C3PR Test Plan

TODO: Number all sections

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Sub Pages

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.

Scope

Resources

The C3PR project development page can be found at:

- https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR_Project

Document Organization

This document is organized by major application component (e.g. study management, subject management, subject registration, etc.). Each section is then divided further into a set of tests that describe specific business cases. Each test has a high level description, a set of steps to execute the test, special circumstances that should be considered, and the expected output.

1. Studies

1.1 Create Simple Treatment Study

User creates a basic non-randomized treatment study. In this study, the physician directly assigns the subject to an arm (it is not a randomized study). It has a single epoch named Treatment, and eligibility is captured electronically by selecting whether the subject is eligible or not.

1.1a Steps

1. Enter the study flow by clicking the Studies tab.
2. Click create Study.
3. Specify the short title, Long title, and target accrual.
4. Select the type of study and study phase.
5. Set blinded to No.
6. Specify stratified as No.
7. Specify randomized as No.
8. Choose coordinating center as site NC010 [Duke University Medical Center]
9. Specify the coordinating center study identifier.
10. In the principal investigator section, choose organization as NC010.
11. Type the first few characters of the name of the PI in the principal investigator auto-suggest box. If the PI is not already existing in C3PR, you can create one by clicking "create principal investigator"
12. Click save and continue.
13. You are now in the Consent page.
14. Choose mandatory consents value as one.
15. Click on add consent and specify the consent name as 'consent 1'.
16. Click save and continue.
17. You are now in the Epochs and Arms page.
18. Click' Add epoch'
19. A new blank epoch panel will be created.
20. Specify the name of the epoch as 'treating epoch'
21. Set other values as following:
    a. order =1
    b. treating = yes
    c. enrolling = yes
    d. randomized = no
    e. reserving= no
22. Click 'Add arm' button twice and specify the arms names as 'aa' and 'bb'
23. You are now in the Eligibility tab.
24. Add any required inclusion and exclusion criteria and click save and continue.
25. You are now in the Stratification tab.
26. This study does not require stratification.
27. Click save and continue.
28. You are now in the Randomization tab.
29. This study does not require randomization.
30. Click save and continue.
31. You are now in the Diseases tab.
32. Add diseases if any and click save and continue.
33. You are now in the Companion studies tab.
34. We will not be adding any companion studies, hence click save and continue.
35. You are now in the overview tab.
36. Verify all details are correctly recorded then click on the 'Open study' link.
37. In the 'confirm' pop up specify a valid date and click 'Open study'
38. You should get a 'Study opened successfully' message
39. You have now successfully created a simple treatment study.

1.1b Special Considerations

None

1.1c Expected Output

1.2 Create Phone Call Randomized Study

A Site Coordinator / Study Coordinator creates a study with phone call randomization. In this study, randomization occurs after all registration details are entered. Once randomized, the subject is considered enrolled and should be assigned a study subject identifier.

1.2a Steps

1. Enter the create study flow by clicking the Studies tab
2. Click Create Study.
3. Specify the short title, Long title, and target accrual.
4. Select the type of study and study phase.
5. Set blinded to No.
6. Specify stratified as yes.
7. Specify randomized as yes.
8. Specify type as Phone call.
9. Choose coordinating center as site NC010 [Duke University Medical Center]
10. Specify the coordinating center study identifier.
11. In the prinicipal investigator section, choose organization as NC010.
12. Type the first few characters of the name of the PI in the principal investigator auto-suggest box. If the PI is not already existing in C3PR, you can create one by clicking "create principal investigator"
13. Click save and continue.
14. You are now in the Consent page.
15. Choose mandatory consents value as one.
16. Click on add consent and specify the consent name as 'consent 1'.
17. You are now in the Epochs and Arms page.
18. Click' Add epoch'
19. A new blank epoch panel will be created.
20. Specify the name of the epoch as 'treating epoch'
21. Set other values as following:
    a. order =1
    b. treating = yes
    c. enrolling = yes
    d. randomized = yes
    e. reserving= no
    f. stratified = yes
22. Click 'Add arm' button twice and specify the arms names as 'aa' and 'bb'
23. You are now in the Eligibility tab.
24. Add any required inclusion and exlusion criteria and click save and continue.
25. You are now in the Stratification tab.
26. Click 'add stratification critierion' tab twice.
27. Enter question as 'q1' and answers as 'a11' and 'a12' for the first stratification question.
28. Similarly enter values for the second stratification question as q2 and 'a21' and 'a22' respectively.
29. Click on 'generate stratum groups'
30. 4 groups will be created for you numbered as 0,1,2 and 3.
31. Click save and continue.
32. You are now in the Randomization tab.
33. Enter the phone number used to determine the arm assignment.
34. Click save and continue.
35. You are now in the Diseases tab.
36. Add diseases if any and click save and continue.
37. You are now in the Companion studies tab.
38. We will not be adding any companion studies, hence click save and continue.
39. You are now in the overview tab.
40. Verify all details are correctly recorded then click on the 'Open study' link.
41. In the 'confirm' pop up specify a valid date and click 'Open study'
42. You should get a 'Study opened successfully' message
43. You have now successfully created a phone call randomized study.

1.2b Special Considerations

None

1.2c Expected Output

- User should see confirmation pop-up window with today's date
- After user confirms activation date and clicks Yes, clicks Open Study, the study should be open and ready for enrollment
- The study should be open and ready for enrollment

1.3 Create a Book Randomized Study

A Site Coordinator / Study Coordinator creates a study with the randomization book encoded in C3PR. In this study, randomization occurs after all registration details are entered and is automatically performed by C3PR. Once randomized, the subject is considered enrolled and should be assigned a study subject identifier.

1.3a Steps

1. Enter the create study flow by clicking the Studies tab
2. Click Create Study.
3. Specify the short title, Long title, and target accrual.
4. Select the type of study and study phase.
5. Set blinded to No.
6. Specify stratified as yes.
7. Specify randomized as yes.
8. Specify type as Book.
9. Choose coordinating center as site NC010 [Duke University Medical Center]
10. Specify the coordinating center study identifier.
11. In the prinicipal investigator section, choose organization as NC010.
12. Type the first few characters of the name of the PI in the principal investigator auto-suggest box. If the PI is not already existing in C3PR, you can create one by clicking "create principal investigator"
13. Click save and continue.
14. You are now in the Consent page.
15. Choose mandatory consents value as one.
16. Click on add consent and specify the consent name as 'consent 1'.
17. You are now in the Epochs and Arms page.
18. Click' Add epoch'
19. A new blank epoch panel will be created.
20. Specify the name of the epoch as 'treating epoch'
21. Set other values as following:
    a. order =1
    b. treating = yes
    c. enrolling = yes
    d. randomized = yes
    e. reserving= no
    f. stratified = yes
22. Click 'Add arm' button twice and specify the arms names as 'aa' and 'bb'
23. You are now in the Eligibility tab.
24. Add any required inclusion and exclusion criteria and click save and continue.
25. You are now in the Stratification tab.
26. Click 'add stratification criterion' tab twice.
27. Enter question as 'q1' and answers as 'a11' and 'a12' for the first stratification question.
28. Similarly enter values for the second stratification question as q2 and 'a21' and 'a22' respectively.
29. Click on 'generate stratum groups'
30. 4 groups will be created for you numbered as 0,1,2 and 3.
31. Click save and continue.
32. You are now in the Randomization tab.
33. Click on the 'Insert book' tab and enter the following values:

```
0,0,aa
0,1,aa
1,0,bb
1,1,bb
```

34. Click on 'upload randomization book'
35. On the right hand side panel you will be shown values for the randomization book.
36. Click save and continue.
37. You are now in the Diseases tab.
38. Add diseases if any and click save and continue.
39. You are now in the Companion studies tab.
40. We will not be adding any companion studies, hence click save and continue.
41. You are now in the overview tab.
42. Verify all details are correctly recorded then click on the 'Open study' link.
43. In the 'confirm' pop up specify a valid date and click 'Open study'
44. You should get a 'Study opened successfully' message
45. You have now successfully created a book randomized study.

1.3b Special Considerations

None

1.3c Expected Output

- User should see confirmation pop-up window with today's date
- After user confirms activation date and clicks Yes, clicks Open Study, the study should be open and ready for enrollment
- The study should be open and ready for enrollment

1.4 Edit Study

c3pr Admin is able to change core study details for an opened study.

