Contents

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 the consent signed date, eligibility criteria, 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 (CCTS). 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. We are currently in the next phase of development with releases slated for the end of September, 2008 and March, 2009.

Note: Study Management is not the primary function of C3PR. However, Study Management is critical for the independent functioning of C3PR because registration is driven by the structure of the study. Therefore, it is included as a function of C3PR.

Related Documentation

End User	Analysis	Technical	Management
C3PR Main Project Page Tool Landing Page **End User Guide 2.5.5** Installation Guide 2.5.5	Use Cases 2.5.5 Requirements Specification 2.5.5 Activity Diagrams 2.5.5	Architecture Guide 2.5.5 Deployment Diagrams 2.5.5	Project Plan 2.5.5 Scrum Artifacts Adoption Plan 2.5.5 Communications Plan 2.5.5

Configuration Guide 2.5.5 Release Notes Tear Sheet			Test Plan 2.5.5 User Acceptance Tests 2.5.5 Arc Requests

Before You Begin

The information below must be initially entered into C3PR by the administrator before C3PR can function properly.

1. Study Organizations - In C3PR, the names of all Coordinating Centers, Funding Sponsors and Study Sites are entered as Organizations.
2. Principal Investigators
3. Personnel Research Staff

If any of the steps above have not been completed by the C3PR system administrator, a study cannot be created. If this is your first time using the C3PR application after it has been installed and configured please check with your C3PR administrator to confirm this has already been done. C3PR administrators can go to the administration section of this guide for more information.

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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

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Logging In

The C3PR application can be accessed with any standard Web browser. Investigators and Research Staff are added to the system through the administration tab of the C3PR Web interface by the C3PR administrator.

1. Enter your **Username** and **Password** into the appropriate fields on the C3PR login page.
2. Click the **Log in** button.

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Registration

Create Registration

After you have created a study and created subjects in C3PR, you can register subjects to a study. To register subjects, go to the C3PR home page, click the **Registration** tab and click **Create Registration**.

There are six task pages that you need to complete to enter a Registration in C3PR.

1. Select Subject & Study.
2. Enrollment Details.
3. Check Eligibility.
4. Stratification.
5. Select Arm.
6. Review & Submit.

To create a new registration:

Complete the Select Subject & Study task page:

1. **Select a Subject:** There are two ways for a subject to be selected. It can be either (1) select an existing subject using the search subject feature, or (2) create a new subject.

    1. On the **Search Subject** tab of the **Select a Subject** section, select one of the options from the **Search Subjects By** drop down list.
    2. Enter **Search Criteria**.
       Note: You can enter a **%** symbol as a wild card to return search results for all available subjects.
    3. Click **Search**. C3PR displays the results. Select the subject from the results by moving the cursor to the name and click the mouse. C3PR displays the selected subject. To restore the **Select a Subject** screen to full screen size, click on the icon under the **Select a Subject** screen.
       OR
2. Create a **New Subject:**

    1. Click the **Create Subject** tab in the **Select a subject** section of the **Create Registration** page.
    2. Enter the **First Name** for the subject.
    3. Enter the **Last Name** for the subject.
    4. Enter the **Middle Name** for the subject.
    5. Enter the **Maiden Name** for the subject.
    6. Select the **Gender** for the subject from the drop down list.
    7. Enter the **Birth Date** for the subject. Date format should be mm/dd/yyyy.
    8. Select the **Ethnicity** for the subject. This field indicates the person?s self declared ethnic origination, independent of racial origination.
    9. Select the **Race(s)** for the subject.
    10. Enter the **Organization** This is a prepopulated field. Enter the first few letters of the name of the Organization and select it from the drop down list that appears. **Note:** If the name of the Organization does not appear in the drop down list go to **Person & Organization > Organization >Create Organization** in the navigation bar and enter it. If your permissions do not allow you to enter Organizations contact your C3PR administrator.
    11. Enter the **Medical Record Number**.
    12. Click the **Organization Assigned Identifiers** link (Organization Assigned Identifiers are a number or code assigned by an Organization such as Mayo Clinic, Wake Forest or Duke University) and then click the **Add Another Identifier** in the right hand side of the page.

        1. Enter the **Assigning Authority**. This is the name of the Organization (such as Mayo Clinic, Duke University or Wake Forest) that created the identifier number or code. Enter the first few letters of the name of the Organization and select it from the drop down list that appears. **Warning:** If the name of the **Assigning Authority** you are looking for does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
        2. Select the **Identifier Type** from the drop down list.
        3. Enter the **Identifier**.
        4. Select **Primary Indicator**, if applicable.
    13. To add the Address and Contact info, click the **Address & Contact Info** link.

1. 1. Enter **Street Address**.
   2. Enter the **City**.
   3. Enter the **State**.
   4. Enter the **Zip**.
   5. Enter the **Country**.
   6. Enter the **Email**.
   7. Enter the **Phone**.
   8. Enter the **Fax**.

   14. Click **Save**. C3PR saves the subject, and the new subject has been selected. Thus, the Select a Subject screen gets highlighted and C3PR displays the selected subject. To restore to a **Select a Subject** screen to full screen size, click on the icon under the **Select a Subject** screen.

3. **Select a study:**

   1. Select an option from the **Search Studies By** drop down list.
   2. Enter **Search Criteria**. **Note:** You can enter a **%** symbol as a wild card to return search results for all the available studies.
   3. Click **Search**.
   4. Click on a study to select it from the search results. If the Study has more than one site, then select the Site, along with the Study. **Warning:** If the study is not on the list, please contact your C3PR system administrator or create the Study.
   5. C3PR displays all the available epoch treatments. Click on an epoch treatment to select it from the list.
      Note: An Epoch is a portion of the study containing one or more study segments with a consistent objective such as screening subjects or treating disease.
   6. Click **Continue** to go to the next page.

2. **Complete the Enrollment Details page:**
   Note: If the subject is already registered to this epoch (a subject can only be registered to one epoch at a time) and you would like to move the subject to a different epoch, go to Search Registration for instructions.
   Fill out the Enrollment Details.

   1. Enter the **Informed Consent Signed Date**.
   2. Indicate what the **Current Consent Version** is. This is the version of the consent document that the subject signed.
   3. Enter the **Registration Start Date**.
   4. Select the **Primary Disease** from the drop down list. If the selection is **Other**, then C3PR provides the user with an addition text field to which it represents a type of disease other than the primary disease for which the patient is being treated could be typed in.
   5. Enter the **Primary Disease Site**. This is a prepopulated field. Enter the first few letters of the name of the Primary Disease Site and select it from the drop down list that appears.
   6. Select the **Payment Method** from the drop down list.
   7. Click the **Continue** to go to the next page (Check Eligibility).

3. **Complete the Check Eligibility page:**

   1. Select the appropriate options from the drop down lists under the **Inclustion Criteria** and **Exclusion Criteria** sections.
   2. If the selected epoch does not involve checking eligibility, then click **Continue** to go to the next page (Stratify).

4. **Complete the Stratify page:**

1. Make the appropriate selections from the drop down list(s) under the **Criteria** section.
2. If the selected epoch does not involve stratification, click **Continue** to go to the next page (Select Arm).

5. **Complete the Select Arm page:**

    1. Select an Arm from the list.
    2. Click **Continue** to go to the next page (Review & Submit).
6. **Complete the Review & Submit page:**

    1. Review the Registration data.
    2. Click **Save** at the bottom of the page.
    3. Read the Confirmation Message and follow any related instructions.

