration status on a given study.
Secondary Actor(s)	Registrar
Preconditions	1. The subject is pre-registered to a study at a particular healthcare site. 2. The user is logged into the system with a user account that has role authority to upda registration status for a subject on a given study.
Basic Flow of Events	1. The user searches for a given subject. 2. The user selects desired subject to view the subject details. 3. The user indicates that he/she wants to view the desired registration details from a lis registrations the subject is on. 4. The user indicates that he/she wants to view the registration status of the subject on t study by selecting the registration tab. 5. The user selects the desired registration status and indicates to the system that he/she save the status.
Post Conditions	1. If the user has the role authority to change registration status of the subject on the giv the registration status of the subject stands changed.
Alternate Flow	None.
Special Requirements	None.

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Unblind Registered Subject

Brief Description	This use case involves the unblinding of a subject registered to a blinded study. The purpose of un is to make the previously unknown treatment known. This use case is invoked for a variety of rea including the subject having an adverse event, the subject requesting to know the treatment, and s other than the subject taking the subject's medication. Note that this use case does not result in an functionality in C3PR because there is no need to track unblinded information in the registration t tracked in the CDMS. However, it is included for completeness.
Primary Actor(s)	Unblinding Requester (e.g. treating physician), Kit Manager (e.g. coordinating site, drug provider
Secondary Actor(s)	Study Coordinator
Preconditions	1. The subject is registered to a treatment epoch of a (double) blinded study.
Basic Flow of Events	1. The Unblinding Requestor requests that a subject is unblinded by providing a kit number

	reason to the Kit Manager 2. The Kit Manager provides the treatment information to the Unblinding Requestor 3. The Unblinding Requestor fills out the appropriate unblinding CFRs and logs them in the
Post Conditions	1. The study subject is unblinded
Alternate Flow	# The Study Coordinator intervenes in the flow before the Kit Manager provides the treatment inf to determine which information is released to which individuals
Special Requirements	Note: this use case does not result in any functionality within C3PR.

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View a Registration

Use Case Model

Brief Description	This use case allows the user to view a registration record.
Primary Actor(s)	Registrar
Secondary Actor(s)	System Admin, Site Coordinator, Study Coordinator

Preconditions	The registration record exists in the system.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a registration. 2. The user enters the search criteria for the registration and submits the information system. 3. The system displays 0, 1 or multiple subjects depending on the search criteria. 4. The user selects a registration. 5. The user views the registration details
Post Conditions	1. The subject details are displayed. 2. The user can transition to Edit Use Case.

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Reporting

Advanced Registration Search

Use Case Model

Brief Description	This use case allows the user to enter information in 4 different kinds of criteria and run a regi search. The search results table also allows the user to download the results in .xls format.
Primary Actor(s)	Site Coordinator, Study Coordinator and Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an account that has permission to search regis
Basic Flow of Events	1. The user enters the desired search criteria. The four criteria are: Study, Site, Registrati Subject. 2. The user retrieves the corresponding registrations. 3. The user downloads the table in the .xls format.
Post Conditions	1. The search results are displayed in a table on the same page. 2. This table provides a export as excel button which lets the user download the table co excel format.
Alternate Flow	None.
Special Requirements	None.

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Study Search and Export

Use Case Model

Brief Description	This use case allows the user to search for studies and export the search result as an excel fil
Primary Actor(s)	Site Coordinator, Study Coordinator and Registrar
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with appropriate privileges 2. One or more studies must exist in the C3PR database
Basic Flow of Events	1. The user enters the desired search criteria. The user can search on 3 criteria's: Study Identifiers, Study Short Title and Study Status 2. The system retrieves the corresponding studies 3. The user downloads the table in the .xls format.
Post Conditions	1. The search results are displayed in a table on the same page. 2. This table provides a export as excel button which lets the user download the table o excel format.
Alternate Flow	None.
Special Requirements	None.