1.4a Steps

1. Enter the create study flow by clicking the Studies tab.
2. click on manage study.
3. Here you will be shown the study search tab.
4. Select 'search by' to identifier.
5. In the search criteria text box enter the identifier for the study.
6. Click search.
7. In the search results table, click on the appropriate study.
8. You will now be taken to manage study flow.
9. Click on the edit study action.
10. You will now be in the edit study flow for the chosen study.
11. Add study description in the description text box.
12. Click save and continue.
13. You are now in the consent tab.
14. Click on the add consent button.
15. In the new consent text box, specify a value for the consent name.
16. Click save.
17. user can optionally change values for Epochs& Arms, Eligibility, Diseases etc.
18. These changes are persisted once user clicks save in the respective tab.
19. Finally click on the summary tab.
20. Verify details are correct in this tab.

1.4b Special Considerations

None

1.4c Expected Output

- User should be able to change study details using edit study flow

1.5 Search Study

c3pr Admin is able to change core study details for an opened study.

1.5a Steps

1. Enter the create study flow by clicking the Studies tab.
2. click on manage study.
3. Here you will be shown the study search tab.
4. Select 'search by' to identifier.
5. In the search criteria text box enter the identifier for the study.
6. Click search.
7. In the search results table, click on the appropriate study.
8. You will be taken to manage study flow where a summary of study details will be shown.

1.5b Special Considerations

None

1.5c Expected Output

- User should be able to search available studies and view them

1.4 Create a Study with Multiple Epochs

A Site Coordinator Study Coordinator creates a study with a screening, treatment, and follow-up epoch. This study model is used for sites that use

C3PR for tracking a subject registration across these parts of the study.

1.4a Steps

1. Enter the study flow by clicking the Studies tab
2. Click Create Studycreate study flow
3. Fill in study details in each create study screen
4. Save the study
5. Search for the study in the manage study flow
6. Select the study
7. Add the local site as a study site
8. Open study and activate the study
9. Add the local site as a study site
10. Activate the study site for the study

1.4b Special Considerations

- Mark the study as non-randomized
- Mark the study as non-stratified
- Create three epochs:
    - Screening: non-enrolling, non-reserving, one arm called Screening
    - Treatment: enrolling, three arms
    - Follow-up: enrolling, one arm called Follow-up
- Do not create any stratification criteria
- Create a single inclusion eligibility criteria with text "Subject is eligible for the study"

1.4c Expected Output

- User should see confirmation pop-up window with today's date
- After user confirms activation date and clicks Yesclicks Open Study, the study should be open and ready for enrollment The study should be open and ready for enrollment

1.5 Create a Multi-site Trial

A Site Coordinator Study Coordinator creates a multi-site study that is coordinated by their study site. The other participating sites and the coordinating site will be responsible for registering subjects to the trial, though the final enrollment occurs at the coordinating site. The study will be relatively simple, with one Treatment Epoch, non-randomized, and no stratification.

1.5a Steps

1. Enter the create study flow by clicking the Studies tab
2. Click Create Study
3. Fill in study details in each create study screen
4. Save the study
5. Search for the study in the manage study flow
6. Select the study
7. Add the local site as a study site
8. Add three additional sites as study sites
9. Open and activate the study for all study sites (from the coordinating site perspective)
10. Login with users from each study site and activate the study for registration at those sites

1.5b Special Considerations

- Mark the study as non-randomized
- Mark the study as non-stratified
- Create one Treatment epoch
- Create three arms within the Treatment epoch
- Do not create any stratification criteria
- Create a single inclusion eligibility criteria with text "Subject is eligible for the study"
- Be sure to logout as Site from the Ccoordinatoring site and login with a user that has been associated with each participating site (Note: this may require that you create additional users/research staff and associate them with a participating site)

1.5c Expected Output

- User should see confirmation pop-up window with today's date
- After user confirms activation date and clicks Yesclicks Open Study, the study should be open and ready for enrollment
- User should be able to log in as the user created for each siteThe study should be open and ready for enrollment at each study site

1.6 Create a Companion study

A Site Coordinator Study Coordinator creates a study that has associated companion studies. The parent study is a treatment study, and the additional companions can be non-treatment studies (such as quality of life, tissue banking, etc.) The specific details of the study can be fairly general, e.g. non-randomized, non-stratified, etc.

1.6a Steps

1. Execute scenario 1.3 -- Create Book randomized study -- up to step 39
2. In the companion studies tab, click on 'Create new companion' button
3. Click Continue on the confirm pop up dialog box.
4. You will now be taken to the create companion study flow.
5. Specify the short title, Long title, and target accrual.
6. Select the type of study and study phase.
7. Set blinded to No.
8. Specify stratified as no.
9. Specify randomized as no.
10. Choose coordinating center as site NC010 [Duke University Medical Center]
11. Specify the coordinating center study identifier.
12. In the prinicipal investigator section, choose organization as NC010.
13. Type the first few characters of the name of the PI in the principal investigator auto-suggest box. If the PI is not already existing in C3PR, you can create one by clicking "create principal investigator"
14. Click save and continue.
15. You are now in the Consent page.
16. Choose mandatory consents value as one.
17. Click on add consent and specify the consent name as 'consent 1'.
18. You are now in the Epochs and Arms page.
19. Click' Add epoch'
20. A new blank epoch panel will be created.
21. Specify the name of the epoch as 'treating epoch'
22. Set other values as following:
    a. order =1
    b. treating = yes
    c. enrolling = yes
    d. randomized = no
    e. reserving= no
    f. stratified = no
23. Click 'Add arm' button twice and specify the arms names as 'aa.1' and 'bb.1'
24. You are now in the Eligibility tab.
25. Add any required inclusion and exclusion criteria and click save and continue.
26. You are now in the Stratification tab.
27. No Stratification is required. Click save and continue.
28. You are now in the Randomization tab.
29. No Randomization is required. Click save and continue.
30. You are now in the Diseases tab.
31. Add diseases if any and click save and continue.
32. You are now in the summary tab.
33. Verify all details are correctly recorded.
34. Note that if the parent study is pending then the companion study cannot be opened independently.
35. Click on the return to parent action.
36. You will now be taken back to the companion study tab of the parent study.
37. Make sure that you set the mandatory column to yes.
38. You have successfully created the mandatory companion study.

1.6b Special Considerations

None

1.6c Expected Output

- User should be able to add companion studies to a parent study.

1.7 Create Complex Study

A Site Coordinator Study Coordinator creates a complex study that involves randomization, stratification, companion studies, etc. This is a macro user acceptance test that insures that, when combined, the functionality validated by the previous tests are still valid.

1.7a Steps

Enter the study flow by clicking the Studies tab

1. Click Create StudyEnter the create study flow
2. Fill in study details in each create study screen
3. Add two additional companion studies, filling in the details for each study
4. Save the study
5. Search for the study in the manage study flow
6. Select the study
7. Add the local site as a study site
8. Add three additional sites as study sites
9. Open and activate the study for all study sites (from the coordinating site perspective)
10. Login with users from each study site and activate the study for registration at those sites

1.7b Special Considerations

- Follow the guidance of the above test cases
- Mark the parent study as randomized by phone call
- Enter a phone number for the randomization office (it can be a fake phone number)
- Create a multiple epochs, e.g. Screening, Treatment, Follow-up
- Create multiple arms within Treatment
- Create a single inclusion eligibility criteria with text "Subject is eligible for the study"
- Create two companion studies
- Be sure to logout from the coordinating site and login with a user that has been associated with each participating site (Note: this may require that you create additional users/research staff and associate them with a participating site)

1.7c Expected Output

- User should see confirmation pop-up window with today's date
- After user confirms activation date and clicks Open Study, the study should be open and ready for enrollment

The study should be open and ready for enrollment

1.8 Amend Study 

A Site Coordinator / Study Coordinator creates a simple study then amends that study. The focus will be on amending the eligibility criteria, e.g. to add additional criteria for patient safety. The study version and consent should change. The amendment should be required by all study sites, though, for convenience in this test case, the coordinating site will be the only study site.

1.8a Pre-conditions

- The study should be created and opened.