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Search Registration

You can search for registrations to view, export and/or edit information. You can take a subject off a study or move subjects from one epoch to another. To search for a registration, go to the C3PR home page, click the **Registration** tab and click **Search Registration**.

To search for a registration:

1. Select **Subject**, **Study**, or **Registration Identifier** from the **Search By** drop down list.
2. Enter **Search Criteria**. This is a pre-populated field. Enter the first few letters of the search term and select an option from the drop down list that appears.
3. Click **Search**.
4. C3PR displays the results. Click on a study in the search results to select it.

Once the Study has been selected you can do any of the following:

- Move subjects from one epoch to another.
- View the registration
- Edit the enrollment details
- Print the Study
- Export the Study

To move a subject to a different epoch: An epoch is portion of the study containing one or more study segments with a consistent objective such as screening subjects or treating disease. A subject can be registered to only one epoch at a time.

1. Click the **Related Tasks** tab in the left hand side of the page and click on **Change Current Epoch** in the menu that appears.
2. C3PR displays all related epoch treatments for this registration. Drag and drop the subject to the appropriate epoch.

To view the registration:

1. Click on a study to select it from the search results. C3PR displays the Overview page.
2. You can edit the enrollment details if the registration status is **Registered**. Click **Edit** under the **Enrollment Details** section. If the registration status is **Take subject off study** you cannot edit the registration.

To take a subject off the study:

1. Click **Take subject off study**. **Note:** The **Take subject off study** button will only appear under the **Enrollment Details** heading if the subject has a status of **Registered** in the study.
2. Enter the **Reason**.
3. Enter the **Date**.
4. Click **ok**.

To print the registration:

1. Scroll to the bottom of the page and click **Print**.

To export the registration:

1. Scroll to the bottom of the page and click **Export**.

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Studies

Create Study

To create a study, go to the C3PR home page, click the **Studies** tab in the top navigation bar and click on **Create Study**.

There are eight **Task** pages of the C3PR **Create Study** form that must be completed in order for a new study to be entered in C3PR.
Note: To enter Study Site information, or if you are creating a multi-site study, click the **Manage** button at the bottom of the **Overview** page (the last step listed below) and click **Study Sites**.

1. Details
2. Epochs & Arms
3. Eligibility
4. Stratification
5. Randomization
6. Diseases
7. Companion Studies

8. Overview

Important: When you click on the **Back**, **Save** or **Save & Continue** buttons at the bottom of each task page, C3PR will validate the field entries. If there are errors, C3PR will display the error message on the screen. All errors must be corrected in order to continue to the next task page. Data will only be saved if all the Required Fields of the task page that have a red asterisk next to them have been filled out correctly.

You must complete and save all the task pages in the **Create Study** form to receive a confirmation page that states the Study has been created successfully. When C3PR saves the data from each of the task pages, the study has not been created in C3PR until you click the **Create** or **Open** button at the bottom of the **Overview** page and view the confirmation page. Once you have received a confirmation page that states the Study has been created, the study may still need to be activated.

To Create A Study: Complete the instructions for the eight task pages listed below. **Note:** Any field with a red asterisk is required.

1. **Complete the Details task page:**

    1. Enter the **Short Title** for the study. This field limited to 30 characters in length.
    2. Enter the **Long Title** for the study. This is the descriptive text used to represent the long title name or name of a protocol.
    3. Enter the **Description** for the study. Enter the type of study being conducted by the Cancer Therapy Evaluation Program (CTEP).
    4. Enter the **Precis** for the study. This is the structure summary description of a protocol document.
    5. Enter the **Target Accrual** for the study. This is the total number of patients/subjects/participants needed for protocol enrollment (accrual).
    6. Select the **Type** of study. There are six types to select from.
    7. Select a **Phase** of the study. There are six phases to select from.
    8. Select if the study is **Blinded**. Select Yes or No from the drop down list. **Note:** If the selection is Yes, the Randomized field will default to Yes and the type is a Phone Call randomization.
    9. Select whether or not if the study is a **Multi-Institutional**. Select Yes or No
    10. Enter or select the **Consent Version/Date**. (mm/dd/yyyy)
    11. Select if the study is being **Stratified** from the drop down list.
    12. Select if the study is being **Randomized** from the drop down list. If the selection is Yes, select the **Type** of the randomization. The Type can be either **Book** or **Phone Call**. **Note:** If the type of the randomization is Book, then be prepared to locate and upload the Book randomization later on.
    13. Enter the name of the **Coordinating Center**. This is a pre-populated field. Enter the first few letters of the name of the Coordinating Center and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your

C3PR system administrator before you can continue. **Warning:** If the Name is not on the list you must notify your system administrator before you can continue.

14. Enter the name of the **Principle Investigator**. This is a pre-populated field. Enter the first few letters of the name of the Principle Investigator and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
15. Enter the Coordinating Center **Identifier**. This is the identifier assigned by the main site hosting the trial. This Identifier may be different from the identifier your site is using if you are not the coordinating center. The value can be text and/or numeric.
16. Enter the name of the **Funding Sponsor**. This is a pre-populated field. Enter the first few letters of the name of the **Funding Sponsor** and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
17. Enter the Funding Sponsor **Identifier**. The value can be text and/or numeric.
18. Click **Save** or **Save & Continue** to go to the next task page.

2. **Complete the Epochs & Arms task page:**
   An Epoch is a portion of the study containing one or more study segments with a consistent objective such as screening subjects or treating disease. No subject can take part in more than one epoch at any point in time. There are two types of Epochs ? The first type is Treatment epoch and the second type is Non-Treatment epoch (i.e. screening or follow up). Each treatment approach in a trial is referred to as an arm of the trial.

    1. Click **Add Epoch**.
    2. Enter the **Name**. This is a coded value which indicates the general scope of the activities that occur in the various arms of the Epoch. For Example: screening, treatment, follow-up, etc.
    3. Enter the **Order** of the epoch. The field accepts only an integer value. It uses to describe a period of time that cuts across the arms of a Study assuming time is depicted horizontally.
    4. Select **Yes** or **No** from the **Treating** drop down list to indicate in the epoch involves treatment.
    5. Select **Yes** or **No** from the **Enrolling** drop down list to indicate if entry into the epoch requires enrollment.
    6. Select **Yes** or **No** from the **Randomized** drop down list. This field determines whether the cross-cutting period of time in the Study requires that Subjects be randomized onto the Study. This selection available only if the randomization in the previous Details task page was selected as Yes. Also, if the study is blinded then the Randomization defaults to Yes and the type defaults to Phone call. At this point, it does not matter what type (book or phone call) of the randomization is being used.
    7. Enter the **Description** of the epoch. Add as much detail as possible.
    8. Enter the **Accrual Ceiling**. This is the maximum number of participants allowed or expected to participate in the epoch.
    9. Select **Yes** or **No** from the **Stratified** drop down list to indicate if the epoch involves stratification.
    10. Select **Yes** or **No** from the **Reserving** drop down list to indicate if a reservation for a position in the epoch can be made.
    11. Click **Add Arm** to add an Arm to the treatment epoch.

        1. Enter the **Name** of the Arm. An active Study requires having two or more Arms for each of the treatment epochs. If there is one Arm, then the Study is in a pending status. A treatment epoch can exist without adding an arm but only if it has no randomization.

2. Enter the **Description** of the arm. This is the full description of the details of the protocol treatment arm or group.
3. Enter the **Accrual Ceiling**. This field indicates the total number of patients targeted for accrual to an arm of a treatment epoch. Click on the if you wish to remove the Arm information.