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Create Summary 3 Report

Use Case Model

Brief Description	This use case allows the user to generate a Summary 3 for registrations in the syste
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with appropriate privileges 2. One or more studies must exist in the C3PR database
Basic Flow of Events	1. The user accesses the application's reporting module. 2. The user navigates to the Summary 3 section. 3. The user enters the organization name he wishes to use to generate the repo 4. The user enter the start and end dates for the reporting period. 5. The user clicks a button to generate the report.
Post Conditions	1. The user is presented with a screen that shows the Summary 3 report results 2. The user is given the option to export the report as PDF or Excel.
Alternate Flow	None.
Special Requirements	None.

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Administration

Create Investigator

Use Case Model

Brief Description	This use-case deals with the manual creation of an Investigator at the specified healthcare sites entering each data element of the investigator.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an administrative account that has role author create an investigator. 2. The investigator doesn't already exist.
Basic Flow of Events	1. The user indicates to the system that he/she wants to perform an administrative task 2. The user indicates to the system that he/she wants to create an investigator. 3. The system displays the screen that gives the user option of entering the investigator information manually. 4. The user enters the Investigator data elements in the fields.

	5. The user indicates to the system that the required investigator information has been en creation of a new investigator.
Post Conditions	1. If the user is logged in to the system with a user account that has administrative privile create an Investigator (for example, a System Administrator), the created Investigator approved.
Alternate Flow	None.
Special Requirements	None.

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Add Investigator Group

Use Case Model

Brief Description	This use-case deals with the manual creation of Investigator Groups at a healthcare site.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	

	1. The user is logged in to the system with an administrative account that has role autho create an investigator group. 2. The investigator group doesn't already exist.
Basic Flow of Events	1. The user indicates to the system that he/she wants to perform an administrative task 2. The user indicates to the system that he/she wants to create an investigator group. 3. The system displays the screen that gives the user option of selecting an organization entering the investigator group information manually. 4. The user enters the group's data elements in the fields. 5. The user indicates to the system that the required investigator group information has entered for creation of a new investigator group.
Post Conditions	1. If the user is logged in to the system with a user account that has administrative privi create an Investigator group, the Investigator group is created.
Alternate Flow	None.
Special Requirements	None.

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Add Investigator To A Group

Use Case Model

Brief Description	This use-case deals with the manual addition of Investigators to a group at a healthcare site.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an administrative account that has role autho create an investigator group. 2. The desired investigator(s) do not already belong to the group.
Basic Flow of Events	1. The user indicates to the system that he/she wants to perform an administrative task 2. The user indicates to the system that he/she wants to add investigators to a group. 3. The system displays the screen that gives the user option of selecting an organization desired investigator group. 4. The user selects from the list of existing investigators at the organization, those that h intends to be add to the group. 5. The user indicates to the system to save the new information.
Post Conditions	1. If the user is logged in to the system with a user account that has administrative privil add Investigators to a group, the Investigators would be added to the group.
Alternate Flow	None.
Special Requirements	None.

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Create Research Staff

Use Case Model

Brief Description	C3PR is a secure system and all users require a username (ID) and password for system access. use-case deals with the manual creation of research staff user account by entering each associat element into the C3PR system.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. C3PR is installed and configured to use an email server (SMTP) 2. A user is logged in to the system with the role authority to create research staff. 3. The research staff member account does not already exist.

Basic Flow of Events	1. The C3PR Administrator or Site Coordinator accesses the user interface for adding/ma research staff
	2. Basic info is entered (first name, last name, user ID)
	3. The new user's designated organization is selected
	4. Organization specific contact info is entered (email address,phone, fax, mailing address
	5. The role(s) of the user at the organization are selected.
	6. The studies to which the user should be assigned to (for the given organization) are sel
	    1. There will be an "all-studies" option which will associate the user to all current future studies for the organization.
	    2. The one limitation for this assignment compared to the assignments available a level is that the study level assignments will allow specific user roles to be

	selected/unselected. 7. An additional organization can be selected and steps 3-6 then repeat. 8. The C3PR Admin clicks on the "Create User" button 1. The C3PR system confirms that the information has been saved and the new us created. 9. The C3PR system sends an email to the new user instructing them how to change their and login.
Post Conditions	#If the user is logged in to the system with a user account that has administrative privileges to c research staff (for example, a System Administrator), the created research staff member is appr
Alternate Flow	None.
Special Requirements	None.