1.8b Steps

1. Start the flow by clicking Studies tab.
2. Click on the manage study tab.
3. In the search box, enter the identifier of the study which needs to be amended.
4. Make sure 'Search by' is set to 'Identifier'
5. In the search results table, click on the appropriate study.
6. You will be taken to study summary page.
7. Verify that the study status is open.
8. Click on 'Amend study' in the actions bar on the top of study summary.
9. Confirm the amend by clicking on 'Amend study' in the pop up
10. You will now be taken to the amend study flow.
11. Enter a version number as 'v2'.
12. Select amendment type as 'Immediate'
13. Set amendment date as today's date.
14. In reasons for amendment check 'eligibility' and 'consent'.
15. Click save and continue.
16. You will be taken to the 'Details' tab.

17. All fields in this tab will be grayed out since this is not one of the reasons for the amendment.
18. Click save and continue.
19. You will be taken to the 'Consents' tab.
20. Click 'Add Consent' and add the consent name in the new consent text box.
21. Click save and continue.
22. You will be taken to the 'Epochs and Arms' tab.
23. Click save and continue.
24. You will be taken to the 'Eligibility' tab.
25. Click 'Add exclusion criteria' button and Add a question in the new text box.
26. Click save and then click the summary tab.
27. In the study summary page, you will be shown an action for 'Apply amendment'
28. Click on the link and in the pop up dialog confirm by clicking 'Apply amendment'
29. You will get a 'Study amended successfully.' message

1.8c Special Considerations

1.8d Expected Output

- The study should require registration to the amended version.

1.9 Manage Study

A Site Coordinator / Study Coordinator creates a simple study then Manages that study. The focus will be on adding a new site to the study, then apply the latest amendment to that study. In addition add new personnel to the study that belong to the newly added site

1.9a Pre-conditions

- The newly added site should have Research staff associated to it.

- The study should be created and opened.

1.9b Steps

1. Start the flow by clicking Studies tab.
2. Click on the manage study tab.
3. In the search box, enter the identifier of the study which needs to be managed.
4. Make sure 'Search by' is set to 'Identifier'
5. In the search results table, click on the appropriate study.
6. You will be taken to study summary page.
7. Verify that the study status is open.
8. Click on the sites tab.
9. In the sites tab, type MN026 and choose 'Mayo Clinic Rochester ' from the autocompleter results.
10. Click 'Add study site'
11. Mayo Clinic Rochester will be added as study site with pending status.
12. Enter appropriate IRB approval date and click 'activate study site'
13. In the pop up that appears choose the appropriate effective date and click OK.
14. You will get a 'Study site activated successfully.' message.
15. Click save.
16. Click the personnel tab
17. In the personnel tab, you will be shown the list of organizations and their research staff
18. Choose Mayo Clinic Rochester as the organization.
19. The list of all personnel associated with Mayo Clinic Rochester will be shown.
20. Choose the appropriate ones and click add.
21. The added research staff will be shown on the 'Selected personnel' panel on the right.
22. Click save.
23. This completes the manage study flow.

1.9c Special Considerations

1.9d Expected Output

- The study should be activated on the latest version to a new study site.

1.11.1 Close Study Permanently to Accrual

User creates a simple study and then closes it permanently to accrual (study cannot be reopened at a later date. Subjects should no longer be able to be registered to the study)

Pre-conditions

Study exists with study sites and study status is open

1.11.1a Steps

1. Enter the study flow by clicking the Studies tab
2. User clicks manage study
3. User Searches for study by identifier.
4. In the search results table, user clicks on appropriate study to enter the manage study flow.
5. User clicks on the close study action.
6. in the pop up, user is shown the list of possible actions that can be taken.
7. User chooses 'Closed To Accrual' and clicks close study.
8. In the confirmation pop up user confirms close study.
9. User is shown confirmation message for 'Study closed successfully.'
10. User navigates to Registration>>create registration.
11. User searches for study by identifier.
12. This study is not shown in the search results since it is not eligible for registration.

1.11.1b Special Considerations

None

1.11.1c Expected Output

- Study status should be 'Closed To Accrual'
- New subjects cannot be registered on this study

1.11.2 Close Study Permanently to Accrual and Treatment

User creates a simple study and then closes it permanently to accrual and treatment (study cannot be reopened at a later date. Subjects should no longer be able to be registered to the study)

Pre-conditions

Study exists with study sites and study status is open

1.11.2a Steps

1. Enter the study flow by clicking the Studies tab
2. User clicks manage study
3. User Searches for study by identifier.
4. In the search results table, user clicks on appropriate study to enter the manage study flow.
5. User clicks on the close study action.
6. in the pop up, user is shown the list of possible actions that can be taken.
7. User chooses 'Closed To Accrual and Treatment' and clicks close study.
8. In the confirmation pop up user confirms close study.
9. User is shown confirmation message for 'Study closed successfully.'
10. User navigates to Registration>>create registration.
11. User searches for study by identifier.
12. This study is not shown in the search results since it is not eligible for registration.

1.11.2b Special Considerations

None

1.11.2c Expected Output

- Study status should be 'Closed To Accrual and Treatment'
- New subjects cannot be registered on this study

1.12.1 Close Study Temporarily to Accrual

User creates a simple study and then closes it temporarily to accrual (study may be reopened at a later date. Subjects should no longer be able to be registered to the study unless study is reopened.

Pre-conditions

Study exists with study sites and study status is open

1.12.1a Steps

1. Enter the study flow by clicking the Studies tab
2. User clicks manage study
3. User Searches for study by identifier.
4. In the search results table, user clicks on appropriate study to enter the manage study flow.
5. User clicks on the close study action.
6. in the pop up, user is shown the list of possible actions that can be taken.
7. User chooses 'Temporarily Closed To Accrual' and clicks close study.
8. In the confirmation pop up user confirms close study.
9. User is shown confirmation message for 'Study closed successfully.'
10. User navigates to Registration>>create registration.
11. User searches for study by identifier.
12. This study is not shown in the search results since it is not eligible for registration.

1.12.1b Special Considerations

None

1.12.1c Expected Output

- Study status should be 'Temporarily Closed To Accrual'
- New subjects cannot be registered on this study

1.12.2 Close Study Temporarily to Accrual and Treatment

User creates a simple study and then closes it temporarily to accrual and treatment (study may be reopened at a later date. Subjects should no longer be able to be registered to the study unless study is reopened.

Pre-conditions

Study exists with study sites and study status is open

1.12.2a Steps

1. Enter the study flow by clicking the Studies tab
2. User clicks manage study
3. User Searches for study by identifier.
4. In the search results table, user clicks on appropriate study to enter the manage study flow.
5. User clicks on the close study action.
6. in the pop up, user is shown the list of possible actions that can be taken.
7. User chooses 'Temporarily Closed To Accrual and Treatment' and clicks close study.
8. In the confirmation pop up user confirms close study.
9. User is shown confirmation message for 'Study closed successfully.'
10. User navigates to Registration>>create registration.
11. User searches for study by identifier.
12. This study is not shown in the search results since it is not eligible for registration.

1.12.2b Special Considerations

None

1.12.2c Expected Output

- Study status should be 'Temporarily Closed To Accrual and Treatment'
- New subjects cannot be registered on this study

1.13 Reopen Study Temporarily Closed to Accrual and Treatment

User wishes to reopen a study that was previously closed temporarily to accrual and treatment. Subject registration for the study should only be possible after it is reopened.

Pre-conditions

Study exists with study sites and study status is 'Temporarily Closed To Accrual and Treatment'

1.13a Steps

1. Enter the study flow by clicking the Studies tab
2. User clicks manage study
3. User Searches for study by identifier.
4. In the search results table, user clicks on appropriate study to enter the manage study flow.
5. User clicks on the open study action.
6. In the confirmation pop up user confirms open study.
7. User is shown confirmation message for 'Study open successfully.'
8. User navigates to Registration>>create registration.
9. User searches for study by identifier.
10. This study is shown in the search results since it is eligible for registration.

1.13b Special Considerations

None

1.13c Expected Output

- Study should be open and ready for enrollment.
- New subjects can be registered on this study

There should no longer be a link named Open Study on the summary page

1.14 Import Study

User should be able to import study into c3pr in XML format.

1.14a Steps

1. Click on the Administration tab.
2. Click on the Import sub tab.
3. Click on Import study sub sub tab.
4. Click on browse, and locate the study XML file located in your computer.
5. Note that the XML should conform to the study schema.
6. A copy of the schema is available in the import study tab.
7. After choosing the appropriate study XML file, click import.
8. If study has been imported successfully, you will see the study listed in uploaded studies panel.
9. If there is a failure in study import, a link will be shown for 'Download Output XML File'.
10. Click on this link and view the XML.
11. All study import related errors will be listed at the bottom of the output XML

1.14b Special Considerations

None

1.14c Expected Output

- Study should be open and ready for enrollment.

2. Subjects

2.1 Create New Subject

A User creates a new Subject independently of a study by entering basic details and demographics about the Subject.

2.1a Steps

1. Click on the Person and organizations tab.
2. Navigate to Subject>> Create subject page.
3. Specify the First name, Last name, Gender, Birth date, Ethnicity and Race.
4. For creating the Subject Primary identifier execute the following steps:
5. Specify the organization as MN026, Mayo Clinic Rochester.
6. Specify an appropriate identifier string.
7. Choose Identifier type as MRN.
8. You can add more optional Organization Assigned Identifiers by clicking on the 'add Organization Assigned Identifiers' button.
9. Similarly more System Assigned Identifiers can be added as well.
10. Click save and continue.
11. You will be taken to the 'Address & Contact Information' tab.
12. Here user can enter optional contact information for the subject.
13. Click save and done after completing this page.
14. You will get a confirmation page with the message: 'Subject successfully created.'

2.1b Special Considerations

- None

2.1c Expected Output

- The Subject should be viewable via the Search Subject flow, as well as the Register Subject flow

2.2 Edit subject

A User creates a new Subject independently of a study by entering basic details and demographics about the Subject and then updates those details at a later date. Those details should be reflected in all associated records, such as registration, etc.

2.2a Steps

1. Click on the Person and organizations tab.
2. Navigate to Subject>>Manage subject.
3. Choose search by 'Last Name'
4. In Search criteria enter the last name of the subject.
5. Click search.
6. In the search results table, clicks on the appropriate subject.
7. You will now be Subject>>Summary page.
8. Click on the Edit action.
9. This starts the edit subject flow.
10. Change any of the subject details demographic information.
11. Click save and continue.
12. You will now be in the Address and Contact information page.
13. Add / modify the desired contact information.
14. Click save and done.
15. You should see a 'Subject successfully updated' message.

2.2b Special Considerations

- None

2.2c Expected Output

- The Subject should be viewable via the Search Subject flow, as well as the Register Subject flow
- The latest details should be viewable

2.3 Search Subject

A User creates a new Subject independently of a study by entering basic details and demographics about the Subject.

2.1a Steps

1. Click on the Person and organizations tab.
2. Navigate to Subject>> Manage subject page.
3. Select 'Search by' criteria to last name
4. Enter the last name of the subject in the 'Search critieria' box.
5. Click search.
6. The search results table will display the list of subjects matched by the search critieria.
7. Click on the appropriate subject in the results table.
8. You will now be taken to the manage subject flow.

2.1b Special Considerations

- None

2.1c Expected Output

- The Subject should be viewable via the Search Subject flow.

3. Registrations

Note: many of these test cases require specific studies to be setup. Where appropriate, a test case is the study module is referenced for an appropriate study to use.
These cases assume that the instance of C3PR is located at the coordinating center and being accessed by registrars at study sites.

3.1 Correct data entry for registration

3.1.1 c3pr admin should be able to edit completed registrations

3.1.1a Steps

1. User is logged in as c3pr admin. [duke.staff@duke.org]
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.

3.1.1b Expected Output

User is able to edit various details for the registration through in-place editor.

3.1.2 site coordinator should not be able to edit completed registrations

3.1.2a Steps

1. User is logged in as site coordinator. [vinayrg78@yahoo.com]
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.

3.1.2b Expected Output

User is not able to edit various details for the registration through in-place editor.

3.1.3 study coordinator should not be able to edit completed registrations

3.1.3a Steps

1. User is logged in as study coordinator. [c3pr_study_coordinator]
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.

3.1.3b Expected Output

User is not able to edit various details for the registration through in-place editor. CPR-1836

3.1.4 registrar should not be able to edit completed registrations

3.1.4a Steps

1. User is logged in as registrar. [c3pr_registrar]
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.

3.1.4b Expected Output

User is not able to edit various details for the registration through in-place editor.

3.1.5 c3pr admin can update inclusion criteria for completed registration

3.1.5a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User changes inclusion criteria to No using in-place editor.

3.1.5b Expected Output

Eligible status should change to No

3.1.6 Changing exclusion criteria updates eligiblity status for completed registration

3.1.6a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User changes exclusion criteria to Yes using in-place editor.

3.1.6b Expected Output

Eligible status should change to No

3.1.7 Invalid date format not accepted as consent date for completed registration

3.1.7a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User specifies date for consent as 04/15/201000 using in-place editor.

3.1.7b Expected Output

Error is thrown for invalid consent date
** Incorrect date format is accepted by C3PR

3.1.8 Blank date not accepted as consent date for completed registration

3.1.8a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User specifies date for consent as blank string using in-place editor.

3.1.8b Output

Error is thrown for invalid consent date
** blank string is accepted by C3PR

3.1.9 c3pr admin is able to edit informed consent dates for completed registration

3.1.9a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on informed consent edit icon using in-place editor.

3.1.9b Expected Output

All consent dates are made editable.

3.1.10 c3pr admin is able to edit Enrollment Details for completed registration

3.1.10a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on Enrollment Details edit icon using in-place editor.

3.1.10b Expected Output

Following fields are made editable

Registration date 

Enrolling physician: 

Primary disease: 

Primary disease at a site: 

Payment method: 

3.1.11 Invalid date format not accepted as Registration date for completed registration

3.1.11a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User specifies date for Registration date as 04/15/201000 using in-place editor.

3.1.11b Expected Output

Error is thrown for invalid Registration date

** Incorrect date format is accepted by C3PR 

3.1.12 c3pr admin is able to edit Stratification criteria for completed registration 

3.1.12a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on Stratification edit icon using in-place editor.

3.1.12b Expected Output

All Stratification criteria are made editable.

3.1.13 c3pr admin is able to update Stratification criteria for completed registration 

3.1.13a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on Stratification edit icon using in-place editor.
6. User changes the value and clicks save.

3.1.13b Expected Output

The changed value for Stratification critieria is saved.

3.1.14 c3pr admin is able to change stratum group for completed registration

3.1.14a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on Stratification edit icon using in-place editor.
6. User changes the value and clicks save.

3.1.14b Expected Output

The stratum group of the subject is updated to new value.

3.1.15 c3pr admin is able to edit epoch arm for completed registration

3.1.15a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'Registered'.
4. User is in registration>>overview page.
5. User clicks on Epoch & Arm edit icon using in-place editor.

3.1.15b Expected Output

The epoch arm is made editable.

3.1.16 In place editor is not available for incomplete registrations

3.1.16a Steps

1. User is logged in as c3pr admin.
2. User clicks on registration >> manage registration page.
3. User searches for a registration which has epoch status 'pending'.
4. User is in registration>>overview page.

3.1.16b Expected Output

The user is shown 'Resume registration' link and the in-place editor is not enabled.

3.2 Register Subject to Non-randomized Study

A Registrar registers a Subject to a simple, non-randomized study. Details of the registration should be appropriate captured.

3.2a Steps - Enter the create registration flow

1Click on the Registration tab
2Click Manage (to search) or Create Registration (to create new subject)
Select or create a subject
3 Select an appropriate study
4 Fill in details in each screen of the subject registration processof the registration flow
5 Save the registration record and enroll the subject

3.2b Special Considerations

- An appropriate study can be used from test case 2.1

3.2c Expected Output

- The subject should be enrolled an assigned a new study subject identifier - this can be verified by performing a search with the new identifier

3.3 Register Subject to a Phone Call Randomized Study

A Registrar registers a Subject to a simple study that uses phone call randomization. Randomization and enrollment is provided by the coordinating site and is entered by the participating site into their instance of C3PR.

3.3a Pre-conditions

1. Phone call randomized study should already exist. It should be opened and activated at a study site.
2. Registrar is associated to coordinating center or study site of the study as study personnel.

3.3b Steps

Login to c3pr as registrar.
2.Click on registration tab.
3. Click on 'Create registration' tab.
4. Search for the study.
5. Set search studies by 'identifier'
6. Enter the study identifier in the search criteria and click the search button.
7. A list of results will be shown for studies that match the input criterion.
8. Click on the appropriate study.
9. This will expand into a list of sites at the study which are active.
10. Select the site as 'Mayo clinic rochester'.
11. The selection will be recorded and the study panel will collapse.
12. The 'Select Epoch' panel will expand and the list of available epochs for the chosen study will be shown.
13. Select a treating epoch.
14. The selection will be recorded and the epoch panel will collapse.
15. In the 'Select subject' panel, enter all mandatory fields highlighted in red:
    1. first name,
    2. last name,
    3. gender,
    4. birth date
    5. ethnicity
    6. primary identifier organization
    7. primary identifier string
    8. primary identifier type
16. Click on create subject.
17. The selection will be recorded and the subject panel will collapse.
18. Expand the subject panel and you will see confirmation that the subject was created and selected.
19. Click save and continue.
20. You will be taken to the enrollment details tab.
21. Enter the registration date and consent signed date.
22. C3pr will throw error for if registration date is before consent signed date.
23. Click save and continue.
24. You will be taken to the Eligiblity tab.
25. Answer yes to all inclusion critieria and no all exclusion critieria. This will ensure that the subject is made eligible to the study.
26. Click save and continue.
27. You will be taken to the stratification tab.
28. Choose appropriate answers for each stratification question.
29. Click save and continue.
30. You will be taken to the arm tab.
31. For phone call randomization, the arm is assigned directly and there will be no details to fill here.
32. Click save and continue.
33. You will be taken to the companion registrations tab.
34. Since the study does not have associated companion studies C3PR will not prompt for companion registrations.
35. Click save and continue.
36. You will be taken to the review and submit tab.
37. You will shown a notice stating randomization of the registration is still pending.
38. Scroll to the bottom of the page.
39. Determine the arm to be assigned to this subject [generally by calling the phone number listed]
40. Click on randomize and enroll button.
41. You will get a confirmation for successful registration of subject on study.

3.3c Special Considerations

3.3d Expected Output

- The subject should be enrolled an assigned a new study subject identifier - this can be verified by performing a search with the new identifier
- The subject should be enrolled and assigned a new study subject identifier

3.4 Register Subject to a Book Randomized Study

A Registrar registers a Subject to a simple study that uses book randomization. Randomization and enrollment is provided by the coordinating site instance of C3PR. This process is completely automated by C3PR.

3.4a Steps

1Click on the Registration tab

1. 2Click Manage (to search) or Create Registration (to create new subject) Enter the create registration flow
2. Select or create a subject

3 Select an appropriate study

1. 4 Fill in details in each screen of the registration flow

5 Save and enroll the subject

3.4b Special Considerations

- An appropriate study can be used from test case 2.3

3.4c Expected Output

- The subject should be enrolled an assigned a new study subject identifier as well as the appropriate arm from the book

3.5 Register Subject to a Study with Companions

A Registrar registers a Subject to a simple study that uses book randomization. Randomization and enrollment is provided by the coordinating site instance of C3PR. This process is completely automated by C3PR.

3.5a Steps

1Click on the Registration tab
2Click Manage (to search) or Create Registration (to create new subject) Enter the create registration flow

1. 3

Select or create a subject

1. 4

Select an appropriate study5
5 y
Fill in details in each screen of the registration flow

1. 6

Fill in details for all required and non-required companions
7
Save and enroll the subject

1.

3.5b Special Considerations

- An appropriate study can be used from test case 2.6

3.5c Expected Output

- The subject should be enrolled an assigned a new study subject identifier and should be enrolled on the companion studies

3.6 Move a Subject from Screening to Treatment - NEEDS TO BE REFACTORED

A Registrar registers a Subject to the screening epoch of a multi-epoch study, filling in the appropriate details. The Registrar then moves the study subject from the screening epoch to the treatment epoch, adding any requisiteadditional details that are needed.

3.6a Steps

1Click on the Registration tab
2Click Manage (to search) or Create Registration (to create new subject)
Enter the create registration flow

1. Select or create a subject3

Select an appropriate study

1. 4 y

Select the screening epoch

1. 5

Fill in details in each screen of the registration process of the registration process of the registration flow.

1. 6

Save and register the subject - assign subject to Screening epoch

1. 7

Click Registration tab and then click Manage RegistrationEnter the search registration flow

1. 8

Search for and select the previously registered subject
9
On subject Overview page, click Change Epoch, give reason for moving subjectSelect move epoch and transfer the subject from screening to treatment

1. 10

Fill in any additional data items on the following screens

1. 11
2. Save and enroll the study subject

3.6b Special Considerations

- An appropriate study can be used from test case 2.4

3.6c Expected Output

- The subject should be registered but not enrolled when placed on the screening epoch
- The subject should be enrolled and assigned a study subject identifier when placed on the treatment epoch

3.7 Take a Subject Off-study

A User registers a Subject to a basic study, filling in the appropriate details. The user then takes the subject off-study, for example because the subject chooses no longer to participate.

3.7a Steps

1. Click on the Registration tab.
2. Click on manage registration subtab.
3. Set registration search criteria to search by study identifier.
4. Enter the study identifier string and choose one of the results from the auto-suggest.
5. For the chosen study, a list of registrations will be shown.
6. Click on a registration with a registration status of 'enrolled'
7. You will be taken to manage registration flow.
8. Click on the 'Take subject off study' action.
9. In the pop up enter the reason for taking subject off study and the date.
10. click save.
11. You will get a 'Subject has been taken off study' message.
12. Subject has been taken off the study.

3.7b Special Considerations

None

3.7c Expected Output

- The subject should be initially enrolled and assigned a study subject identifier.
- Once taken off study, the subject is no longer actively enrolled.

3.8 Create a Back-dated Registration

A Registrar registers a subject on a study with the registration date and consent signed date before the current date. The Registrar should fill in details from the study version of the back-date.

3.8a Steps

1. Click on the Registration tab
2. Click Manage (to search) or Create Registration (to create new subject) Enter the create registration flow
3. Select or create a subject
4. Select an appropriate study
5. Fill in details in each screen of the registration flow.
6. Enter a registration and consent signed date before the latest amendment
7. Save and enroll the subject

3.8b Special Considerations

- An appropriate study can be used from test case 2.8

3.8c Expected Output

- The subject should be enrolled with details from the back-dated study version (e.g. the eligibility list should come from that version)

3.9 Register Subjects to a Blinded Study

3.9a Steps

1 Click on the Registration tab
2 Click Manage (to search) or Create Registration (to create new subject)
3 Select an appropriate study (blinded in this case)

1. 4 Fill in details in each screen of the registration flow.

5 Save and enroll the subject

3.9b Special Considerations

- An appropriate study can be used from test case 2.4

3.9b Expected Output

The subject should be enrolled an assigned a new study subject identifier - this can be verified by performing a search with the new identifier

An appropriate study can be used from test case 2.4

ADD BLINDED REGISTRATION

3.10 Create Study Subject Record Snapshot for a Registration

3.10.1 Study selection status is maintained for unselected study

3.10.1a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User does not select any study
6. In the select subject panel, user searches for a subject by last name
7. In the subject results table, user clicks on one of the subjects
8. In the expanded subject details panel, user clicks on edit
9. User is taken to edit subject flow
10. User returns from edit subject flow to create registration flow

3.10.1b Expected Output

In the select study panel, the list of studies is shown in the study results table and none are selected.

3.10.2 Study selection status is maintained for selected study

3.10.2a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select subject panel, user searches for a subject by last name
7. In the subject results table, user clicks on one of the subjects
8. In the expanded subject details panel, user clicks on edit
9. User is taken to edit subject flow
10. User returns from edit subject flow to create registration flow

3.10.2b Expected Output

In the select study panel, the study selected prior to edit subject flow is marked as selected.

3.10.3 Epoch selection status is maintained for unselected epoch

3.10.3a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User does not select any epoch.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow
12. User returns from edit subject flow to create registration flow

3.10.3b Expected Output

In the select epoch panel, the list of epochs is shown in the epoch results table and none are selected.

3.10.4 Epoch selection status is maintained for selected epoch

3.10.4a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User select an epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow
12. User returns from edit subject flow to create registration flow

3.10.4b Expected Output

In the select epoch panel, the epoch selected prior to edit subject flow is marked as selected.

3.10.5 Changes to subject first name updated in registration

3.10.5a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User select an epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow.
12. User changes the first name of the subject.
13. User clicks on 'save and return to registration'
14. User returns from edit subject flow to create registration flow

3.10.5b Expected Output

In the select subject panel, the updated first name of the subject is shown.

3.10.6 Subject details are correctly persisted in registration flow

3.10.6a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User select an epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow.
12. User changes the middle name ,gender, and birth date of the subject.
13. User clicks on 'save and return to registration'
14. User returns from edit subject flow to create registration flow.
15. User exits create registration flow
16. User navigates to Persons And Organization >>Subject >> Manage subject tab
17. User searches for the above chosen subject and enter manage subject flow

3.10.6b Expected Output

In the manage subject flow, user is able to see the updated middle name ,gender, and birth date of the subject.

3.10.7 Registration cannot be searched by stale subject details information

3.10.7a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User select an epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow.
12. User changes the last name of the subject from 'smith' to 'roberts'.
13. User clicks on 'save and return to registration'
14. User returns from edit subject flow to create registration flow.
15. User exits create registration flow
16. User navigates to registration >> manage registration.
17. User searches for registrations by subject last name smith

3.10.7b Expected Output

The 'Search criteria' auto-suggest does not give results for danny smith

3.10.8 Registration can be searched by latest subject details information

3.10.8a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table

6. In the select epoch panel, the list of applicable epochs are shown.
7. User select an epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on edit
11. User is taken to edit subject flow.
12. User changes the last name of the subject from 'smith' to 'roberts'.
13. User clicks on 'save and return to registration'
14. User returns from edit subject flow to create registration flow.
15. User exits create registration flow
16. User navigates to registration >> manage registration.
17. User searches for registrations by subject last name roberts

3.10.8b Expected Output

The 'Search criteria' auto-suggest gives results for danny roberts

3.10.11 Pending reserving registration reflects master subject record information

3.10.11a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User selects a reserving epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on select
11. User clicks save and continue
12. User completes the registration flow, but does not reserve subject on the study.
13. User exits the registration flow.
14. User navigates to the Persons And Organization >>Subject >> Manage subject tab
15. user searches for subject danny smith
16. User edits this subject and changes the name to danny roberts
17. User exits the edit subject flow
18. User navigates to registration >> manage registration.
19. User searches for registration by subject last name roberts.
20. The user enter manage registration flow for appropriate pending registration

3.10.11b Expected Output

The name of the subject in the registration is updated since the registration is in pending status.

3.10.12 completed reserving registration reflects subject snapshot information

3.10.12a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User selects a reserving epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on select
11. User clicks save and continue
12. User completes the registration flow and reserved subject on the study.
13. User exits the registration flow.

14. User navigates to the Persons And Organization >>Subject >> Manage subject tab
15. user searches for subject danny smith
16. User edits this subject and changes the name to danny roberts
17. User exits the edit subject flow
18. User navigates to registration >> manage registration.
19. User searches for registration by subject last name roberts.
20. The user enter manage registration flow for appropriate pending registration

3.10.12b Expected Output

The name of the subject in the registration is not updated since the registration is in reserved status.

3.10.13 Pending enrolling registration reflects master subject record information

3.10.13a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User selects a enrolling epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on select
11. User clicks save and continue
12. User completes the registration flow, but does not enroll subject on the study.
13. User exits the registration flow.
14. User navigates to the Persons And Organization >>Subject >> Manage subject tab
15. user searches for subject danny smith
16. User edits this subject and changes the name to danny roberts
17. User exits the edit subject flow
18. User navigates to registration >> manage registration.
19. User searches for registration by subject last name roberts.
20. The user enter manage registration flow for appropriate pending registration

3.10.13b Expected Output

The name of the subject in the registration is updated since the registration is in pending status.

3.10.14 completed enrolling registration reflects subject snapshot information

3.10.14a Steps

1. User is logged in as c3pr admin.
2. User navigates to registration >> create registration.
3. In the select study panel, User searches for a study by identifier
4. The study results table show a list of study matching the search criteria
5. User selects a study and study site from the study results table
6. In the select epoch panel, the list of applicable epochs are shown.
7. User selects a enrolling epoch from the epoch table.
8. In the select subject panel, user searches for a subject by last name
9. In the subject results table, user clicks on one of the subjects named danny smith
10. In the expanded subject details panel, user clicks on select
11. User clicks save and continue
12. User completes the registration flow and enrolls subject on the study.
13. User exits the registration flow.
14. User navigates to the Persons And Organization >>Subject >> Manage subject tab
15. user searches for subject danny smith
16. User edits this subject and changes the name to danny roberts
17. User exits the edit subject flow
18. User navigates to registration >> manage registration.

19. User searches for registration by subject last name roberts.
20. The user enter manage registration flow for appropriate pending registration

3.10.12b Expected Output

The name of the subject in the registration is not updated since the registration is in enrolled status.

3.11 Search Registration

A User registers a Subject to a basic study, filling in the appropriate details. The user then searches for existing registration in c3pr

3.11a Steps

1. Click on the Registration tab.
2. Click on manage registration sub tab.
3. Set registration search criteria to search by subject last name.
4. Enter the subject last name string and choose one of the results from the auto-suggest.
5. For the chosen subject , a list of registrations will be shown.
6. Click on a registration with a registration status of 'pending'
7. You will be taken to manage registration flow.

3.11b Expected Output

User is able to search for existing registrations in the system.

3.12 Create Registration on Screening epoch

A Registrar registers a Subject to a on a screening epoch of a simple study that uses phone call randomization.

3.12a Steps

1. Login to c3pr as registrar.
2.Click on registration tab.
3. Click on 'Create registration' tab.
4. Search for the study.
5. Set search studies by 'identifier'
6. Enter the study identifier in the search criteria and click the search button.
7. A list of results will be shown for studies that match the input criterion.
8. Click on the appropriate study.
9. This will expand into a list of sites at the study which are active.
10. Select the site as 'Mayo clinic rochester'.
11. The selection will be recorded and the study panel will collapse.
12. The 'Select Epoch' panel will expand and the list of available epochs for the chosen study will be shown.
13. Select a reserving epoch.
14. The selection will be recorded and the epoch panel will collapse.
15. In the 'Select subject' panel, enter all mandatory fields highlighted in red:
    1. first name,
    2. last name,
    3. gender,
    4. birth date
    5. ethnicity
    6. primary identifier organization
    7. primary identifier string
    8. primary identifier type
16. Click on create subject.
17. The selection will be recorded and the subject panel will collapse.
18. Expand the subject panel and you will see confirmation that the subject was created and selected.
19. Click save and continue.
20. You will be taken to the enrollment details tab.
21. Enter the registration date and consent signed date.
22. C3pr will throw error for if registration date is before consent signed date.
23. Click save and continue.
24. You will be taken to the Eligibility tab.
25. Answer yes to all inclusion critieria and no all exclusion critieria. This will ensure that the subject is made eligible to the study.
26. Click save and continue.
27. You will be taken to the stratification tab.

28. Choose appropriate answers for each stratification question.
29. Click save and continue.
30. You will be taken to the arm tab.
31. Since a reserving epoch need not have arms, there is no action available here.
32. Click save and continue.
33. You will be taken to the companion registrations tab.
34. Since the study does not have associated companion studies for this epoch C3PR will not prompt for companion registrations.
35. Click save and continue.
36. You will be taken to the review and submit tab.
37. Scroll to the bottom of the page.
38. Click on reserve button.
41. You will get a confirmation for successful reservation of subject on study.

3.13 Import Registration

A Registrar registers a Subject to a on a screening epoch of a simple study that uses phone call randomization.

3.13a Steps

1. Click on the Administration tab.
2. Click on the Import sub tab.
3. Click on Import registration sub sub tab.
4. Click on browse, and locate the registration XML file located in your computer.
5. Note that the XML should conform to the registration schema.
6. A copy of the schema is available in the import registration tab.
7. After choosing the appropriate registration XML file, click import.
8. If study has been imported successfully, you will see the study listed in uploaded registrations panel.
9. If there is a failure in registration import, a link will be shown for 'Download Output XML File'.
10. Click on this link and view the XML.
11. All registration import related errors will be listed at the bottom of the output XML

3.13b Expected Output

User is able to import registrations into c3pr.

3.14 Registration Eligibility Waiver

A Registrar registers a Subject who is fails the eligiblity criteria. The study coordinator should be able to waive eligibility for the subject and allows registrar to proceed with enrollment

3.14.1 c3pr admin is not able to see 'Waive Eligibility' action for ineligible registration

3.14.1a Steps

1. User logs in as c3pr admin.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow

3.14.1b Expected Output

User is not shown the action for 'Waive Eligibility' for this registration

3.14.2 Site coordinator is not able to see 'Waive Eligibility' action for ineligible registration

3.14.2a Steps

1. User logs in as site coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow

3.14.2b Expected Output

User is not shown the action for 'Waive Eligibility' for this registration

3.14.3 registrar is not able to see 'Waive Eligibility' action for ineligible registration

3.14.3a Steps

1. User logs in as registrar.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow

3.14.3b Expected Output

User is not shown the action for 'Waive Eligibility' for this registration

3.14.4 study coordinator is able to see 'Waive Eligibility' action for ineligible registration

3.14.4a Steps

1. User logs in as study coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow

3.14.4b Expected Output

User is shown the action for 'Waive Eligibility' for this registration

3.14.5 Study coordinator is able to Waive Eligibility for ineligible conditions

3.14.5a Steps

1. User logs in as study coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow.
5. User click on 'waive eligibility' condition.
6. User is shown a pop up to pick the list of conditions to waive

3.14.5b Expected Output

User is allowed to check for all ineligible conditions to waive.

3.14.6 Study coordinator is not able to Waive Eligibility for eligible conditions

3.14.6a Steps

1. User logs in as study coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow.
5. User click on 'waive eligibility' condition.
6. User is shown a pop up to pick the list of conditions for waiver.

3.14.6b Expected Output

User is not allowed to check eligible conditions for waiver.

3.14.7 Registrar can complete registration of ineligible record if study coordinator waives eligibility criteria

3.14.7a Steps

1. User logs in as study coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow.
5. User click on 'waive eligibility' condition.
6. User is shown a pop up to pick the list of conditions to waive
7. User waives ineligible conditions
8. User logs in as registrar
9. user navigates to Registration>>manage registration page.
10. User searches for the ineligible incomplete registration.
11. User does not change eligibility values, buts adds all other required details.

3.14.7b Expected Output

User is allowed to complete registration even if subject is ineligible due to waiver by subject coordinator.

3.14.8 Registrar is required to enter waiver id and waiver reason for eligibility waived by study coordinator

3.14.8a Steps

1. User logs in as study coordinator.
2. user navigates to Registration>>manage registration page.
3. User searches for an ineligible incomplete registration.
4. User is in manage registration flow.
5. User clicks on 'waive eligibility' condition.
6. User is shown a pop up to pick the list of conditions to waive
7. User waives ineligible conditions
8. User logs in as registrar
9. user navigates to Registration>>manage registration page.
10. User searches for the ineligible incomplete registration.
11. User resumes registration process.
12. User navigates to eligibility tab.

3.14.8b Expected Output

User is required to enter values for waiver id and waiver reason in eligibility tab.

3.15 Notification of subject updates

Registrar on study site should receive notification of updates to subject demographic details.

3.15.1 Registrar gets notification email for subject update when registration is in pending status

3.15.1a Steps

1. User logs in as c3pr admin
2. user navigates to Registration>>create registration page.
3. User chooses study site, epoch, and subject.
4. User clicks save and continue and is in registration >> enrollment details page.

5. User exits registration flow.
6. user navigates to Registration>>create registration page.
7. In subject panel, user searches for the same subject.
8. User edits this subject and is in edit subject flow.
9. User changes the maiden name to 'mn01' and clicks 'Save and return to registration'
10. registrar on study site checks his email registered on his research staff record.

3.15.1b Expected Output

Notification should be received for change of subject details by registrar.

3.15.2 Registrar gets notification email for subject update when registration is in enrolled status

3.15.2a Steps

1. User logs in as c3pr admin
2. user navigates to Registration>>create registration page.
3. User chooses study site, epoch, and subject.
4. User clicks save and continue
5. User completes registration flow and enrolls subject in an enrolling epoch.
6. user navigates to Registration>>create registration page.
7. In subject panel, user searches for the same subject.
8. User edits this subject and is in edit subject flow.
9. User changes the maiden name to 'mn01' and clicks 'Save and return to registration'
10. registrar on study site checks his email registered on his research staff record.

3.15.1b Expected Output

Notification should be received for change of subject details by registrar.

3.15.3 Registrar gets notification email for subject update when registration is in reserved status

3.15.3a Steps

1. User logs in as c3pr admin
2. user navigates to Registration>>create registration page.
3. User chooses study site, epoch, and subject.
4. User clicks save and continue.
5. User completes registration flow and reserves subject in a reserving epoch.
6. user navigates to Registration>>create registration page.
7. In subject panel, user searches for the same subject.
8. User edits this subject and is in edit subject flow.
9. User changes the maiden name to 'mn01' and clicks 'Save and return to registration'
10. registrar on study site checks his email registered on his research staff record.

3.15.3b Expected Output

Notification should be received for change of subject details by registrar.

3.15.4 Registrar gets notification email for subject update when subject is edited in subject flow

3.15.4a Steps

1. User logs in as c3pr admin
2. user navigates to Registration>>create registration page.
3. User chooses study site, epoch, and subject.
4. User clicks save and continue.
5. User completes registration flow and reserves subject in a enrolling epoch.

6. user navigates to person & organization>>subject page.
7. In manage subject tab, user searches for the same subject.
8. User edits this subject and is in edit subject flow.
9. User changes the maiden name to 'mn01' and clicks 'Save'
10. registrar on study site checks his email registered on his research staff record.

3.15.4b Expected Output

Notification should be received for change of subject details by registrar.

3.15.5 Registrar gets notification email for subject update when subject is updated for companion study registration

3.15.5a Steps

1. User logs in as c3pr admin
2. user navigates to Registration>>create registration page.
3. User chooses study site, epoch, and subject.
4. User clicks save and continue.
5. User is in the companion registrations tab.
6. user clicks on register and completes the companion registration
7. User completes registration flow and reserves subject in a enrolling epoch.
8. user navigates to person & organization>>subject page.
9. In manage subject tab, user searches for the same subject.
10. User edits this subject and is in edit subject flow.
11. User changes the maiden name to 'mn01' and clicks 'Save'
12. registrar on study site checks his email registered on his research staff record.

3.15.5b Expected Output

Notification should be received for change of subject details by registrar.

3.15.6 Registrar should get link-back URL when c3pr is configured for link-back URL as Yes.

3.15.6a Steps

1. User logs in as c3pr admin.
2. User navigates to Configure C3pr.
3. User set the Notification link back to Yes and clicks save.
4. C3PR has to be restarted after this change.
5. user navigates to Registration>>create registration page.
6. User chooses study site, epoch, and subject.
7. User clicks save and continue.
8. User is in the companion registrations tab.
9. user clicks on register and completes the companion registration
10. User completes registration flow and reserves subject in a enrolling epoch.
11. user navigates to person & organization>>subject page.
12. In manage subject tab, user searches for the same subject.
13. User edits this subject and is in edit subject flow.
14. User changes the maiden name to 'mn01' and clicks 'Save'
15. registrar on study site checks his email registered on his research staff record.

3.15.6b Expected Output

Notification should be received for change of subject details by registrar. The email should have a link back to the registrar's inbox which would show a list of recent updates to subject.

3.15.7 Registrar should get subject URL when c3pr is configured for link-back URL as No.

3.15.7a Steps

1. User logs in as c3pr admin.
2. User navigates to Configure C3pr.
3. User set the Notification link back to No and clicks save.
4. C3PR has to be restarted after this change.
5. user navigates to Registration>>create registration page.
6. User chooses study site, epoch, and subject.
7. User clicks save and continue.
8. User is in the companion registrations tab.
9. user clicks on register and completes the companion registration
10. User completes registration flow and reserves subject in a enrolling epoch.
11. user navigates to person & organization>>subject page.
12. In manage subject tab, user searches for the same subject.
13. User edits this subject and is in edit subject flow.
14. User changes the maiden name to 'mn01' and clicks 'Save'
15. registrar on study site checks his email registered on his research staff record.

3.15.7b Expected Output

Notification should be received for change of subject details by registrar. The email should have a URL which will show subject details in c3pr.

4. Searching

The following test cases require that a number of registrations and other data items be entered. Therefore, it may be worthwhile to perform these tests after the study and registration test cases.
Note: Site Coordinator and Administrator are the only roles who have privileges to access the "Advance Search" feature

4.1 Find Registrations within a Date Range

User searches C3PR for all subject registrations within a certain date range, for example to generate a report for the center director. Such a report should include the numbers of registrations, the studies for those registrations, etc.

4.1a Steps

1. User navigates to to report>>search registrations
2. Registrations can be searched by various criteria such as study title, subject DOB etc.
3. User enters the start date and the end date to specify a date range in which registrations have occurred.
4. User clicks search registration and the list of registrations completed in that date range is shown.

4.1b Special Considerations

- None

4.1c Expected Output

- The list of registrations completed in the supplied date range is shown.

4.2 Find Registrations for a Study

User searches C3PR for all subject registrations for specific study. Such a report should include the study short title, study identifier, subject primary identifier, registration status and so on.

4.2a Steps

1. Navigate to Reports tab.
2. Click on Search registration tab.
3. Enter a partial string for study short title or study identifier.
4. Click search registration.

4.2b Special Considerations

- None

4.2c Expected Output

- The list of applicable registrations will be shown in the results table.

5. Reporting

5.1 Create a Summary 3 Report

A Site Coordinator generates a Summary 3 Report that can be integrated into the centers summary report package.

5.1a Steps

1. Enter the Summary 3 Report workflow within the Reporting module
2. Select a study site to generate a report for (typically the site you are logged in from)
3. Enter a date range
4. Generate an Adobe PDF or Microsoft Excel report

5.1b Special Considerations

- None

5.1c Expected Output

- An report in the correct Summary 3 format with the correct data is generated

6. Administration

Note that it may be useful to perform these test cases before the study and registration test cases because you can use them as core data for those tests.

6.1 Add a New Site and Study Site

A Site Coordinator adds a new site to C3PR so that it can be used in studies and registrations. He then adds that site as a new study site for a study. This could be used when a center begins collaboration with a pharmaceutical company or research center that is not included in NCI's list.

6.1a Steps

1. Enter the create site workflow within the administration module
2. Add details for the new site, including a unique identifier
3. Save the site
4. Enter the search study workflow
5. Search for and select a study
6. Navigate to the study sites tab
7. Add the new study site with appropriate data

6.1b Special Considerations

- None

6.1c Expected Output

- A new site exists and is able to register subjects to the study

6.2 Add a New Investigator and Treating Physician

A Site Coordinator adds a new investigator to C3PR that will be the treating physician for new registrations. This is a common occurrence when new clinicians join the center.

6.2a Steps

1. Enter the create investigator workflow within the administration module
2. Add details for the new investigator, including a unique identifier
3. Save the investigator
4. Enter the search study workflow
5. Search for and select a study
6. Add the new investigator as a treating physician

6.2b Special Considerations

- None

6.2c Expected Output

- A new investigator exists and is able to be selected as a treating physician for the study

6.3 Deactivate an Existing Investigator

A Site Coordinator deactivates an investigator who maycan no longer act as a treating physician for any studies. This is a common occurrence when clinicians leave the center.

6.3a Steps

1. Enter the search investigator workflow within the administration module
2. Search for and select the investigator
3. Deactivate the investigator

6.3b Special Considerations

- None

6.3c Expected Output

- The investigator can no longer be selected as a treating physician for any study

7. Research Staff

7.1 Create Research Staff 

User creates a new Research staff

7.1a Steps

1. Navigate to Persons & Organizations >> Research staff
2. Click on Create research staff
3. Type organization as "Duke University Medical Center" and select the suggested value
4. Fill in First name, Last name, Assigned Identifier, email and username.
5. Make sure email is is a valid email address. Notification about creation of new research staff will be sent to the email.
6. Choose one or more roles for the research staff.
7. Clicks save.
8. You will get a "Research Staff member successfully created." message.

9. Check email for notification of creation of new research staff.
10. Click on the URL in the email
11. You will be taken to the C3PR password reset page.
12. Set the password.
13. Use the new password to login to C3PR.

7.1b Special Considerations

- None

7.1c Expected Output

- New Research staff has been created in C3PR

7.2 Search Research Staff

User searches for existing research staff.

7.2a Steps

1. Navigate to Persons & Organizations >> Research staff
2. Click on Manage research staff
3. Type organization as "Duke University Medical Center" and select the suggested value
4. Fill in First name, Last name, Assigned Identifier.
5. Click search.
6. Make sure you see the appropriate results in the Search results table.

7.2b Special Considerations

- None

7.2c Expected Output

- Research staff with given search critieria are shown in the results pane.

7.3 Edit Research Staff

User edits existing research staff.

7.3a Steps

1. Navigate to Persons & Organizations >> Research staff
2. Click on Manage research staff
3. Search for a specific research staff and click on it in the search results page.
4. Add the middle name, maiden name and click save.
5. You will get a "Research Staff member successfully updated." message.

7.3b Special Considerations

- None

7.3c Expected Output

- User able to update existing research staff details.

8. Investigator

8.1 Create Investigator

User creates a new Investigator

8.1a Steps

1. Navigate to Persons & Organizations >> Investigator
2. Click on Create Investigator
3. Type organization as "Duke University Medical Center" and select the suggested value
4. Fill in First name, Last name, Assigned Identifier, and email.
5. Set Investigator status to Active.
6. Clicks save.
7. You will get a "Investigator successfully created." message.

8.1b Special Considerations

- None

8.1c Expected Output

- New Investigator has been created in C3PR

8.2 Search Investigator

User searches for existing Investigator.

8.2a Steps

1. Navigate to Persons & Organizations >> Investigator
2. Click on Manage Investigator
3. Type organization as "Duke University Medical Center" and select the suggested value
4. Fill in First name, Last name, Assigned Identifier.
5. Click search.
6. Make sure you see the appropriate results in the Search results table.

8.2b Special Considerations

- None

8.2c Expected Output

- Investigator with given search critieria are shown in the results pane.

8.3 Edit Investigator

User edits existing Investigator.

8.3a Steps

1. Navigate to Persons & Organizations >> Investigator
2. Click on Manage Investigator
3. Search for a specific Investigator and click on it in the search results page.
4. Add the middle name, maiden name and click save.

5. You will get a "Investigator successfully updated." message.

8.3b Special Considerations

- None

8.3c Expected Output

- User able to update existing research staff details.

9. Organization

9.1 Create Organization

User creates a new Organization

9.1a Steps

1. Navigate to Persons & Organizations >> Organization
2. Click on Create Organization
3. Fill in name, description and CTEP identifier.
4. Click save.
5. You will get a "Organization successfully created." message.

9.2b Special Considerations

- None

9.2c Expected Output

- New Organization has been created in C3PR

9.3 Search Organization

User searches for existing Organization.

9.3a Steps

1. Navigate to Persons & Organizations >> Organization.
2. Click on Manage Organization.
3. Fill in name, CTEP identifier.
4. Click search.
5. Make sure you see the appropriate results in the Search results table.

9.3b Special Considerations

- None

9.3c Expected Output

- Organization with given search critieria are shown in the results pane.

9.4 Edit Organization

User edits existing Organization.

9.4a Steps

1. Navigate to Persons & Organizations >> Organization
2. Click on Manage Organization
3. Search for a specific Organization and click on it in the search results page.
4. Fill in the description and click save.
5. You will get a 'Organization successfully updated.' message

9.4b Special Considerations

- None

9.4c Expected Output

- User able to update existing organization details.