12. Click **Save** or **Save & Continue** to go to the next task page. OR Click the **Save & Back** button if you need to adjust any information on the previous task page.

3. **Complete the Eligibility checklist criteria task page:**

1. **Upload Criteria:** if the Study has a treatment epoch you can select it from the **Select Epoch:** drop down list.
2. If you have a caDSR File to import click **Browse** to the right of the **Select caDSR File to Import:** and locate the file. Once you have located and selected the file, click **Upload**. **Note:** The caDSR file (available at the NCI formbuilder website) contains inclusion/exclusion criteria.
3. Click Add Inclusion Criterion.

    1. Enter a **Question** that would describe a complete set of text for an individual question/criterion on the eligibility checklist of a protocol. **Note:** NA - Allow Not Applicable answer, Yes, and No are permissible answers. Click on the to remove the Question.

4. Click **Add Exclusion Criterion**.

    1. Enter a Question that would describe a complete set of text for an individual question/criterion on the eligibility checklist of a protocol. Note: NA - Allow Not Applicable answer, Yes and No are permissible answers. Click on the to remove the Question.

5. Click **Save** or **Save & Continue** to go to the next task page.

4. **Complete the Stratification Factors Task page:**

1. Click **Add Stratification Factor** and enter the Stratification Question and Answers. This is a specific Question to be answered in order to identify the stratum group for the Study subject. Enter at least two **Answers** from the subject can choose from. Click **Add Answer** to create additional answers. **Note:** these are required fields. Click on the to remove both the question and answer.
2. Click **Generate Stratum Groups** to generate the stratum groups.
3. Click **Save** or **Save & Continue** to go to the next task page.

5. **Complete the Randomization task page:**

If you selected **Yes** for the **Randomization** drop down list and created a Stratification Group on the previous task pages you will need to fill out this page.

1. The information you enter on this page will depend on which Type (Phone Call or Book) you selected on the Details task page.
2. If you selected Phone Call, enter the appropriate number in the Phone Number: field for each Epoch and click Continue.
3. If you selected Book C3PR will accept either the Randomization **Book** or File. The Book allows the participants to manually enter the values in this sequence. The information must be in the following order: **Stratum Group Number, Position**, and **Arm Name**. The position always begins with zero (0) for every Stratum Groups Number. Note that every Randomization entry starts on a new line. The File allows the participants to upload a file instead of manually entering its value. Regardless of whether the Randomization is a Book or

File, the sequence must be the same. It must be in this order - Stratum Group Number, Position, and Arm Name. C3PR accepts either a .txt, .csv, or .doc file and will only accept only the Randomization Book or File. C3PR will accept whatever the last action (Book or File) was.
For Example: A Book Randomization is entered first and later a File Randomization is uploaded, C3PR accepts the File Randomization since it was the last action made to the Randomization procedure.

4. To upload the randomization Book (text containing the Book Randomization Entries), enter the Book in the **Randomization Book** field and then click **Upload the Randomization Book**.
5. Click **Save** or **Save & Continue** to go to the next task page.

6. **Complete the Diseases task page:**

    1. **Search for a Disease Category**. This is a prepopulated field. Enter the first few letters of the name of the Disease Category and select it from the drop down list that appears. The **Select a Sub Category** and **Diseases** fields will automatically display information based on your selection. **Warning:** If the Disease Category you are looking for is not in the drop down list that appears, contact your C3PR administrator. **Warning:** If the Disease Category has not been pre-defined, you must notify your C3PR system administrator before you can continue.
    2. Make a selection in the **Select a Sub Category** field.
    3. Make a selection in the **Diseases** field.
    4. Click **Add Study Disease**. The name of the study disease will appear in the **Selected Disease** box in the right hand side of the page. The Selected Disease box has two sections - **Disease Term** and **Primary**. Select the checkbox to indicate whether if it is the primary disease in the study.. Under the Disease Term, next to the disease?s name, there is a red x icon . You can click on the to remove the study disease or place a check mark in the box to indicate whether if the disease is a primary.
    5. Click **Save** or **Save & Continue** to go to the next task page.

7. **Complete the Companion Studies task page:**
   You may want to add a companion study for comparison of complimentary therapies. If you do not need to add a companion study you can click **Save & Continue** to go to the next task page

    1. Click **Add Companion Study** to add a companion study that is already entered in C3PR.

        1. Enter the **Companion Study Short Title**. The **Companion Study Short Title** field is pre-populated. Enter the first few letters of the name of the Companion Study and select the name from the drop down list that appears. **Note:** If the name of the Companion study does not appear in the drop down list go to **Studies > Create Companion Study** in the navigation bar to enter it and return to this page.
        2. Select the **Status**.
        3. Use the **Mandatory** drop down list to select if the Companion Study is mandatory.
    2. Click **Create Companion Study** if you want to enter a new companion study in C3PR.

        1. A pop-up screen will appear with a new **Create Companion Study** form to fill out. For step by step instructions go to the Create Companion Study section of this guide.
        2. Enter all the information for the Companion Study.
    3. Click **Save** or **Save & Continue** to go to the next task page.

8. **Complete the Overview task page:**
   Review all information entered and go to the bottom of the page and click the Create, Open or Manage button.
   Review the following

1. Review the **Study Details**
2. Review the **Epochs & Arms**
3. Review the **Eligibility**
4. Review the **Stratification**
5. Review the **Randomization**
6. Review the **Diseases**
7. Review the **Stratum Groups**
8. Review the **Diseases**
9. Review the **Companion Studies**
10. Review the **Overview**
11. At the bottom of the Overview task page there are three options:

    1. **Manage:** Click this button to enter and activate Study Sites as well as enter Identifiers, Investigators, Personnel and Notifications.
    2. **Create:** If you click the create button, the system will save the data that has been entered but the Study will not be active. A confirmation page will display that the Study was successfully created.
    3. **Open:** A Study can only be opened if all requirements are met. A confirmation page will display that the Study was successfully created.

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Create Companion Study

You may want to add a companion study for comparison of complimentary therapies. To create a Companion Study click the **Studies** tab in the top navigation bar and click **Create Companion Study**.
There are seven task pages that you will need to complete in the **Create Companion Study** form. Once the Companion Study has been entered you can add it to another study from the Search Study page.

1. Details
2. Epochs & Arms
3. Eligibility
4. Stratification
5. Randomization
6. Diseases
7. Overview

Important: When you click on the **Back**, **Save** or **Save & Continue** buttons at the bottom of each task page, C3PR will validate the field entries. If there are errors, C3PR will display the error message on the screen. All errors must be corrected in order to continue to the next task page. Data will only be saved if all the Required Fields of the task page that have a red asterisk next to them have been filled out correctly.

You must complete and save all the task pages in the **Create Companion Study** form to receive a confirmation page that states the Study has been created successfully. When C3PR saves the data from each of the task pages, the study has not been created in C3PR until you click the **Create** or **Open** button at the bottom of the **Overview** page and view the confirmation page. Once you have received a confirmation page

that states the Study has been created, the study may still need to be activated.

To Create A Companion Study: Complete the instructions for the seven Task pages listed below. **Note:** Any field with a red asterisk is required.

1. **Complete the Details task page:**

    1. Enter the **Short Title** for the study. This field limited to 30 characters in length.
    2. Enter the **Long Title** for the study. This is the descriptive text used to represent the long title name or name of a protocol.
    3. Enter the **Description** for the study. Enter the type of study being conducted by the Cancer Therapy Evaluation Program (CTEP).
    4. Enter the **Precis** for the study. This is the structure summary description of a protocol document.
    5. Enter the **Target Accrual** for the study. This is the total number of patients/subjects/participants needed for protocol enrollment (accrual).
    6. Select the **Type** of study. There are six types to select from.
    7. Select a **Phase** of the study. There are six phases to select from.
    8. Select if the study is **Blinded**. Select Yes or No from the drop down list. **Note:** If the selection is Yes, the Randomized field will default to Yes and the type is a Phone Call randomization.
    9. Select whether or not if the study is a **Multi-Institutional**. Select Yes or No
    10. Enter or select the **Consent Version/Date**. (mm/dd/yyyy)
    11. Select if the study is being **Stratified** from the drop down list.
    12. Select if the study is being **Randomized** from the drop down list. If the selection is Yes, select the **Type** of the randomization. The Type can be either **Book** or **Phone Call**. **Note:** If the type of the randomization is Book, then be prepared to locate and upload the Book randomization later on.
    13. Enter the name of the **Coordinating Center**. This is a pre-populated field. Enter the first few letters of the name of the Coordinating Center and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your C3PR system administrator before you can continue. **Warning:** If the Name is not on the list you must notify your system administrator before you can continue.
    14. Enter the name of the **Principle Investigator**. This is a pre-populated field. Enter the first few letters of the name of the Principle Investigator and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
    15. Enter the Coordinating Center **Identifier**. This is the identifier assigned by the main site hosting the trial. This Identifier may be different from the identifier your site is using if you are not the coordinating center. The value can be text and/or numeric.
    16. Enter the name of the **Funding Sponsor**. This is a pre-populated field. Enter the first few letters of the name of the **Funding Sponsor** and select it from the drop down list that appears. **Warning:** If the name does not appear in the drop down list you must notify your C3PR system administrator before you can continue.

17. Enter the Funding Sponsor **Identifier**. The value can be text and/or numeric.
18. Click **Save** or **Save & Continue** to go to the next task page.

2. **Complete the Epochs & Arms task page:**
   An Epoch is a portion of the study containing one or more study segments with a consistent objective such as screening subjects or treating disease. No subject can take part in more than one epoch at any point in time. There are two types of Epochs ? The first type is Treatment epoch and the second type is Non-Treatment epoch (i.e. screening or follow up). Each treatment approach in a trial is referred to as an arm of the trial.

   1. Click **Add Epoch**.
   2. Enter the **Name**. This is a coded value which indicates the general scope of the activities that occur in the various arms of the Epoch. For Example: screening, treatment, follow-up, etc.
   3. Enter the **Order** of the epoch. The field accepts only an integer value. It uses to describe a period of time that cuts across the arms of a Study assuming time is depicted horizontally.
   4. Select **Yes** or **No** from the **Treating** drop down list to indicate in the epoch involves treatment.
   5. Select **Yes** or **No** from the **Enrolling** drop down list to indicate if entry into the epoch requires enrollment.
   6. Select **Yes** or **No** from the **Randomized** drop down list. This field determines whether the cross-cutting period of time in the Study requires that Subjects be randomized onto the Study. This selection available only if the randomization in the previous Details task page was selected as Yes. Also, if the study is blinded then the Randomization defaults to Yes and the type defaults to Phone call. At this point, it does not matter what type (book or phone call) of the randomization is being used.
   7. Enter the **Description** of the epoch. Add as much detail as possible.
   8. Enter the **Accrual Ceiling**. This is the maximum number of participants allowed or expected to participate in the epoch.
   9. Select **Yes** or **No** from the **Stratified** drop down list to indicate if the epoch involves stratification.
   10. Select **Yes** or **No** from the **Reserving** drop down list to indicate if a reservation for a position in the epoch can be made.
   11. Click **Add Arm** to add an Arm to the treatment epoch.

       1. Enter the **Name** of the Arm. An active Study requires having two or more Arms for each of the treatment epochs. If there is one Arm, then the Study is in a pending status. A treatment epoch can exist without adding an arm but only if it has no randomization.
       2. Enter the **Description** of the arm. This is the full description of the details of the protocol treatment arm or group.
       3. Enter the **Accrual Ceiling**. This field indicates the total number of patients targeted for accrual to an arm of a treatment epoch. Click on the if you wish to remove the Arm information.

   12. Click **Save** or **Save & Continue** to go to the next task page. OR Click the **Save & Back** button if you need to adjust any information on the previous task page.

3. **Complete the Eligibility checklist criteria task page:**

   1. **Upload Criteria:** if the Study has a treatment epoch you can select it from the **Select Epoch:** drop down list.
   2. If you have a caDSR File to import click **Browse** to the right of the **Select caDSR File to Import:** and locate the file. Once you have located and selected the file, click **Upload**. **Note:** The caDSR file (available at the NCI formbuilder website) contains inclusion/exclusion

criteria.

3. Click Add Inclusion Criterion.

    1. Enter a **Question** that would describe a complete set of text for an individual question/criterion on the eligibility checklist of a protocol. **Note:** NA - Allow Not Applicable answer, Yes, and No are permissible answers. Click on the to remove the Question.

4. Click **Add Exclusion Criterion**.

    1. Enter a Question that would describe a complete set of text for an individual question/criterion on the eligibility checklist of a protocol. Note: NA - Allow Not Applicable answer, Yes and No are permissible answers. Click on the to remove the Question.

5. Click **Save** or **Save & Continue** to go to the next task page.

4. **Complete the Stratification Factors Task page:**

    1. Click **Add Stratification Factor** and enter the Stratification Question and Answers. This is a specific Question to be answered in order to identify the stratum group for the Study subject. Enter at least two **Answers** from the subject can choose from. Click **Add Answer** to create additional answers. **Note:** these are required fields. Click on the to remove both the question and answer.
    2. Click **Generate Stratum Groups** to generate the stratum groups.
    3. Click **Save** or **Save & Continue** to go to the next task page.

5. **Complete the Randomization task page:**
   If you selected **Yes** for the **Randomization** drop down list and created a Stratification Group on the previous task pages you will need to fill out this page.

    1. The information you enter on this page will depend on which Type (Phone Call or Book) you selected on the Details task page.
    2. If you selected Phone Call, enter the appropriate number in the Phone Number: field for each Epoch and click Continue.
    3. If you selected Book C3PR will accept either the Randomization **Book** or File. The Book allows the participants to manually enter the values in this sequence. The information must be in the following order: **Stratum Group Number, Position**, and **Arm Name**. The position always begins with zero (0) for every Stratum Groups Number. Note that every Randomization entry starts on a new line. The File allows the participants to upload a file instead of manually entering its value. Regardless of whether the Randomization is a Book or File, the sequence must be the same. It must be in this order - Stratum Group Number, Position, and Arm Name. C3PR accepts either a .txt, .csv, or .doc file and will only accept only the Randomization Book or File. C3PR will accept whatever the last action (Book or File) was.
       For Example: A Book Randomization is entered first and later a File Randomization is uploaded, C3PR accepts the File Randomization since it was the last action made to the Randomization procedure.
    4. To upload the randomization Book (text containing the Book Randomization Entries), enter the Book in the **Randomization Book** field and then click **Upload the Randomization Book**.
    5. Click **Save** or **Save & Continue** to go to the next task page.

6. **Complete the Diseases task page:**

1. **Search for a Disease Category**. This is a prepopulated field. Enter the first few letters of the name of the Disease Category and select it from the drop down list that appears. The **Select a Sub Category** and **Diseases** fields will automatically display information based on your selection. **Warning:** If the Disease Category you are looking for is not in the drop down list that appears, contact your C3PR administrator. **Warning:** If the Disease Category has not been pre-defined, you must notify your C3PR system administrator before you can continue.
2. Make a selection in the **Select a Sub Category** field.
3. Make a selection in the **Diseases** field.
4. Click **Add Study Disease**. The name of the study disease will appear in the **Selected Disease** box in the right hand side of the page. The Selected Disease box has two sections - **Disease Term** and **Primary**. Select the checkbox to indicate whether if it is the primary disease in the study.. Under the Disease Term, next to the disease?s name, there is a red x icon . You can click on the to remove the study disease or place a check mark in the box to indicate whether if the disease is a primary.
5. Click **Save** or **Save & Continue** to go to the next task page.

7. **Complete the Overview task page:**
   Review all information entered and go to the bottom of the page and click the Create, Open or Manage button.
   Review the following

    1. Review the **Study Details**
    2. Review the **Epochs & Arms**
    3. Review the **Eligibility**
    4. Review the **Stratification**
    5. Review the **Randomization**
    6. Review the **Diseases**
    7. Review the **Stratum Groups**
    8. Review the **Diseases**
    9. Review the **Overview**
    10. At the bottom of the Overview task page there are three options:

        1. **Manage:** Click this button to enter and activate Study Sites as well as enter Identifiers, Investigators, Personnel and Notifications.
        2. **Create:** If you click the create button, the system will save the data that has been entered but the Study will not be active. A confirmation page will display that the Study was successfully created.
        3. **Open:** A Study can only be opened if all requirements are met. A confirmation page will display that the Study was successfully created.

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Manage & Edit Study

You can manage and edit study information when you click the **Manage** button at the bottom of the **Overview** page after you have finished entering a study, or if you search for a study and click the **Edit Study** button at the bottom of the **Study Summary** page. The instructions below explain how to enter information for Study Sites, Study Identifiers, Study Investigators, Study Personnel and Study Notifications as well as

how to review registrations.

1. Summary
2. Study Sites
3. Manage Sites
4. Study Identifiers
5. Study Investigators
6. Study Personnel
7. Study Notifications
8. Registrations

1. **Summary**
   From the Summary page, you can review all information entered for the following sections:

   1. Study Details
   2. Epochs & Arms
   3. Stratification Factors
   4. Stratum Groups
   5. Diseases
   6. Identifiers
   7. Companion Studies
   8. Amendments

   To change or add information, scroll to the bottom of the page and click the **Edit Study** button. Scroll to the bottom of the page to click the button for any of the following actions:

   - Close Study
   - Amend Study
   - Export Study
   - Print Study

2. **Study Sites:**

   1. Enter the **Organization** conducting the trial. This is a prepopulated field. Enter the first few letters of the name of the Organization and select it from the drop down list that appears. **Note:** If you are entering a multi-site study, click **Add Organization** and enter the name of another site. Repeat until all sites for the study have been added.
   2. Enter the **Activation Date** (mm/dd/yyyy). This is the date that a site begins participation in a Study. You can also click on the Calendar icon to select a date.
   3. Enter the **IRB Approval Date** (mm/dd/yyyy). This is the date that the institutional review board or research ethics board authorized approval or most recent approval of

the Study protocol for that site.

4. Enter the **Target Accrual Number**. This is the total number of patients/subjects/participants needed for protocol enrollment at this site.
5. Click **Save**.

3. **Study Identifiers:**

There are two types of study identifiers used in C3PR, Organization Assigned Identifiers and System Assigned Identifiers. Organization Assigned Identifiers are a number or code assigned by an Organization (such as Mayo Clinic, Wake Forest or Duke University). System Assigned Identifiers are a number or code assigned by a System (such as caAERS, C3PR or PSC). C3PR will automatically add two Identifiers for Organization, based on what was entered for the Coordinating Center and the Funding Sponsor on the initial Details page when the study was created. The Coordinating Center will be listed as the primary indicator. You can add as many Organization and System Assigned Identifiers as you would like.

To add on another **Organization Assigned Identifier**:

1. Click **Add Another Identifier**.
2. Enter the **Assigning Authority**. This is the name of the Organization (such as Mayo Clinic, Duke University or Wake Forest) that created the identifier number or code. Enter the first few letters of the name of the Organization and select it from the drop down list that appears.
   Warning: If the name of the **Assigning Authority** you are looking for does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
3. Select the **Identifier Type** from the drop down list.
4. Enter the **Identifier**. This is the actual identifier number or text.
5. Select **Primary Indicator**, if applicable.

To add on another **System Assigned Identifier**:

1. Click **Add Another Identifier**.
2. Enter the **System Name**. This is the name of the system (C3PR, caAERS or PSC) that created the identifier number or text.
3. Select the **Identifier Type** from the drop down list.
4. Enter the **Identifier**.
5. Select the **Primary Indicator**, if applicable.
6. Click **Save**.

4. **Study Investigators:**

1. Select an **Organization** from the drop down list.
2. Select a **Group**.
3. Select **Investigators. Note:** To select multiple Investigators, hold down the Ctrl button and click on any names listed.
4. Click **Add Investigators**.
5. Investigators will appear in a box in the right hand side of the page. Use the **Status** drop down list to select the status of each investigator.
6. Click **Save**.

5. **Study Personnel:**

1. **Select an Organization**. Make a selection from the drop down list.
2. Select **Research Staff**. **Note:** To select multiple names, hold down the **Ctrl** button and click on any names listed.
3. Click **Add Research Staff**.

4. Research Staff will appear in a box in the right hand side of the page. Select the appropriate **Role** and **Status** from the drop down lists. Go to the Roles section of this guide for an explanation of tasks performed by each role.
5. Click **Save**.

6.**Study Notifications:**
You can set e-mail notifications to be sent out based on specified Threshold criteria.

1. Click **Add Notification**.
2. Enter the **Threshold**. This is the number of subjects that need to be registered in order to trigger an e-mail notification.
3. Click **Add Email** and enter the appropriate e-mail address.
4. Click **Add Role** and select the appropriate Role from the drop down list.
5. Click **Save**.

7. **Registrations:**
Review all registrations listed for the study on the Registrations page. Click on any Registration that is listed to view more information or change the current epoch for a subject.

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Search Study

From the C3PR home page, click the **Studies** tab and click on **Search Study**.
To search for a study:

1. Click on the **Search By:** drop down list and select an option .
2. Enter the **Identifier**, **Short Title** or **Status** in the **Search Criteria** field and click the **Search** button. **Note:** You can also leave the Search Criteria field blank and click Search to list all studies in the system.
3. Search results will appear in the bottom of the page. Click on a study to open it. Go to the bottom of the Study Summary page and click **Edit Study** to change or add information.

Note: You can export search results in Word .xls format by going to the top of the **Search Results** box and clicking the **Export XLS** icon in the top right hand side of the box.

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Exporting Studies

To export a study you will first need to pull up the study from the **Search Study** page in C3PR.

To search for the study you want to export:

1. From the C3PR home page, click the **Studies** tab in the top navigation bar.
2. Click on the **Search By:** drop down list and select an option .
3. Enter the **Identifier**, **Short Title** or **Status** and click the **Search** button.

4. Search results will appear in the bottom of the page. Click on a study to open it.

To export the study:

1. After you have opened the study from the **Search Study** page, scroll to the bottom of the page and click the **Export Study** button.
2. Save the study in XML format.

Editing Studies

To edit a study you will first need to pull up the study from the **Search Study** page in C3PR.

To search for the study you want to edit:

1. From the C3PR home page, click the **Studies** tab in the top navigation bar.
2. Click on the **Search By:** drop down list and select an option .
3. Enter the **Identifier**, **Short Title** or **Status** and click the **Search** button.
4. Search results will appear in the bottom of the page. Click on a study to open it.

To edit the study:

1. After you have opened the study from the **Search Study** page, scroll to the bottom of the page and click the **Edit Study** button.
2. Make edits to the appropriate fields and click the **Save** button or click the **Save & Continue** button to edit the next task page in the study.
   Note: To go to a specific task page of the study, click the **Related Tasks** tab in the left hand side of the page and select the appropriate task page. Make sure to click the **Save** button or the **Save & Continue** button when you are done.
   Note: If you are editing a multi-study site, make sure to come back to this page and click the **Refresh** and **Broadcast** buttons after you have saved your edits.

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Amending Studies

A study must have an **Active** status before it can be amended. To amend a study you will first need to pull up the study from the **Search Study** page in C3PR.

To search for the study you want to edit:

1. From the C3PR home page, click the **Studies** tab in the top navigation bar and click on **Search Study** in the drop down list that appears.
2. Click on the **Search By:** drop down list and select an option.
3. Enter the **Identifier**, **Short Title** or **Status** and click the **Search** button.
4. Search results will appear in the bottom of the page. Click on a study to open it.

To amend the study:

1. After you have opened the study from the **Search Study** page, scroll to the bottom of the page and click the **Amend Study** button.
2. Under the **New Amendment** heading enter the Version #.
3. Enter the **Amendment Date**.
4. Enter any **Comments**.
5. Select appropriate checkboxes under **Reasons for Amendment** .
6. Click the **Save** button or click the **Save & Continue** button to edit the next task page in the study.
   Note: To go to a specific task page of the study, click the **Related Tasks** tab in the left hand side of the page and select the appropriate task page. Make sure to click the **Save** button or the **Save & Continue** button when you are done editing a task page.
   Related Tasks Tab

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Printing Studies

To print a study you will first need to pull up the study from the **Search Study** page in C3PR.

To search for the study you want to edit:

1. From the C3PR home page, click the **Studies** tab in the top navigation bar and click on **Search Study** in the drop down list that appears.
2. Click on the **Search By:** drop down list and select an option.
3. Enter the **Identifier**, **Short Title** or **Status** and click the **Search** button.
4. Search results will appear in the bottom of the page. Click on a study to open it.

To print the study:

1. After you have opened the study from the **Search Study** page, scroll to the bottom of the page and click the **Print** button.

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Person and Organization

Subject

Search Subject

From the C3PR home page click the **Person And Organization** tab in the main navigation bar, select **Subject** and click **Search Subject** in the drop down list that appears.

To search for a subject:

1. Click on the **Search By:** drop down list and select **Last Name**, **First Name** or **Identifier**.
2. Enter the **Last Name**, **First Name** or **Identifier** in the **Search Criteria** field and click the **Search** button. **Note:** You can also leave the Search Criteria field blank and click Search to list all studies in the system.
3. Search results will appear in the bottom of the page. Click on a subject to view and/or edit the summary profile.

Create Subject

From the C3PR home page click the **Person And Organization** tab in the main navigation bar, select **Subject** and click **Create Subject** in the drop down list that appears.

You will need to complete the following task pages to enter a new subject into C3PR.

1. Details.
2. Address & Contact Information.
3. Review and Submit.

To Create A Subject:

1. **Complete the Details task page:**
    1. Enter the **First Name** for the subject.
    2. Enter the **Last Name** for the subject.
    3. Enter the **Middle Name** for the subject.
    4. Enter the **Maiden Name** for the subject.
    5. Select the **Gender** for the subject.
    6. Enter the **Birth Date** for the subject.
    7. Select the **Ethnicity** for the subject.
    8. Select the **Race(s)** for the subject.
    9. Enter the **Organization**. Type the first few letters of the name of the organization and select the name from the drop down list that appears. **Warning:** This is a pre-populated field. If the Organization field has not being pre-populated you must notify your system administrator before you can continue.
    10. Enter an Identifier for **Organization Assigned Identifiers**. Click the **Add Another Identifier** button under the **Organization Assigned Identifiers** header.
        1. Enter the **Assigning Authority**. This is a prepopulated field. This is the name of the Organization (such as Mayo Clinic, Duke University or Wake Forest) that assigned the identifying number or code. Enter the first few letters of the name of the Organization and select it from the drop down list that appears. Warning: If the name

of the Assigning Authority you are looking for does not appear in the drop down list you must notify your C3PR system administrator before you can continue.
2. Select the **Identifier Type**.
3. Enter the **Identifier**.
4. Indicate whether or not if the subject is a Primary Indicator.

11. Enter an Identifier for **System Assigned Identifiers**.

    1. Enter **System Name**. This is the system (such as C3PR, caAERS or PSC) that assigned the identifying number or code.
    2. Select the **Identifier Type**.
    3. Enter the **Identifier**.
    4. Indicate whether or not if the subject is a **Primary Indicator**.

12. Click **Continue**.

2. **Complete the Address & Contact Info task page:**

    1. Enter the **Street Address**.
    2. Enter the **City**.
    3. Enter in the **State**.
    4. Enter in the **Zip**.
    5. Enter in the **Country**.
    6. Enter in the **Email**.
    7. Enter in the **Phone**.
    8. Enter in the **Fax**.
    9. Click the **Continue** button.

3. **Complete the Review and Submit task page:**

    1. Review the **Basic Details**.
    2. Review the **Address**.
    3. Review the **Contact Information**.
    4. Review the **Identifier**.
    5. Click the **Save** button.

If all the task pages have been completed correctly C3PR will display that the Subject has been created successfully.

Investigator

Search Investigator

To search for an investigator, go to the C3PR home page click the **Person & Organization** tab, select **Investigator** and click on **Search Investigator** in the drop down list that appears.

To search for an investigator:

1. Enter the **First Name**, **Last Name** or **NCI Identifier**. **Note:** A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
2. Click **Search**.
   Note: You can also leave the search fields blank and click Search to list all investigators in the system.
3. Search results will appear in the bottom of the page. Click on an investigator in the search results to view and/or edit the profile.

Create Investigator

From the C3PR home page click the **Person & Organization** tab, select **Investigator** and click on **Create Investigator** in the drop down list that appears.
To add a new Investigator:

1. Select the **Organization** or the study site where the investigator exists. **Note:** This is a pre-populated field. Enter the first few letters of the name of the Organization and select it from the drop down list that appears. If the Organization is not on the list you can go to **Person & Organization > Organization > Create Organization** in the navigation bar. After you have entered the Organization, return to this page and it should appear in the drop down list.
2. Select the **Investigator Status** from the drop down list. Select **Active** or **Inactive**. This is the code value that represents the activity status of the Study site investigator that will grant that investigator activity capability within that site context.
3. Enter the **First Name** of the investigator.
4. Enter the **Last Name** of the investigator.
5. Enter the **Middle Name** of the investigator.
6. Enter the **Maiden Name** of the investigator.
7. Enter the **NCI Identifier** of the investigator. **Note:** A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
8. Enter the **Email** or **Username** of the investigator.
9. Enter the **Phone number** of the investigator.
10. Enter the **Fax** number of the investigator.
11. Click on **Save** to create a new investigator.
12. Select the **Organization**.
13. Select a **Group**. If a group does not exist, and the participants want to add a group for the investigator, then click on **Add Group**.
14. To add an investigator group, click on **Add Group**.
15. Enter the **Name** of the group.
16. Enter the **Start** Date.
17. Enter the **End** Date.
18. Enter the **Description** of the group investigator.
19. To add a new Investigator to the group investigator, click on **Add Investigator**.
    1. Select the Investigator from the list by typing a first or few letters of the investigators first or last name.
    2. Enter the **Start Date**.
    3. Enter the **End Date**.
20. Click **Save**.

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Investigator Groups

From the C3PR home page click the **Person & Organization** tab, select **Investigator** and click on Investigator Groups in the drop down list that appears.

To add an investigator group:

1. Enter an Organization. This is a prepopulated field. Enter the first few letters of the name of the Organization and select it from the drop down list that appears.
   Note: If the name of the Organization does not appear in the drop down list go to **Person & Organization > Organization> Create Organization** in the navigation bar and enter it. If your permissions do not allow you to enter Organizations contact your C3PR administrator.
2. **Select a Group** to view and edit information. Click **Add Group** in the right hand side of the page to enter and save information for new groups. If you want to add investigators to the group click **Add Investigator** in the right hand side of the page and enter the first few letters of the name of the **Investigator** in the text field and select it from the drop down list that appears.
3. Click **Save** when you are done making any edits.

Research Staff

Search Research Staff

From the C3PR home page click the **Person & Organization** tab and select **Research Staff** and click on **Search Research Staff** in the drop down list that appears.

To search for research staff personnel:

1. Enter the First Name, Last Name or NCI. Identifier.
   Note: A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
2. Click **Search**.
   Note: You can also leave the search fields blank and click Search to list all research staff in the system.
3. Search results will appear in the bottom of the page. Click on research staff in the search results to view and/or edit staff profiles.

Create Research Staff

From the C3PR home page click the **Person And Organization** tab and select **Research Staff** and click on **Create Research Staff** in the drop down list that appears.

To create new Research Staff:

1. Select the **Organization** where the research staff are located.
2. Enter the **First Name** of the research staff.
3. Enter the **Last Name** of the research staff.
4. Enter the **Middle Name** of the research staff.
5. Enter the **Maiden Name** of the research staff.
6. Enter the **NCI Identifier** of the research staff. **Note:** A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
7. Enter the **Email** or **Username** of the research staff.
8. Enter the **Phone** number of the research staff.
9. Enter the **Fax** number of the research staff.
10. Check the user role for the research staff. Check at least one or check all the roles that apply and click the **Save** button.

    - C3pr admin
    - Study coordinator
    - Registrar
    - Site coordinator

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Organization

Search Organization

From the C3PR home page click the **Person & Organization** tab and select **Organization** and click on **Search Organization** in the drop down list that appears.

To search for an organization:

1. Enter the **Name** of the Organization.
2. Enter the NCI Identifier.
   Note: A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt
3. Click **Search**.
   Note: You can leave the search fields blank and click Search to list all organizations in the system.
4. Search results will be listed in the bottom of the page. Click on an Organization to view and/or edit it. You can sort results by entering the appropriate information in the Name and NCI Identifier text fields at the top of each column and clicking the **Filter** button at the top right column of the **Search Results** box.

Create Organization

C3PR includes a list of hundreds of CTEP organizations as part of the basic install. In C3PR, the names of all Coordinating Centers, Funding Sponsors and Study Sites are entered as Organizations. If needed, additional organizations can be added to the list on this page. To manually enter an Organization not found in the installed list, go to the C3PR home page click the **Person & Organization** tab and select **Organization** and click on **Create Organization** in the drop down list that appears.

To add a new Organization:

1. Enter the **Name** of the oganization.
2. Enter the **Description** of the organization.
3. Enter the **NCI Institue Code** of the organization.
4. Enter the **Street Address** of the organization.
5. Enter the **City** of the organization.
6. Enter the **State** of the organization.
7. Enter the **Zip** code of the organization.
8. Enter the **Country** that the organization located.
9. Click on the **Save** button.

Administration

Important: C3PR Administrators must enter information for Investigators, Research Staff, Organizations, Studies and Registrations before end users can enter information into the C3PR application.

Notification

You can set notifications that will send out e-mail updates (notifications/reports) to investigators and research staff when a specific event occurs in a study. For example, you can create an e-mail notification to be sent if you want users to receive an e-mail message when a study is activated or has new registrations.
From the C3PR home page click the **Administration** tab and click on **Notification** in the drop down list that appears.
To create an e-mail notification:

1. Click **Add Notification**.
2. Select the type of **Event** from the drop down list. The notification e-mail will be sent immediately after the event occurs.
   Note: You have the option in this drop down list to select New Registrations Report. This will not send an e-mail notification every time a patient is registered to a study. Select Annual, Monthly or Weekly from the Frequency drop down list to determine how often the report is sent out.
3. Enter **Message Details**. This is the message body of the notification that is sent out every time the chosen event occurs. Click **Update** after you have entered the message. You can select Substitution Variables into the message and these are replaced with the actual value when the e-mail is sent.

Note: For example, if you select **Study Short Title** from the substitution variables drop down list ${STUDY_SHORT_TITLE} will be inserted into the message and will automatically enter the short title of the study into the message. The message details section does not need to be filled out for New Registrations Report.

4. To enter recipients of the notification individually, click **Add Email/Name** to add recipients for the e-mail notification. This is a prepopulated field. Enter the first few letters of the first/last name or e-mail address of the investigator or research staff and select it from the drop down list that appears.
   OR
5. To enter recipients based on their role in the study, click **Add Role** and make a selection from the drop down list.
   Note: Only investigators and research staff that are entered in C3PR for the hosted site will appear in the drop down list. To add investigators and research staff for the hosted site go to **Person & Organization > Investigators> Create Investigator** OR **Person & Organization > Research Staff > Create Research Staff** in the navigation bar. You can add multiple notifications for the hosted site. Click **Add Notification** to enter additional notifications.
6. Click **Save**.

Import Study

To import studies, go to the C3PR home page and click the **Administration** tab and click on **Import Study** in the drop down list that appears.
To Import a Study:

1. Select XML file to import by clicking on the **Browse** button and locating the file. To see an example of how an XML file should be formatted before it is imported, click the **Download Schema File** and **Download Sample XML File** links.
2. Click on **Import** to import Study.
3. Click on the Study that has just been imported and change the status of the **Study Sites** before you import the registration.
   Note: For instructions on how to enter a study manually go to the Studies section.

Import Registration

From the C3PR home page click the **Administration** tab and click on **Import Registration** in the drop down list that appears.

Important: The Study site must already be activated before you can import registrations.

To import a Registration:

1. Select XML file to import by clicking on the **Browse** button and locating the file.
2. Click the **Import** button.
   Note: To enter a registration manually, go to Registration.

Configure C3PR

From the C3PR home page click the **Administration** tab and click on **Configure C3PR** in the drop down list that appears.
The configurations for C3PR are as follows:

Authentication Mode
This defines the strategy C3PR uses to authenticate. Possible values are 'local' and 'webSSO' (Default: local)

Authorization enable switch
Switch to turn on/off authorization. The value may not be applied until the application is restarted (Default: false)

C3D hotlink URL
The base URL for the C3D deployment to which this C3PR instance can link (Default: https://octrials-train.nci.nih.gov/opa45/rdclaunch.htm)

C3PR URL
This is the URL of this C3PR instance.

caAERS hotlink URL
The base URL for the caAERS deployment to which this C3PR instance can link (Default: https://cbvapp-d1017.nci.nih.gov:28443/caaers/pages/ae/list)

WebSSO base URL
(Default: https://cbvapp-d1017.nci.nih.gov:48443/cas)

WebSSO certificate file
websso certificate file path (Default: /System/Library/Frameworks/JavaVM.framework/Versions/1.5.0/Home/lib/security/cacerts)

ESB enable switch
Switch to turn on/off esb (Default: false)

ESB URL
URL for the enterprise service bus -- the value may not be applied until the application is restarted (Default: https://cbvapp-d1017.nci.nih.gov:28445/wsrf/cagrid/CaXchangeRequestProcessor)

Host certificate file (host certificate file path)
(Default: /Users/kherm/certs/manav.local-cert.pem)

Host key
Host key path (Default: /Users/kherm/certs/manav.local-key.pem)

Hosted Mode
If the value is false, C3PR will not send a registration request to Co-ordinating center for approval for Multi-Site trials (Default: true)

Local site NCI institute code
The NCI institute code of the site where this C3PR instance is running

SMTP authentication
(Default: true)

From address
The "from" address for all mail sent by C3PR. This address need not be a real e-mail address. The value may not be applied until the application is restarted (Default: admin@semanticbits.com)

SMTP password
Mail server password (only necessary if the mail server requires authentication). The value may not be applied until the application is restarted (Default: biju1234)

SMTP server
The address of the outgoing mail server (e.g.: smtp.gmail.com). The value may not be applied until the application is restarted (Default: smtp.comcast.net)

SMTP port
The port number of the outgoing mail server. The value may not be applied until the application is restarted (Default: 25)

SMTP user name
Mail server username (only necessary if the mail server requires authentication). The value may not be applied until the application is restarted (Default: biju.joseph@semanticbits.com)

Study Calendar hotlink URL
The base URL for the Study Calendar deployment to which this C3PR instance can link (Default: https://cbvapp-d1017.nci.nih.gov:28443/psc/pages/schedule)

Save Your Configuration
Once you have completed C3PR configurations, click **Save**.

Configure Password Policy

From the C3PR home page click the **Administration** tab and click **Configure Password Policy** in the drop down list that appears.

1. Enter the appropriate criteria for the following:
    1. Login Policy
    2. Password Creation Policy
    3. Complexity Requirement
2. Click **Save**.

Advanced Search

Search Registration

From the C3PR home page click the **Advanced Search** tab and click **Search Registrations** in the drop down list that appears.

Study Criteria:

1. **Short Title** - Enter the Short Title of the study the registration is associated with.
   Note: If you do not know the full name of the Short Title or any of the other search criteria on this page, you can enter the first two letters of the name of the title in the Short Title field and click Search. C3PR will list all registrations in the system that belong to a study that begins with those two letters.
2. **Identifier** - Enter the study Identifier, if known.

Registration Criteria:

1. **Start Date** - Enter the start date (mm/dd/yyyy) or click the calendar icon to select it.
2. **End Date** - Enter the start date (mm/dd/yyyy) or click the calendar icon to select it.

Site Criteria:

1. **Site Name** - Enter the site name.
2. **NCI ID** - Enter the NCI ID. Note: A list of NCI Identifier Codes can be found at http://ctep.cancer.gov/forms/Organization_Codes.txt

Search Study

From the C3PR home page click the **Advanced Search** tab and click **Search Study** in the drop down list that appears.

To search for a Study:

Study Criteria:

1. Enter the **Short Title** and/or the **Identifier**.
2. If you do not know the full name of the Short Title or know the Identifier, you can enter the first two letters of the name of the title in the Short Title field and click Search. C3PR will list all studies in the system that begin with those two letters.

Participant Criteria:

1. Enter the **Short Title** or **Status** in the Search Criteria field and click the **Search** button.
2. Search results will appear in the bottom of the page. Click on a study to view and/or edit it.

3. You can sort results by entering the appropriate information in the text fields at the top of each column in the Results section and clicking the Filter button.

Note: You can export search results in Word .xls format by going to the top of the Search Results box and clicking the Export XLS icon in the top right hand side of the box.

Appendix A: Glossary

Term	Definition
AJAX	Asynchronous JavaScript and XML
API	Application Programming Interface
BC	Binding Component
caArray	cancer Array Informatics
caBIG	cancer Biomedical Informatics Grid
caBIO	cancer Biomedical Infrastructure Objects
caCORE	cancer Common Ontologic Representation Environment
caDSR	cancer Data Standards Repository
C3PR	Cancer Translational Research Informatics Platform
CDE	Common Data Element
CSM	Common Security Module
CSV	Comma Delimited
DAO	Data Access Objects
DCQL	Distributed Common Query Language
DWR	Direct Web Remoting
EA	Enterprise Architect
ESB	Enterprise Service Bus
EVS	Enterprise Vocabulary Services
GAARDS	Grid authentication and authorization with Reliably Distributed Services
GUI	Graphical User Interface
HASTE	High-level Automated System Test Environment
HTTP	Hypertext Transfer Protocol
IdP	Identity Provider
JAAS	Java Authentication and Authorization Service
JAR	Java Archive
Javadoc	Tool for generating API documentation in HTML format
JDBC	Java Database Connectivity
JMS	Java Message Service
JSP	JavaServer Pages
JUnit	A simple framework to write repeatable tests
metadata	Definitional data that provides information about documentation or other data
NCI	National Cancer Institute

NCICB	National Cancer Institute Center for Bioinformatics
NMR	Normalized Message Router
ORM	Object Relational Mapping
RDBMS	Relational Database Management System
SDK	Software Development Kit
SE	Service Engine
Semantic connector	A development kit to link model elements to NCICB EVS concepts
SQL	Structured Query Language
UML	Unified Modeling Language
WSRF	Web service resource framework

Appendix B: References

Technical Manuals/Articles

1. National Cancer Institute. "caCORE 3.2 Technical Guide", ftp://ftp1.nci.nih.gov/pub/cacore/caCORE3.2_Tech_Guide.pdf
2. Java Bean Specification: http://java.sun.com/products/javabeans/docs/spec.html
3. Foundations of Object-Relational Mapping: http://www.chimu.com/publications/objectRelational/
4. Object-Relational Mapping articles and products: http://www.service-architecture.com/object-relational-mapping/
5. Hibernate Reference Documentation: http://www.hibernate.org/hib_docs/reference/en/html/
6. Basic O/R Mapping: http://www.hibernate.org/hib_docs/reference/en/html/mapping.html
7. Java Programming: http://java.sun.com/learning/new2java/index.html
8. Javadoc tool: http://java.sun.com/j2se/javadoc/
9. JUnit: http://junit.sourceforge.net/
10. Extensible Markup Language: http://www.w3.org/TR/REC-xml/
11. XML Metadata Interchange: http://www.omg.org/technology/documents/formal/xmi.htm

caBIG Material

1. caBIG: http://cabig.nci.nih.gov/
2. caBIG Compatibility Guidelines: http://cabig.nci.nih.gov/guidelines_documentation

caCORE Material

1. https://wiki.nci.nih.gov/display/CommonProjects/caBIG-CBIIT+Tools+DOCUMENTATION+Index+Page+(C