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Create Organization

Use Case Model

Brief Description	This use-case deals with the manual creation of an Organization by entering organization relat The user can enter information and select save or select reset tab to clear the entered data.
Primary Actor(s)	Site Coordinator

Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with an administrative account that has role author create Organization. 2. The Organization doesn't already exist.
Basic Flow of Events	1. The user indicates to the system that he/she wants to do administrative tasks 2. The user indicates to the system that he/she wants to create an Organization. 3. The system displays the screen that lets the user enter the Organization information ma 4. The user enters Organization's data elements in the fields. 5. The user indicates to the system that the required Organization information has been e creation of a new Organization.
Post Conditions	1. If the user is logged in to the system with a user account that has administrative privile create a research staff (for example, a System Administrator), the created research staf is approved.
Alternate Flow	None.
Special Requirements	None.

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Associate Investigator to Study Organization

Use Case Model

Brief Description	This use case allows the user to associate an investigator to a study organization.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with an administrative account that has role autho investigator to a study organization. 2. The site already exists. 3. The intended investigator already exists at the organization 4. The intended investigator does not already exist at that study organization
Basic Flow of Events	1. The user enters the create study work flow for a new study or edit study flow for an e study. 2. The user selects the desired site for which the association should take place. 3. The user chooses the list of investigators associated for this site to be assigned as stu investigator, which is commonly referred to as the enrolling physician. 4. The user adds other relevant information for the association. 5. The user may select more site investigators repeating the steps 1-4
Post Conditions	None.
Alternate Flow	#Instead of selecting a single Study Investigator, the user selects a group of Investigators.
Special Requirements	None.

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Associate Investigator Group to Study Organization

Use Case Model

Brief Description	This use case allows the user to associate an investigator group to a study organization
Primary Actor(s)	Site Coordinator and Study Coordinator
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with an administrative account that has role auth add an investigator group to a study organization. 2. The study organization already exists. 3. The intended group already exists at the organization. 4. The study organization does not already have the intended group.
Basic Flow of Events	1. The user enters the create study work flow for a new study or update study flow for existing study. 2. The user selects the desired site for which the association should take place. 3. The user chooses the investigator group that is intended to be associated to the study organization. 4. The user chooses other relevant information for the association. 5. The user may select more groups repeating the steps 1-4
Post Conditions	None.
Alternate Flow	1. Instead of selecting an investigator group, the user selects a single investigator.

Special Requirements	None.

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Search for a Study Personnel

Use Case Model

Brief Description	This use case allows the user to search a Study Person (Research Staff Member) depending u search criteria. Reasons for searching for a study person include: • Looking for a duplicate research staff member. • View research staff member details. • Update research staff member details.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to searc research staff member at the given site.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a research staff memb 2. The user either enters the first name and/or last name and/or the NCI Identifier. 3. The user searches for the research staff member by clicking on search.

	4. The system displays 0, 1 or multiple research staff members matching the search crite
Post Conditions	1. The resulting research staff member in a state where his/her details can be viewed and if the user has the necessary privileges to do so.
Alternate Flow	None.
Special Requirements	None.

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View and Update Research Staff Details

Use Case Model

Brief Description	This use case allows the user to view or/and update a Study Person (Research Staff Member) upon the search criteria (FN, LN, NCI Identifier). Reasons for this include: • Looking for a duplicate Research Staff member. • View Research Staff member details. • Update Research Staff member details.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	None.

Preconditions	#The user is logged in to the system with a user account that has role authority to view or/and details of a Research Staff member at the given site.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a Research Staff mem 2. The user either enters the first name and/or last name and/or the NCI Identifier. 3. The user searches for the Research Staff member by clicking on search. 4. The system displays 0, 1 or multiple Research Staff members matching the search cri 5. The user selects the desired Research Staff member whose details he/she wants to see 6. The user views or/and updates the details of that member.
Post Conditions	1. The resulting research staff member in a state where his/her details can be viewed and if the user has the necessary privileges to do so.
Alternate Flow	None.
Special Requirements	None.

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Search for an Investigator

Use Case Model

Brief Description	This use case allows the user to search an Investigator. Reasons for searching for an Investig include:

	• Looking for a duplicate Investigator. • View Investigator details. • Update Investigator details.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to sea Investigator at the given site.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for an Investigator. 2. The user either enters the first name and/or last name and/or the NCI Identifier. 3. The user searches for the Investigator by clicking on search. 4. The system displays 0, 1 or multiple Investigators matching the search criteria.
Post Conditions	1. The resulting Investigator in a state where his/her details can be viewed and updated user has the necessary privileges to do so.
Alternate Flow	None.
Special Requirements	None.

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List Investigators In A Group

Use Case Model

Brief Description	This use-case deals with the search for Investigators in a group at a healthcare site.
Primary Actor(s)	Site coordinator or any other designated user of C3PR with administrative privilege to search f investigators at a given site.
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with an administrative account that has role author search for investigators. 2. The desired group and the healthcare site already exist.
Basic Flow of Events	1. The user indicates to the system that he/she wants to perform an administrative task 2. The user indicates to the system that he/she wants to search for investigators belongin group. 3. The system displays the screen that gives the user option of selecting an organization a desired investigator group at that organization. 4. The user indicates to the system that he/she want to search for investigators. 5. The system displays all the investigators belonging to the group.
Post Conditions	1. If the user is logged in to the system with a user account that has administrative privile search for the Investigators, the system displays the information of the investigators be that group
Alternate Flow	None.
Special Requirements	None.

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View or Update Investigator Details

Use Case Model

Brief Description	This use case allows the user to view or/and update an Investigator depending upon the searc (FN, LN, NCI Identifier). Reasons for this include: • Looking for a duplicate Investigator member. • View Investigator member details. • Update Investigator member details.
Primary Actor(s)	Site Coordinator
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with a user account that has role authority to view update details of an Investigator member at the given site.
Basic Flow of Events	1. The user indicates to the system that he/she wants to search for a Investigator membe 2. The user either enters the first name and/or last name and/or the NCI Identifier. 3. The user searches for the Investigator member by clicking on search. 4. The system displays 0, 1 or multiple Investigator members matching the search crite 5. The user selects the desired Investigator member whose details he/she wants to see. 6. The user views or/and updates the details of that member.
Post Conditions	

	1. The resulting Investigator member in a state where his/her details can be viewed and the user has the necessary privileges to do so.
Alternate Flow	None.
Special Requirements	None.

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Disassociate Study Person from Study Site

Use Case Model

Brief Description	Each study site can have one or more research staff members associated with them. The associa research staff members are called study personnel. These study personnel can be disassociated study site. This use case deals with this scenario.
Primary Actor(s)	Site Coordinator and Study Coordinator
Secondary Actor(s)	Admin
Preconditions	1. The study person already exists.
Basic Flow of Events	1. The user searches for the desired study.

	2. He/she enters the edit flow of the desired study. 3. The user selects a study site at which he/she wishes to disassociate the study person. 4. The user indicates to the system that he/she wants to remove the study person.
Post Conditions	1. The study person will be successfully disassociated from the study site if the user had p do so.
Alternate Flow	None.
Special Requirements	None.

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Change the Study Site Investigator status

Use Case Model

Brief Description	Each study site can have one or more investigators associated with them. The associated inves status can be set from Active to Inactive and vice-versa.. This use case deals with this scenario
Primary Actor(s)	Site Coordinator and Study Coordinator
Secondary Actor(s)	Admin

Preconditions	1. The investigator already exists and is associated with the study.
Basic Flow of Events	1. The user searches for the desired study. 2. He/she enters the edit flow of the desired study. 3. The user selects a study site at which he/she wishes to update the investigator status. 4. The user toggles the investigator status by selecting the new status. 5. The user indicates to the system that he/she wants to save the changes.
Post Conditions	1. The status of the study site investigator will be updated if the user had privilege to do
Alternate Flow	None.
Special Requirements	None.

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Export Study Definition to a File

Use Case Model

Brief Description	This use-case deals with exporting a Study to a File that can be saved on the users local file
Primary Actor(s)	Study Coordinator, Site Coordinator and Registrar

Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to vie Study. 2. The Study exists in the C3PR database
Basic Flow of Events	1. The user searches for a Study 2. The user is taken to the Study details page where there is an "Export Study" link. 3. The system generates a XML export of the Study definition and the user is asked to study on their local system
Post Conditions	None.
Alternate Flow	None.
Special Requirements	User may need special software to view the exported Study XML.

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Export Registration Definition to a File

Use Case Model

Brief Description	This use-case deals with exporting a Registration to a File that can be saved on the users lo system.
	Registrar, Site Coordinator and Study Coordinator

Primary Actor(s)	
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with a user account that has role authority to vie Registration. 2. The Registration exists in the C3PR database
Basic Flow of Events	1. The user searches for Registration(s) from the Advanced Search section. 2. The user indicates to the system that he/she wants to export the registration to an ex 3. The system generates a XML export of Registration and the user is asked to save th registration on their local system
Post Conditions	None.
Alternate Flow	None.
Special Requirements	User may need special software to view the exported Registration XML.

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Import Study Definition from a File

Use Case Model

Brief Description	This use-case deals with importing one or more Studies from a file that is on the user's loca

Primary Actor(s)	Site Coordinator and Admin
Secondary Actor(s)	Admin
Preconditions	1. The user is logged in to the system with a user account that has role authority to cre Study. 2. The Study definition is in XML format 3. The Study definition XML conforms to the C3PR Study XML schema 4. The Study Sites that is participating in the Study already exist in C3PR
Basic Flow of Events	1. The user indicates to the system that he/she wants to create a new study definition f 2. The system displays a screen that allows the user to browse their local file system. 3. The user selects the appropriate file which contains the information about the study loaded into the system. 4. After selecting the file, the user indicates to the system to import the study definitio on the information in the file. 5. The system reads the file and validates the file. 6. If the file is valid, new study definitions are created. 7. The system indicates to the user the status of the import by displaying a list of the n created Study definitions.
Post Conditions	1. The Study definitions that have been imported can be (depending on the users privi viewed and edited by the user.
Alternate Flow	None.
Special Requirements	None.

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Get Study Definition via Study Message from External Source

Use Case Model

Brief Description	This use-case deals with creation of a Study at the local system after getting/importing it from external source via a Study Message.
Primary Actor(s)	Study Administrator, Study Coordinator or any other designated user of C3PR with role author create a Study.
Secondary Actor(s)	None.
Preconditions	1. The user is logged in to the system with a user account that has role authority to create 2. C3PR is configured to receive messages from the external source.
Basic Flow of Events	1. The user indicates to the system that he/she wants to create a new study definition 2. The system displays a screen that displays the import methods. This screen allows the import a new study. 3. The study is imported 4. If errors occur during the import, they are displayed to the user 5. If the study is imported successfully, the user views the study. 6. The user checks the study for correctness and updates the study entries to correspond t site requirements (IRB approval, accrual ceiling, etc). 7. After importing the study, the user confirms the study creation.
Post Conditions	1. The imported study waits for further changes/validation with respect to the local site c (IRB approval, accrual ceiling, etc) before it is available for use at the local site.
Alternate Flow	1. If the study already exists, an error is returned
Alternate Flow	None.

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Correct Error in Study Subject's Record

Use Case Model

Brief Description	This use case allows for a system administrator at a coordinating center to rectify a data entry er by a registrar or other protocol staff member during subject registration. Any data element relat subject's registration could be corrected via the UI.
Primary Actor(s)	Registration QA Manager
Secondary Actor(s)	None.
Preconditions	• The subject has been enrolled in the study • A data entry error has been made • The user is logged in as a system administrator at the coordinating center and corrects e
Basic Flow of Events	1. System admin logs in to C3PR 2. System admin accesses study subject record and identifies the error 3. System admin corrects data entry
Sub-Flow	System administrator reassigns to proper arm, possibly after re-randomization, or deactivates th subject record
Post Conditions	Study subject data have been corrected.
Alternate Flow	If the study subject's epoch requires randomization, the system administrator reassigns to the pr possibly after re-randomization, or invalidates the study subject record.
Special Requirements	• Only Administrators can correct data entry error for a study subject record. • As of now we will support current schedules epoch's data entry correction. • In case administrator need to change either subject or epoch, we will provide functional invalidate current record. After invalidating current record user can start new registratio

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Name (required):

Website:

Comment: