Shared Investigator Platform

Site User Handbook

Version 1.0

Contents

Revision History

Version	Date	Author	Changes
0.1	2/20/2015	CI Content Team Cognizant Technology Solutions	First Draft
0.2	3/16/2015	CI Content Team Cognizant Technology Solutions	Second Draft
0.3	4/20/2015	CI Content Team Cognizant Technology Solutions	Third Draft

1 Shared Investigator Platform

The Shared Investigator Platform (SIP) offers a central point of access for Principal Investigators and Site Staff to interact with participating clinical trial Sponsors. SIP offers sites, harmonized content, and services to reduce the burden on investigative sites, and increased visibility to new study opportunities with participating clinical trial Sponsors.

The following are the benefits of SIP:

- Additional clinical trial efficiencies
- Reduced administrative burden because of the decrease in redundant requests for information and documents
- Increased visibility to new study opportunities with participating clinical trial Sponsors
- Consolidated view of study tasks so that Site User can prioritize across studies and participating Sponsors
- Ability to exchange documents between Sponsors and Site Users
- Easy access to central repository of study documents
- Ability to generate Curriculum Vitae (CV)
- Single Site User account in which the Site User can log on with access to multiple Sponsors
- Centralized profile information and credentials which can be easily updated and re-used across the platform

1.1 About the User Manual

This manual describes the various functions and tasks that the Site Users perform in the Shared Investigator Platform (SIP). Tasks include the following:

- Managing your profile
- Updating Facility capabilities in the Facility Profile
- Accessing clinical trial information and documents by using the Study Workspace
- Exchanging study startup documents and communications in the Documents portal
- Completing clinical program or trial feasibility surveys in the Feasibility portal
- Completing training assignments
- Updating your training history in the Training portal and Reports

1.1.1 Icons

The following table lists the icons that are used in this manual.

Document Icons	Description
	Important information that needs to be highlighted regarding a concept or task is provided in the form of a note.
	These are good-to-know information about a page or field.
CAUTION	These are error messages for invalid data or missing data, in addition to warning/reminder messages.
	This symbol indicates a Site User.

Table 1. List of Conventions Used in the Document

1.1.2 Acronyms and Abbreviations

The following table lists the document conventions used in this manual.

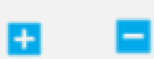
Acronyms/Abbreviations	Description
CV	Curriculum Vitae
CSV	Comma Separated Values
CTMS	Clinical Trial Management System
DIA	Drug Information Association

Acronyms/Abbreviations	Description
EC	Ethics Committee (for other countries)
EDC	Electronic Data Capture
ER	Electronic Records
ERB	Ethics Review Board
eSIG	Electronic Signatures
eTMF	Electronic Trial Master File
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IRB	Institutional Review Board (For US)
MRT	Mutually Recognized Training
RBAC	Role Based Access Control: Assigns a set of permissions or entitlements based on role and not an individual
SIP	Shared Investigator Platform
Single User Account	Allows an individual to authenticate and be authenticated using a single user account

Table 2. Acronyms and Abbreviations

1.1.3 Common Icons

The following table lists the common icons that you will use in the platform.

Icon	Icon Name	Description
	Calendar	Click the Calendar icon to populate any date field with a selected date.
	Search	These icons help Site Users search for a document, training, User Profile, Facility, and Study Site. Click the + icon to expand the search area, and the - icon to close the search area.
	Notifications	Click the Notifications icon to view a list of received notifications.
	Settings	Click the Settings icon to modify SIP settings such as Change Password and Update Challenge Questions.

Icon	Icon Name	Description
	Help	Click this icon to view SIP section or field-level help.
Edit	Edit	Click this link to modify the details.
Delete	Delete	Click this link to delete the selected item.
	Help Text	Point to this icon to view the help information.

Table 3. Common Icons

1.1.4 Navigational Elements

The following table lists the navigational elements that are used in the system.

Navigational Tools	Description
	To sort values, in the header, click this icon.
Showing 11-20 of 1034 2	Pagination bar. 'Showing 11 -20 of 1034' indicates that the Site User is viewing record numbers 11 to 20 from a total of 1034 records. It also indicates the number of records per page. In this example, on every page, 10 records are being displayed. The Number '2' indicates that the Site User is on page 2 of the records and the records 11-20 are on page 2.
	To go to the **Next** page of the records, click this icon.
	To go to the **Previous** page of the records, click this icon.
	To go to the **Last** page of the records, click this icon.
	To go to the **First** page of the records, click this icon.
Documents > Upload New Document	To know the links back to each previous page that the Site User navigates through to get to the current page, see the breadcrumbs near the top of the web page.
	To navigate horizontally in a page
	To navigate vertically in a page

Table 4. Navigational Elements

1.1.5 Common Actions

The following table lists the common action buttons available in the SIP system.

Common Actions	Button	Description
Save	Save	To save the entered data when exiting a page or section, click **Save**.
Submit	Submit	Submit triggers processing of the data and notifications are sent to Sponsors or other Site Users.
Cancel	Cancel	To cancel the activity, click **Cancel**.
Reset	Reset	To clear data from an entire SIP page or section to restart data entry, click **Reset**.
Previous	Previous Section	To go to the previous section, click **Previous Section**.
Next	Next Section	To go to the Next section, click **Next Section**.
Search	Search	To perform a search, click **Search**.
Download	Download	To download a document, click **Download**.
Delegate	Delegate	To delegate a task to another Site User, click **Delegate**.

Table 5. Common Actions

1.1.6 Intended Users

This guide is intended for the following Site Users:

- Investigators
- Other Site Personnel

1.1.7 Roles and Privileges

SIP manages user roles and tasks. Each user account is assigned privileges that the Site User can view and complete assigned actions and tasks. The following are the primary roles:

- **Principal Investigator**

Any Site User with appropriate qualifications/experience to potentially serve as a Principal Investigator on a study that is the primary person responsible for managing and conducting a clinical study. This role may delegate specific actions to other qualified Site Personnel.

- **Study Site Personnel**

All other Site Users of SIP, for example Study Nurses, Clinical Trial Coordinators, and Pharmacists are Study Site Personnel. These personnel may perform actions in the SIP system on behalf of the Principal Investigator with appropriate delegation of authority.

- **Facility Profile Manager**

The Facility Profile Manager is responsible for the entry and maintenance of the Facility Profile. Each Site needs to have at least one Facility Profile Manager. The person who first creates the Facility becomes the Facility Profile Manager, by default. This role can be delegated to another site staff member, and additional Facility Profile Managers can be added.

- **Primary Site Contact**

A site has the option to assign a Primary Site Contact for SIP clinical trials; this role can be assigned in the Facility Profile. The Primary Site Contact will receive copies of, and can act on the following SIP notifications that are sent to the Facility that include:

  - Invitations to participate in pre-study evaluations
  - Invitations to participate in a study
  - Invitations to participate in a Sponsor Survey

- **Designated Study Site Contact**

A Designated Study Site Contact receives all communications that are sent to the Study Site in terms of notifications in the SIP system and an email. Designated Site Contact only receives Study Site communications and there are no other privileges.

- **Clinical Research User**

A Clinical Research User performs all tasks of a Site User in addition to the responsibilities of a Principal Investigator.

SIP provides various user roles and tasks. This user guide is primarily intended for Site Users.
The following flowchart depicts the user roles and access privileges for a Site User.

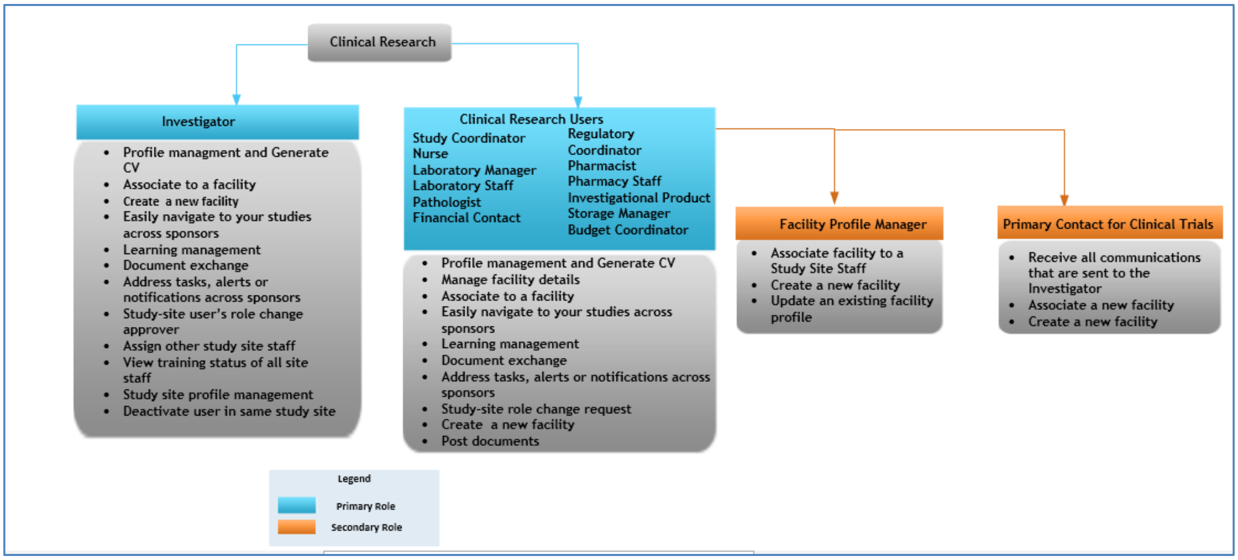


Figure 1. Site User Roles

2 SIP Public Landing Page

The SIP Public Landing Page displays the logon section for the Site Users. This page displays the registration link for new Site Users to register in the platform. This page also displays helpdesk details and other important references to important news and links to SIP Facts videos.

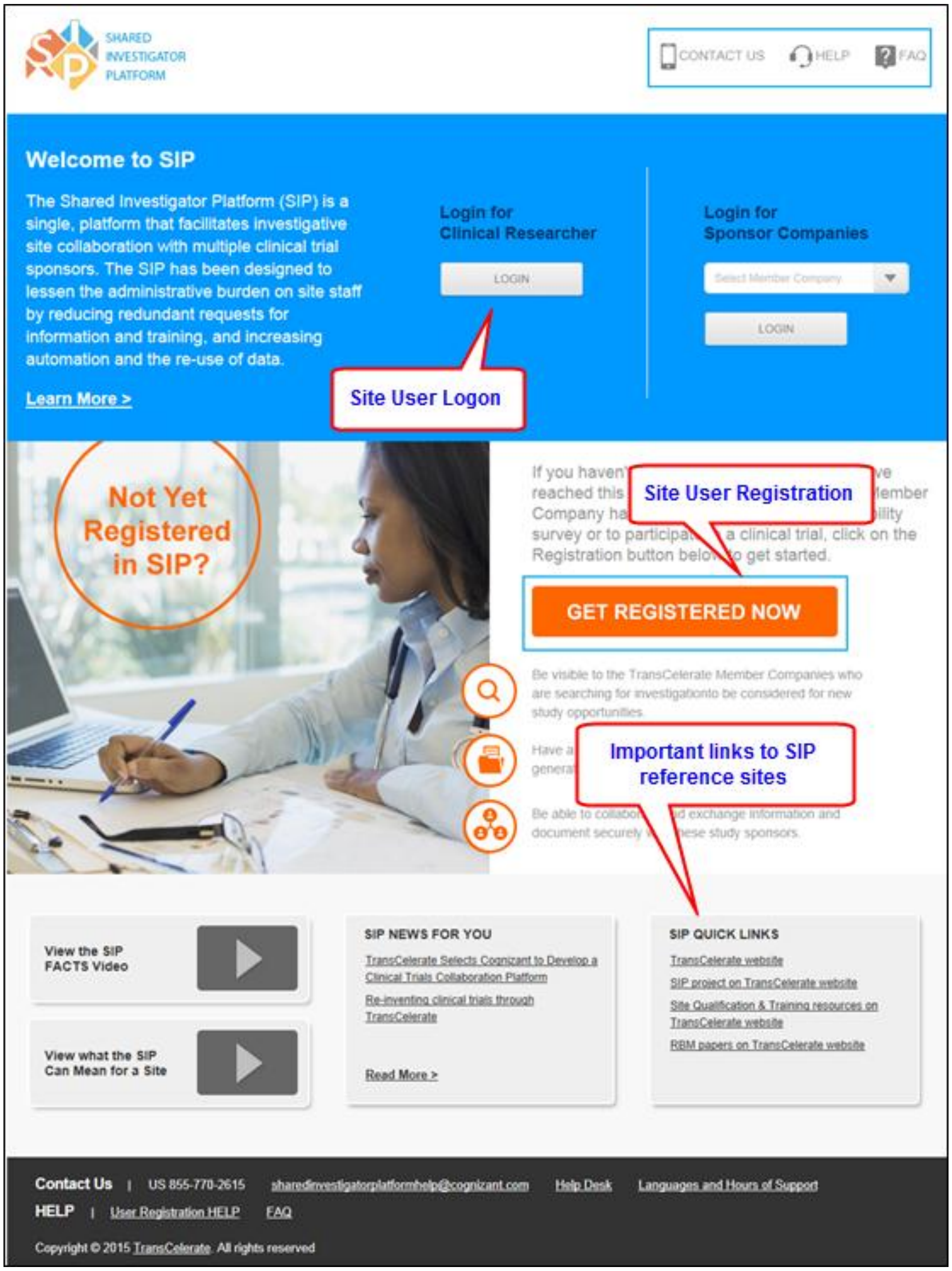


Figure 2. SIP Public Landing Page

2.1 Important References

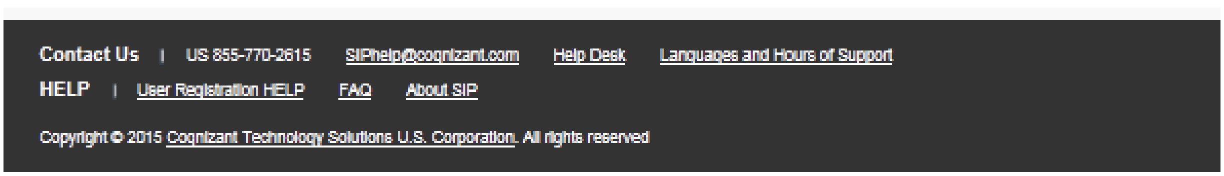
The Important References section in the SIP Public Landing Page provides important reference videos, relevant news items, and some SIP links.

For learning more about SIP, you can access important reference links by using the following options:

- *To watch the SIP Facts Video or to watch What the SIP Can Mean for a site, click .*
- *To read SIP news, click the relevant link in the SIP News for You section.*
- *To access SIP quick links, click the relevant link in the SIP Quick Links section.*

2.2 Contact Us

The Contact Us section in the SIP Public Landing Page provides the SIP Helpdesk contact numbers, email address, and reference materials that help Site Users in the registration process. The page also includes details on how the Site User receives the logon information in an email message, after which the Site User can proceed to log on to SIP.



For any immediate assistance on SIP modules, you can contact the SIP Helpdesk by using the following options:

Global Helpdesk Numbers

E-mail: SIPHelp@cognizant.com

*To refer to FAQs on Site User Registration, click **FAQ**.*

To refer to the registration process and steps to register in the SIP system, click User Registration HELP.

To refer to support information on other languages, click Languages and Hours of Support.

The Helpdesk Support team is available 24 hours on all seven days a week. See the Appendix for more information.

2.3 Site User Registration

Registered Site Users navigate to the SIP Public Landing Page to log on to SIP. New Site Users need to register themselves in the SIP system by using the **Get Registered Now** link. To complete the SIP registration process, the Site Users need to accept the SIP terms of use and the privacy policy, enter the requested user information, and complete the SIP orientation tutorial.

Before you register, you can add the following email address: CustomerService@exostar.com to the Trusted Source Settings in your mailbox. This is to ensure that Registration email messages reach your mailbox. The Service Helpdesk team is available 24 hours on all seven days a week.

If the Sponsor has already registered you in the SIP system and you have received your User ID and passwords by email, you need not register again. You may directly go to First Time Logon section to log on to SIP.

To ensure that system-generated notification emails are delivered to you, you can add the following email address: do-not-reply@sharedinvestigator.com to the Trusted Source Settings in your mailbox.

To register with SIP

1. Launch the browser (IE, Chrome, or Firefox).

SIP is best viewed on Microsoft® Internet Explorer (IE) 9+, Mozilla® Firefox 24+, and Google® Chrome 35+. The version numbers provided here are the lowest versions that SIP supports.

2. In the address bar, enter the web address: www.SharedInvestigator.com and press **Enter** on your keyboard. The SIP Public Landing Page is displayed.

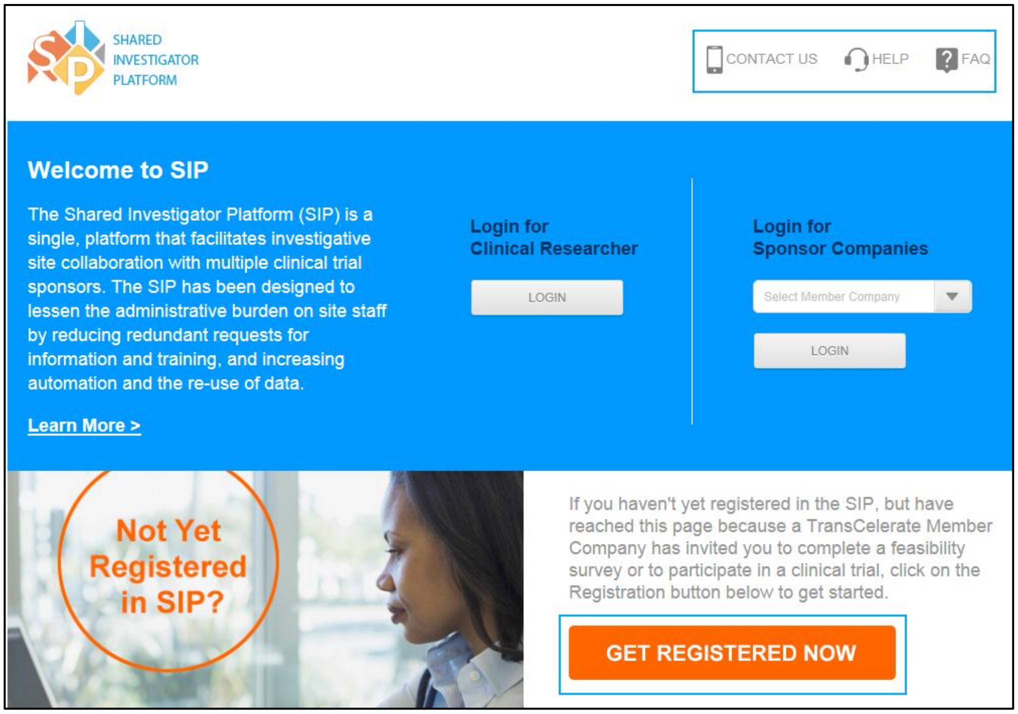


Figure 3. Site User Registration Page

3. To register with SIP, click **Get Registered Now** GET REGISTERED NOW. The Terms and Conditions/Policies dialog box is displayed.

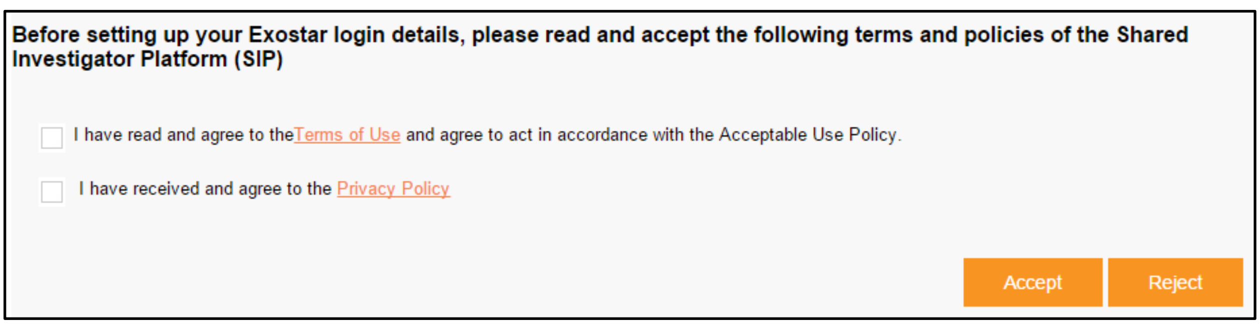


Figure 4. Terms and Conditions or Policies Dialog Box

4. Review the Terms of Use, and select the **Terms of Use** check box to confirm acceptance.
5. Review the Privacy Policy, and select the **Privacy Policy** check box to confirm acceptance.
6. To accept the terms and policies, click **Accept**. The **Personal Information** page is displayed.

To complete your registration and gain access to SIP, you need to accept the terms of use and privacy policy. Click the links to read the policies and then select the check boxes. If you reject any of these policies, the registration process will end.

*To reject the registration, click **Reject**.*

*To refer to SIP Registration help topics, click **User Registration Help**.*

*To contact the Helpdesk, click **Help Desk**.*

7. On the **Personal Information** page, enter the required details. For Site User Registration field descriptions, refer to Table 7.

You need to provide the five-digit numerical ZIP/Postal Code.

If your ZIP/Postal Code is greater than five digits, the system will consider the first five digits for validation.

If you do not have a ZIP/Postal Code, you need to provide a five-digit code, which will be used for validation to reset your User ID and Challenge Questions.

Single asterisk (*) on the Site User Registration fields indicates mandatory fields for Profile completion.

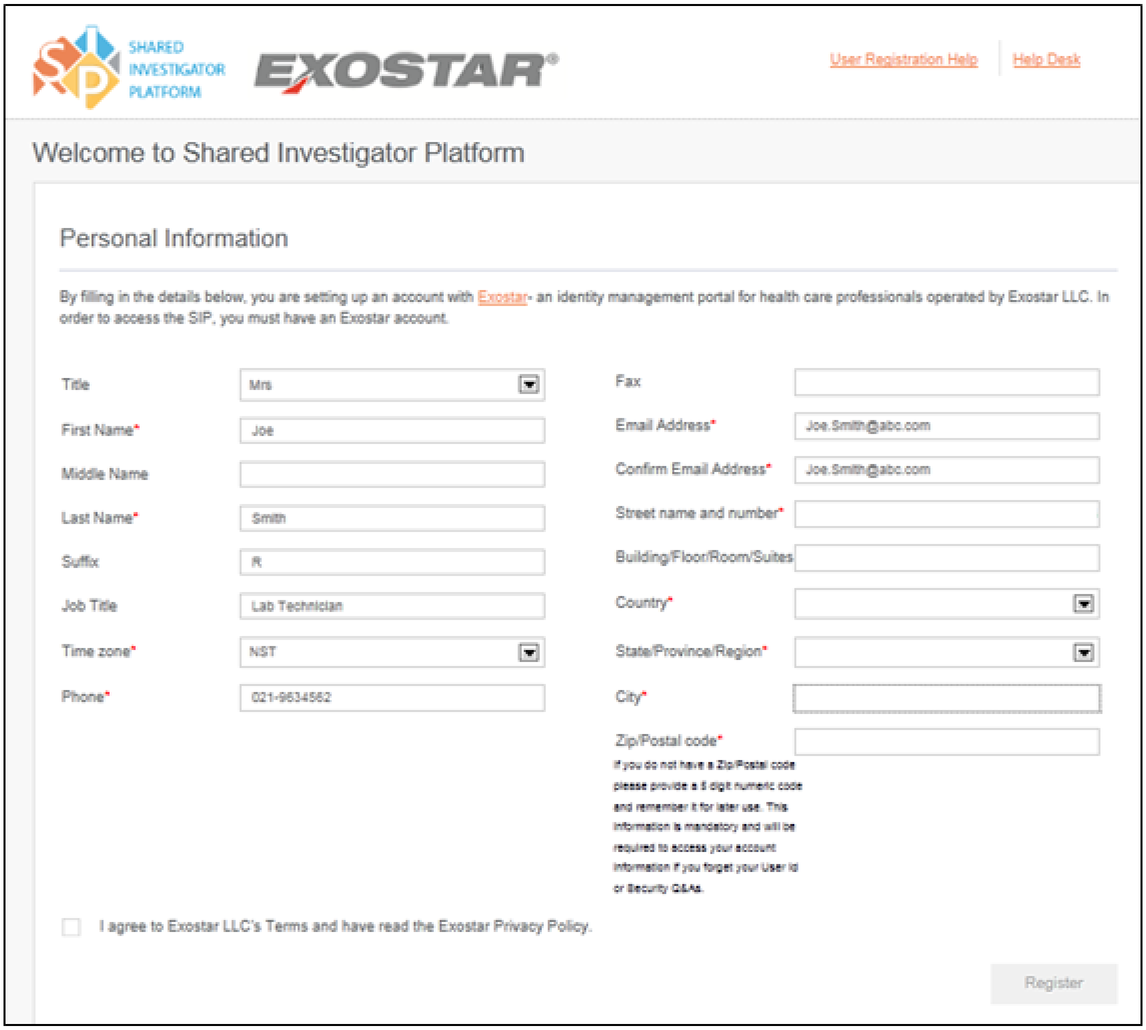
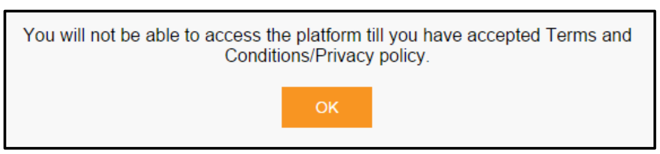


Figure 5. Personal Information Page

*To reject the registration, click **Reject**. The following message is displayed. Click **OK**.*



8. Select the **I agree to Exostar LLC's Terms and have read the Exostar Privacy Policy** check box. The **Register** button is enabled.

Figure 6. Register Button

9. Click **Register**. The Submission Confirmation page is displayed along with a confirmation message.

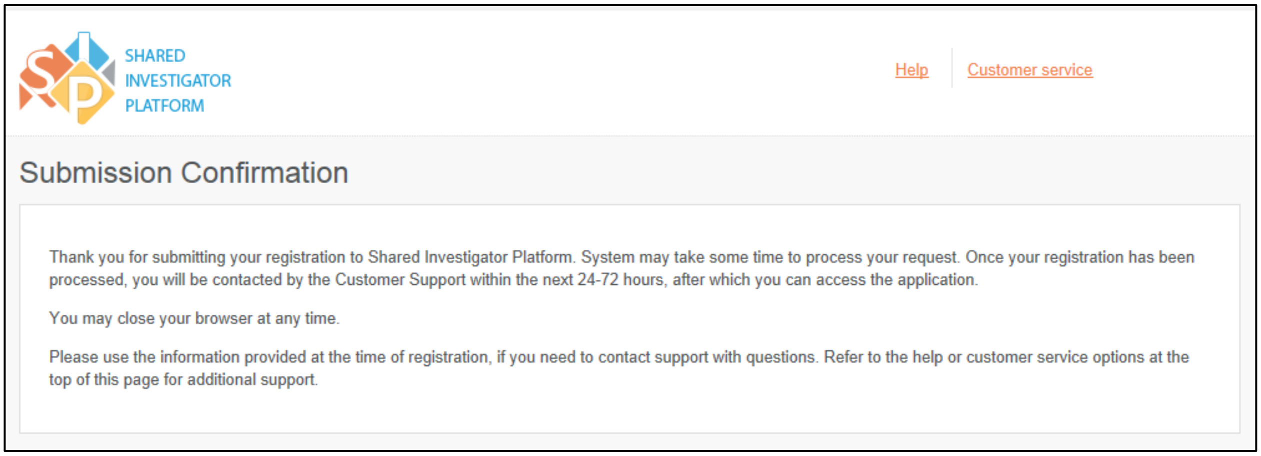


Figure 7. User Registration Submission: Confirmation Message

Once you submit your SIP registration, it will be processed. After your registration is processed, you will receive a system generated User ID and a set of temporary passwords (System Generated Password and one-time password) in two separate email messages within one to four hours from the SIP Administrator (Exostar Customer Service).

The Service Helpdesk team is available 24 hours, seven days a week. If you do not receive the emails within this time period, check the Junk or Spam folder of your mailbox.

It may take up to 30 minutes for your application(s) access to become active. If you cannot access the application right away, please wait for 30 minutes and re-attempt access to confirm.

The following are the sample registration email messages:

One-time Password Email

Subject: FW: Action Required: Activate TransCelerate SAM Account

Dear xxxxx

You should have received your TransCelerate SAM Account Created email with user ID and a system-generated password. To activate your account, you will also need your one-time password provided below.

ACTIVATION INSTRUCTIONS:

Go tohttps://TransCelerateSIPTest.cognizant.comand click on 'First Time Login'

- Use the following information for your initial login:

User ID: Provided in the Account Registration email.

System-Generated Password: Provided in the Account Registration email.

One-time Password: 2477-3370-2612-3241

NEED HELP? http://www.myexostar.com/myexostarAll.aspx?id=2438

DO NOT reply to this email. This is an automated email and replies are not being monitored.

User ID and System Generated Password Email

Subject: Action Required: First Time Login TransCelerate SAM Account

ACTIVATION INSTRUCTIONS:

- Go to https://TransCelerateSIPTest.cognizant.com and click on Log In Link

- Click on 'First Time Login' on login page.

- Use the following information for your initial login:

User ID : xxxxx_1809

One-time Password : Look for One Time Password Email with login instructions.

System-Generated Password : 1204-4062-8665-9875

NEED HELP? http://www.myexostar.com/myexostarAll.aspx?id=2438

DO NOT reply to this email. This is an automated email and replies are not being monitored.

The following table describes the fields on the User Registration page.

Field	Field Type	Mandatory Field	Field Descriptions
Personal Information			
Title	Drop-down list	N	Title of the Site User's name. For example, Mr., Mrs., Ms., Prof., Sir., Dr.
First Name*	Text box	Y	First name of the Site User
Middle Name	Text box	N	Middle name of the Site User
Last Name*	Text box	Y	Last name of the Site User
Suffix	Text box	N	Suffix, if any, in the Site User's name. For example, Jr., Sr. IV
Job Title	Text box	N	Job title of the Site User
Time Zone*	Drop-down list	Y	Time zone of the Site User location
Phone*	Text box	Y	Phone number of the Site User
Fax	Text box	N	Fax number of the Site User
Email Address*	Text box	Y	Email address of the Site User. This is the email address where the registration email, with the User ID, System Generated Password and One-Time Password is sent.

Field	Field Type	Mandatory Field	Field Descriptions
Confirm Email Address*	Text box	Y	Reconfirm the email address specified in the Email Address box.
Street Name and Number*	Text box	Y	Street name and number of the address that the Site User wants to provide for any correspondence. For example, Waterford Valley Dr., Highway 54
Building/Floor/Room/Suites	Text box	N	Name of the building, floor, room, or suite of the Site User. For example, Building 3, 5th floor, Suite 201.
Country*	Drop-down list	Y	Name of the Country of residence
State/Province/Region*	Text box	Y	State, province, or region of the Site User's City (as specified in the City box)
City*	Text box	Y	Name of the city where the Site User resides
ZIP/Postal Code*	Text box	Y	ZIP/Postal Code of the location Note: If you do not have a ZIP/Postal Code, then enter a five-digit number you will remember. This five-digit number will be needed if you have forgotten your User ID or Security questions and answers. Only the first five digits/characters are used to verify the Site User's identity.

Table 6. Field Descriptions for User Registration

2.4 Site User Logon

The Site User will receive logon information in two emails, after which the Site User can proceed to log on to SIP. The User ID and the system-generated password are sent in one email and the one-time password is sent in another email.

2.4.1 System Requirements

For the standard navigation framework and content display, the platform must scale to a resolution appropriate to a Site User's screen with a screen resolution of 1024 x 786 pixels and a color depth of 16-bit (65 536 colors).

2.4.2 First Time Site User Logon

If you are logging on to SIP for the first time, click **First Time Logon** (See Figure 8: First Time logon) below. Refer to the email you received from CustomerService@exostar.com titled "Action Required:

First Time Login TransCelerate SAM Account". This email contains your User ID, One-Time Password, and System-Generated Password**.**

1. On the **Welcome to SIP** page, in the **Login for Clinical Researcher** section, click **Login**. The Sign In page is displayed.

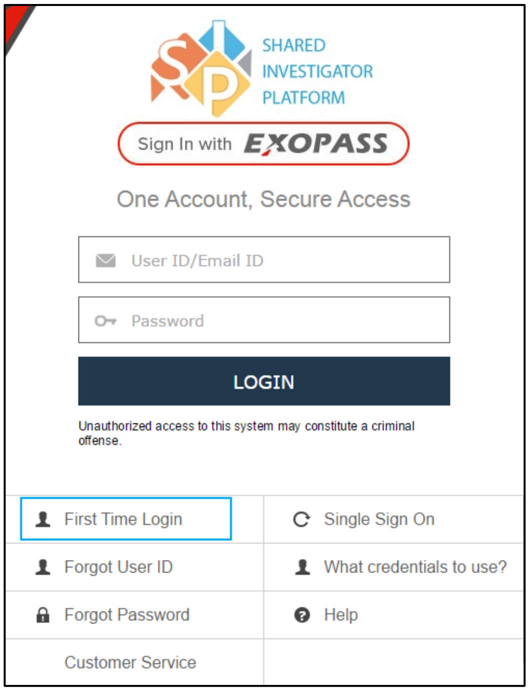


Figure 8. First Time Logon

2. To log on to the SIP for the first time, on the **Sign In** page, click **First Time Login**. The First Time Login page is displayed.

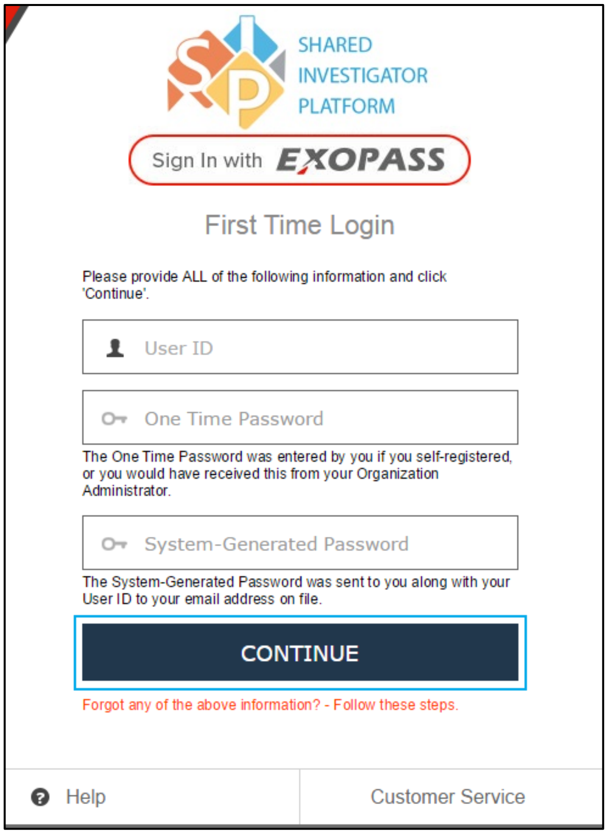


Figure 9. First Time Login Page

3. On the **First Time Login** page, In the **User ID** box, enter the User ID that you received in the email.
4. In the **One Time Password** box, enter the one-time password that you received in the email.
5. In the **System-Generated Password** box, enter the system-generated password you received in the email.

A system-generated password is sent to you along with your User ID, to your email address specified in the file.

6. In the **One Time Password** box, enter the one-time password that you received in the email.

A one-time password is sent to you in a separate email, to your email address specified in the file.

7. Click **Continue**. After successfully logging on for the first time, a page to reset the password is displayed.

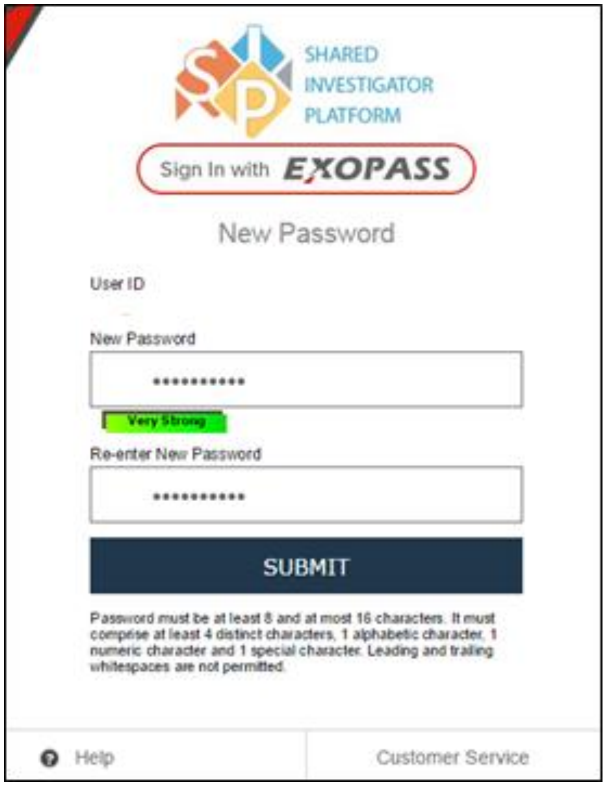


Figure 10. New Password Page

8. On the **New Password** page, in the **New Password** box, enter a new password.

The password needs to be a minimum of eight and a maximum of 16 characters. The password needs to contain at least one letter, one numeric value, and one special character (_&^ %$#@!).*

9. In the **Re-Enter New Password** box, re-enter the password and click **Submit**. The Password Reset Secrets page is displayed.

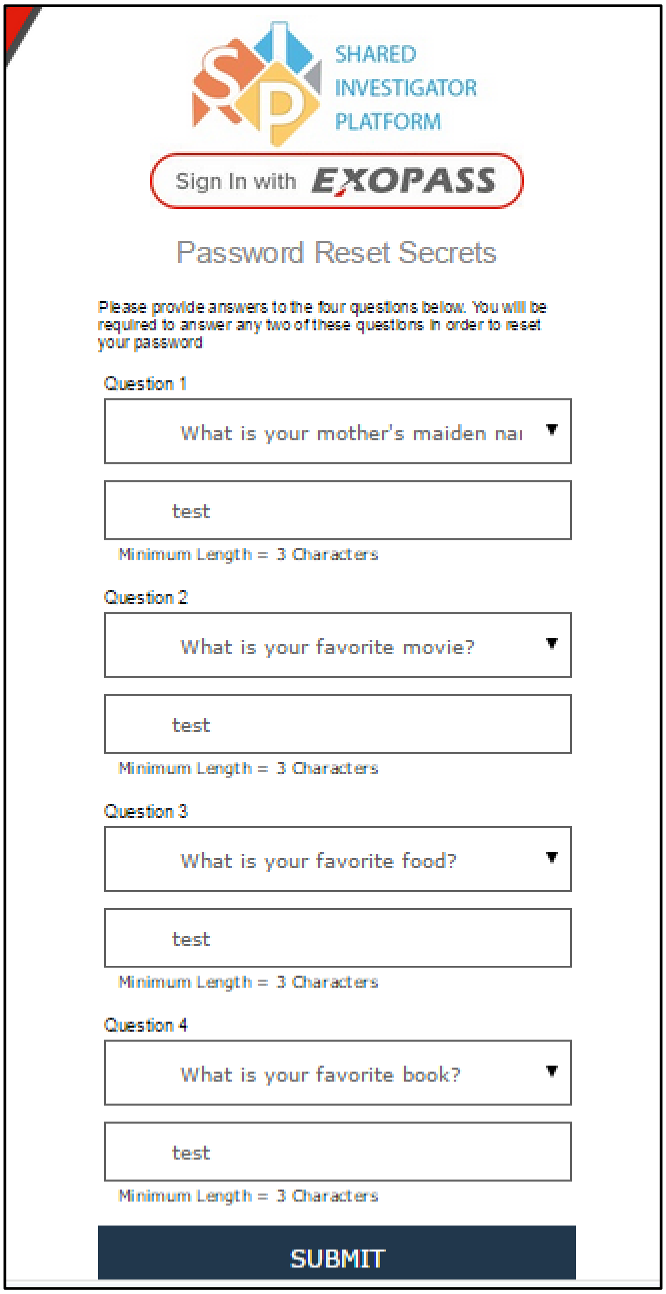


Figure 11. Password Reset Secrets Page

10. On the **Password Reset Secrets** page, click a question in each of the **Question** boxes and enter answers for them. Now, click **Submit**.

A mandatory prerequisite training is listed on the page, which you need to complete to gain access to the Site User Landing Page.

2.4.2.1. Forgot First Time Login Information

If you have misplaced or forgotten you First Time Login information, you need to enter your email address, ZIP/Postal Code or the five-digit code entered at the time of Registration and a new one-time password.

1. If you have misplaced or forgotten you First Time Login information, on the **First Time Login** page, click the **Forgot any of the Above Information? – Follow These Steps** link.

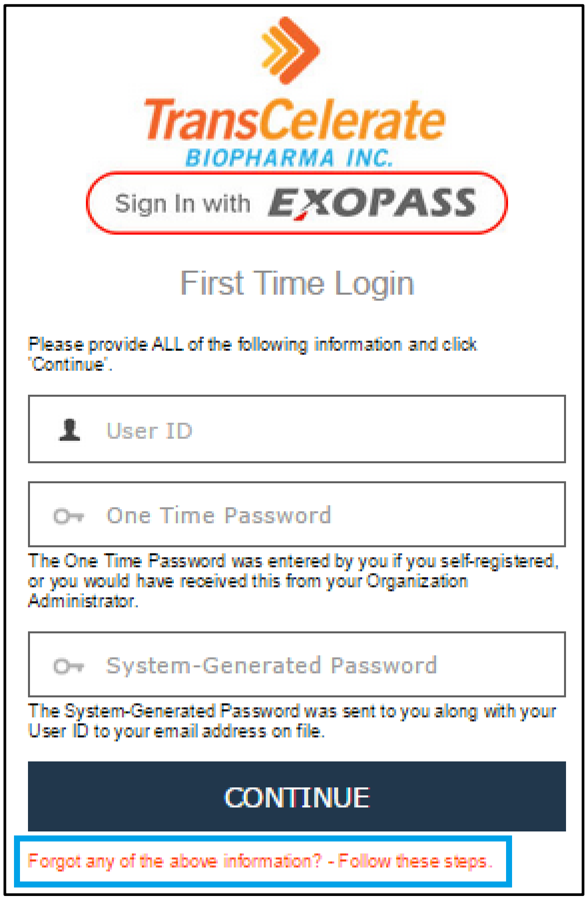


Figure 12. First Time Login Page

2. On the **Forgot First Time Login Information** page, enter your email address, ZIP/Postal Code or the five-digit code entered at the time of Registration along with a new one-time password.

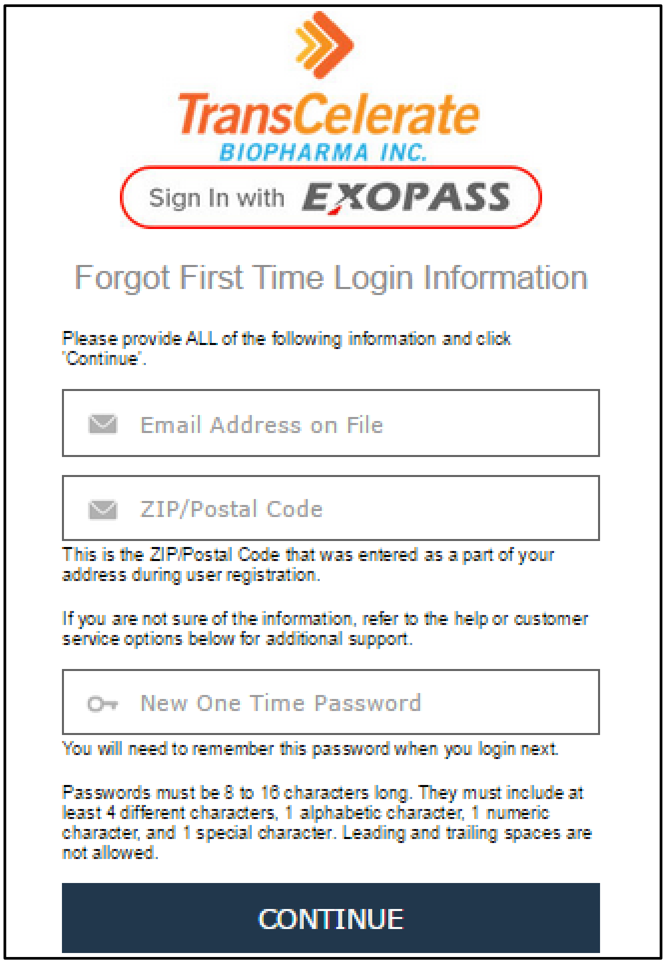


Figure 13. Forgot First Time Login Information Page

3. Click **Continue**. The following message is displayed.

Figure 14. Confirmation Message

2.5 Logging On

This section explains how you can log on to SIP.

To log on to SIP

1. On the **Welcome to SIP** page, in the **Login for Clinical Researcher** section, click **Login**. The Sign In page is displayed.

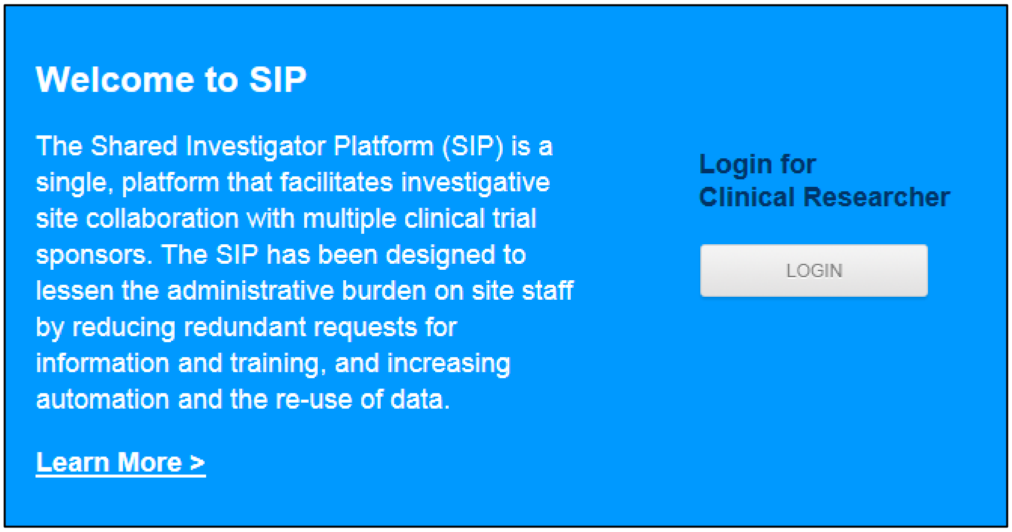


Figure 15. SIP Public Landing Page

2. To log on, on the **Sign In** page, in the **User ID/Email ID** box, enter the User ID or your email address.

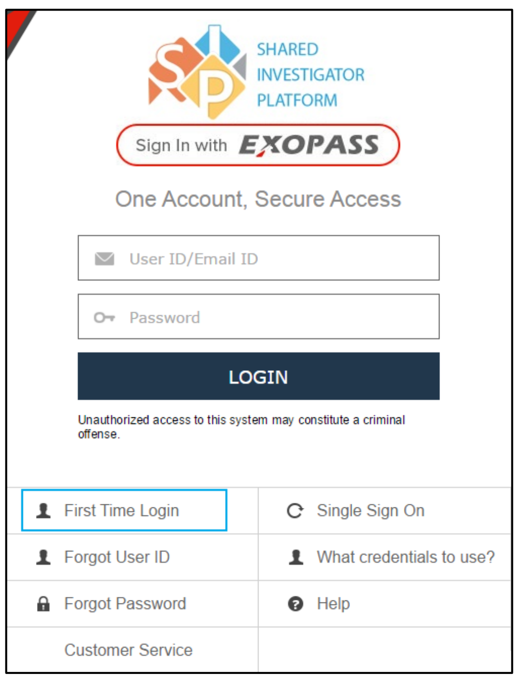


Figure 16. Sign In Page

3. In the **Password** box, enter the password, and then click **Login**. The SIP Site User Landing Page is displayed.

In some of the following scenarios, you may be prompted to answer the Security Questions:

- *Logging on from a new system*
- *Logging on after a prolonged time*
- *Logging on after deleting cookies on the browser*
- *Logging on from different browsers*
- *Logging on to the same system by different Site Users with different logon credentials*
- *Click a question in each of the Question boxes and enter answers for them. Now, click **Submit**.*

2.6 Forgot User ID

The Forgot User ID feature allows the Site Users to receive the User ID.

To receive the User ID

1. On the Sign In page, click **Forgot User ID**. The Forgot User ID page is displayed.

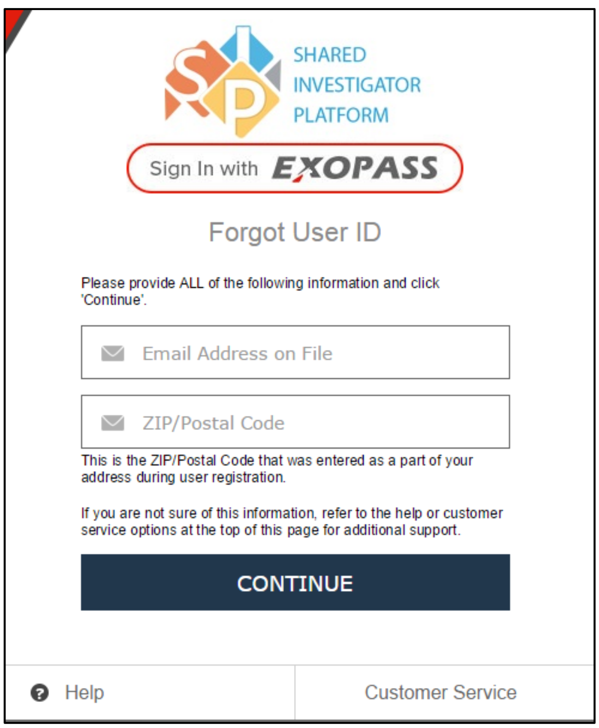


Figure 17. Forgot User ID Page

2. In the **Email Address on File** box, enter the email address.

3. In the **ZIP/Postal Code** box, enter the postal code. For those users where ZIP/Postal Codes are not applicable, enter the five-digit code provided during registration.

The ZIP/Postal Code is used for resetting the password. You need to provide the five-digit numerical ZIP/Postal Code, if you have forgotten your User ID or Security Questions and Answers.

If your ZIP/Postal Code is greater than five digits, then the system will consider the first five digits for validation. If you do not have a ZIP/Postal Code, you need to provide the five-digit code that you entered during Registration as this code is used to reset your User ID and Challenge Questions.

4. Click **Continue**. The confirmation message is displayed.

Figure 18. Confirmation Message

2.7 Forgot Password

The Forgot Password feature allows Site Users to reset the password. Challenge questions are mentioned for the first time under forgot password.

Existing Site Users with active User Profiles can create a new password by using the Forgot Password link. Site Users who log on to SIP for the first time can change their password by clicking the 'Forgot any of the above information? - Follow these steps' link.

To reset the password

1. On the **Sign In** page, click **Forgot Password**. The Forgot/Reset Password page is displayed.

Figure 19. Forgot/Reset Password Page

2. In the **User ID** box, enter the User ID, and then click **Continue**. The Answer Security Questions page is displayed.

Figure 20. Answer Security Questions Page

3. On the **Answer Security Questions** page, in the **Question** drop-down list, select a question.
4. In the **Answer** box, enter your answer to the question.
5. Click **Continue.** The Site User Landing Page is displayed.

*The challenge questions are set when you log on to SIP for the first time. If you have forgotten the security question, you need to enter the email address and the ZIP/Postal Code that was entered at registration. If the Site User answers one of the challenge questions and clicks **Continue**, the following message is displayed: User must answer both the questions in order to reset their password.*

6. If you have forgotten the security questions, click **Forgot Security Questions/Answers? - Follow these steps to reset your password**. The Forgot Security Questions page is displayed.

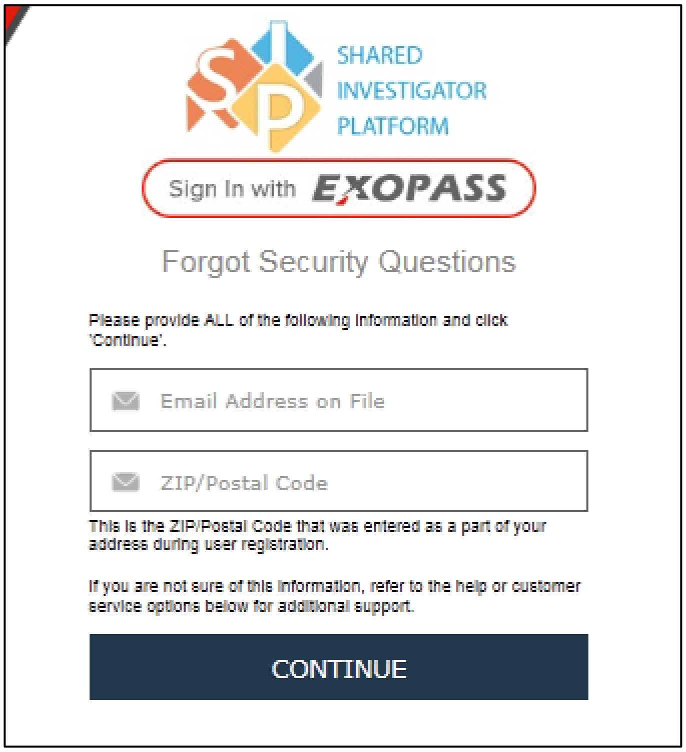


Figure 21. Forgot Security Questions Page

7. In the **Email Address on File** box, type your email address.
8. In the **ZIP/Postal Code** box, type the ZIP/Postal Code, or the five-digit code entered at registration.
9. Click **Continue**. The following message is displayed.

Figure 14: Forgot Security Questions: Confirmation Message

You can log on to SIP by using the User ID and the new system-generated password.

The password needs to be a minimum of eight and maximum of 16 characters. The password should contain at least one letter, one numeric value, and one special character (_&^ %$#@!). The Site User needs to select the challenge question from the Question list and type the answer in the Answer box. The Site User needs to answer all the four challenge questions.*

2.8 Credentials to Use

The Credentials to Use feature allows the Site Users to view the logon credentials that need to be used to logon to SIP. If the User ID is not known, the Site User can also use the email address that was used for SIP registration when logging on.

To view the credentials to use

1. On the Sign In page, click **What Credentials to Use?** The Direct Prompt page is displayed.

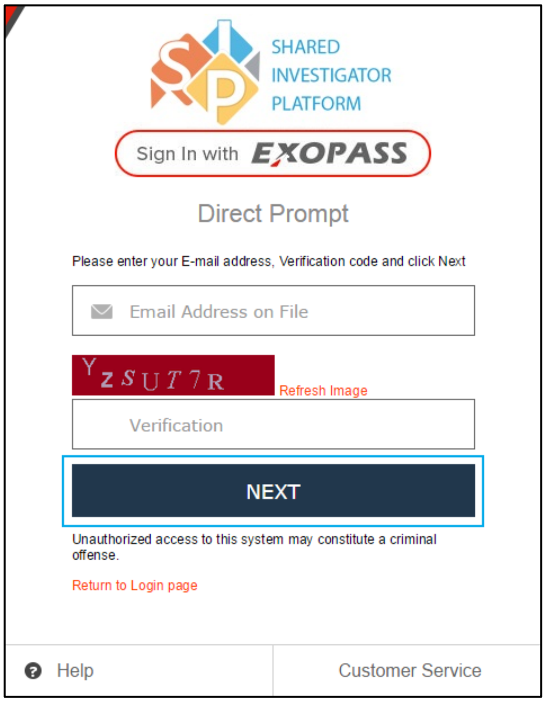


Figure 22. Direct Prompt Page

2. In the **Email Address on File** box, enter the email address on file.
3. In the **Verification** box, enter the displayed verification code.

*To refer to the help topics, on the Sign In page, click **Help**.*

*To obtain customer support, on the Sign In page, click **Customer Service**.*

4. Click **Next**. The Sign In page is displayed.

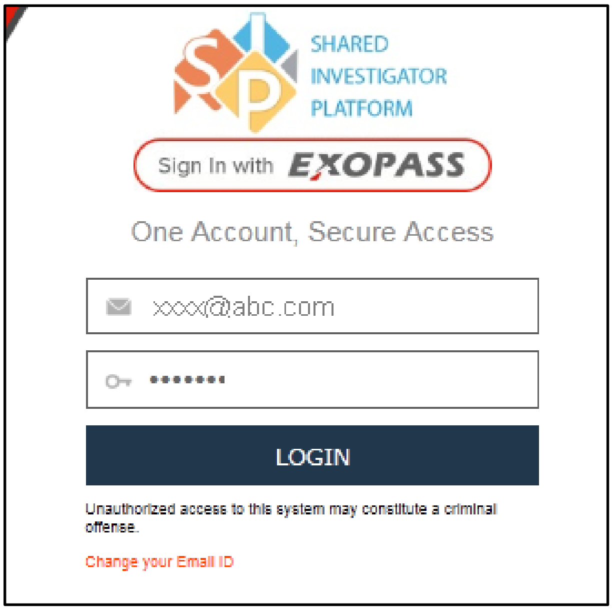


Figure 23. Sign In Page

*If you want to change the email address entered in the previous step, click **Change your Email ID**. The Direct prompt page is displayed.*

5. To log on to SIP, enter the password (User ID is displayed by default), and then click **Login.** The Answer Security Questions page is displayed.

Figure 24. Answer Security Questions Page

6. On the **Answer Security Questions** page, in the **Question** drop-down list, select a question.

7. In the **Answer** box, enter your answer to the question.

8. Click **Continue.** The Site User Landing Page is displayed.

2.9 Change Password

The Change Password feature allows the Site User to reset a password in the SIP system. You may change your password any number of times. However, it is mandatory that you reset the password every 90 days. Ten days prior to the password expiry date, when logging on, the system will prompt the Site User to change the password.

To change the password

1. On the Site User Landing Page, click . Now, click **Change Password**.

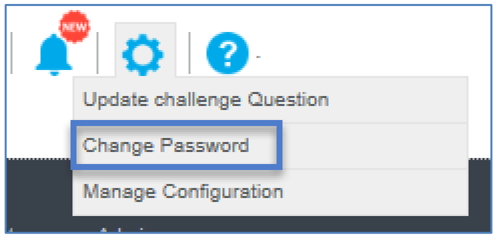


Figure 25. Change Password Option

The challenge questions are set when you log on to the application for the first time.

If the user answers one of the challenge questions and clicks ***Continue****, 'User must answer both the questions in order to reset their password' message is displayed.*

2. On the **Change Password** page, in the **Old Password** box, enter the password.

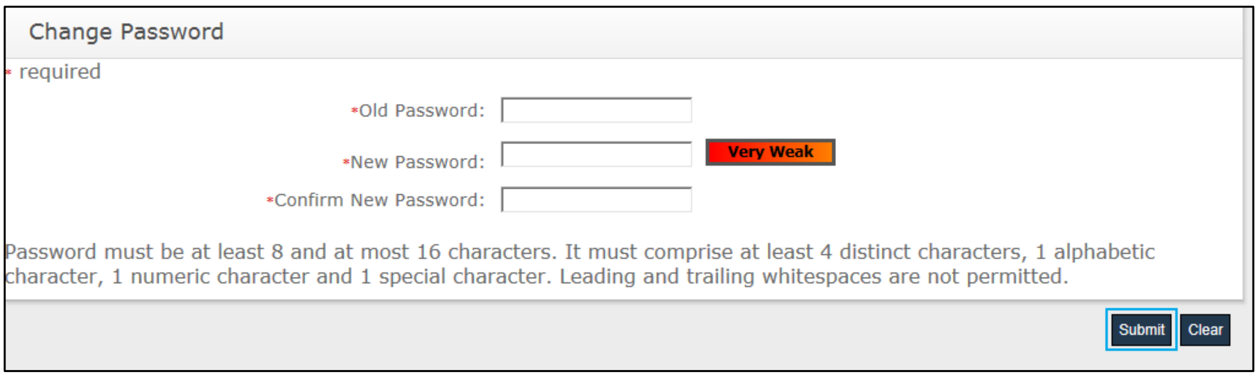


Figure 26. Change Password Page

3. In the **New Password** box, enter the new password.
4. In the **Confirm New Password** box, re-enter the new password.

The password needs to be a minimum of eight and maximum of 16 characters. The password should contain at least one letter, one numeric value, and one special character (_&^ %$#@!).*

5. Click **Submit**. The password is changed.

2.10 Update Challenge Question

The Site User can update the challenge questions and answers.

To update the challenge question

1. On the Site User Landing Page, click . Now, click **Update Challenge Question**.

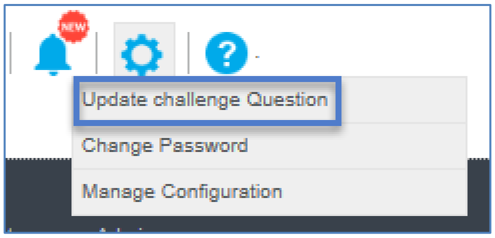


Figure 27. Update Challenge Question Option

2. On the **Change Security Questions** page, select the question that needs to be updated.

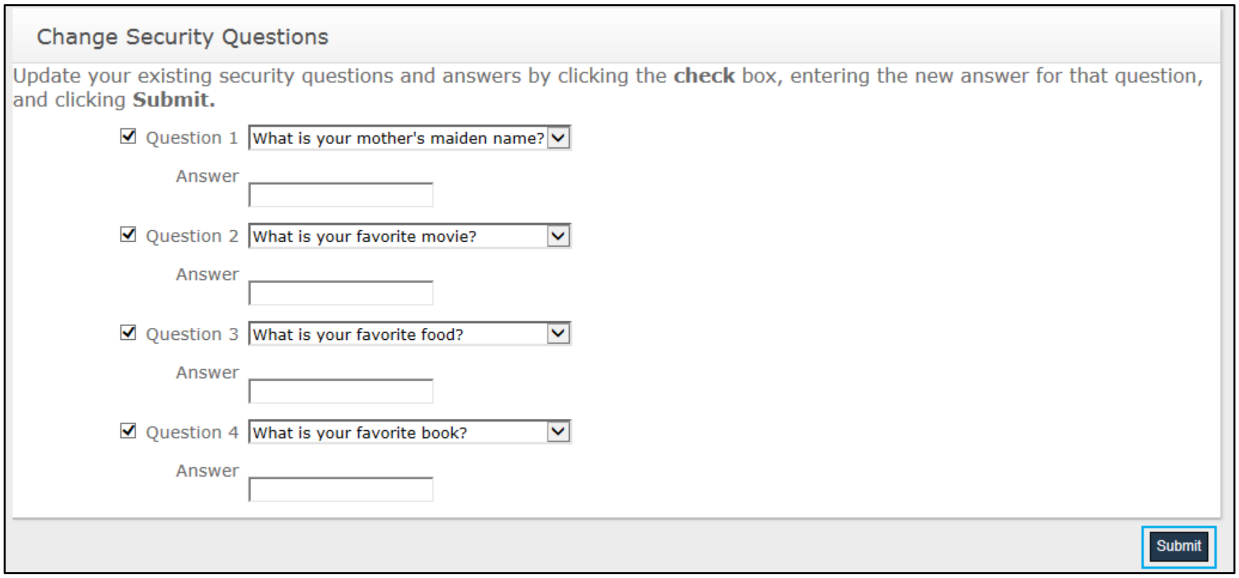


Figure 28. Security Questions Page

3. In the **Answer** box, enter the answer for the selected question.

4. Click **Submit**. The changes are updated in the SIP system.

2.11 Log Off

This section explains how you can log off from SIP.

To log off from SIP

1. On the upper-right corner of the SIP Public Landing Page, click , and then click **Logout**. A confirmation message is displayed.

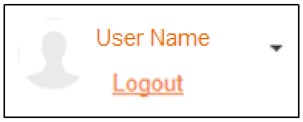


Figure 29. Logout Option

2. To accept the confirmation message, click **Yes**. You have logged out from SIP successfully.

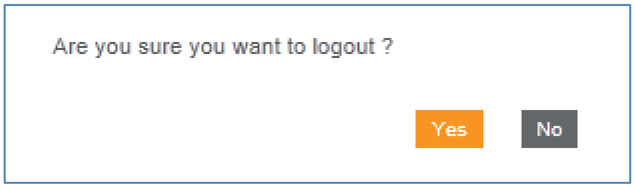


Figure 30. Logout: Confirmation Message

If the system is inactive for 30 minutes, you will be logged out automatically. If the Site User closes all the tabs in the browser window when the session is active, the Site User is logged out of SIP. To start a new session, the Site User needs to logon to SIP.

2.12 SIP Site User Landing Page

The SIP Site User Landing Page provides an at-a-glance view of specific tasks or activities for the currently logged on user. Recent activities and tasks are displayed in the current user's queue.

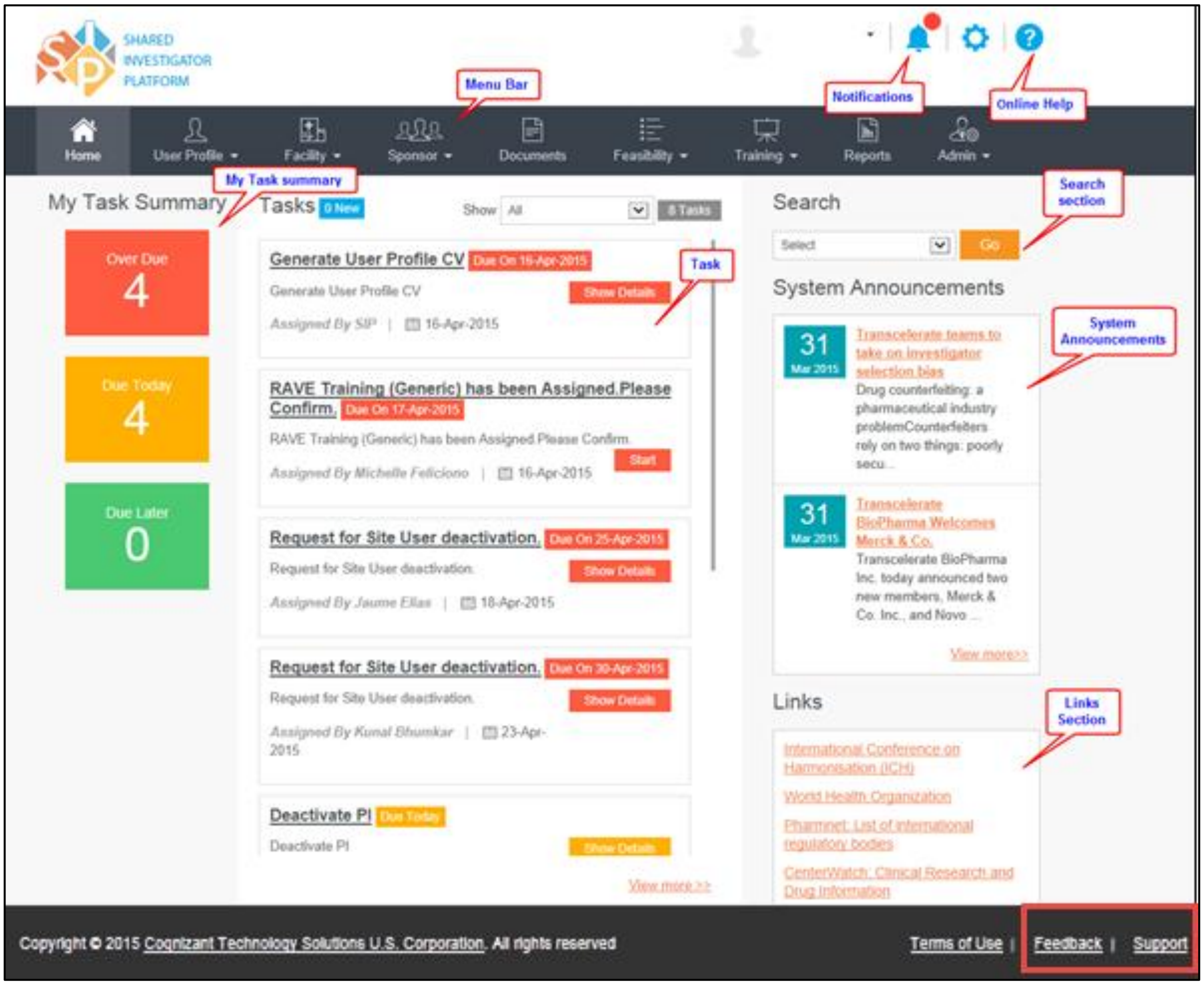


Figure 31. SIP Site User Landing Page

To submit a request in the Service Now Ticketing tool, click [Feedback | Support].

2.13 Dashboard Menus

The SIP Site User Landing Page displays the following sections:

- My Tasks Summary
- Tasks
- Notifications
- Search Section
- Links
- System Announcements
- Menu Bar

2.13.1 My Tasks Summary

The **My Tasks Summary** section displays the tasks that are in queue on a daily basis:

- **Due Today**: Tasks that are to be performed for the day
- **Overdue**: Tasks that are due from previous day
- **Due Later**: Tasks that need to be performed in the following days

2.13.2 Tasks

The **Tasks** section lists all tasks requiring an action. The list is refreshed on a daily basis. Task items include the following:

- Launch a training course when it has been assigned.
- Facility Profile needs to be completed.
- Update a User Profile when a Profile Owner delegates completion of his or her User Profile.
- Approve or reject User Profile updates when submitted by the Delegate.
- Respond to a Survey when a survey has been received.
- Update Study Site details when the Site User assignment to the Study Site is complete.
- Confirm participation in a Study Site when invited.
- Generate a CV when User Profile is updated.

2.13.3 Notifications

A notification is an automated message indicating that a task has been completed or assigned. An e-mail notification is sent to the Site User in the following instances:

- A User Profile has been updated
- A Facility Profile to which a Site User has associated his or her User Profile has been updated
- New documents have been posted
- A User Profile has been delegated for completion
- A User Profile has been submitted for approval
- A Survey has been delegated
- Study Site Staff has been added
- Password has been changed
- Request for association to a study has been accepted or rejected
- A Training Course has been assigned
- Training Credits have been approved or rejected

2.13.4 Search Section

You can perform a **Search** for the following:

SIP Users at My Facilities

Perform this search for Site Users who are assigned to the Facilities that are part of the User Profile of the logged on Site User.

Principal Investigators at My Facilities

Perform this search for Principal Investigators for Study Sites associated with the Facilities that are part of the User Profile of the logged on Site User.

Facility

Perform a search for Facilities.

2.13.5 Links

You can use the **Links** section in the Site User Landing Page to go to other webpages.

- Job Aids
- Links to other external resources

2.13.6 System Announcements

The System Announcements section displays general announcements about the system, for example, system outages.

2.13.7 Menu Bar

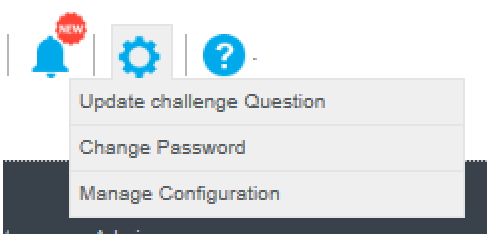
The following table provides the menu options available for the Site User.

Module	Menu Options
User Profile	My Profile, Delegated Profiles, and Approve or Reject Update(s)
Facility	Facility List, My Facility, and Create New Facility
Sponsor	Study Site Profile, Study Documents, and Study Training
Documents	Search and Upload documents, Document Exchange Actions
Surveys	Delegate and Respond to a Survey
Training	Find a Course, My Training, and Request for Credit
Reports	Generate a Report

Table 7. Menu Options

To view the alerts or notifications received, click .

To change the password or update challenge question or manage configuration, click .



To refer to the Help System, Job Aids, FAQs, and Site User Handbook click .

To learn more about a particular section, click View More in that section.

To view the task details, click Show Details.

To view the tasks, in the Tasks section, click the required option in the Show drop-down list.

2.14 Key Functionalities

SIP offers the following functionalities:

2.14.1 The User Profile

The User Profile is the central repository of the Site User information: education, research experience, licensing, credentials, and centralized training history. All Investigators and Site Personnel or their designated SIP Delegate An SIP User Profile must create a SIP User Profile. The User Profile contains key contact information for the Site User and data regarding training and research experience of the Site User. This data is updated by the Site User as needed and can be used to generate an abbreviated CV as needed during the site selection or site start-up processes. For more information, refer to Manage User Profile.

2.14.2 The Facility Profile

The Facility Profile is the central repository of information about the Facility: physical location address, capabilities, equipment as well as associated labs, IRBs, and other ancillary details. A Facility is the physical location (for example, hospital or doctor's office) in which the investigators perform clinical research. This Facility is associated with the Study Workspace at the time when the Facility is selected for a clinical trial.

The Facility Profile feature allows Site Users to share information regarding the physical location where they conduct research. This includes detailed information regarding their research capabilities and operating procedures that Sponsor companies can use to select sites for a new study. Site staff will associate their SIP User Profile with an appropriate Facility Profile. For more information, refer to Manage Facility Profile.

2.14.3 Manage Study Workspace

The Study Workspace is the Study/Site-specific area of SIP in which the Principal Investigator or Delegate defines a Study Site Profile that communicates to the Sponsor on the Staff and Facility details. Such details are used to support the study, including IRB/EC, and local lab details. The Study team and research sites collaborate and interact in the study workspace. The Study Workspace consists of essential study information and allows access to study documents. For more information, refer to Manage Study Workspace.

2.14.4 Manage Documents Exchange

The Document Exchange capability is used to facilitate the electronic exchange of Non–Study-specific documents between Site and Sponsor Users. Both Sponsor and Site Users can upload, store, and download documents through the Document Exchange feature in the platform. Site users use this feature to access Sponsor-generated Study-specific documents distributed through SIP and to submit

Site-generated essential Study documents as requested by Sponsors. For more information, refer to Manage Documents Exchange.

2.14.5 Manage Surveys

The Surveys section provides centralized visibility and access to all SIP feasibility surveys. Investigators or survey recipients can view, respond to, or delegate feasibility surveys. Completed surveys can be downloaded or printed. Key survey information, such as status, due date and Sponsor can be easily accessed. For more information, refer to Manage Feasibility Survey.

2.14.6 Manage Training

The Manage Training feature allows Site Users to complete assigned training, view completed training history, self-assign select courses or self-report completion of select training as a request for Sponsor training credit. SIP enables credit for certain "Mutually Recognized Training (MRT)" such as GCP training to cascade across multiple Sponsors with whom you are work. This eliminates redundant training that Site Personnel previously were required to complete. For more information, refer to Manage Training.

2.14.7 Manage Reports

The Reports function allows Site Users and their Delegates to generate, view, and export their training report to Microsoft® Excel or PDF. For more information, refer to Manage Reports.

3 Getting Started

The following flowchart depicts the activities that a Site User can perform in the SIP system.

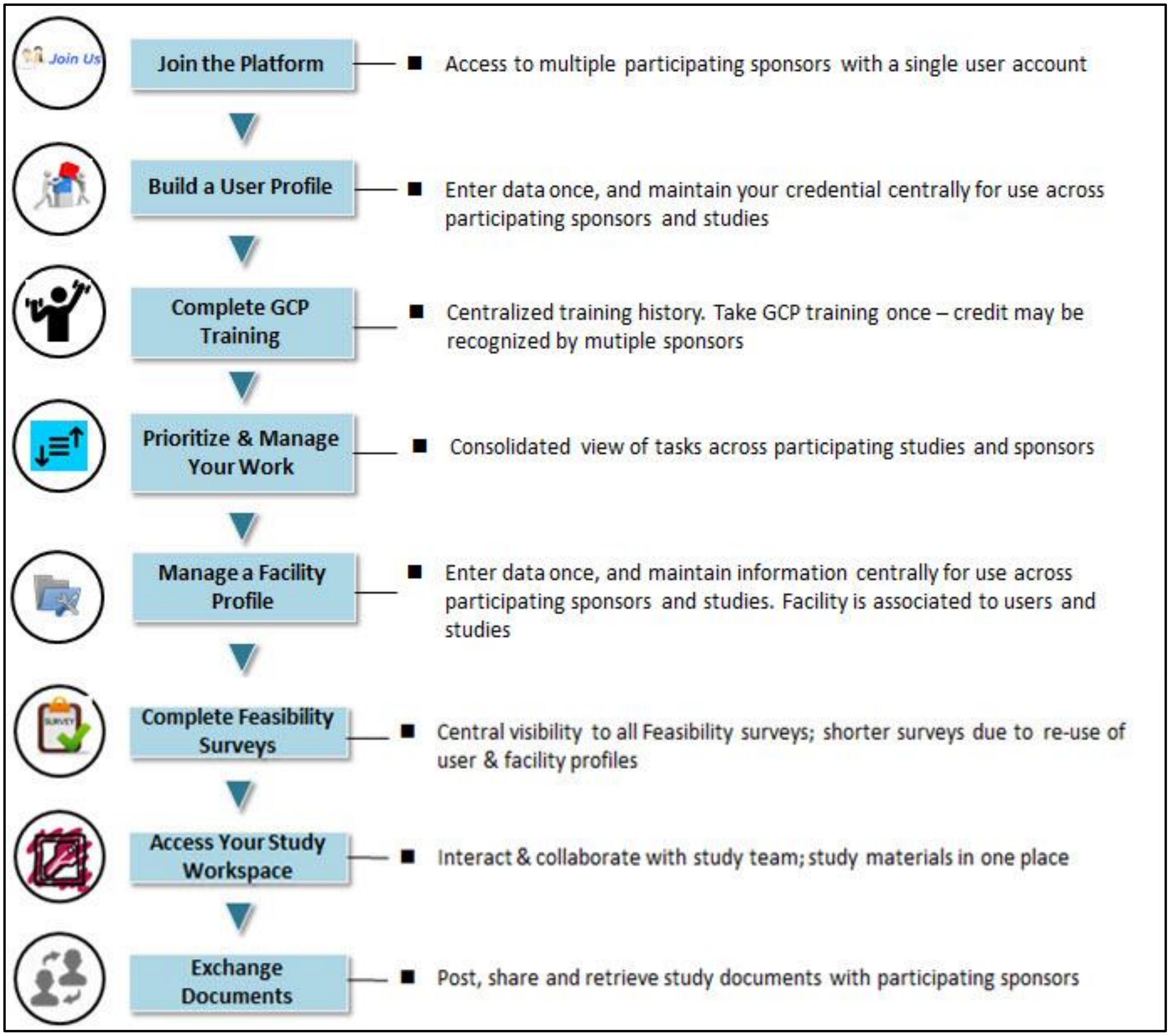


Figure 32. Site User Roles and Access Privileges Flow Chart

4 Manage User Profile

The Manage User Profile feature allows Site Users to enter their profile details such as personal information, educational history, research experience, training, and medical license details. Site Users can either manually enter the CV details or upload the abbreviated CV template with the added profile details. From the User Profile, Site Users can generate a CV, delegate completion of their profile, request training credit, and request their Principal Investigator to associate them to a study.

After a Site User completes Registration, the Site User can create/update the User Profile details.

***Manually**: The basic details entered during registration by the Site User are populated in the Basic Details page. Site Users can then update basic details and other details. Site User can update rest of the sections of the User Profile manually.*

Uploading a TransCelerate Abbreviated CV: The Site User can upload his or her completed Site Profile Form so that the information is added to his or her User Profile. The Site User can then manually update the information and add additional details in the User Profile. Site User can upload the completed TransCelerate Abbreviated CV template if already in place. It is only the editable PDF version of the approved TransCelerate Abbreviated CV that will result in partial completion of the User Profile. The Site User Fields needs to flag the fields for manual data entry that are not populated by the imported CV.

***Assign a Delegate**: Site Users can delegate completion of the User Profile to another Site User for a defined or indefinite period of time.*

Site Users can perform the following tasks:

- Edit/Update a User Profile
- Delegate your User Profile
- Upload TransCelerate Abbreviated CV Template
- Generate a CV
- Request Association to a Study
- Associate to Facility
- Approve or Reject User Profile Updates
- Provide Training Details

4.1 My Profile

The My Profile page allows Site Users to share contact information and basic profile data such as training or experience and research area of interest with Sponsors during site selection or study startup. Site Users with a completed TransCelerate Abbreviated CV template can upload it to SIP to automatically populate most of the User Profile, reducing the need for manual data entry to only a few additional data points.

Additionally, Site Users can delegate the data entry or User Profile updates or both to another Site User. On this page, Site Users can also request Principal Investigators to add them to studies.

To view the User Profile details

1. On the **User Profile** menu of the Site User Landing Page, click **My Profile**. The User Profile page is displayed.

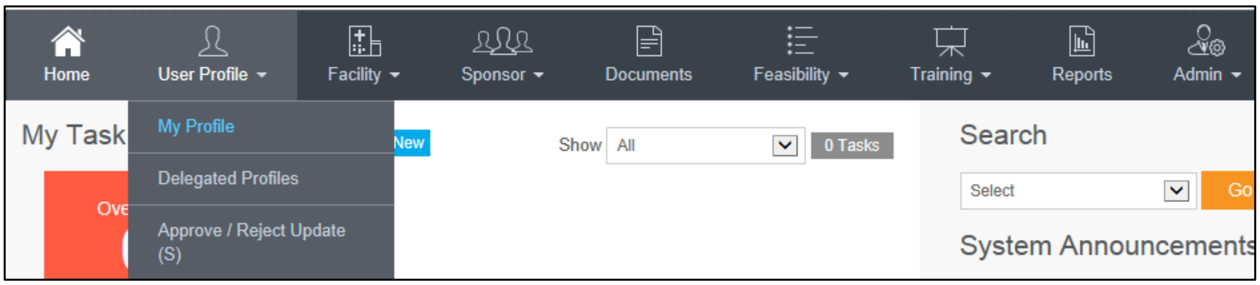


Figure 33. User Profile: My Profile

2. To generate a CV, click **Profile Complete-Generate CV**. To generate a CV, refer to Section 4.3 Generate a CV (*see 1 in the diagram below*).
3. To upload the TransCelerate abbreviated CV, on the **My Profile** page, click **Upload TransCelerate Abbreviated CV**. To upload CV Template, refer to Section 4.4. (*see 2 in the diagram below*)
4. To delegate the profile, click **Delegate**. To delegate a User Profile, refer to Section 4.7 (*see 3 in the diagram below*).
5. To ask the Principal Investigator to add you to a study, click **Ask PI to Add Me to a Study**. To request a Principal Inestigator to add to a study, refer to Section 4.6 (*see 4 in the diagram below*).

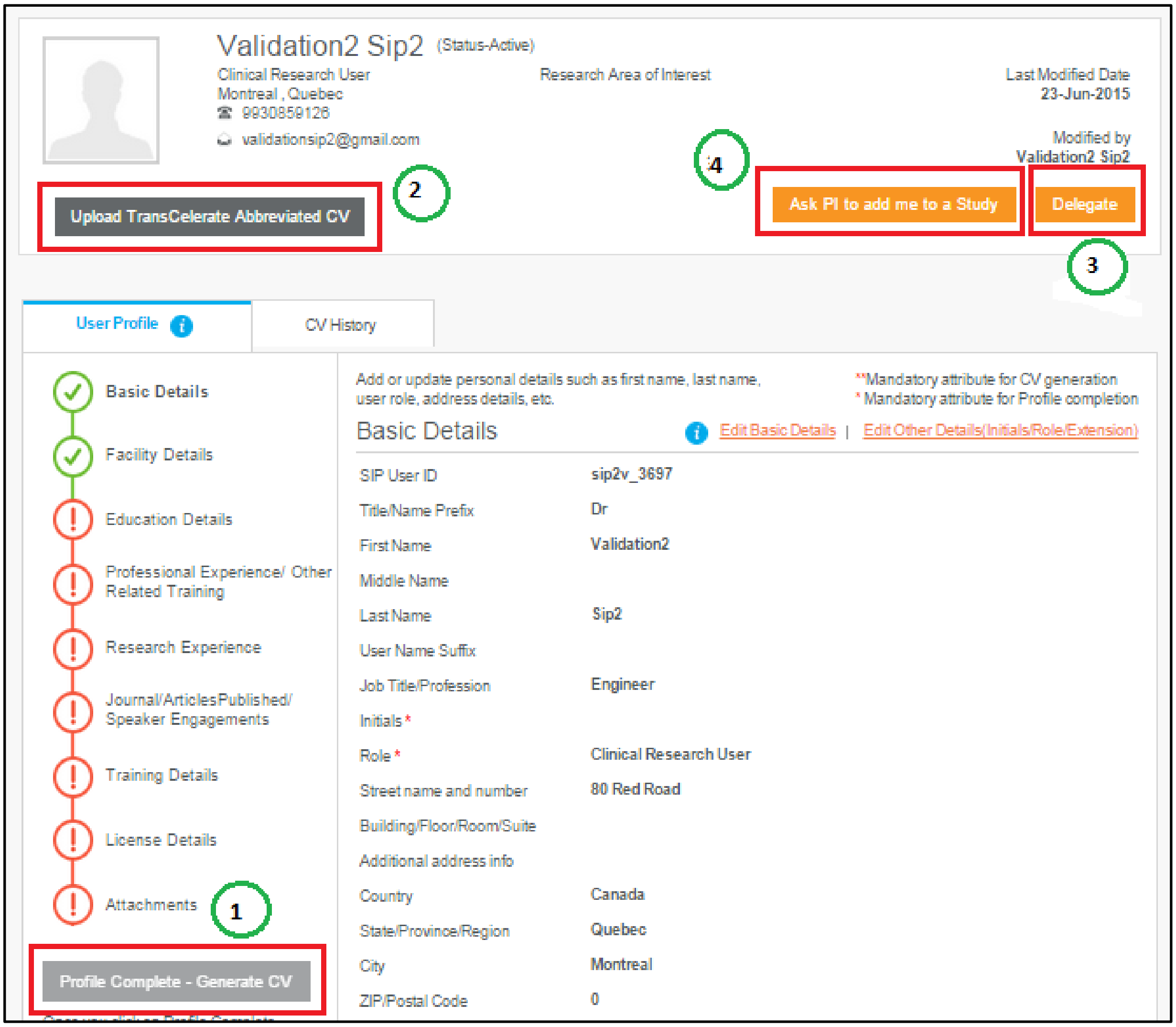


Figure 34. My Profile Page

4.2 Add or Edit User Profile

The Add/Edit User Profile feature allows Site Users to create a new User Profile or edit existing User Profile details such as education, research experience, and medical license details. Site Users (who are Facility Profile Managers) can edit their own User Profiles or edit other Site Users' User Profiles if they have Delegate permissions. A Site User can download the completed TransCelerate Abbreviated CV from the TransCelerate website and then upload it in the system.

Single asterisk (*) on the User Profile fields indicates mandatory attributes for Profile completion.

Double asterisk (**) on the User Profile fields indicates mandatory attributes for CV generation.

The Green Check Mark  *beside each User profile section ensures that you have completed filling* *out all details in that section.*

Site User can add or modify the following User details:

- Upload Profile Picture
- Basic Details
- Facility Details
- Educational Details
- Professional Experience/Other Related Training
- Research Experience
- Journal/Articles Published/Speaker Engagements
- GCP Training Details
- License Details
- Attachments

4.2.1 Upload Profile Picture

This feature allows the Site Users to upload their profile picture.

To upload a profile picture

1. On the **User Profile** menu of the Site User Landing Page, click **My Profile**.
2. On the **My Profile** page, click the profile picture.

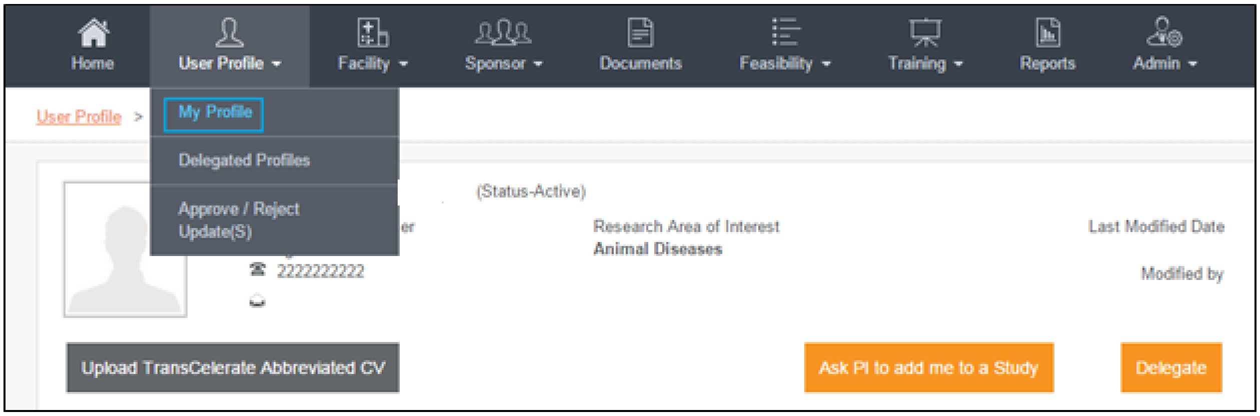


Figure 35. My Profile Page: Upload Profile Picture

3. In the **Upload Profile Photo** dialog box, click **Choose File**. The **Choose File to Upload** dialog box is displayed.
4. Browse to the location of the picture, and then click **Open**.
5. To upload the profile picture, click **Upload**.

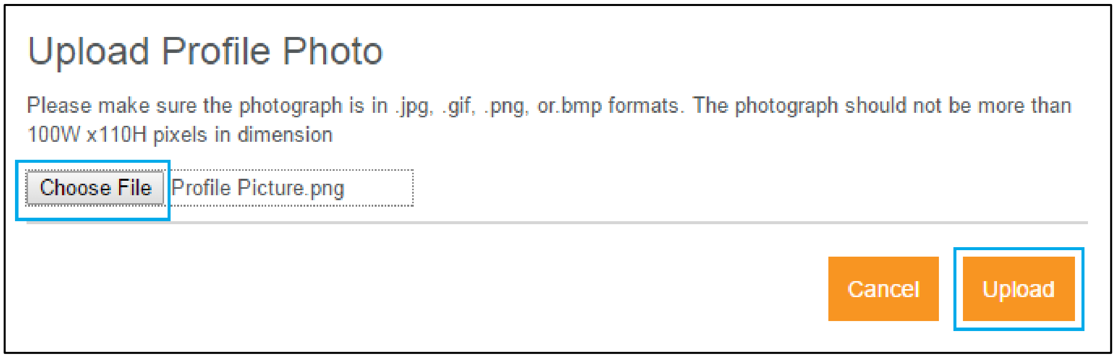


Figure 36. Upload Profile Photo Dialog Box

The upload process workflow may vary with the browser (Chrome or IE) being used.

4.2.2 Edit Basic Details

The Basic Details page allows the Site Users to update personal details such as first name, last name, user role, phone, postal code, and address details that were provided during the SIP Registration process. Site Users can update the other basic details added during registration such as the initials, role, and phone extension number.

The upload process workflow may vary with the browser (Chrome or IE) being used. Single asterisk (*) on the User Profile fields indicates mandatory fields for Profile completion.

To edit basic details

1. On the **User Profile** menu, click **My Profile**. The Basic Details page is displayed.

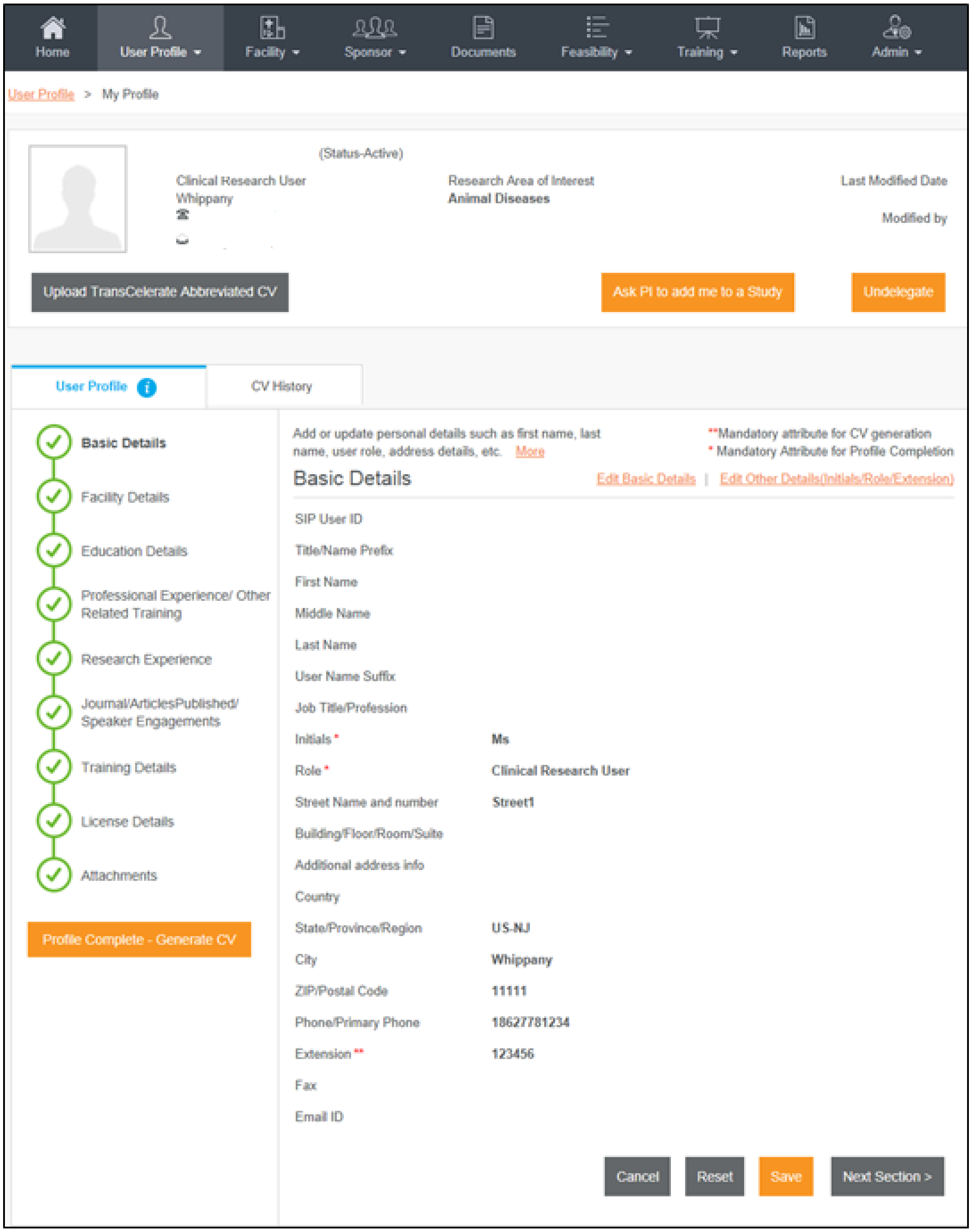


Figure 37. Basic Details Page

2. On the **Basic Details** page, click **Edit Basic Details**. The following notification message is displayed.

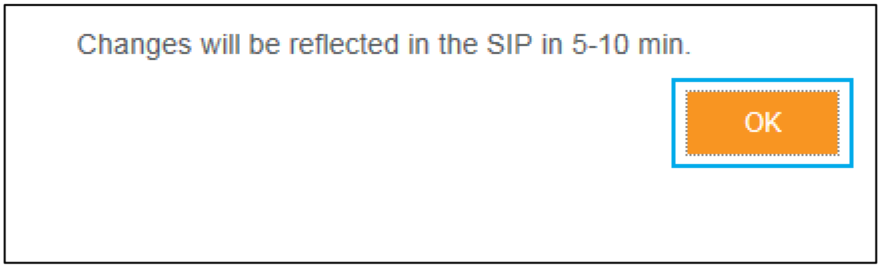


Figure 38. Edit Basic Details: Notification Message

3. To acknowledge the message, click **OK**.

4. On the **User Profile** page, edit the basic details as shown in the following figure. For Edit Basic Details field descriptions refer to Table 9.

5. Click **Continue**. The basic details fields are disabled.

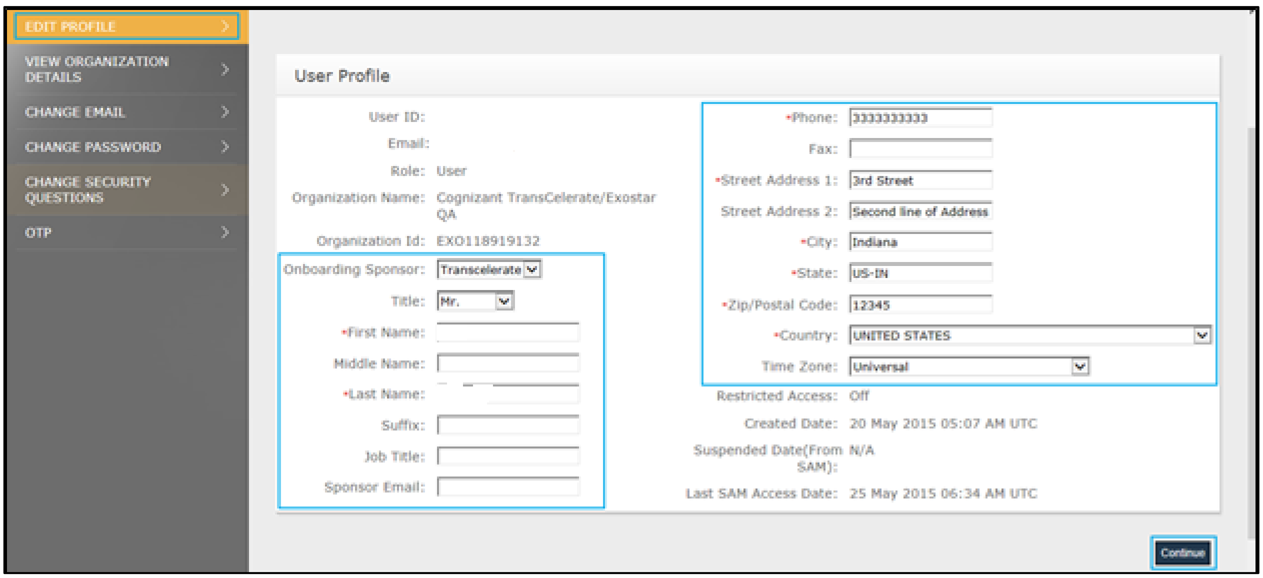


Figure 39. Exostar: Edit User Profile Page

6. To submit the changes, click **Submit**.

*To update the basic details, click **Modify**.*

The ZIP/Postal Code is used for resetting the password. If your ZIP/Postal Code is greater than five digits, then the system will consider the first five digits for validation.

If you do not have a ZIP/Postal Code, you will need to provide a five-digit code as this code is used to reset your User ID and Challenge Questions.

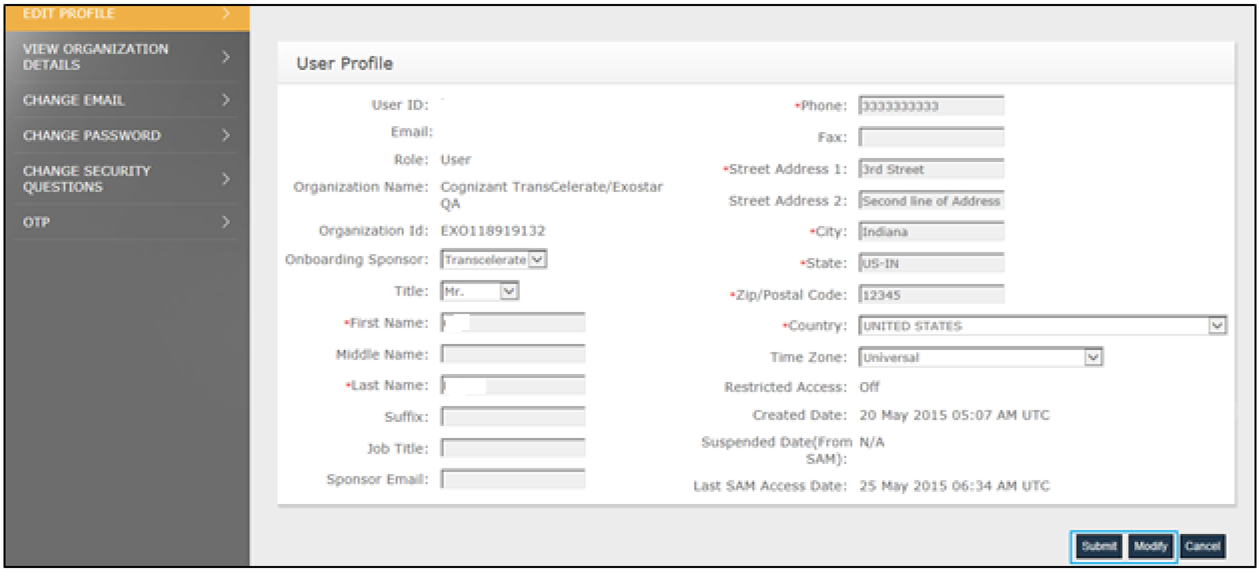


Figure 40. Exostar: Submit User Profile Details

4.2.3 Edit Other Basic Details

In the Edit Other Details section, you need to edit data that was not provided during the registration process.

1. To edit other details, on the Basic Details page, click **Edit Other Details (Initials/Role/Extension)**. The Initials, Role, and Extension fields are displayed.

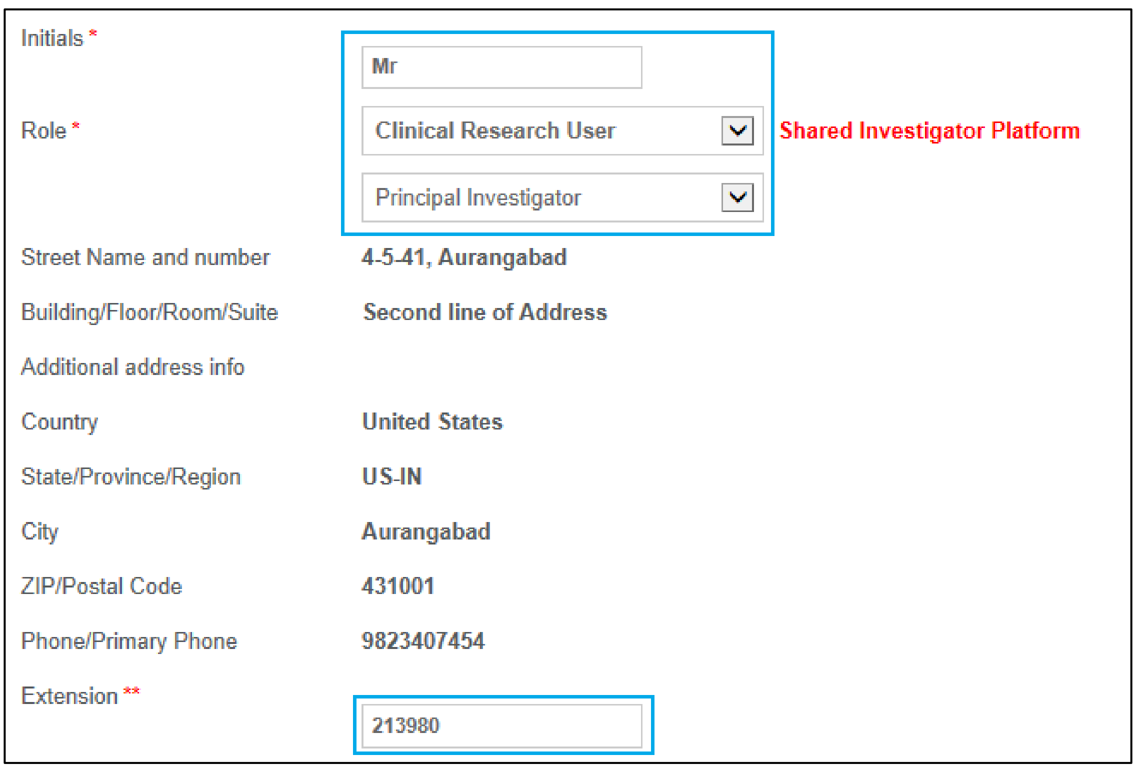


Figure 41. Edit Other Basic Details

2. Edit the other basic details. For Edit Other Basic Details field descriptions, refer to Table 10.

3. To save the basic details, click **Save**. The confirmation message is displayed.

4. To accept the confirmation message, click **OK**.

5. To navigate to the next section of the User Profile, click **Next Section**.

The following table provides the field descriptions for the Edit Basic Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Onboarding Sponsor	Drop-down list	This is not a mandatory field.	Name of the Sponsor
Title	Drop-down list	This is not a mandatory field.	Title or prefix of the user's name. Example: Mr., Mrs., and Ms.
First Name*	Text box	This is a mandatory field.	First name of the user
Middle Name	Text box	This is not a mandatory field.	Middle name of the user
Last Name*	Text box	This is a mandatory field.	Last name of the user
Suffix	Text box	This is not a mandatory field.	Suffix of the user name Example: Senior, Junior, I, and II
Job Title	Text box	This is not a mandatory field.	Job title of the user
Sponsor Email	Text box	This is not a mandatory field.	Email address of the Sponsor
Phone*	Text box	This is a mandatory field.	Phone number of the user
Fax	Text box	This is not a mandatory field.	Fax ID of the user
Street Address 1*	Text box	This is a mandatory field.	Street address of the user
Street Address 2	Text box	This is not a mandatory field.	Street address of the user
City*	Text box	This is a mandatory field.	Name of the city in which the Site User resides
State*	Text box	This is a mandatory field.	Name of the state in which the Site User resides
ZIP/Postal Code*	Text box	This is a mandatory field.	ZIP/Postal Code of the location in which the Site User resides. The ZIP/Postal Code is

Field	Field Type	Mandatory Field	Field Descriptions
			used for resetting the password. You need to provide the five digit numerical ZIP/Postal Code entered at the time of registration, if you have forgotten your User ID or Security Q&A.
Country*	Text box	This is a mandatory field.	Name of the country in which the Site User resides
Time Zone	Drop-down list	This is not a mandatory field.	Time zone associated with the location in which the Site User resides

Table 8. Field Descriptions for Edit Basic Details

The following table provides the field descriptions for the Edit Other Basic Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Initials*	Text box	This is a mandatory field.	Initials of the user. This is the first letter of the name.
Role*	Drop-down list	This is a mandatory field.	This is the role of the Site User at the Facility. For example you can select the role as Principal Investigator. There are fifteen Site User roles. For more information on these user roles, refer to Roles and Privileges. **Note**: To specify other user roles, click **Others**.
Extension*	Text box	This is a mandatory field.	This is the phone extension number of the Site User.

Table 9. Field Descriptions for Edit Other Basic Details

4.2.4 Facility Details

The User Profile – Facility Details page allows Site Users to associate a Research Facility to their User Profile. Site Users as Facility Profile Managers can edit the research Facility type and location details. The Primary Facility ID and Facility name are display fields.

Site Users who are Facility Profile Managers can edit the Research Facility type and Location details.

4.2.4.1. Associate a Facility to a User Profile

This feature allows Site Users to associate a Facility to a User Profile.

A Facility needs to be in Active status in order to be available to be associated to a User Profile. The status of each Facility is provided in the corresponding row. Check boxes corresponding to Facilities in Draft status are not enabled. The Site User will be able to select only Facilities that are in Active *status.*

1. On the **Facility Details** page, click **Associate Facility to My Profile**. The Search Facility window is displayed.

To associate a Facility to a Site User

2. On the **User Profile** navigation pane, click **Facility Details**. The Facility Details page is displayed.

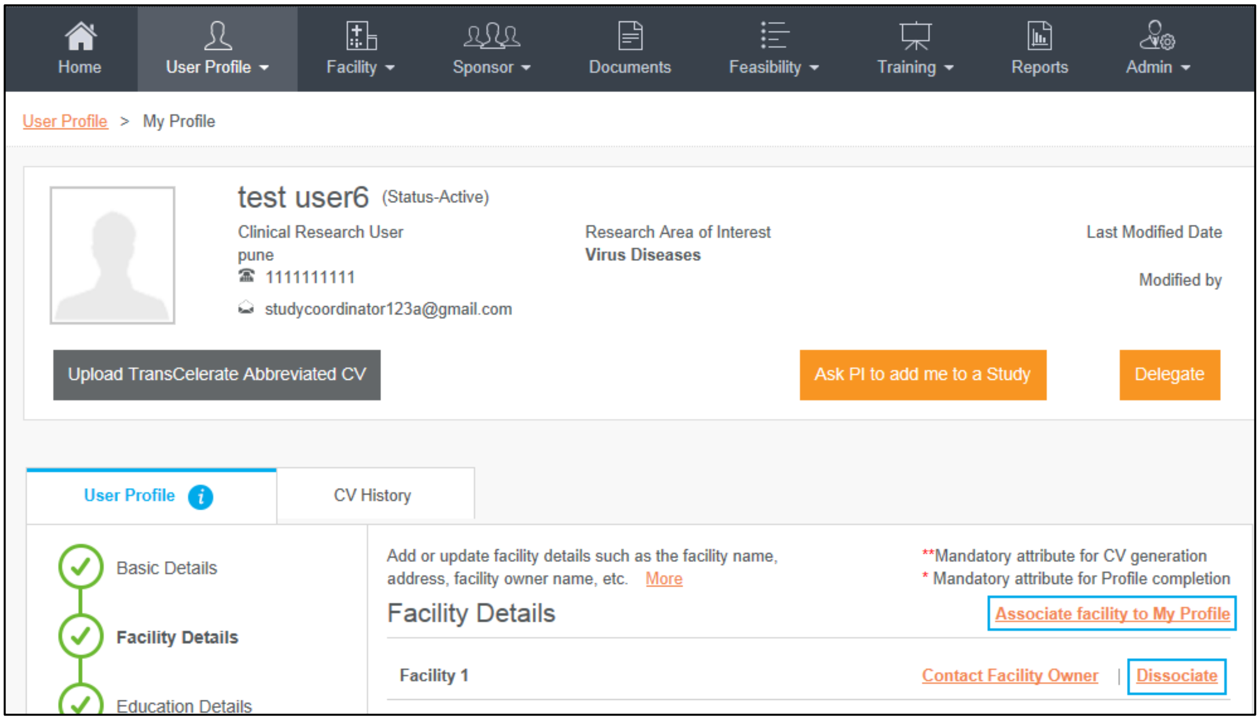


Figure 42. Facility Details Page

*If you need to associate a Facility to a User Profile, click the **Associate Facility to My Profile** link.*

3. In the **Search Facility** window, enter or select any or all of the search criteria, and then click **Search**. For Search Facility field descriptions, refer to Table 11.

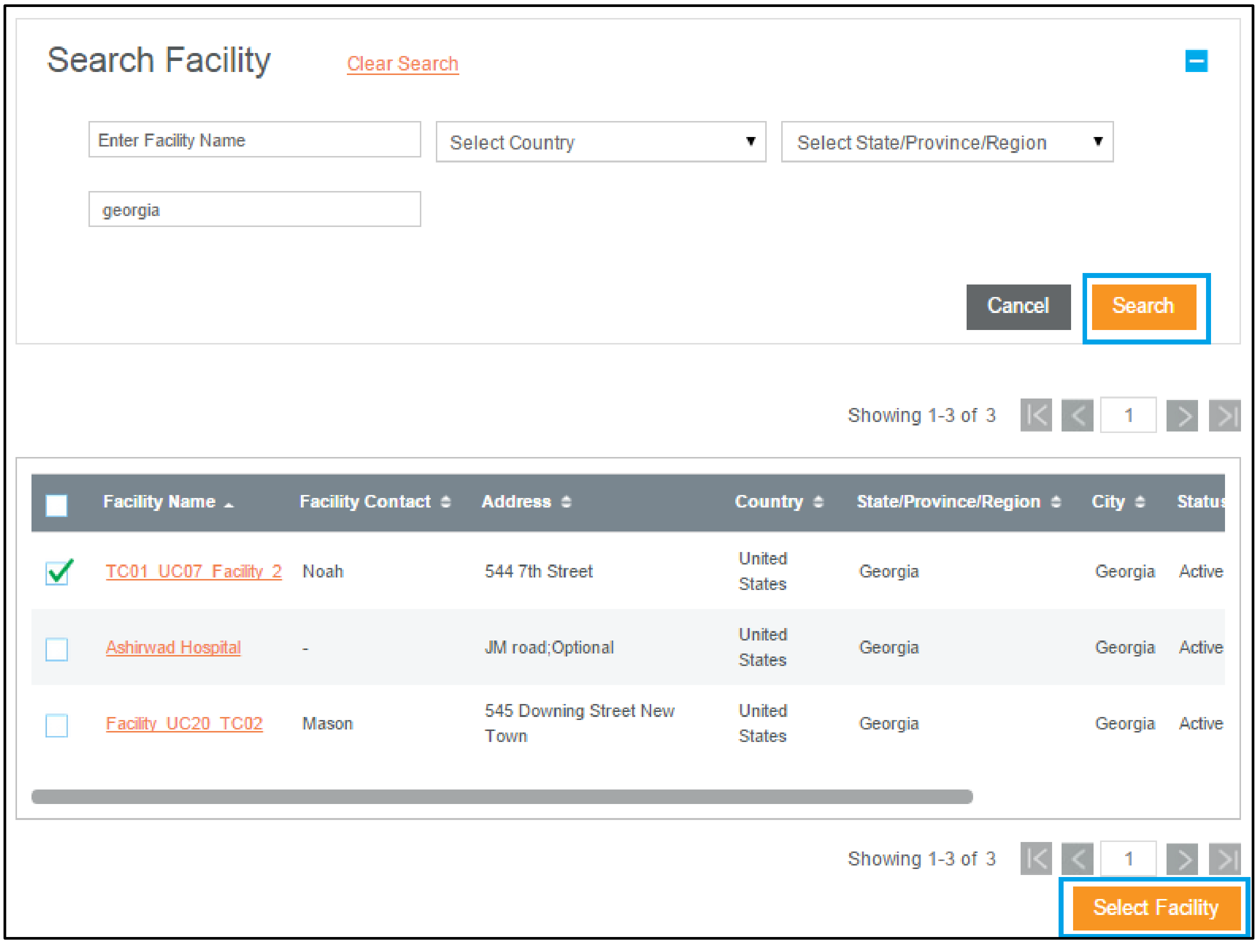


Figure 43. Search Facility Window

4. In the search results displayed, select the check box corresponding to the Facility that needs to be associated. You can select only check boxes of Facilities in Active status.

5. Click **Select Facility**. The Facility gets associated to the User Profile.

The following table lists the descriptions for all the fields displayed on the Search Facility window.

Field	Field Type	Mandatory Field	Field Descriptions
Facility Name	Text box	This is not a mandatory field.	Name of the Facility in which the research is conducted.
Country	Text box	This is not a mandatory field.	Name of the country in which the Facility is located.
State/Province/Region	Text box	This is not a mandatory field.	Name of state, province, or region in which the Facility is located.
City	Text box	This is not a mandatory field.	Name of the city in which the Facility is located.

Table 10. Field Descriptions for Search Facility

4.2.4.2. Edit Facility Details

1. On the **User Profile** navigation pane, click **Facility Details**. The following Facility details page is displayed.

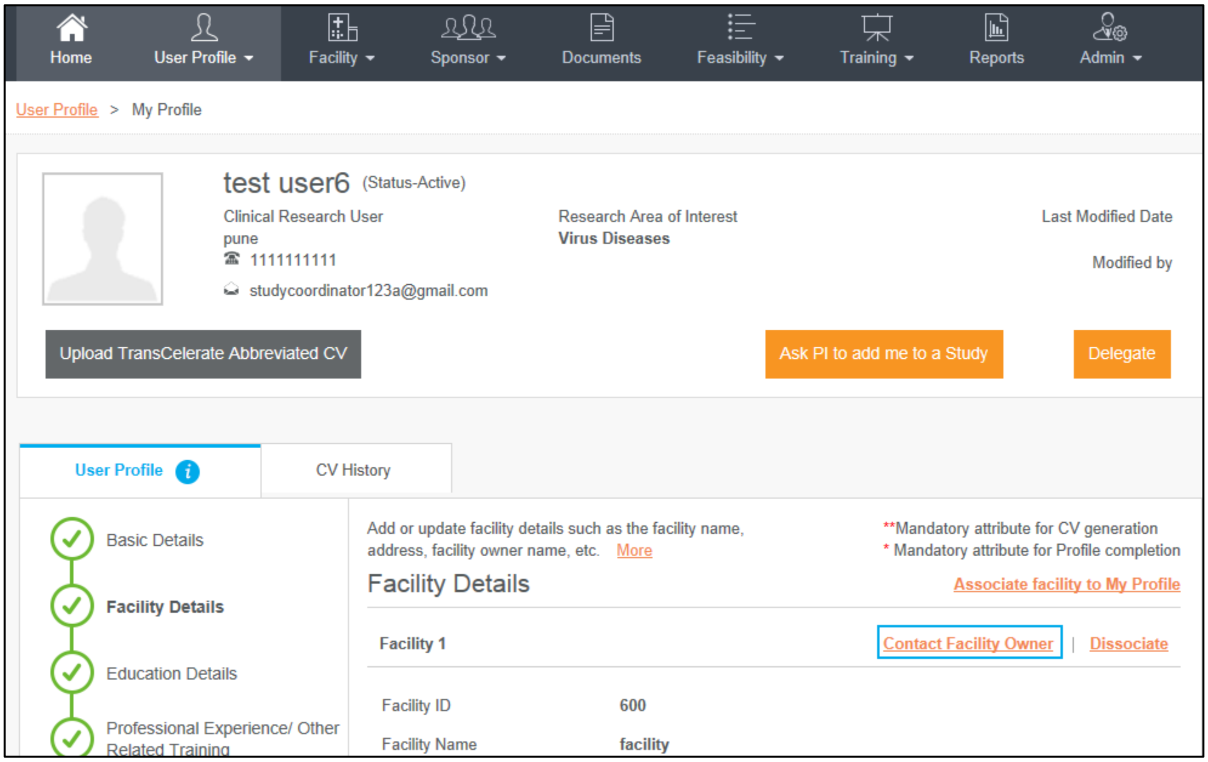
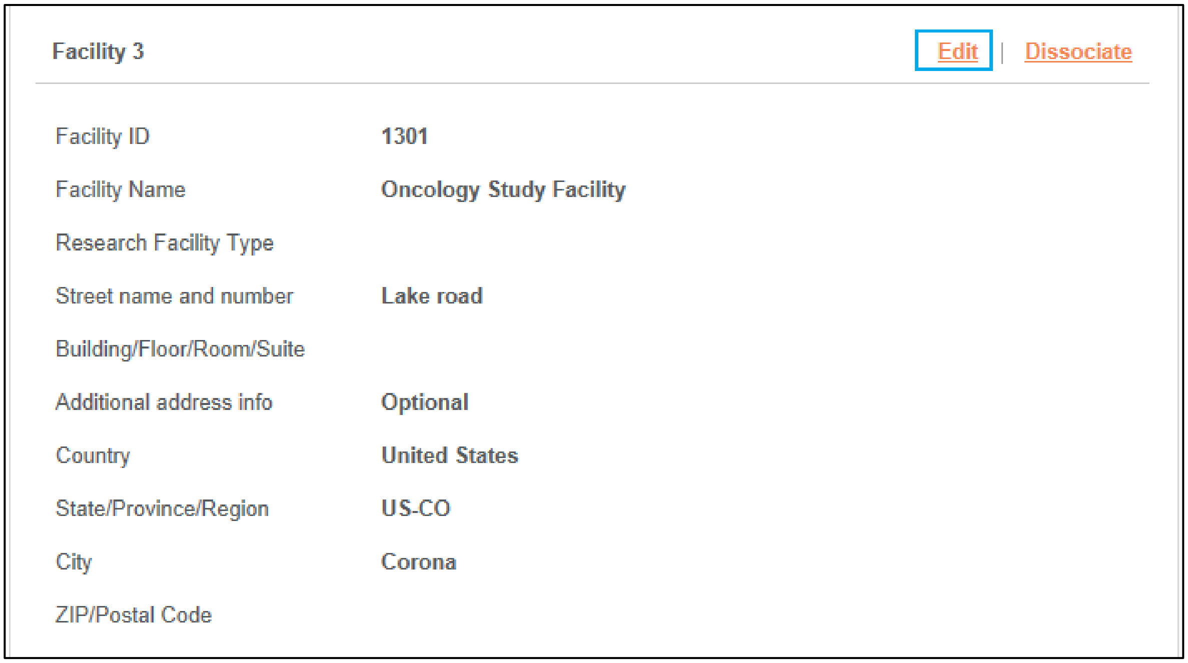


Figure 44. Facility Details Page

2. If the Site User is the Facility Profile Manager for the Facility, to edit the Facility details, click **Edit**.



Facility 3 Edit | Dissociate

Facility ID	1301
Facility Name	Oncology Study Facility
Research Facility Type	
Street name and number	Lake road
Building/Floor/Room/Suite	
Additional address info	Optional
Country	United States
State/Province/Region	US-CO
City	Corona
ZIP/Postal Code	

Figure 45. Facility Details Page - Edit

3. On the **Research Facility Details** page, edit the required Facility details, and then click **Submit**. For detailed description on edits to Facility Details and the field descriptions, refer to **Create a Facility: Manually** section in this document.

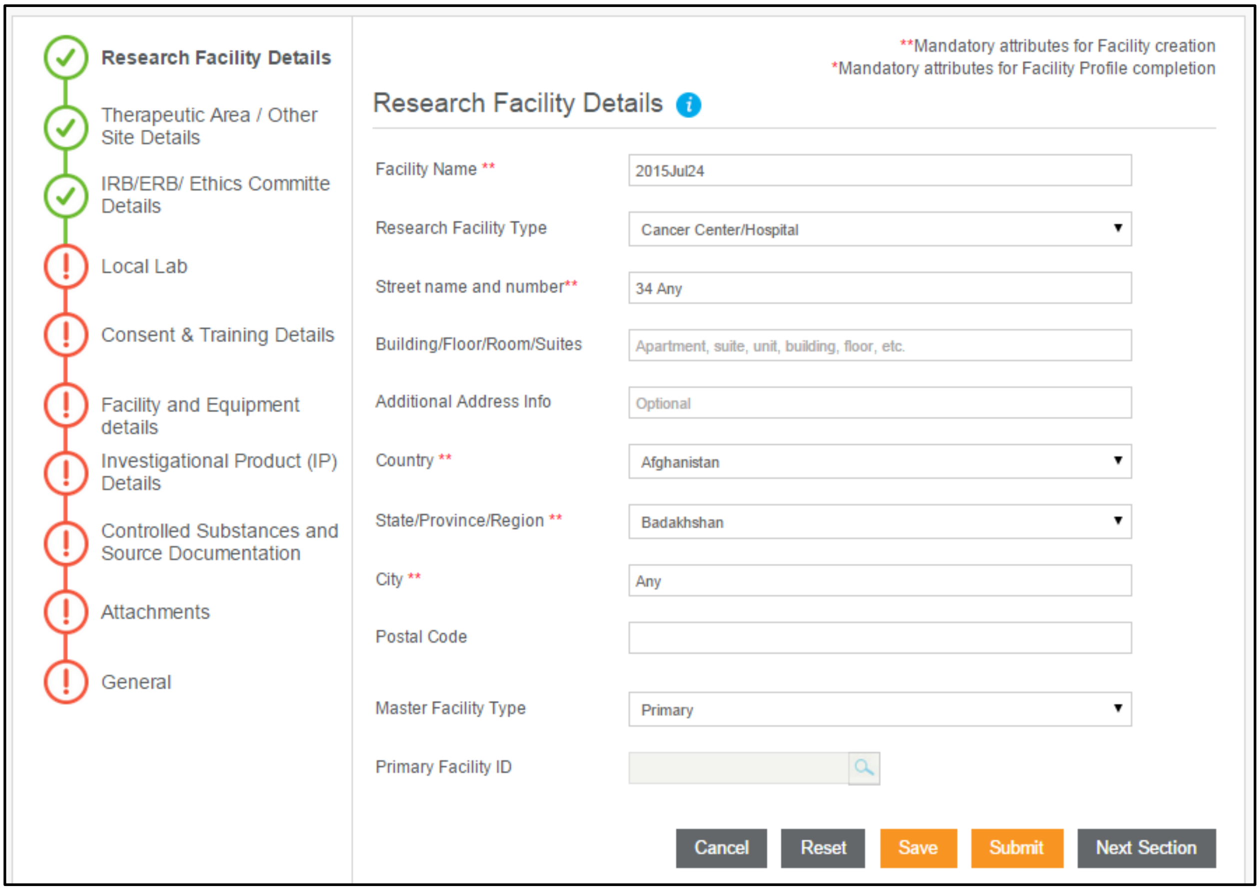


Figure 46. Edit Facility Details Page

4. The following confirmation message is displayed. Click **OK**.

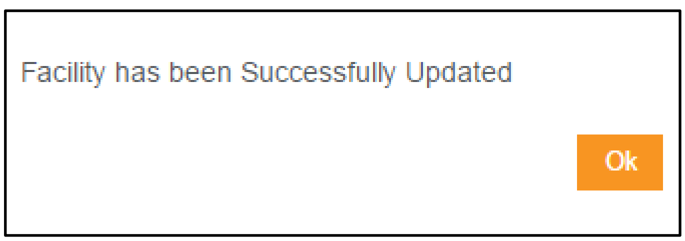


Figure 47. Facility Details Update Confirmation Message

5. If the Facility is associated to a Study Site, the following message is displayed.

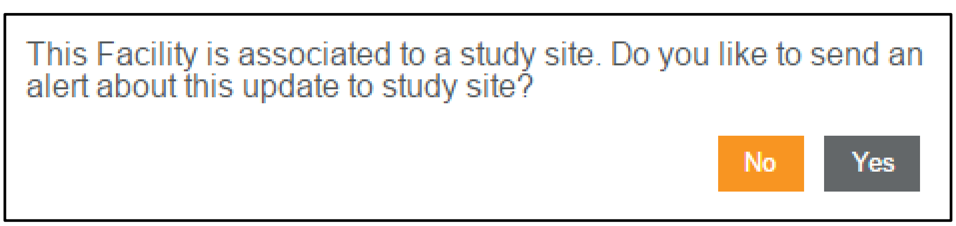


Figure 48. Alert to Study Site

6. If you want to send an alert about the Facility updates to the Study Site, click **Yes**.

*If a Site User other than the Facility Profile Manager is viewing the page and if information in the Facility Profile needs to be changed, click **Contact Facility Owner** to contact the Facility Profile Manager.*

4.2.4.3. Disassociate an Existing Facility

This feature allows Site Users to disassociate a Facility from the User Profile.

To disassociate a Facility from the User Profile

1. On the **Facility Details** page, click **Disassociate**. The Facility is removed from the User Profile.

4.2.5 Add or Edit Education Details

Site Users can add educational details such as undergraduate degrees, certifications and masters programs. Medical education programs such as R.N., M.D. can also be added.

To add education details

1. On the **User Profile** navigation pane, click **Education Details**. The Education Details page is displayed.

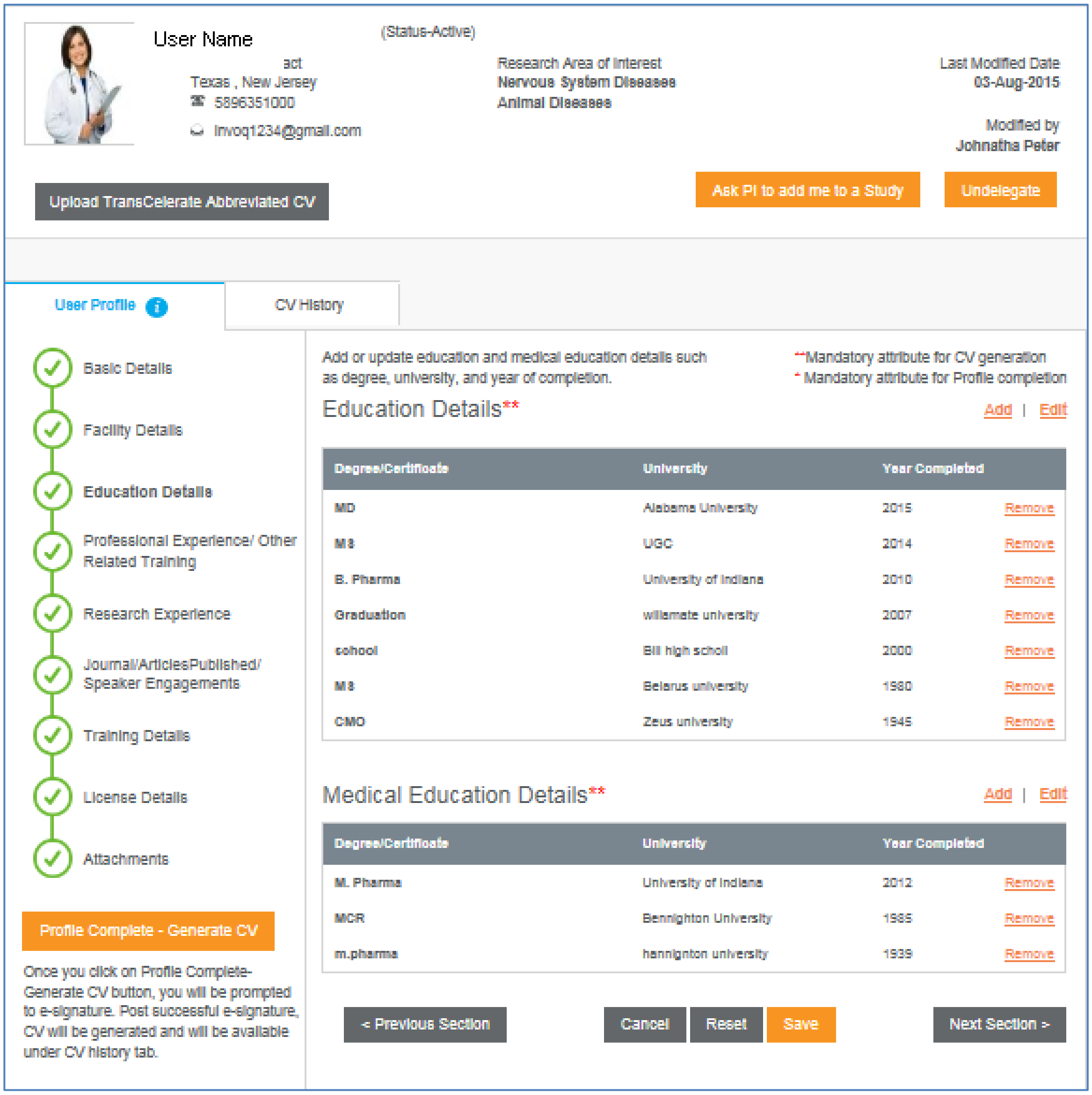


Figure 49. Education Details Page

2. To add the education details, in the **Education Details** section, click **Add**. The **Add Education Details** dialog box is displayed.

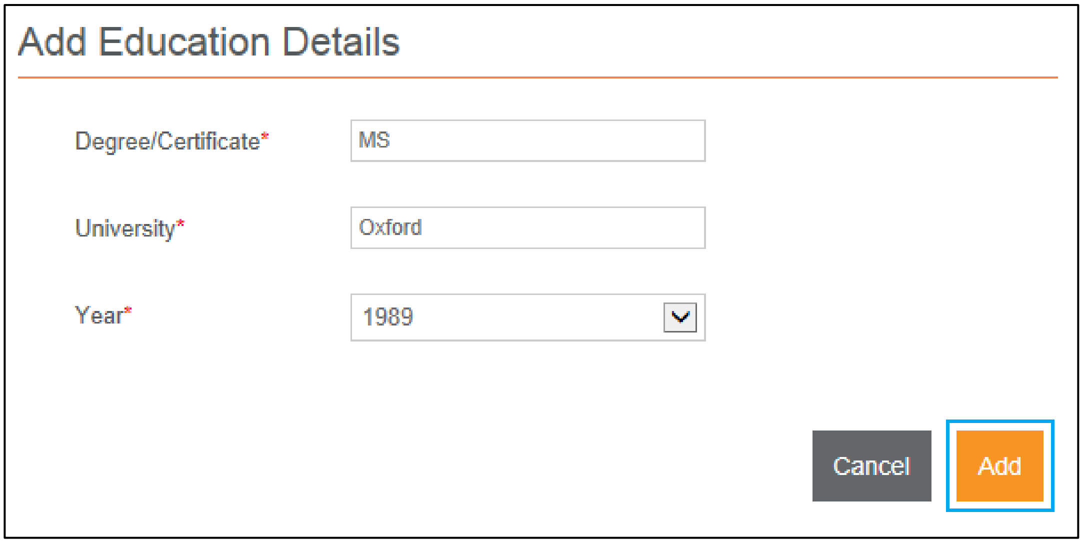


Figure 50. Add Education Details Dialog Box

3. In the **Add Education Details** dialog box, enter the education details. For Add Education Details field descriptions, refer to Table 13.

4. Click **Add**. The education details are updated in the **Education Details** section.

5. To save the details, click **Save**.

To edit the education details

1. To edit the education details, in the **Education Details** section, click **Edit**. The Degree/Certificate, University, and Year fields are enabled.

2. Edit the required education details.

3. To save the details, click **Save**. The updated education details are displayed.

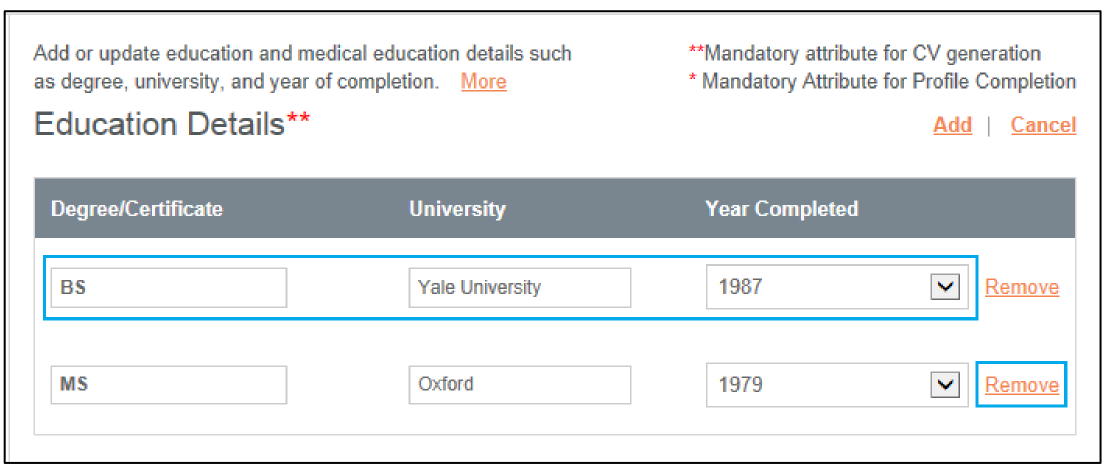


Figure 51. Edit Education Details

4.2.5.1. Add or Edit Medical Education Details

To add the medical education details

1. In the **Medical Education Details** section, click **Add**. The **Add Medical Education Details** dialog box is displayed.
2. In the **Add Medical Education Details** dialog box, enter the required details. Click **Add**. The medical education details are updated in the system.

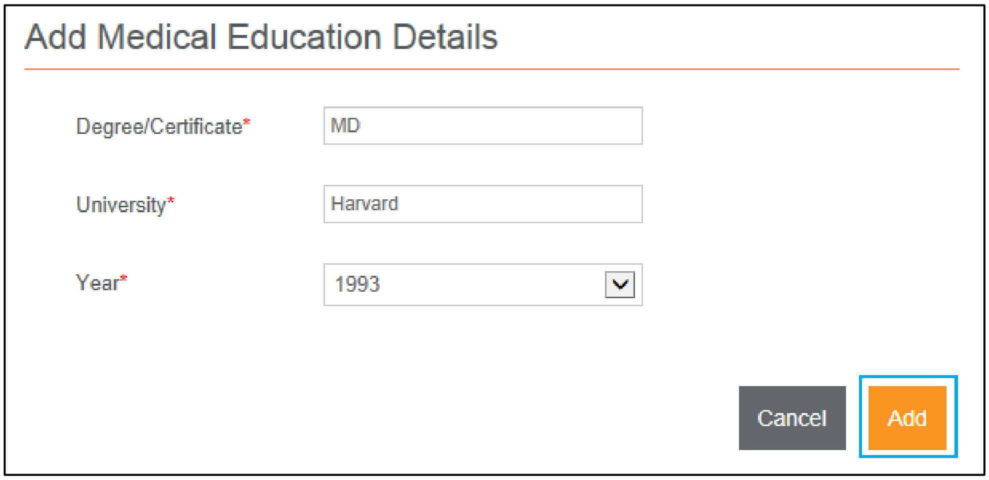


Figure 52. Add Medical Education Details Dialog Box

3. To save the details, click **Save**.

To edit the medical education details

1. To edit the medical education details, in the **Medical Education Details** section, click **Edit**. The Degree/Certificate, University, and Year fields are displayed.
2. Edit the required details.

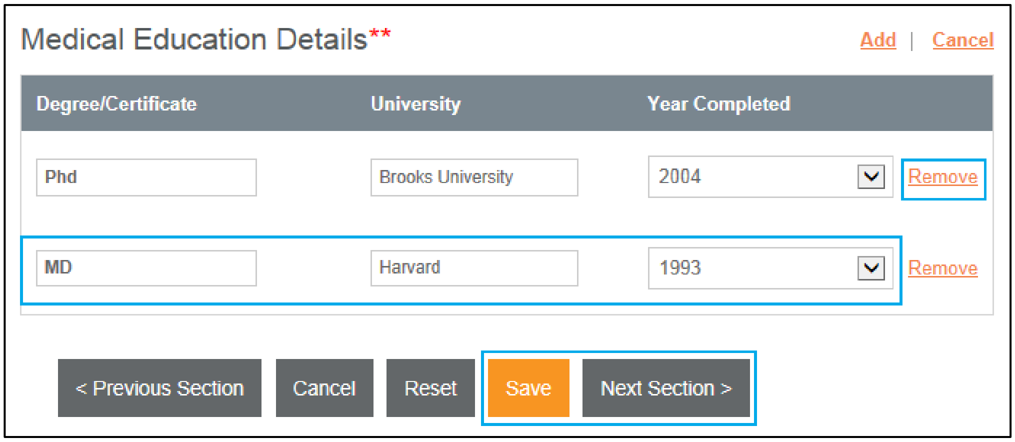


Figure 53. Edit Medical Education Details

3. To save the details, click **Save**.

4. To navigate to the next section of the User Profile, click **Next Section**.

The following table provides the field descriptions for the Education Details page.

Field	Field Type	Mandatory Field	Field descriptions
Degree/Certificate*	Text box	This is a mandatory field.	This is the professional degree of the Site User.
University*	Text box	This is a mandatory field.	This is the institute where the degree was completed.
Year*	Drop-down list	This is a mandatory field.	This is the year in which the Site User had completed the degree.

Table 11. Field Descriptions for Add/Edit Education Details

4.2.6 Add or Edit Professional Experience or Other Related Training

The User Profile-Professional Details page is the place where Site Users summarize their training and professional experience. Examples include: medical training through a residency, or fellowship program in ophthalmology, or an Assistant professor in endocrinology.

To add professional experience or other related training details

1. On the **User Profile** navigation pane, click **Professional Experience/Other Related Training**.

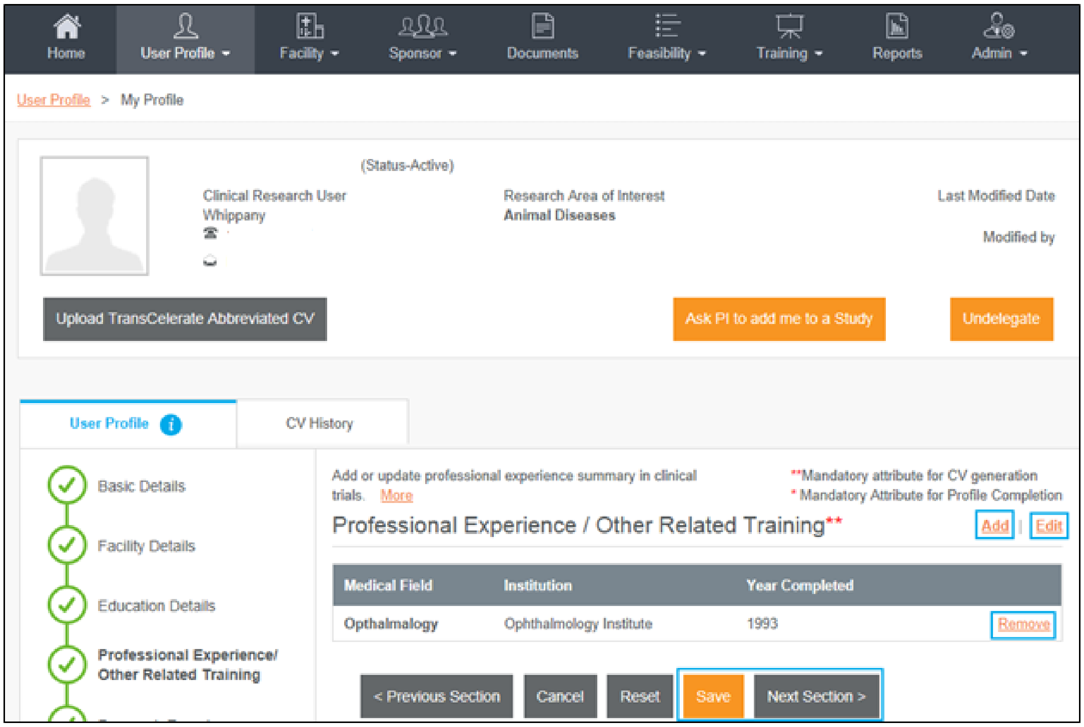


Figure 54. Professional Experience or Other Related Training Page

2. On the **Professional Experience/Other Related Training** page, click **Add**. The Add Professional Experience/Other Related Training dialog box is displayed.

3. In the **Add Professional Experience/Other Related Training** dialog box, enter the required details. For Add/Edit Professional Experience or Other Related Training field descriptions, refer to Table 14.

*To add the details, click **Add**.*

*To close the dialog box, click **Cancel**.*

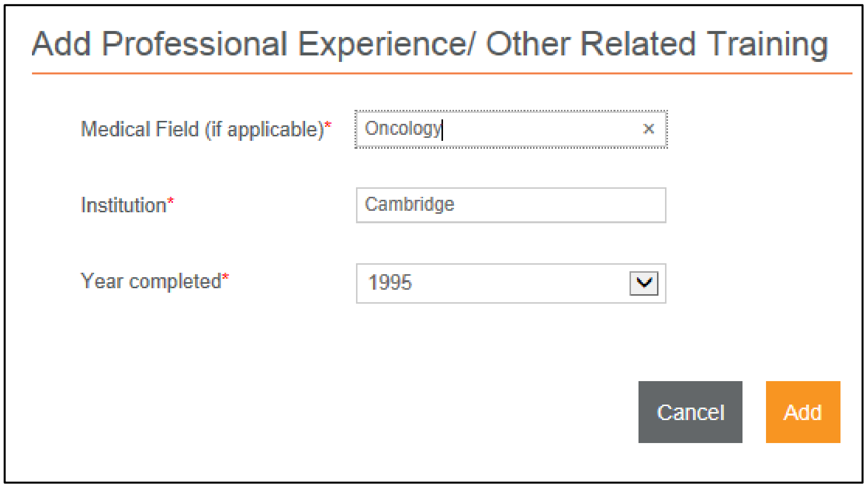


Figure 55. Add Professional Experience or Other Related Training Dialog Box

4. To save the education details, click **Save**.

5. To navigate to the next section of the User Profile, click **Next Section**.

To edit professional experience or other related training details

1. On the **Professional Experience/Other Related Training** page, click **Edit**. The Medical Field, Institution, and Year Completed fields are enabled.

2. Edit the required details.

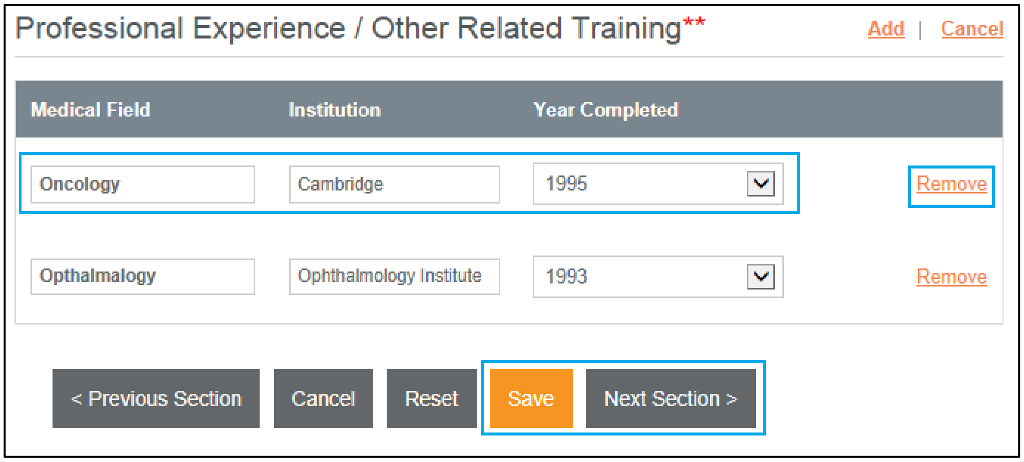


Figure 56. Edit Professional Experience or Other Related Training Page

3. To save the details, click **Save**.

The following table provides the field descriptions for the Professional Experience or Other Related Training page.

Field	Field Type	Mandatory Field	Field Descriptions
Medical Field	Text box	This is not a mandatory field.	This is the field of specialization of the user.
Institution	Text box	This is not a mandatory field.	This is the institution in which the user has worked or been trained.
Year Completed	Drop-down list	This is not a mandatory field.	This is the year in which the Site User had completed the degree.

Table 12. Field Descriptions for Add or Edit Professional Experience or Other Related Training

4.2.7 Add or Edit Research Experience

The User Profile – Research Experience page is the place where Site Users add and update their clinical trial research experience.

To add research experience

1. On the **User Profile** navigation pane, click **Research Experience**. The Research Experience page is displayed.

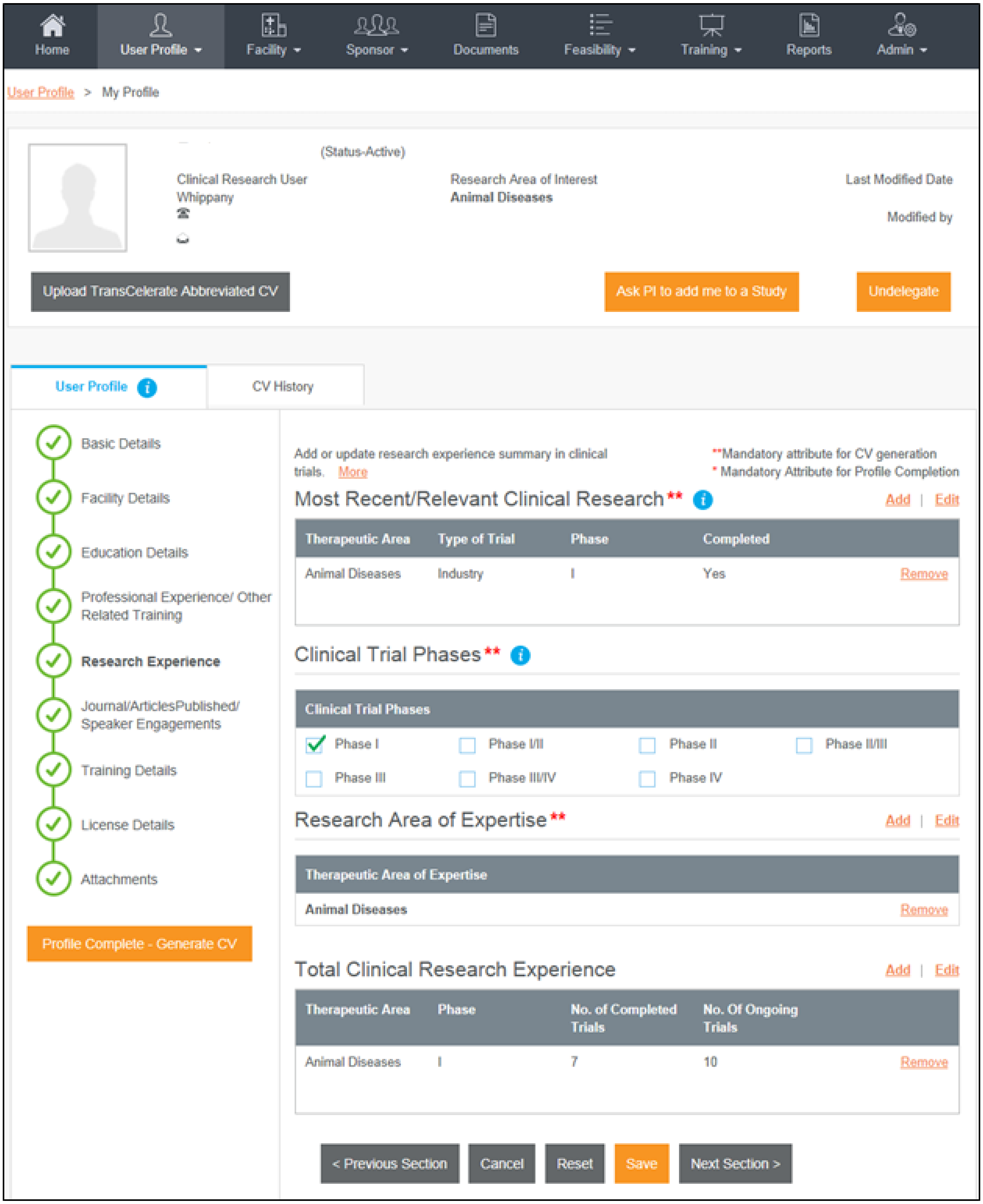


Figure 57. Research Experience Page

2. On the **Research Experience** page, in the **Most Recent/Relevant Clinical Research** section, click **Add**. The Add Most Recent or Relevant Clinical Research dialog box is displayed.

3. In the **Add Most Recent/Relevant Clinical Research** dialog box, list active and recent trials based on therapeutic area, phase of trial, type of trial (i.e. academic or industry) and open/completed status of the trial. For Add Research Experience Details field descriptions, refer to Table 15.

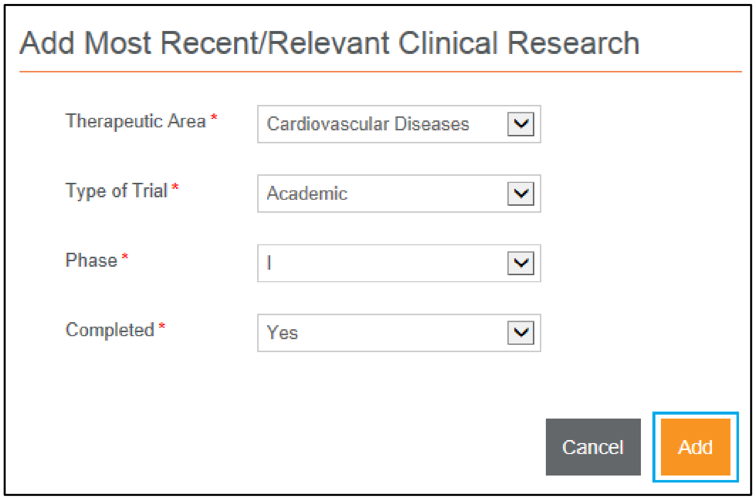


Figure 58. Add Most Recent/Relevant Clinical Research Dialog Box

*To add the details, click **Add**.*

*To close the dialog box, click **Cancel**.*

4. In the **Clinical Trials Phases** section, multi-select phases of studies in which you have worked.

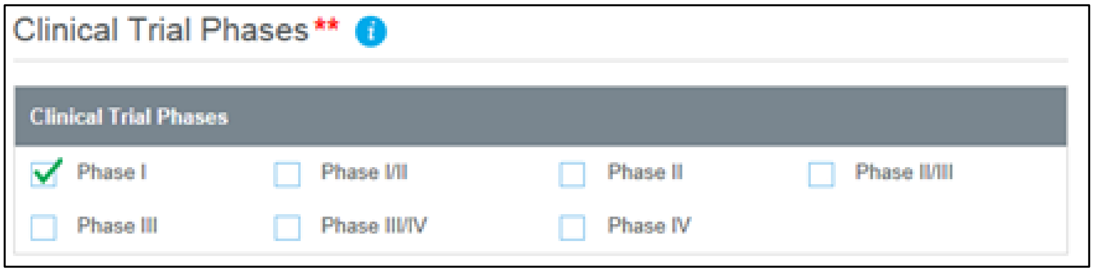


Figure 59. Clinical Trial Phases Section

5. In the **Research Area of Expertise** section, click **Add**. List all therapeutic areas in which you have expertise in conducting clinical trials. The Add Research Area of Expertise dialog box is displayed.

Figure 60. Add Research Area of Expertise Dialog Box

6. In the **Add Research Area of Expertise** drop-down, click a research area of expertise, and then click **Add**.

*To close the dialog box, click **Cancel**.*

7. In the **Total Clinical Research Experience** section, click **Add**. The Add Total Clinical Research Experience dialog box is displayed. You can multi-select phases. Provide a summary of trials with a completed and ongoing status, grouped by therapeutic area and phase. List each phase of trial experience separately such as Oncology Phase 2, and Oncology Phase 3. Include relevant and recent research experience that summarizes your expertise and support the potential for new trial opportunities.

8. In the **Add Total Clinical Research Experience** dialog box, enter the required details. For Add/Edit Research Experience Details field descriptions, refer to Table 15.

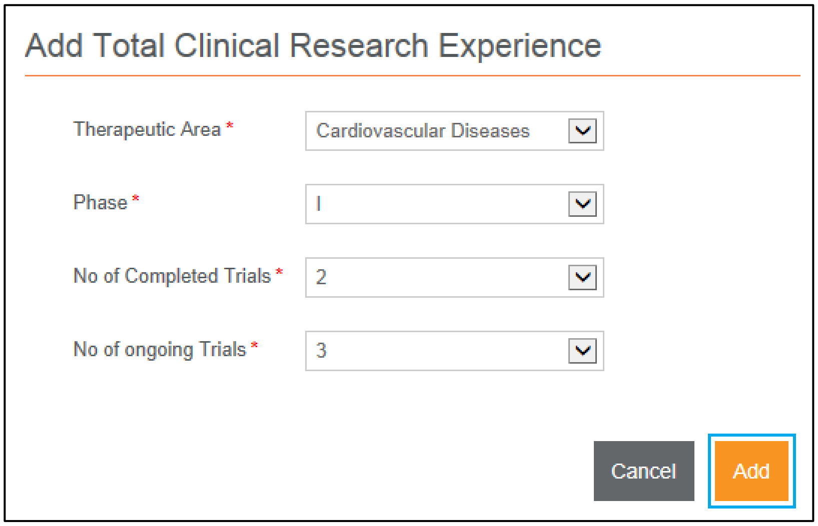


Figure 61. Add Total Clinical Research Experience Dialog Box

9. To save the details, click **Save**.

10. To navigate to the next section of the User Profile, click **Next Section**.

*To close the Research Experience page, click **Cancel**.*

*To clear the details, click **Reset**.*

*To navigate to the previous section of the User Profile, click **Previous Section**.*

To edit research experience details

1. In the **Most Recent or Relevant Clinical Research** section, click **Edit.**

2. Edit the required details.

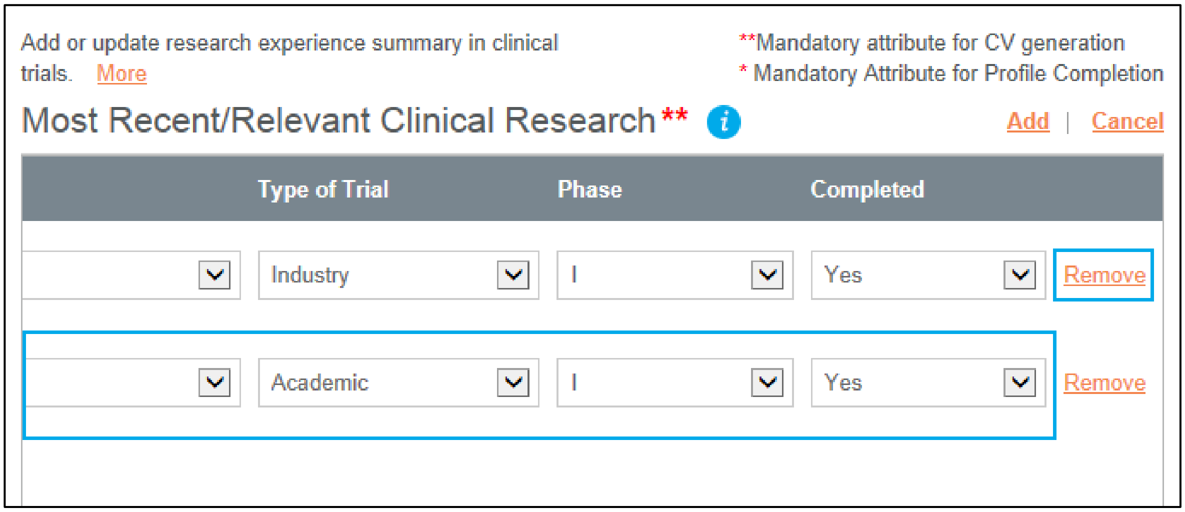


Figure 62. Edit Most Recent or Relevant Clinical Research Details

3. In the **Research Area of Expertise** section, click **Edit**. The Therapeutic Area of Expertise field is enabled. List all therapeutic areas in which you have expertise in conducting clinical trials.

4. In the **Therapeutic Area of Expertise** drop-down list, click a required option. List all therapeutic areas in which you have expertise in conducting clinical trials.

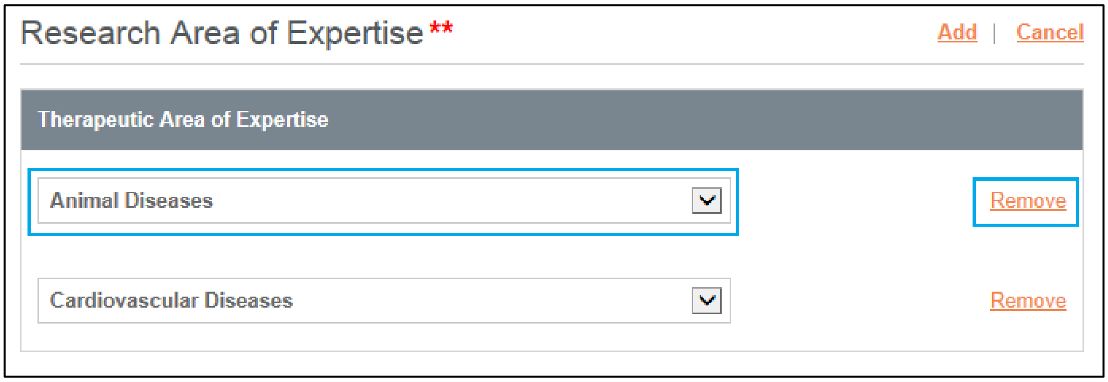


Figure 63. Edit Research Area of Expertise

5. In the **Total Clinical Research Experience** section, click **Edit**.

6. Edit the required details. Provide a summary of trials with a completed and ongoing status, grouped by therapeutic area and phase. List each phase of trial experience separately such as Oncology Phase 2, and Oncology Phase 3. Include relevant and recent research experience that summarizes your expertise and support the potential for new trial opportunities.

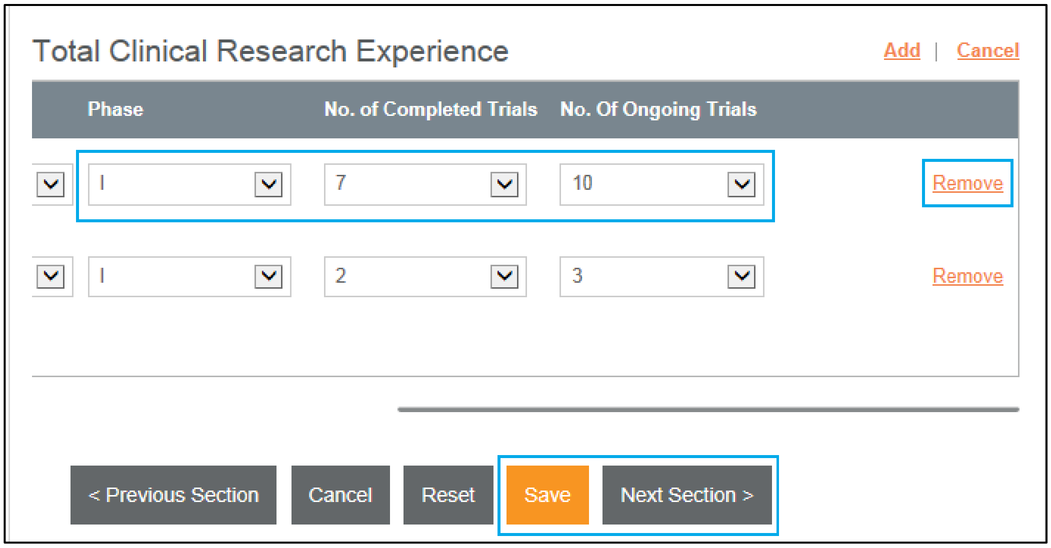


Figure 64. Edit Total Clinical Research Experience

7. To save the details, click **Save**.

*To delete the details, click **Remove**.*

The following table provides the field descriptions for all of the fields on the Research Experience page.

Field	Field Type	Mandatory Field	Field descriptions
Research Area of Interest			
Therapeutic Area of Expertise	Drop-down list	This is not a mandatory field.	This is the area or field in which the Site User has prior work experience.
Clinical Trial Phases			
Clinical Trial Phases*	Check box	This is a mandatory field.	This is the clinical trial phase of the research. Multi-select phases of studies in which you have worked.
Most Recent/ Relevant Clinical Research			

Therapeutic Area	Drop-down list	This is not a mandatory field.	This is the field in which the user has recently performed research. List active and recent trials based on therapeutic area, phase of trial, type of trial (i.e. academic or industry) and open/completed status of the trial.
Type of Trial	Drop-down list	This is not a mandatory field.	This refers to the type of trial used in the research.
Phase	Drop-down list	This is not a mandatory field.	This refers to the phase of trial.
Completed	Drop-down list	This is not a mandatory field.	This refers to the status of the trial.
Research Area of Expertise			
Therapeutic Area of Expertise	Drop-down list	This is not a mandatory field.	
Add Total Clinical Research Experience			
Therapeutic Area	Drop-down list	This is not a mandatory field.	This is the research area or field.
Phase	Drop-down list	This is not a mandatory field.	This refers to the phase of the trial.
No. of Completed Trials	Drop-down list	This is not a mandatory field.	This refers to the number of trials completed in the phase
No. of Ongoing Trials	Drop-down list	This is not a mandatory field.	This refers to the number of ongoing trials in the phase.

Table 13. Field Descriptions for Add or Edit Research Experience Details

4.2.8 Add/Edit Journal/Articles Published/Speaker Engagements

The User Profile – Journal or Article Published Details page allows the Site Users to add or update the journal, article, or speaker engagement details. You can add relevant articles/engagements that are within the last ten years.

To add Journal/Articles Published/Speaker Engagements

1. On the **User Profile** navigation pane, click **Journal/Articles Published/Speaker engagements**.

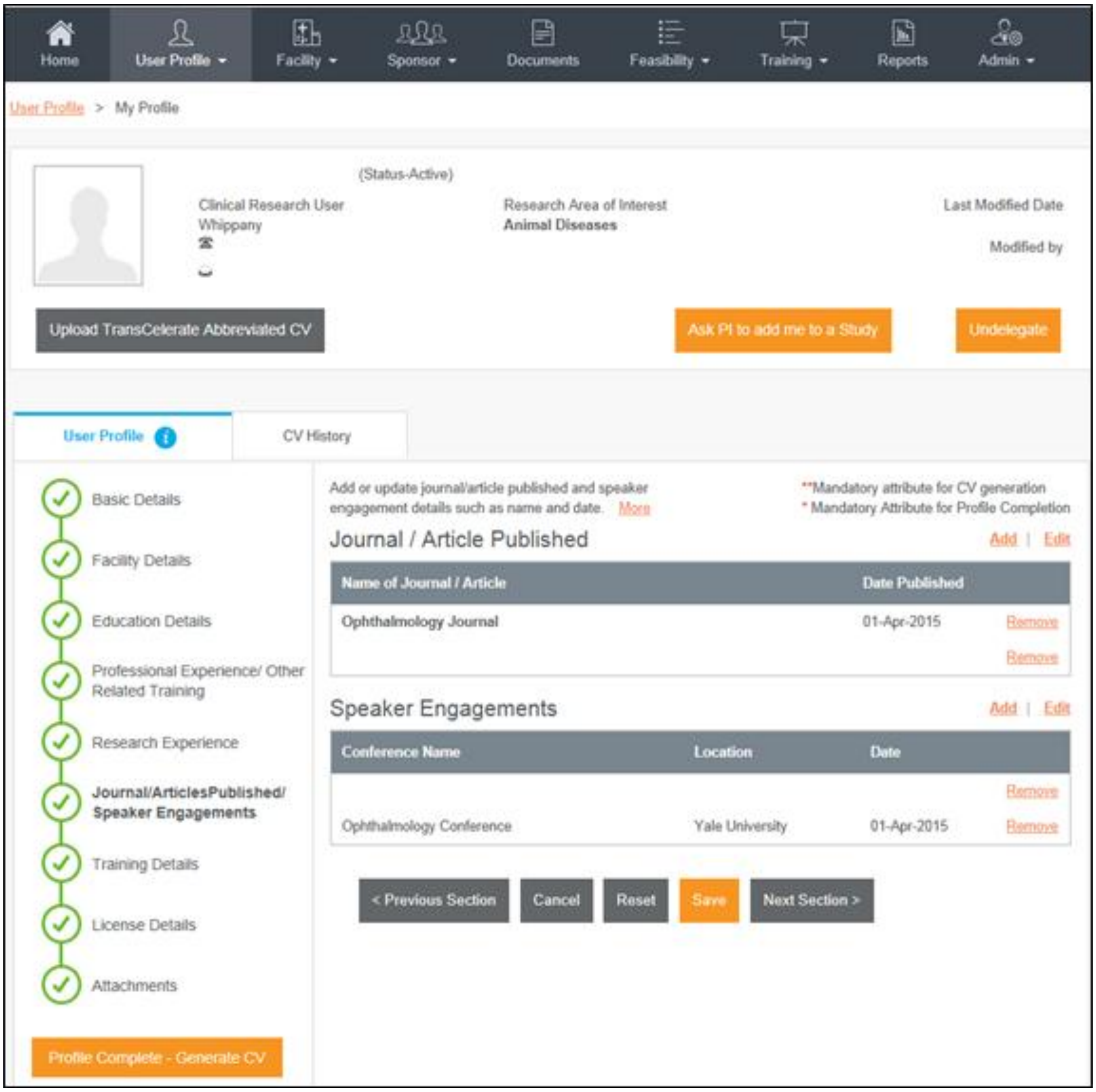


Figure 65. Journal/Articles Published/Speaker Engagements Page

2. On the **Journal/Articles Published/Speaker Engagements** page, in the **Journal/Article Published** section, click **Add**. The Add Journal/Articles Published dialog box is displayed.

3. In the **Add Journal/Articles Published** dialog box, enter the required details. For Add/Edit Journal or Article Published or Speaker Engagements Details field descriptions, refer to Table 16.

Figure 66. Add Journal or Article Published Dialog Box

*To add the details, click **Add**.*

*To close the dialog box, click **Cancel**.*

4. In the **Speaker Engagements** section, click **Add.** The Add Speaker Engagements dialog box is displayed.
5. In the **Add Speaker Engagements** dialog box, enter the required details. For Add/Edit Journal or Article Published or Speaker Engagements Details field descriptions, refer to Table 16.

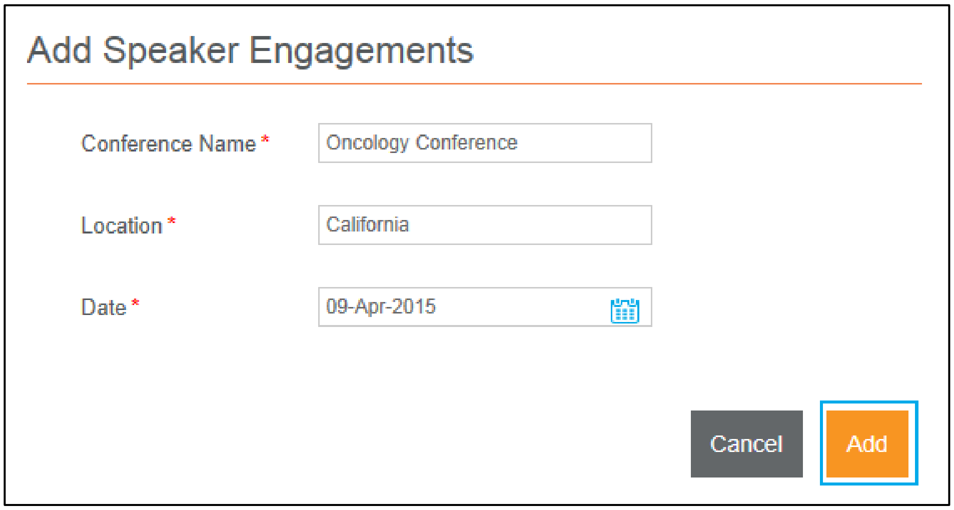


Figure 67. Add Speaker Engagements Dialog Box

*To add the details, click **Add**.*

*To close the dialog box, click **Cancel**.*

6. To save the entered details, click **Save**.

7. To navigate to the next section of the User Profile, click **Next Section**.

*To close the Journal/Articles Published page, click **Cancel**.*

*To clear the details, click **Reset**.*

*To navigate to the previous section of the User Profile, click **Previous Section**.*

To edit Journal/Articles Published or Speaker Engagements

8. In the **Journal/Articles Published** section, click **Edit**.
9. Edit the required details such as Name of Journal or Article and Date Published.

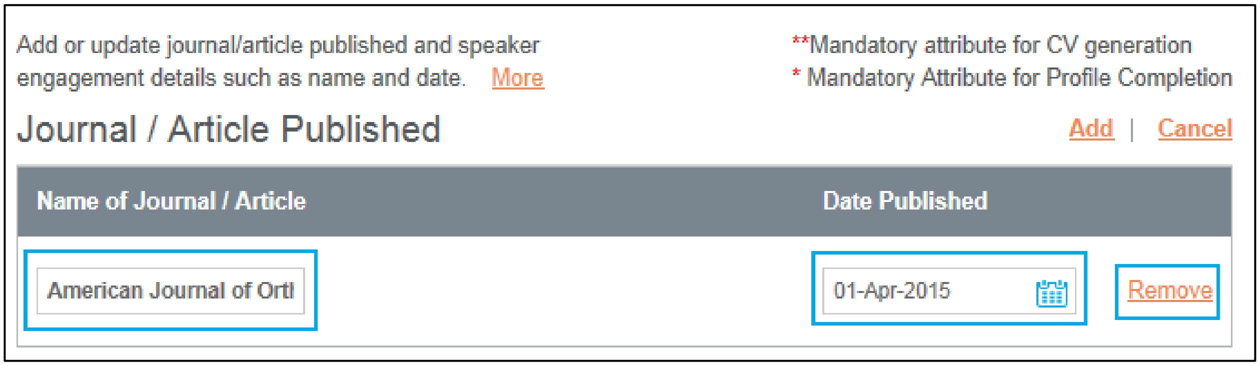


Figure 68. Edit Journal/Articles Published/Speaker Engagements

10. In the **Speaker Engagements** section, click **Edit**.
11. Edit the required details such as Conference Name, Location, and Date on which the conference was held.

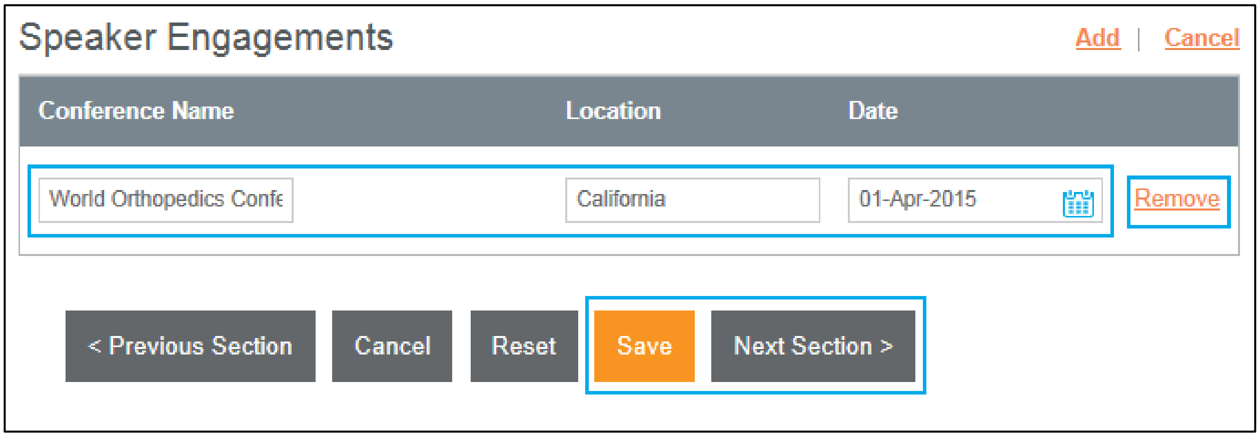


Figure 69. Edit Speaker Engagements

12. To save the details, click **Save**.

*To delete the details, click **Remove**.*

The following table provides the field descriptions for the Journal or Article Published or Speaker Engagement details page.

Field	Field Type	Mandatory Field	Field Descriptions
Journal or Article Published			
Name of the Journal/Article	Text box	This is not a mandatory field.	Name of the journal in which the article was published
Date Published	Date Picker	This is not a mandatory field.	Date on which the article was published
Speaker Engagements			
Conference Name	Text box	This is not a mandatory field.	Name of the conference in which the user had participated
Location	Text box	This is not a mandatory field.	Location in which the conference was held
Date	Date Picker	This is not a mandatory field.	Date on which the conference was held

Table 14. Field Descriptions for Add/Edit Journal or Articles Published or Speaker Engagements

4.2.9 Training Details

The User Profile–Training Details feature allows the Site Users to add their GCP Training records into their SIP User Profile. Some GCP training courses are designated Mutually Recognized Training (MRT) as the training completion record is accepted by multiple Sponsors. Site Users can update training details and send to Sponsors for approval. If approved, credit will be cascaded across SIP participating Sponsors who may accept the credit.

To manage training details

1. On the **User Profile** navigation pane, click **Training Details**. The training details are auto populated from the Training module.

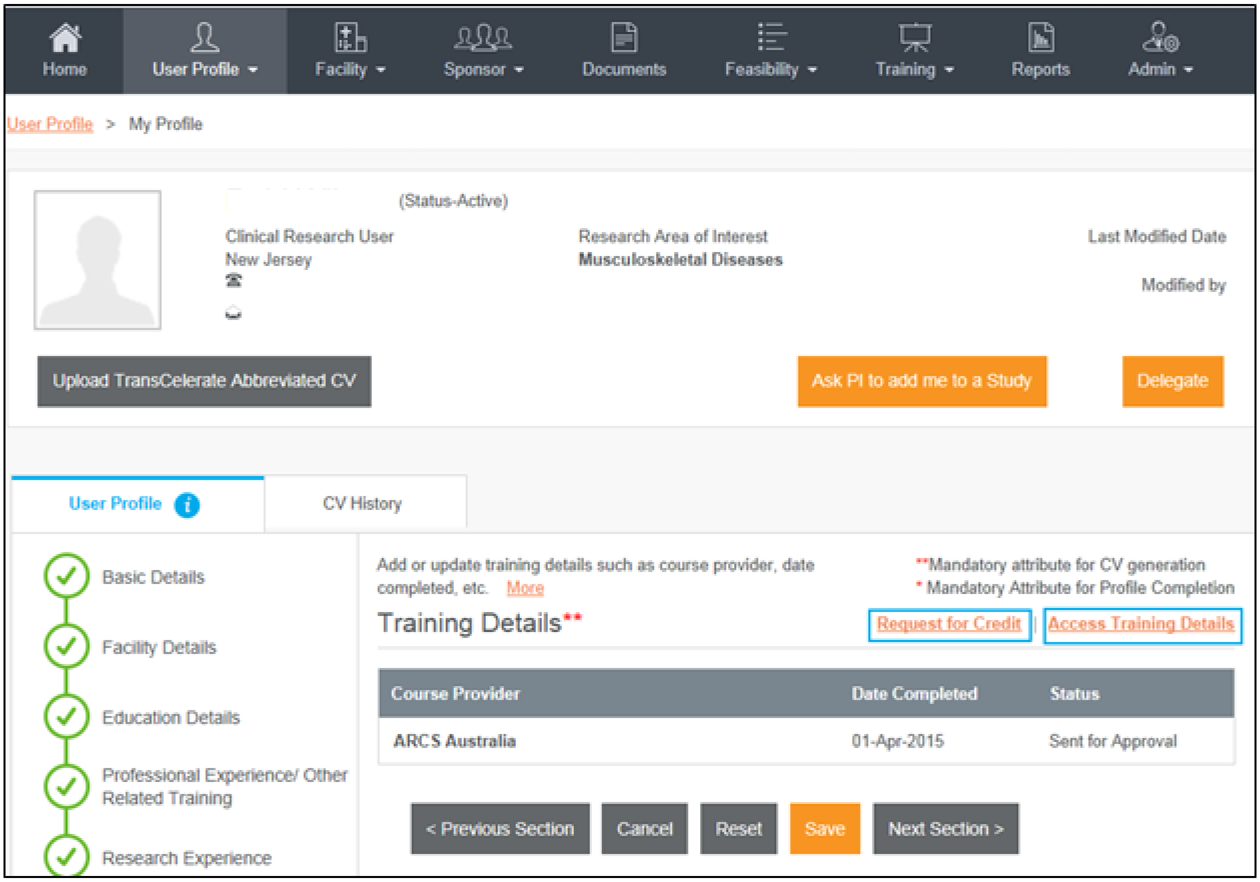


Figure 70. Training Details Page

2. To access the training details, click **Access Training Details**. For Access Training Details, refer to Section 9.1.1.

3. To request credits for the trainings completed, click **Request for Credit**. For Request for Credit, refer to Section 9.3.

4. To save the training details, click **Save**.

5. To navigate to the next section of the User Profile, click **Next Section**.

4.2.10 Add or Edit License Details

The User Profile – License Details page allows the Site Users to enter and update medical license details. Site Users can also upload their medical license.

If the current medical license needs to be replaced with a new license, Site Users can remove the current medical license details by using the Expire feature.

To upload medical license

1. On the **User Profile** navigation pane, click **License Details**. The License Details page is displayed.

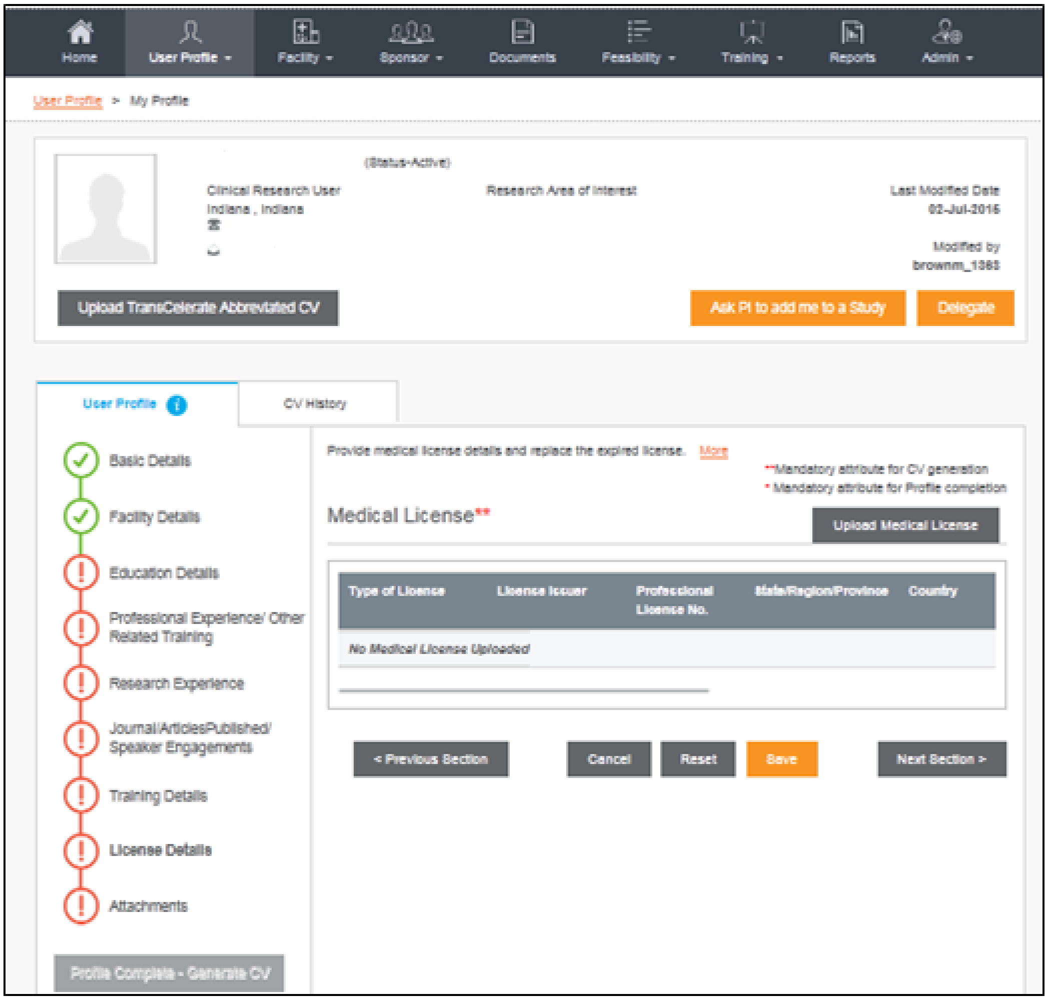


Figure 71. License Details Page

2. In the **Medical License** section, click **Upload**. The following Upload Medical License dialog box is displayed.

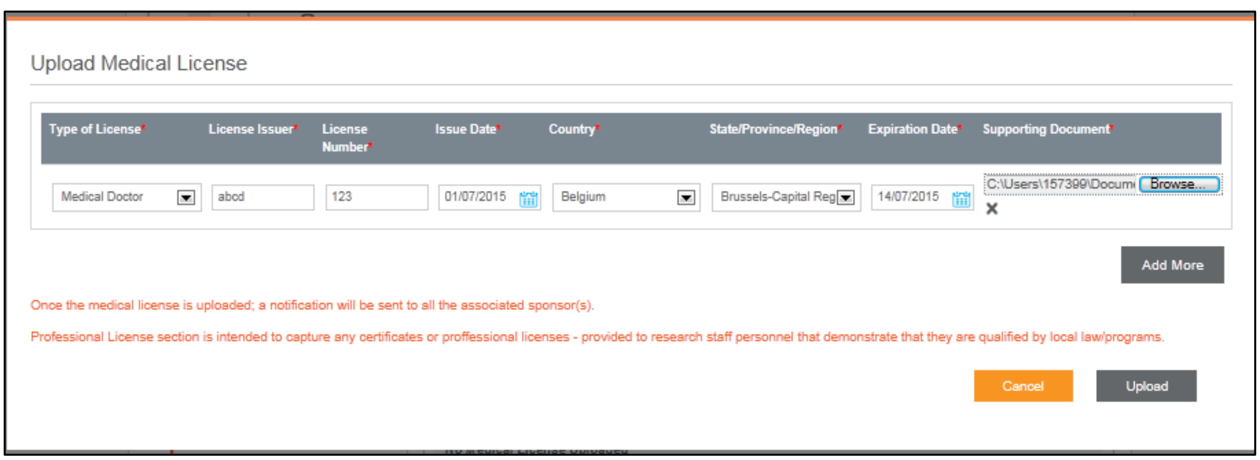


Figure 72. Upload Medical License Dialog Box

3. In the **Upload Medical License** dialog box, enter the medical license details. For Upload Medical License field descriptions, refer to Table 17.

*To add additional details, click **Add More**.*

4. To upload supporting documents, click **Browse**.

5. In the **Choose a File to Upload** dialog box, browse to the location of the medical license, and then click **Open**.

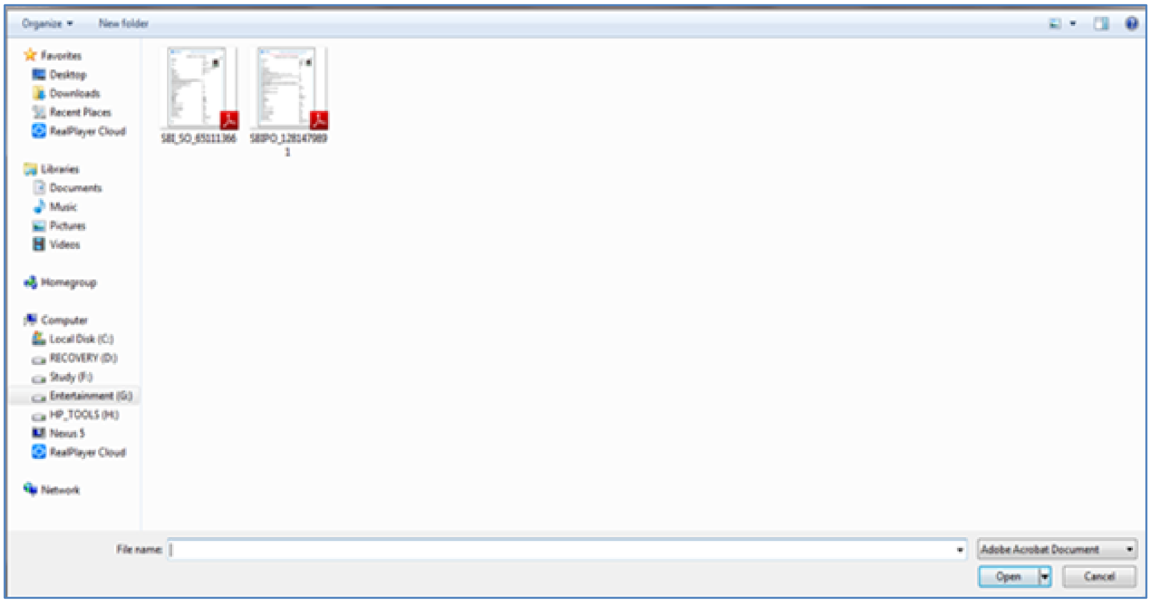


Figure 61. Choose a File to Upload Dialog Box

6. To upload the medical license document, click **Upload**. The confirmation message is displayed.

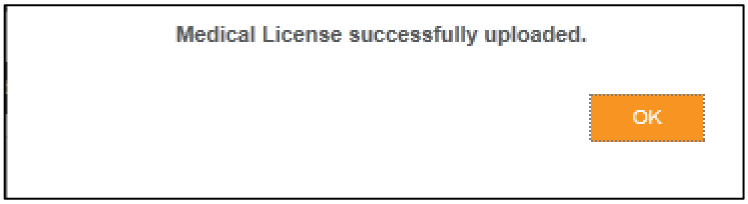


Figure 61. Upload Medical License Confirmation Message

7. Click **OK**. The medical license is uploaded in the License Details page.

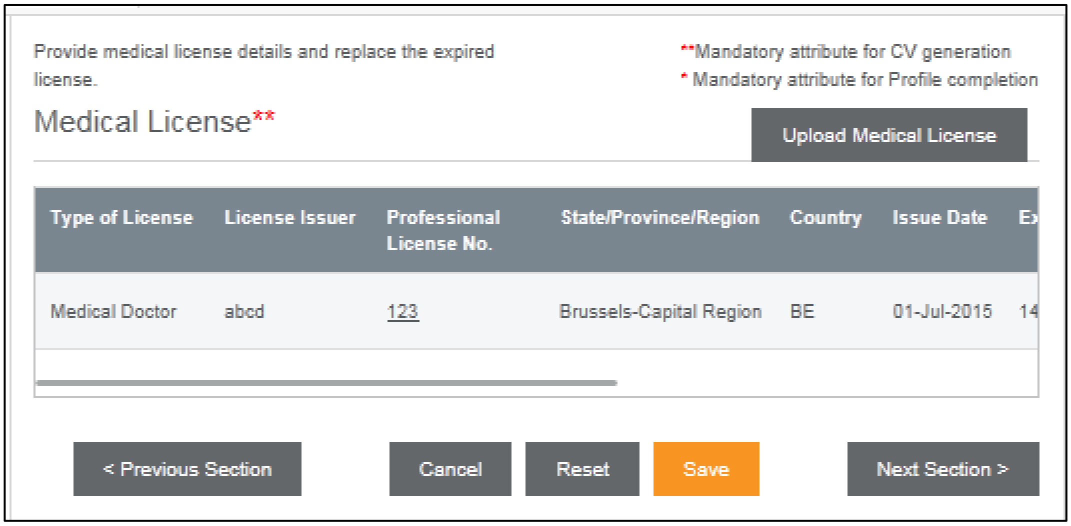


Figure 61. Medical License Page

8. To save the details, on the **License Details** page click **Save**. The following message is displayed.

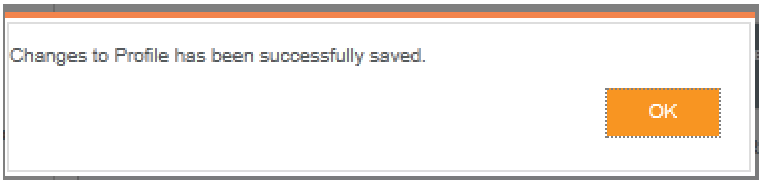


Figure 73. Edit Medical License Details: Confirmation Message

9. Click **OK**. The license details page with the updated medical license details is displayed.
10. To navigate to the next section of the User Profile, click **Next Section**.

To edit the license details

1. On the **Medical License** section, click **Edit**. The **Edit Medical License** dialog box is displayed.

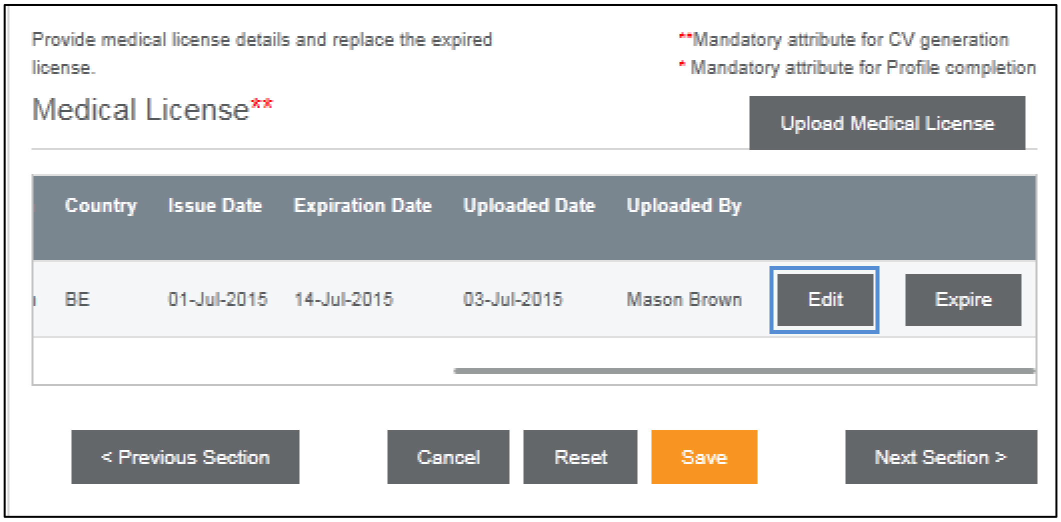


Figure 74. Medical License Section

2. In the **Edit Medical License** dialog box, edit the required details. For Edit Medical License Details field descriptions, refer to Table 17.

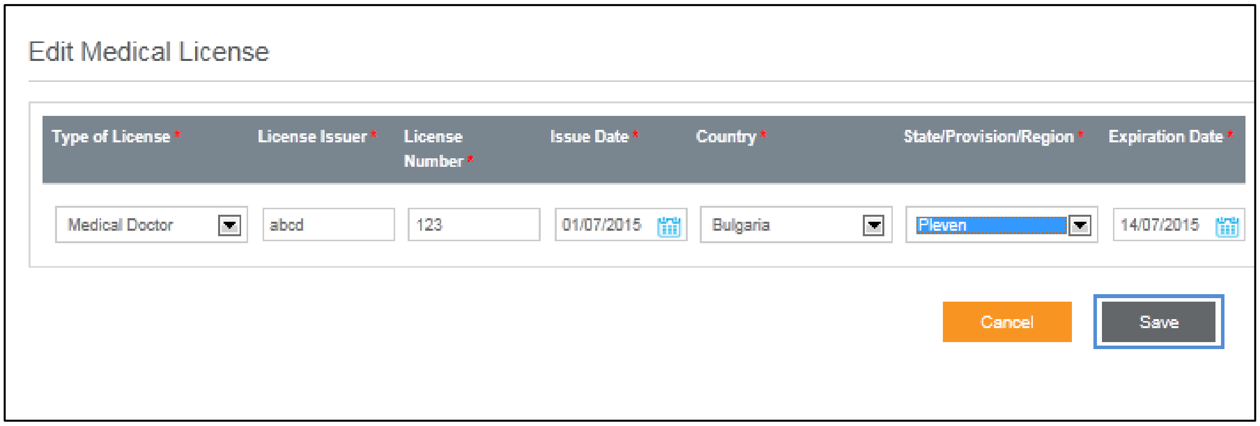


Figure 75. Edit Medical License Details Dialog Box

3. To save the details, click **Save**. The Confirmation message is displayed.

Figure 76. Edit Medical License Details: Confirmation Message

4. Click **OK**. The Medical License Details page with updated medical license details is displayed.

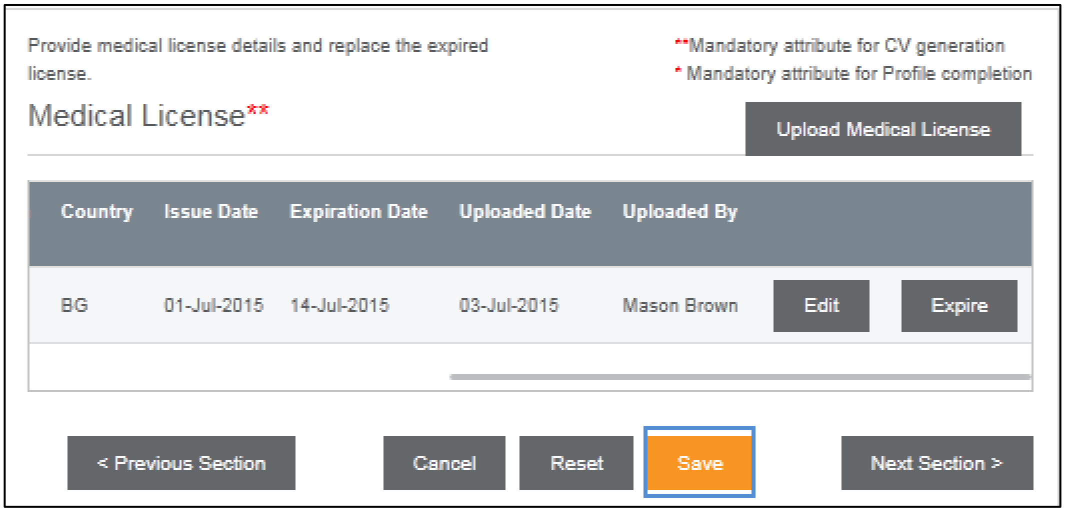


Figure 77. Edit Medical License Details Page

5. To save the updated medical license details, click **Save**. The confirmation message is displayed.

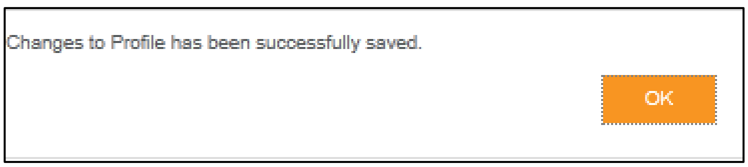


Figure 78. Edit Medical License Details: Confirmation Message

6. Click **OK**. The license details page with the updated medical license details is displayed.

To remove the expired license

1. In the Medical License page, click **Expire**.

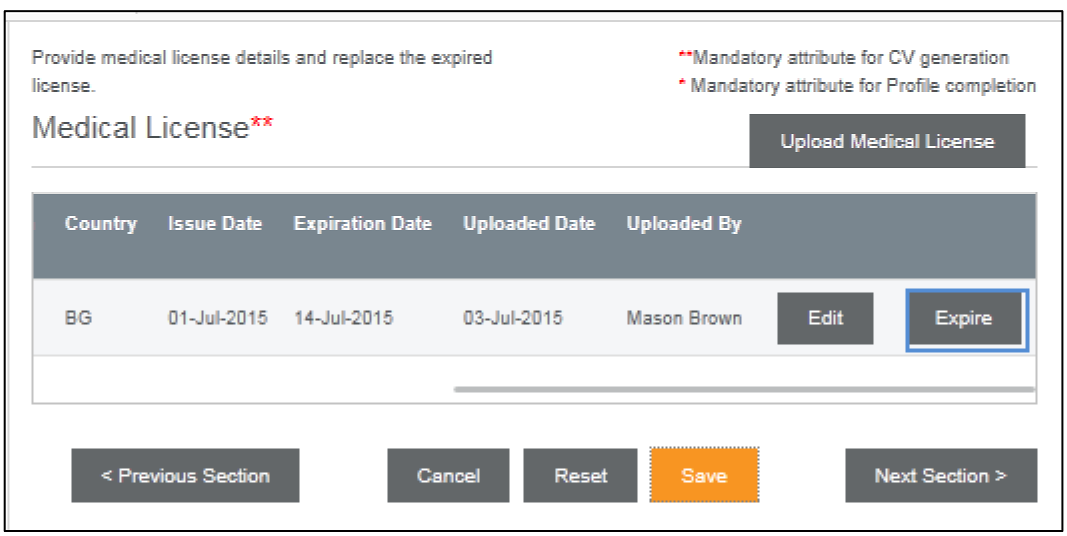


Figure 79. Medical License Details Page

2. To remove the medical license details, in the medical details section, click **Expire**. A confirmation message is displayed.

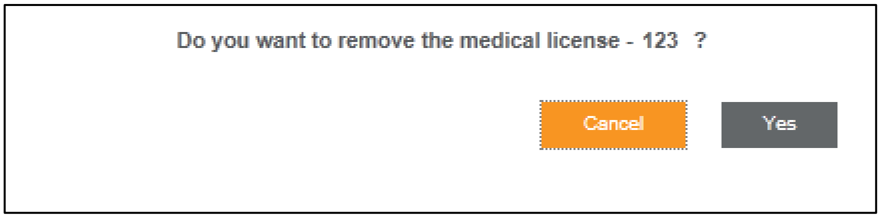


Figure 80. Expire Medical License: Confirmation Message

3. Click **Yes.** The expired medical license is removed and the following page is displayed.

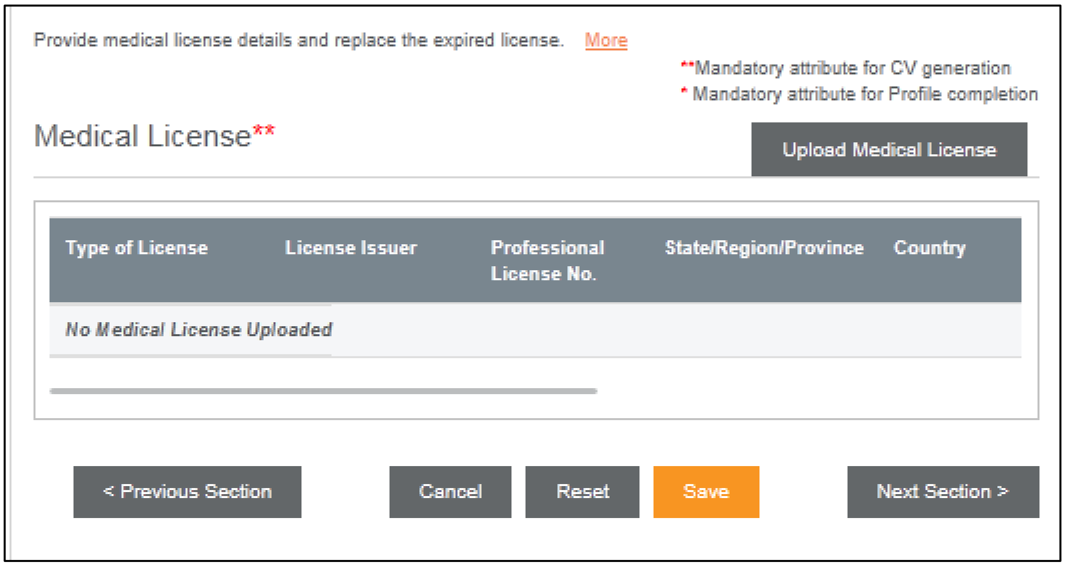


Figure 81. Expired Medical License Page

The following table provides the field descriptions for the License Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Type of License*	Drop-down list	This is a mandatory field.	Type of license that the Site User owns
Licenser Issuer*	Text box	This is a mandatory field.	Name of the license issuer
License Number*	Text box	This is a mandatory field.	License number of the Site User
Issue Date*	Date picker	This is a mandatory field.	Issue date of the license
Country*	Drop-down list	This is a mandatory field.	Name of the country specified in the license
State/Province/Region*	Drop-down list	This is a mandatory field.	State, province, or region specified in the license
Expiration Date*	Date picker	This is a mandatory field.	Date on which the license expires

Table 15. Field Descriptions for Upload or Edit License Details

4.2.11 Add Attachments

This feature allows the Site Users to upload the required documents associated with research experience, professional experience, and certifications.

To attach a file

1. On the **User Profile** navigation pane, click **Attachments**. The attachments page is displayed.
2. To browse and select the attachment from the system's local drive, click **Browse**.

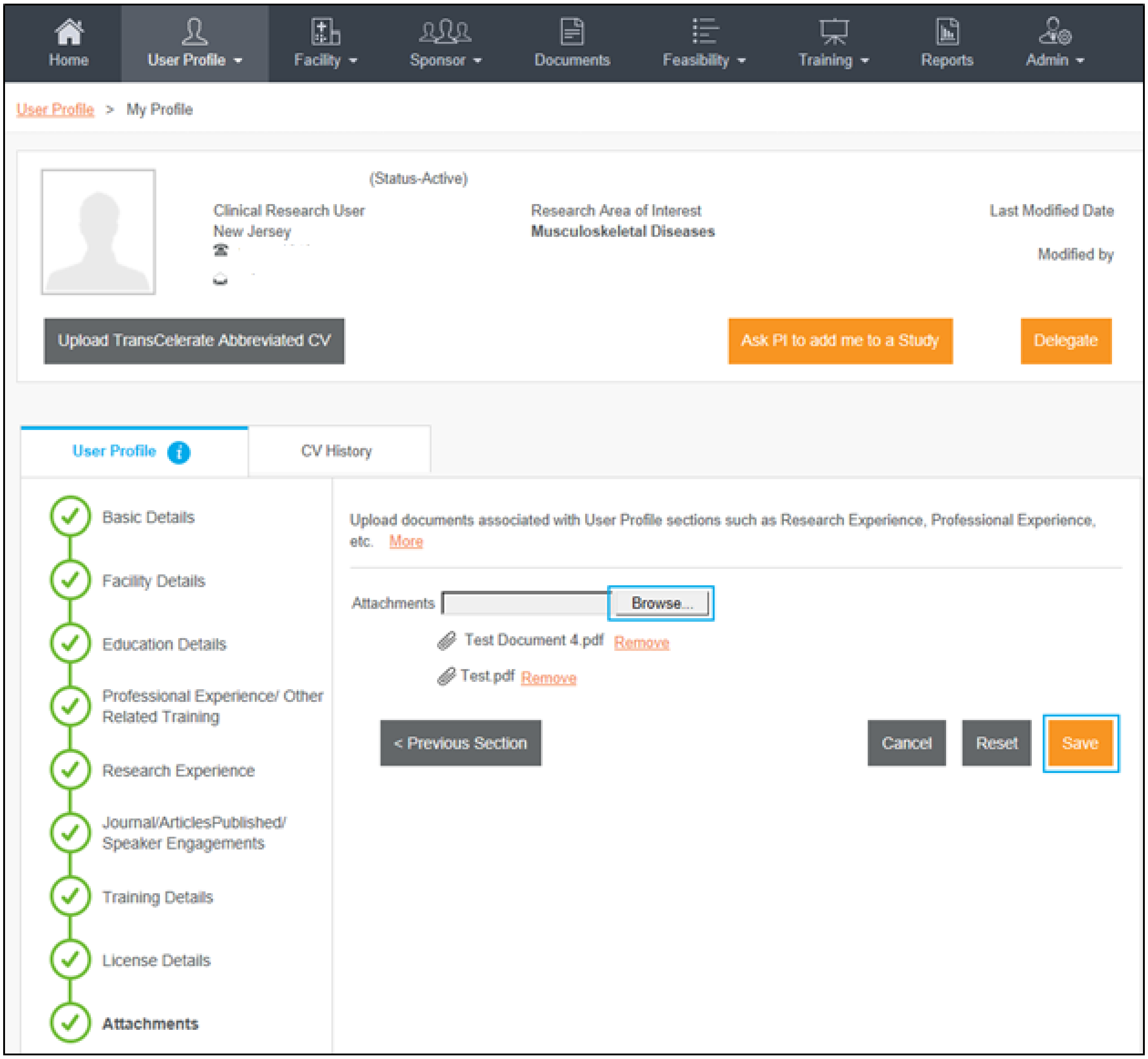


Figure 82. Attachments Page

3. To save the attachment, click **Save**.
4. To navigate to the previous section of the User Profile, click **Previous Section**.

*To delete the added file, click **Remove**.*

The upload process workflow may vary with the browser (Chrome or IE) being used.

4.3 Generate a CV

The Generate a CV feature allows Site Users to generate a curriculum vitae from the existing User Profile details. As the CV is updated, or is downloaded by a Sponsor, the history is maintained by SIP.

To generate a CV

1. On the **User Profile** navigation pane, click **Profile Complete – Generate CV**. The following Confirm and Generate CV confirmation message is displayed.

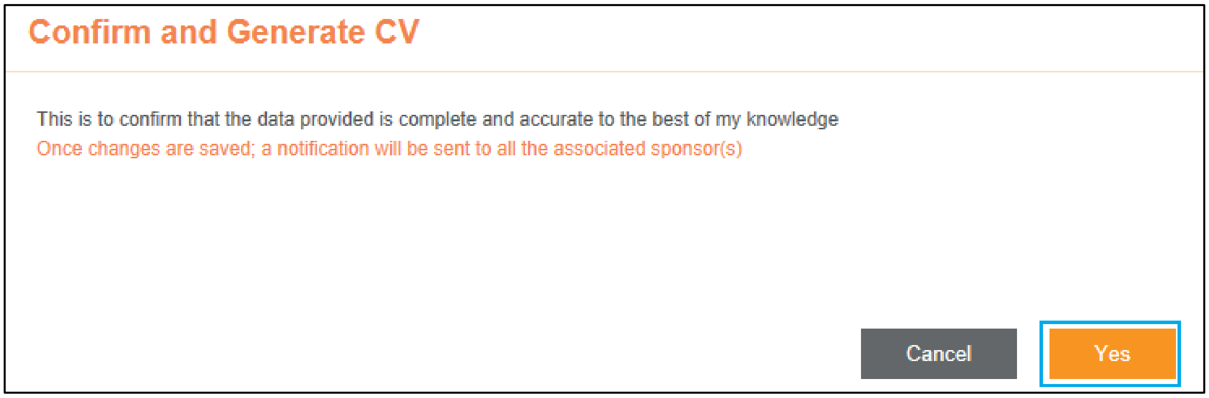


Figure 83. Confirm and Generate CV: Confirmation Message

The user needs to complete all required fields in the User Profile section, before clicking Profile Complete-Generate CV.

2. To accept the confirmation message, click **Yes**.
3. On the **E-Sign** page, In the **User ID** box, enter the user ID.

Figure 84. E-Signature Page

4. In the **Password** box, enter the password.
5. Click **E-Sign**.
6. To accept the CV generated confirmation message, click **OK**.

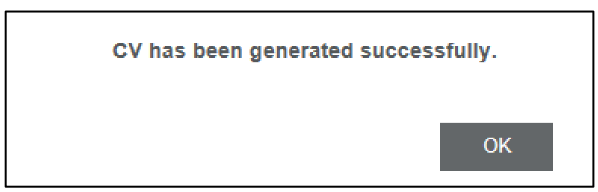
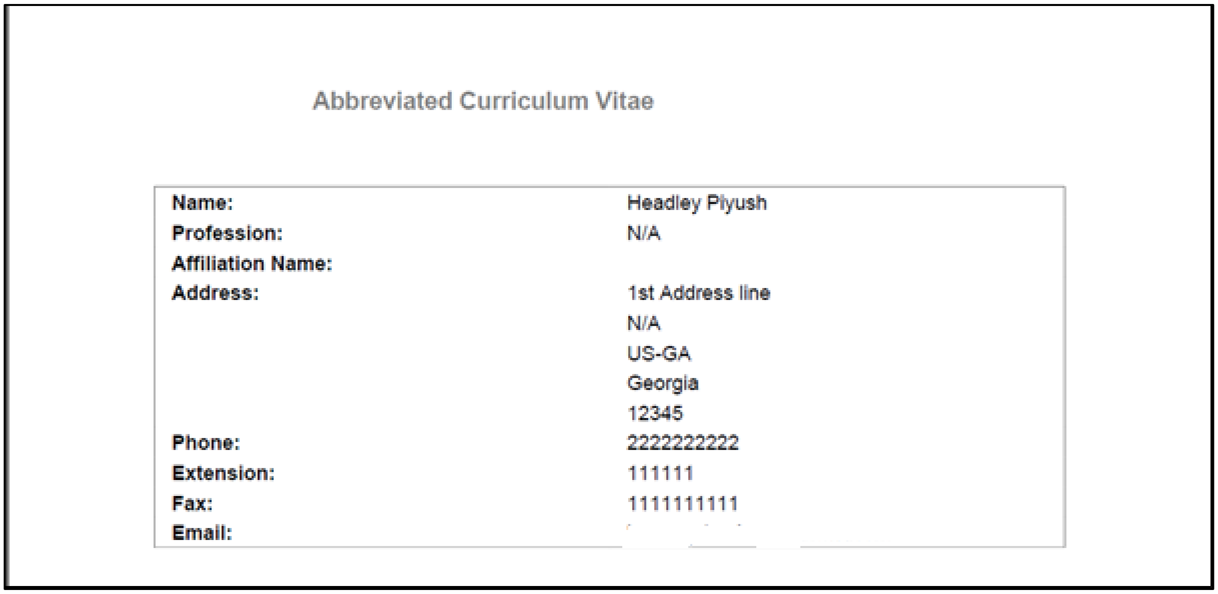


Figure 85. Confirm and Generate CV Window



Abbreviated Curriculum Vitae

Name:	Headley Piyush
Profession:	N/A
Affiliation Name:	
Address:	1st Address line
	N/A
	US-GA
	Georgia
	12345
Phone:	2222222222
Extension:	111111
Fax:	1111111111
Email:	

Figure 86. TransCelerate Abbreviated CV

4.4 Upload TransCelerate Abbreviated CV

Site Users who have the completed TransCelerate Abbreviated CV can upload the CV by using the Upload feature. Upload only the electronic format. The system cannot extract data from any other format.

Additional manual data entry will be needed to complete the profile. However, the amount of data entry required is greatly reduced by using this feature. After the data is imported to the profile from the CV, Site User may update the data as needed. All information must be completed in the template prior to uploading it to SIP.

To upload the CV template

1. On the **User Profile** menu of the Site User Landing Page, click **My Profile**.
2. To upload the CV, click **Upload TransCelerate Abbreviated CV**.
3. In the **Choose File to Upload** dialog box, browse to the location of the CV, and then click **Open**.

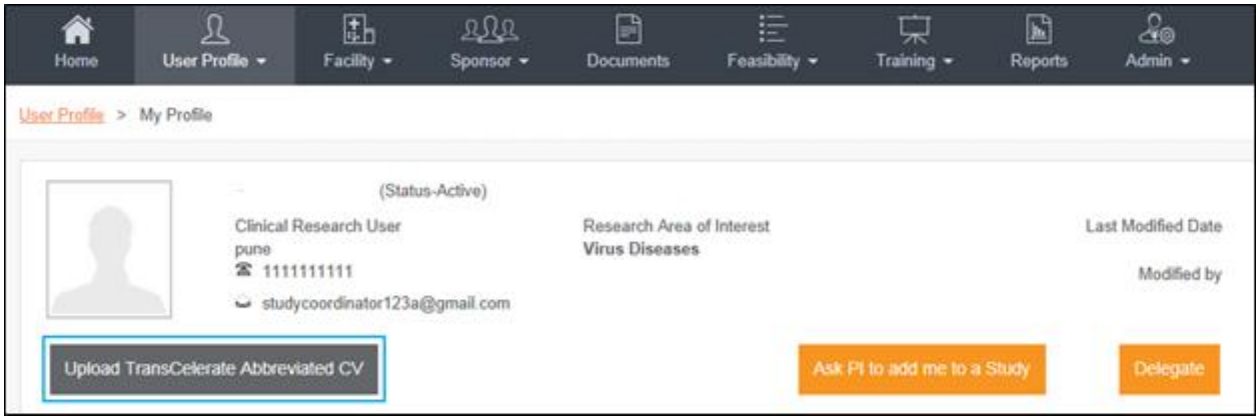


Figure 87. Upload TransCelerate Abbreviated CV

7. To accept the confirmation message, click **OK**.

The upload process workflow may vary with the browser (Chrome or IE) being used.

4.5 CV History

The CV history feature displays the details of all previous versions of the CV so that if required, Site Users can view the significant changes made to the CV. By using this feature, Site Users can view the CV created by them and the CVs that Sponsors had downloaded.

To view the CV history

1. On the **User Profile** menu of the Site User Landing Page, click **My Profile**.
2. On the **My Profile** page, click the **CV History** tab.
3. To view self-created CV, in the **Self-Created CV** section, click **Word format** or **PDF format**. The relevant CV is displayed.
4. To view Sponsor downloaded CV, in the **Sponsor Downloaded CV** section, click **Word format** or **PDF format**. The relevant CV is displayed.

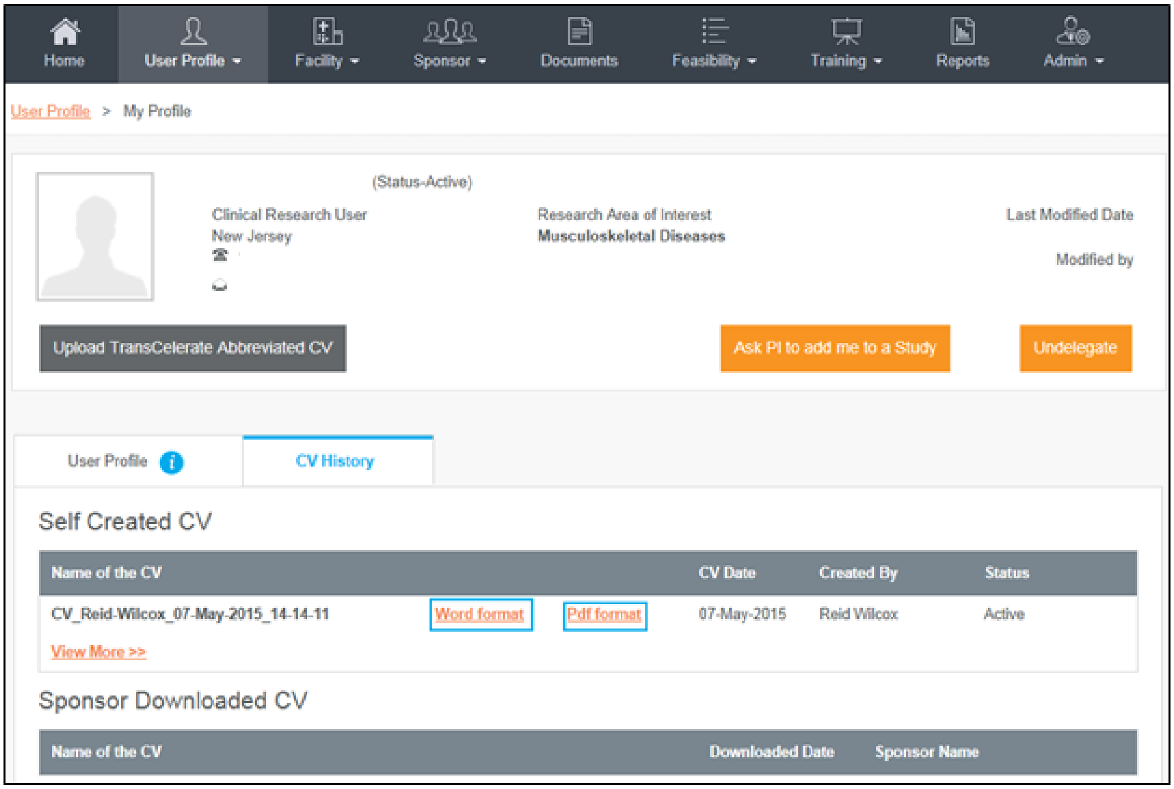


Figure 88. CV History

4.6 Request Association to a Study

This feature allows Site Users such as a study coordinator or a study nurse to request that the Principal Investigator to add them to an active study at their associated Facility. Such a request is limited to only studies conducted at a Facility that is currently associated with the User Profile of the Site User.

The Principal Investigator receives a notification of the request and can approve or reject the request.

Study Site is the combination of a Principal Investigator and Facility assigned to a specific study. For each study site, the PI or his or her delegate must define the following on the SIP Study Site page: Study Site Profile and Study Site Staff.

To request association to a study

1. On the **User Profile** menu of the Site User Landing page, click **My Profile**.
2. On the **My Profile** page, click **Ask PI to Add Me to a Study**. The **Ask PI to add me to a Study** dialog box is displayed.

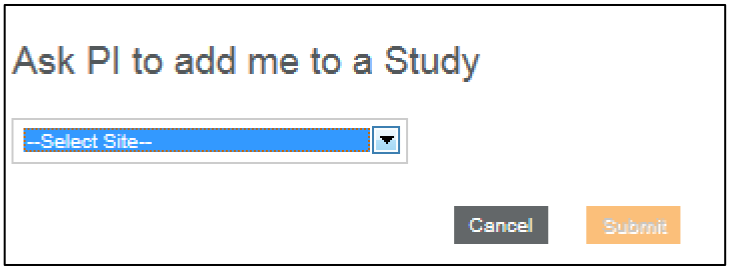


Figure 89. Request Association to a Study

3. In the **Ask PI to add me to a Study** drop-down list, click a required study.

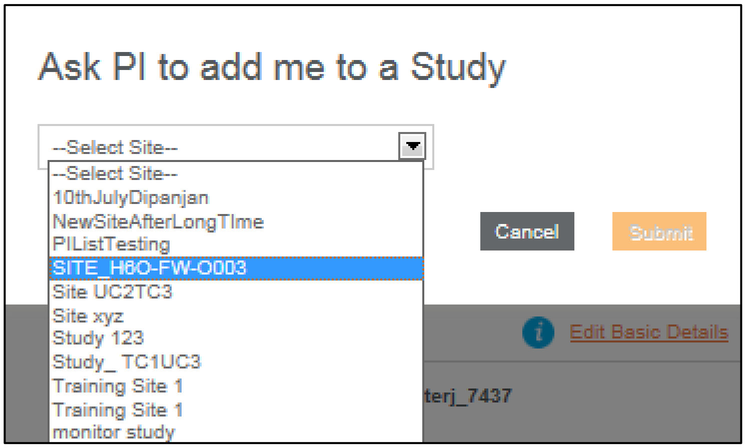


Figure 90. Request Association to a Study: Select a Study

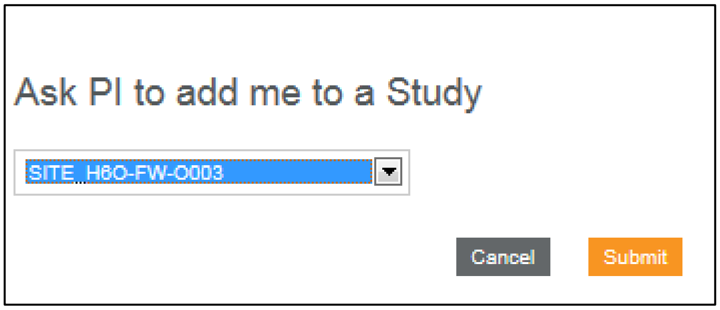


Figure 91. Request Association to a Study: Study Selected

4. To submit the request, click **Submit**.

Principal Investigator receives a notification as well as an email communication on the request for association to a study.

Principal Investigator can manually navigate to a study and add the Study Site Staff to the Study.

4.7 Delegate

The Delegate User Profile feature allows the Site User to delegate data entry or update of his User Profile to another Site User for a defined or indefinite period of time. After the Delegate updates the profile, the Profile Owner verifies and approves, or rejects the updated profile.

To assign a Delegate

1. On the **User Profile** menu of the Site User Landing page, click **My Profile**.
2. On the **My Profile** page, click **Delegate**.

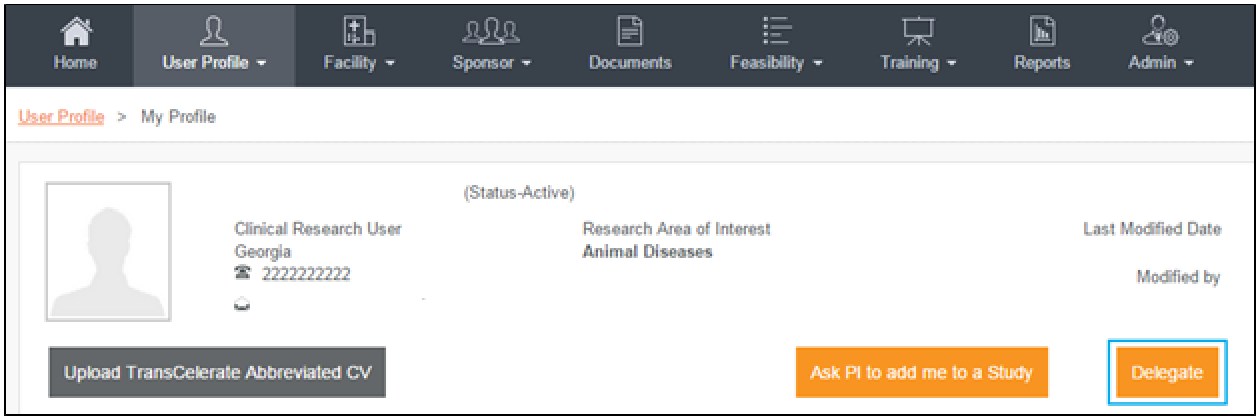


Figure 92. My Profile: Delegate

3. In the **Delegate** dialog box, click .

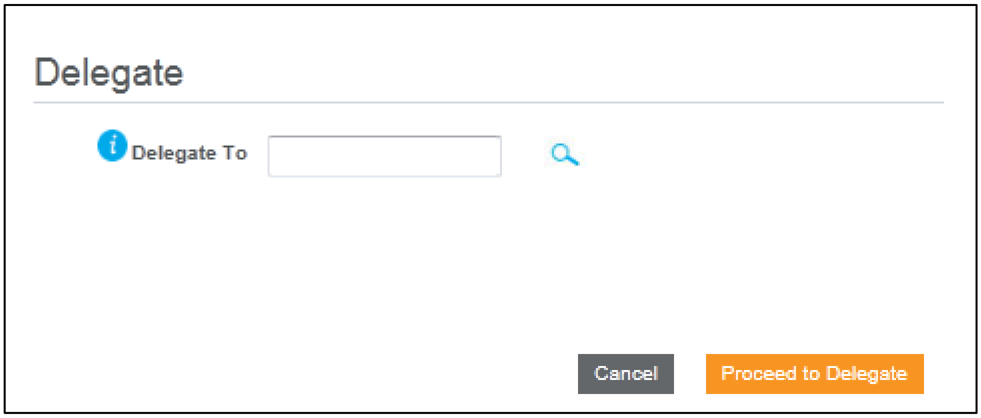


Figure 93. Delegate Dialog Box

4. Enter the email address of the Site User to whom you want to delegate the completion of your User Profile. Now, click **Add**.

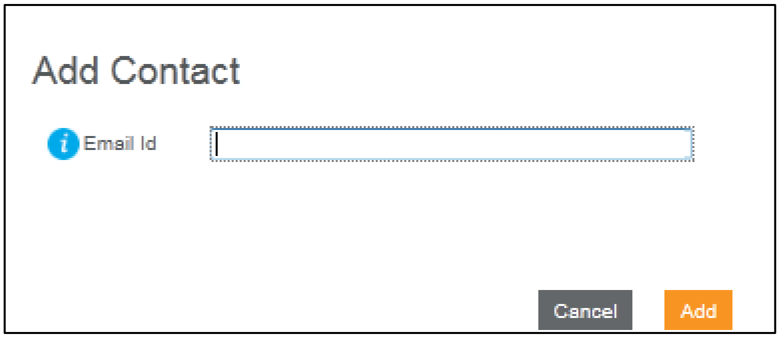


Figure 94. Add Contact Dialog Box

Figure 95. Add Contact Dialog Box: Email Address Entered

5. In the **Delegate** dialog box that contains the email address, click **Proceed to Delegate**.

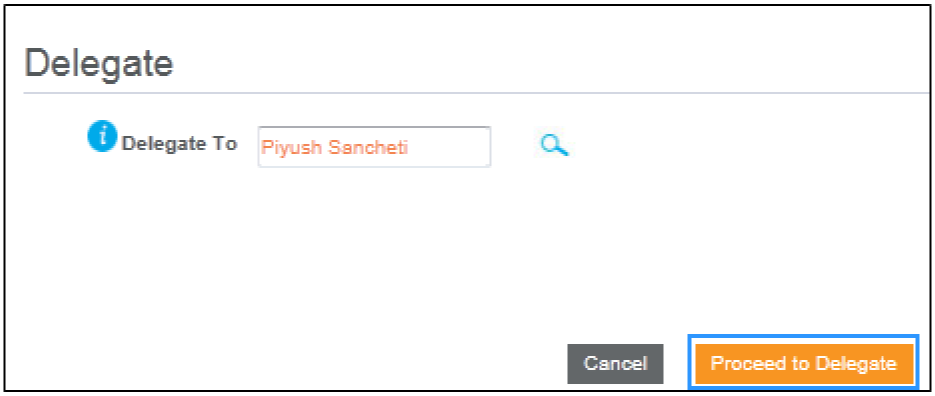


Figure 96. Proceed to Delegate

6. To accept the confirmation message, click **OK**.

Figure 97. Delegate: Confirmation Message

*To remove the delegation authority for your User Profile, click **Undelegate**. The following confirmation message is displayed 'Your profile has been successfully undelegated.'*

4.8 Delegated Profiles

The Delegated Profile feature allows Site Users to view the delegated profiles task list on the Site User Landing Page. The Delegate can update and submit the User Profile to the Profile Owner.

The Delegate needs to perform the following steps to update the User Profile information:

1. To update the User Profile information, on the Site User Landing Page, in the **Tasks** section, click the Delegation task as shown in the following figure.

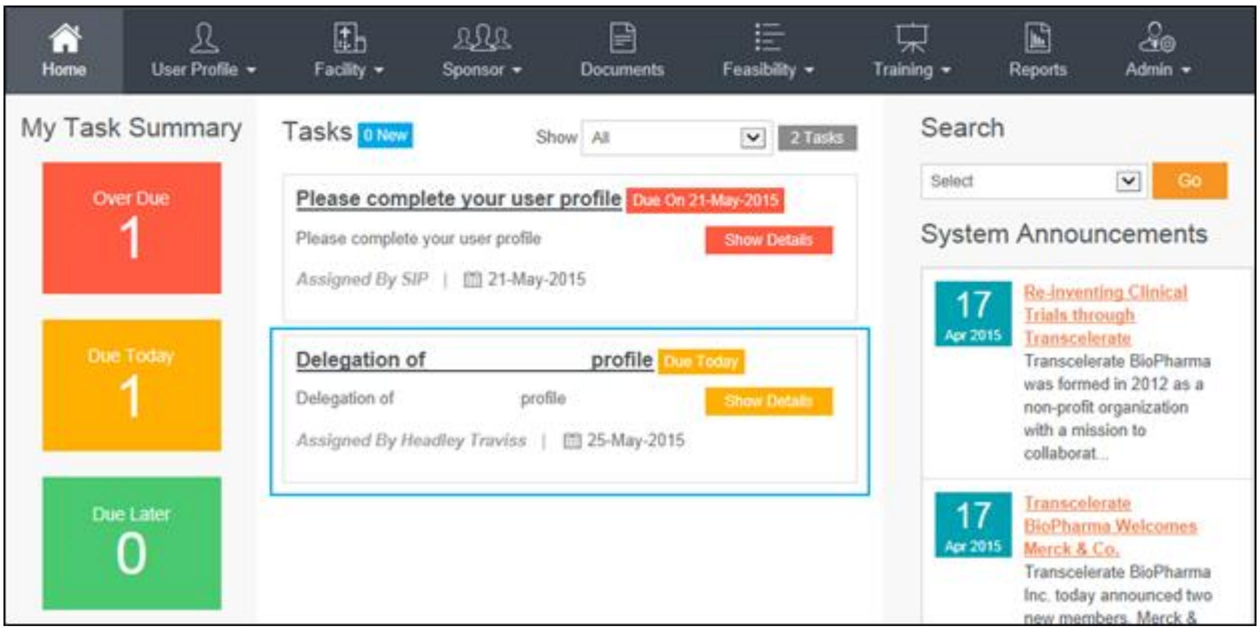


Figure 98. Task List: Delegated Profile

Or,

Alternatively, on the **User Profile** menu of the Site User Landing Page, click **Delegated Profiles**.

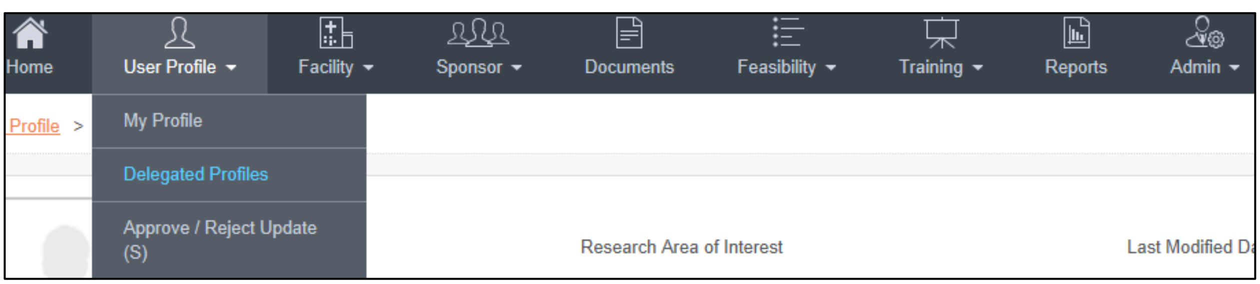


Figure 99. User Profile: Delegated Profiles

2. On the **Delegated Profiles** page, click the SIP User ID link that you want to update.

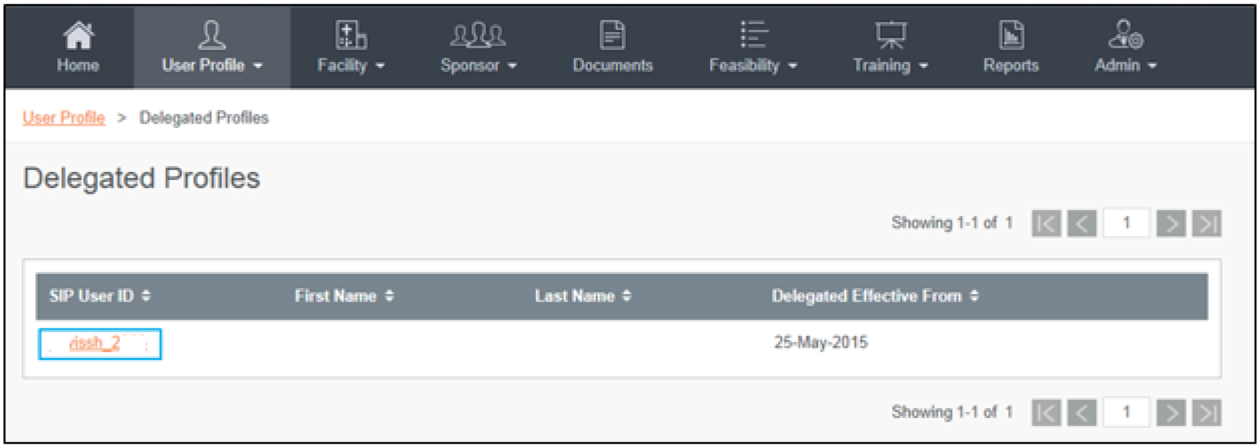


Figure 100. Delegated Profile Page

3. On the **My Profile** page, update the required User Profile details.

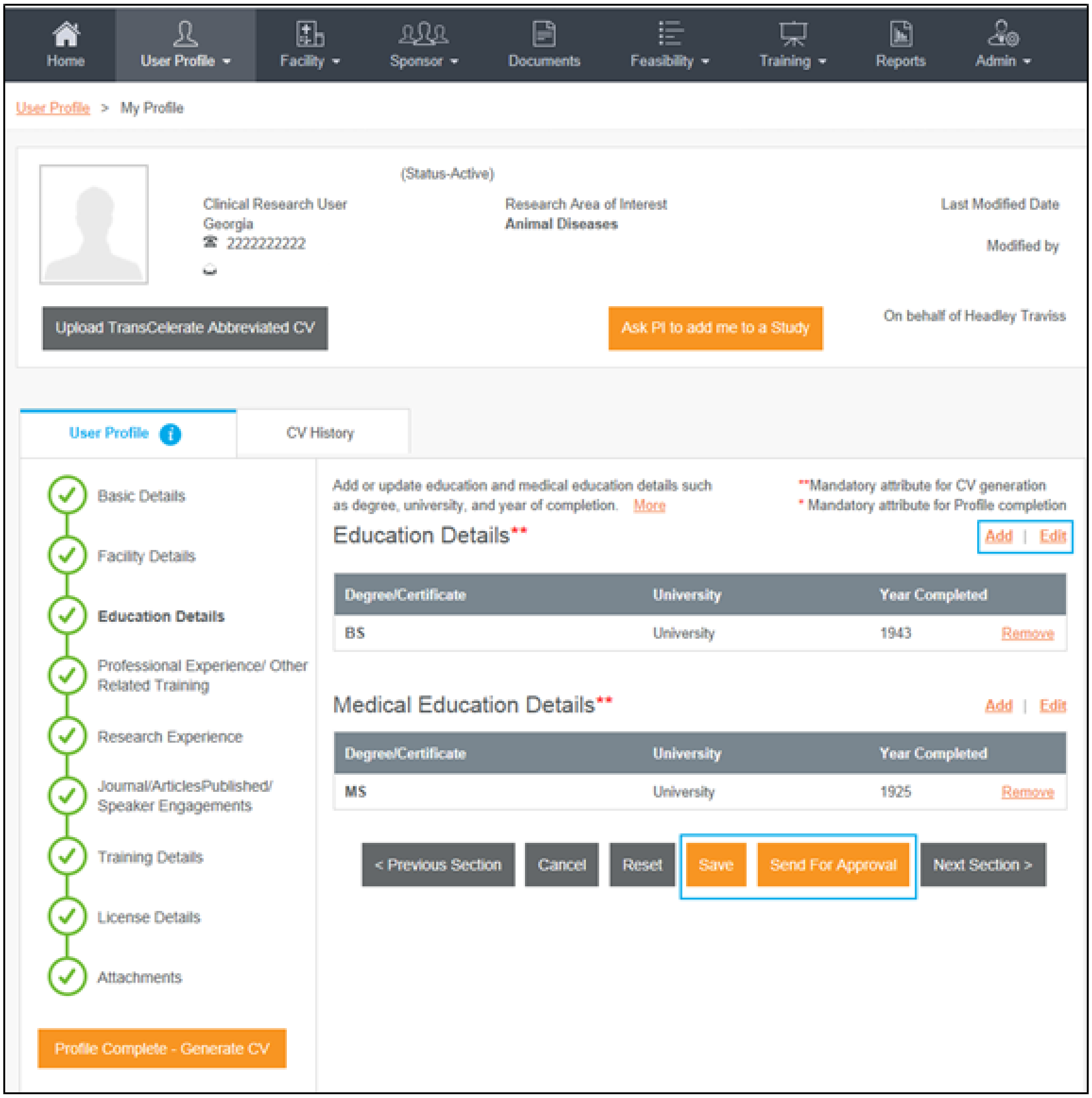


Figure 101. My Profile Page: Send for Approval

4. To save the details, click **Save**.

5. To submit the updated User Profile for approval, click **Send for Approval**.

6. To accept the confirmation message, click **OK**.

Figure 102. Send for Approval: Confirmation Message

4.9 Approve or Reject User Profile Updates

After a Delegate updates the User Profile, the User Profile Owner receives a task notification to approve or reject the User Profile updates.

***Delegate**: Delegate is the Site User who is delegated the task of updating the User Profile.*

***User Profile Owner**: User Profile Owner is the Site User who delegates the tasks to another Site User (Delegate).*

The User Profile Owner performs the following steps to approve the updated User Profile information.

To approve or reject User Profile updates

1. On the Site User Landing Page, in the **Tasks** section, click the User Profile updated task as shown in the following figure.

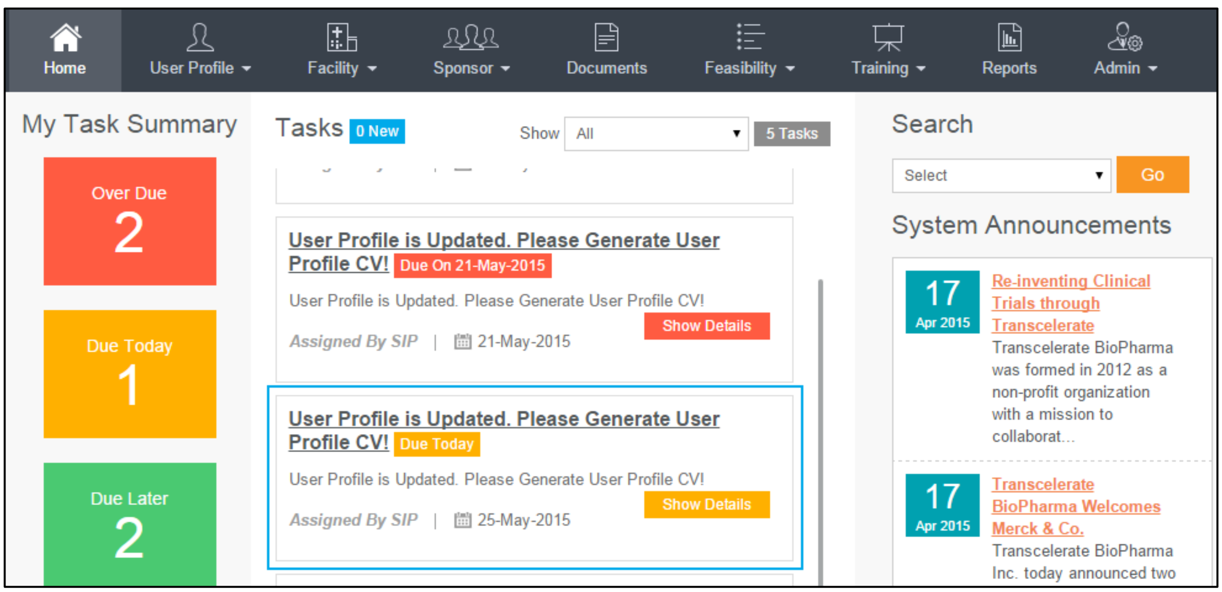


Figure 103. Task List: Updated User Profile

Or,

Alternatively, on the **User Profile** menu of the Site User Landing Page, click **Approve/Reject Update(s)**.

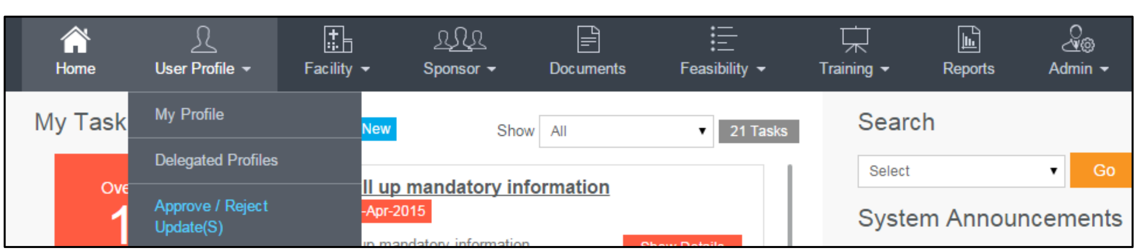


Figure 104. User Profile: Approve/Reject Update(s)

2. Review the User Profile updates.

3. To approve the updates, click **Approve**. A confirmation message is displayed.

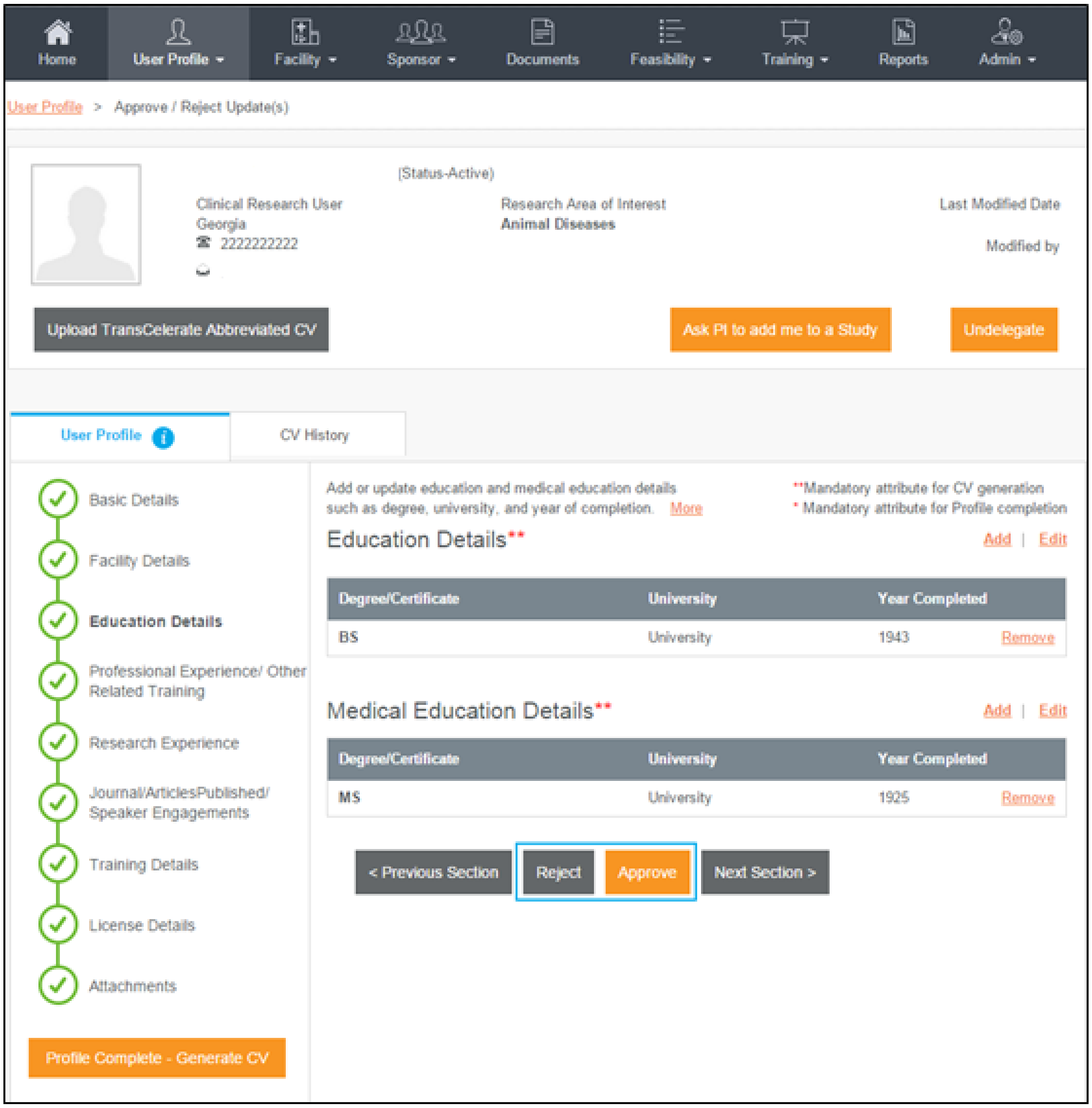


Figure 105. Approve or Reject User Profile Updates Page

4. To accept the confirmation message, click **OK**. A notification is sent to Sponsor Users who have associated this User Profile to an active study.

Figure 106. Approve Updates: Confirmation Message

*To reject the updates, click **Reject**. A notification is sent to the Delegate that the updates have been rejected.*

5 Manage Facility

The Manage Facility feature provides an overview of how to add and associate a Facility to the User Profile. A Facility is the physical location (for example, hospital or doctor's office) where the Principal Investigators perform clinical research. A Facility gets associated with the Study Workspace when the Facility is selected for a clinical trial.

Facility Profile Manager*: The Facility Profile Manager is responsible for the entry and maintenance of the Facility Profile. Each site needs to have at least one Facility Profile Manager. The person who first creates the Facility in the SIP system becomes the Facility Profile Manager, by default. This role can be delegated to another site staff member, and additional Facility Profile Managers can be added.*

Facility Creator is the Facility Profile Manager, by default. This role can be delegated to another site staff member.

Primary Site Contact*: A site has the option to assign a Primary Site Contact for SIP clinical trials; this role can be assigned in the Facility Profile. The Primary Site Contact will receive copies of, and can act on the following SIP notifications that are sent to the Facility that include:*

- *Invitations to participate in pre-study evaluations*
- *Invitations to participate in a study*
- *Invitations to participate in a Sponsor Survey*

Site Users can perform the following tasks in the Facility module:

- Search for a Facility
- Create a New Facility
- Edit a Facility

5.1 Facility List

The Facility List feature allows the Site Users to search for Facility Profiles that are listed in the system by using the Facility name and address details. The search results including Facility ID, Facility contact, address, and Facility status are displayed. There are no restrictions to perform a search for a Site User Facility.

Following are the statuses that can be used to filter the search results:

Draft: The Facility Profile that is saved, but not submitted.

Active: The Facility Profile that is created and submitted. Only active Facilities will appear in the search results.

All Site Users who have associated a Facility to their User Profile will be able to view that Facility Profile from the Facility Details section of their User Profile. The Facility Profile Manager has the rights to modify the Facility details from this page.

To search for a Facility Profile

1. On the **Facility** menu of the Site User Landing Page, click **Facility List**. The **Search Facility** page is displayed.

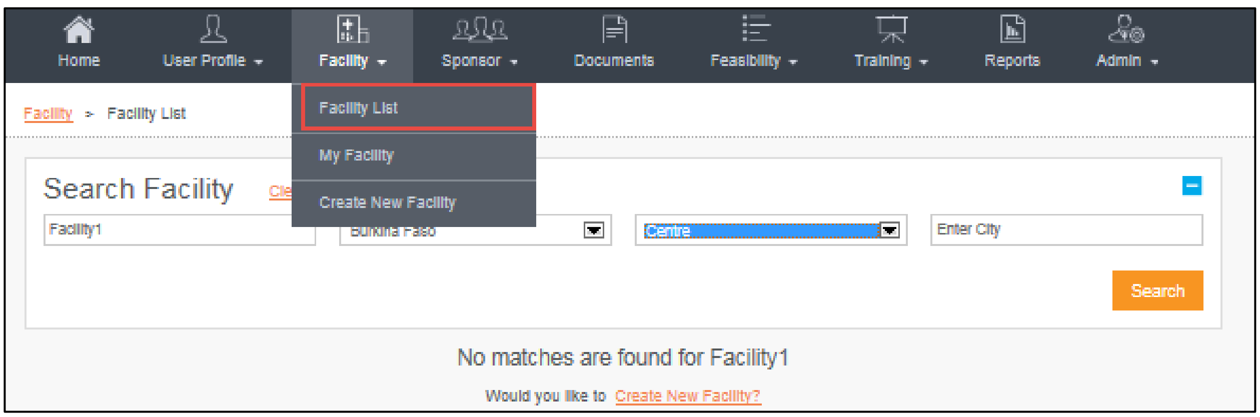


Figure 107. Facility: Facility List

2. On the **Search Facility** page, enter or select the search criteria, and then click **Search**. The search results are displayed. For Search Facility field descriptions, refer to Table 19.
3. To filter the search results, in the **Status** drop-down list, click a required option such as Draft or Active. The Facility Profiles with the selected status are displayed.

If the search criterion does not match the Facility Profiles, the following message is displayed: 'No matches are found. Would you like to create a new Facility?'

To create a new Facility Profile, click Create New Facility?.

The following table lists the description of the fields displayed on the Search Facility page.

Field	Field Type	Mandatory Field	Field Descriptions
Facility Name	Text box	This is not a mandatory field.	Name of the Facility in which the research is conducted
Country	Drop-down list	This is not a mandatory field.	Name of the country in which the Facility is located
State/Province/Region	Drop-down list	This is not a mandatory field.	Name of the state or province or region in which the Facility is located
City	Text box	This is not a mandatory field.	Name of the city in which the Facility is located

Table 16. Field Descriptions for Search Facility

5.2 My Facility

The My Facility feature allows the Facility Profile Managers to view the completed Facility Profile. You can filter the list of Facilities based on the Facility status such as draft, activation in progress, and active. This page allows the Facility Profile Manager to edit the Facility Profile by using the edit link available in the results section.

Site Users who are assigned as Facility Profile Managers for any Facility can view that Facility's details under the My Facility page. The Facility Profile Manager has the rights to make edits to the Facility details from this page.

The person who creates a Facility Profile is designated as the Facility Profile Manager, by default. However, other Site Users can be assigned as the Facility Profile Managers during the Facility creation as well as at any later instance.

If the Site User needs to edit the Facility Profile, but does not have the appropriate rights, Site Users can send a request to the Facility Profile Manager to edit the Facility details on behalf of other Site Users.

To edit Facility details or send a message to the Facility Profile Manager

1. On the **Facility** menu of the SIP Site User Landing Page, click **My Facility**. The **My Facility** page is displayed.

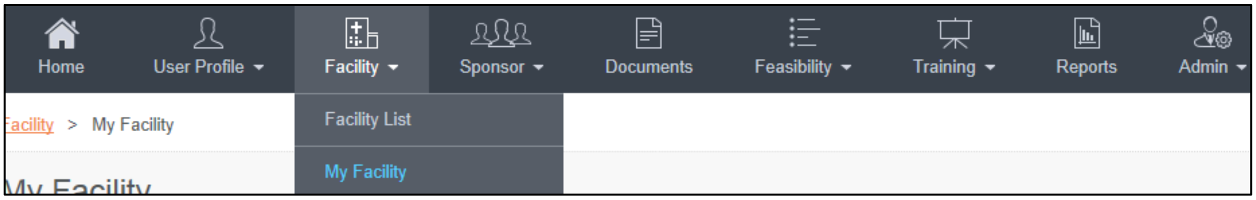


Figure 108. Facility: My Facility

2. In the **Status** drop-down list, click a Facility status. The options include **Draft** or **Active**. The list of Facility Profiles with the selected status is displayed.

   Following are the statuses that can be used to filter the search results:

   - **Draft**: The Facility Profile that has been saved, but not submitted.
   - **Active**: The Facility Profile has been created and submitted. Only active Facilities will appear in the search results.

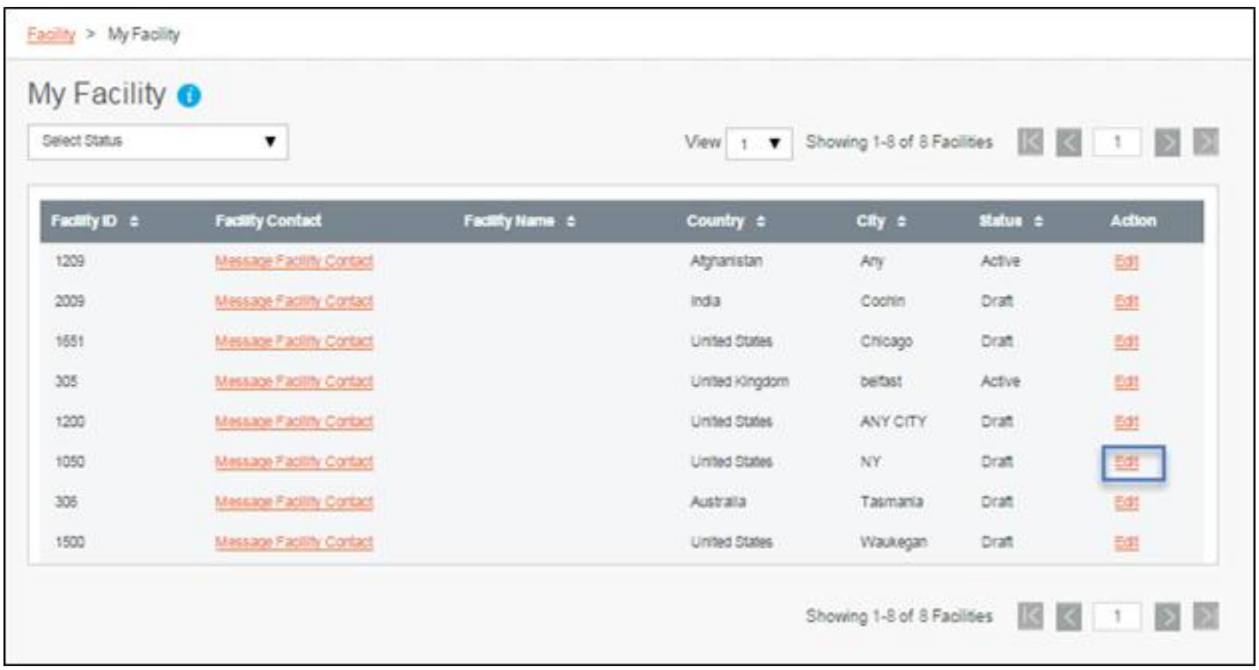


Figure 109. My Facility Page

Edit Facility Details

3. To edit the Facility details, in the results displayed, in the **Action** column, click **Edit**. The **Create Facility** page is displayed.
4. On the Create Facility page, edit the required Facility details, and then click **Save**.

If the Site User needs to edit the Facility Profile, but does not have the appropriate rights, Site Users can request the Facility Profile Manager to edit the Facility details on their behalf.

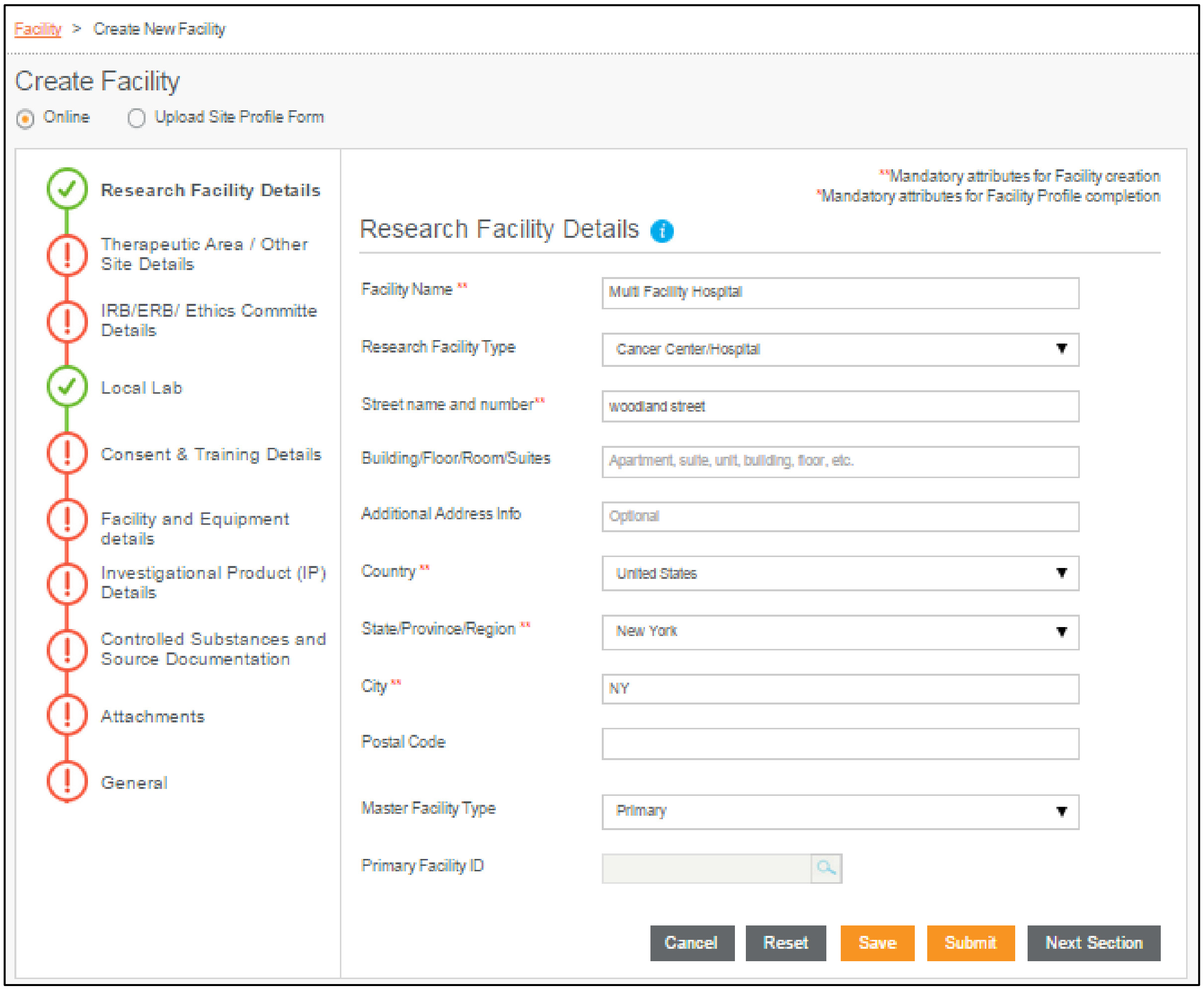


Figure 110. Edit Facility Details Page

5. Click **Submit**. A confirmation message is displayed.

6. Click **OK.** The Facility becomes Active and is available to be associated with the User Profile.

If you do not have privileges to edit the Facility Profile

7. To send a message to the assigned Facility Profile Manager(s), in the Facility Contact column, click the **Message Facility Contact** link. The **Message Facility Details** dialog box is displayed.

8. In the **Message Facility Details** dialog box, enter the message for the Facility Profile Manager.

9. To send the message to the Facility contact, click **Send Message**.

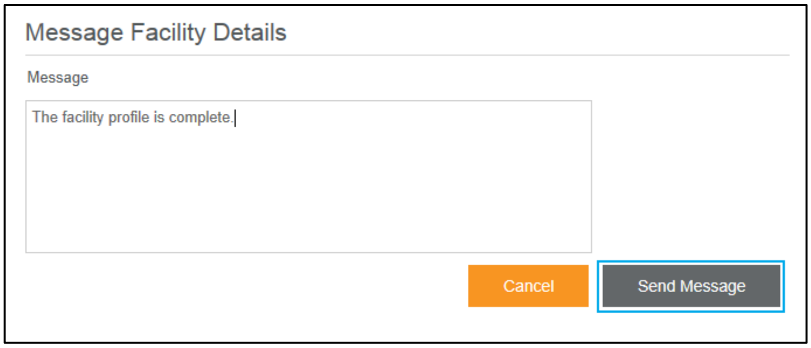


Figure 111. Message Facility Details Dialog Box

5.3 Create a New Facility

The Create a New Facility feature allows the Site Users to create a new Facility and associate that new Facility to studies in the SIP system. Once a Facility is created in the SIP system, the Site Staff can associate their User Profiles to that Facility Profile.

Any Site User can create a Facility. Only a Facility Profile Manager can update the Facility details. The SIP Administrators approve all new Facilities.

** *Double asterisk (*) on the Facility Profile fields indicates mandatory fields for creating a Facility.*

* *Single asterisk (*) on the Facility Profile fields indicates mandatory fields for Facility Profile completion.*

Site Users can create a new Facility by one of the following methods:

- **Creating a new Facility: Upload a Site Profile Form** - Site User can upload the completed Site Profile Form downloaded from the TransCelerate website. Upload only the electronic format. System cannot extract data from any other format.
- **Creating a new Facility manually** - Enter information directly within the system if the Site Profile Form is not already filled out.

5.3.1 Create a New Facility: Upload a Completed Site Profile Form

If Site Users have a completed Site Profile Form, they can create a new Facility by uploading the completed correct Site Profile Form. This Site Profile Form must be the completed editable PDF so that the data can be extracted to populate the profile. System cannot extract data from any other format.

This form has to be used only if the Site Users have already filled out the Site Profile Form. Otherwise they need to enter it directly in the system. You need to upload the Site Profile Form Version 3.2.

To create a new Facility by uploading a Site Profile Form

1. To create a new Facility, click **Create Facility**. The **Create Facility** page is displayed.
2. On the **Create Facility** page, click **Upload Site Facility Profile Form**.

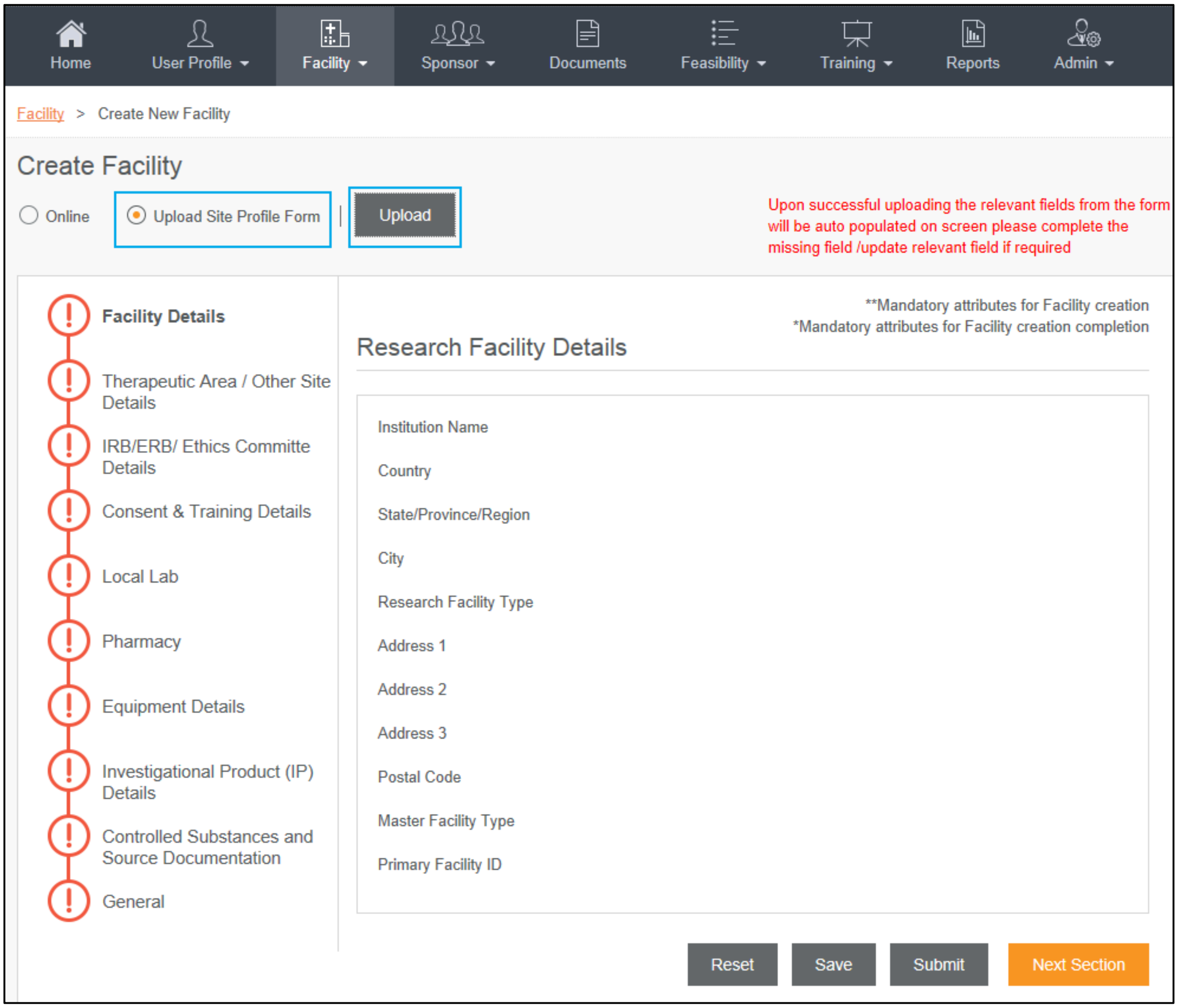


Figure 112. Upload Site Profile Form

3. In the **Choose File to Upload** dialog box, browse to the location of the completed Site Profile Form, and then click **Open**.

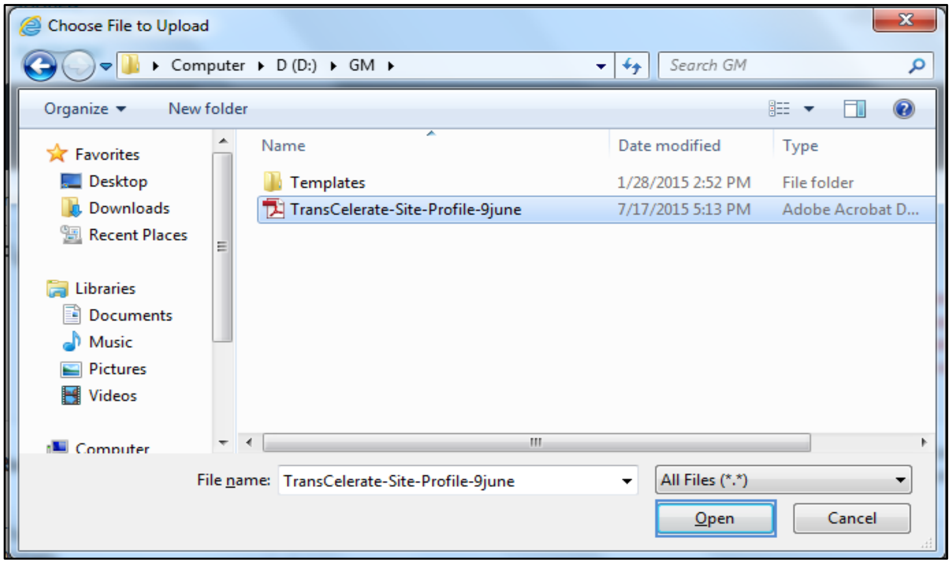


Figure 113. Choose File to Upload Dialog Box

4. Click **Upload**.

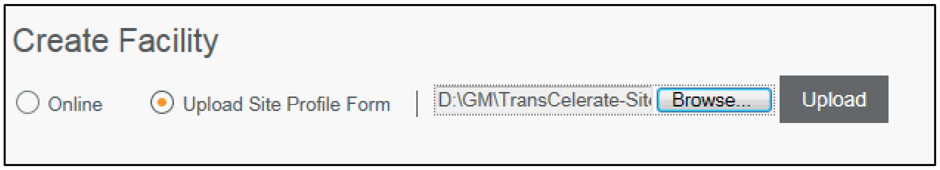


Figure 114. Linked File

5. The document attached link is displayed.

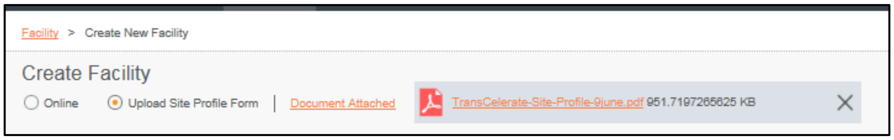


Figure 115. Document Attached

After uploading the completed Site Profile Template, the Facility Profile information is populated in the system. You need to review the uploaded fields and update/add the fields that were not uploaded. Review all sections in the system before submitting the Facility Profile details.

7. *After sections in the Facility Profile are complete, click **Submit**.*

5.3.2 Create a Facility: Manually

The Create New Facility feature allows a Site User to create a new Facility directly (online entry) in the SIP application.

***Save**: In the following sections, the Save action saves the entered details and places them in 'Draft' status. The Site User can proceed with entering other details.*

***Submit**: In the following sections, the Submit action makes the Facility available for other Site Users to associate themselves with the Facility. The status here is 'Active'.*

Single asterisk (*) on the Facility Profile fields indicates mandatory fields for Facility Profile completion.

To create a new Facility manually

1. On the Facility menu, click **Create New Facility**. The **Create Facility** page is displayed.

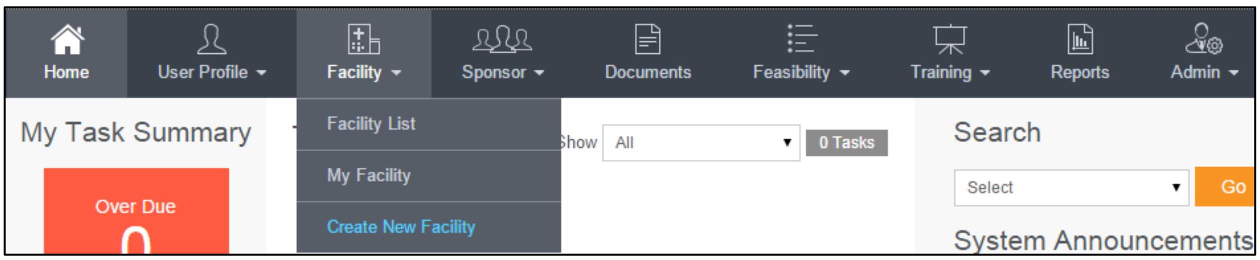


Figure 116. Facility: Create New Facility

2. On the **Create Facility** page, click **Online**.

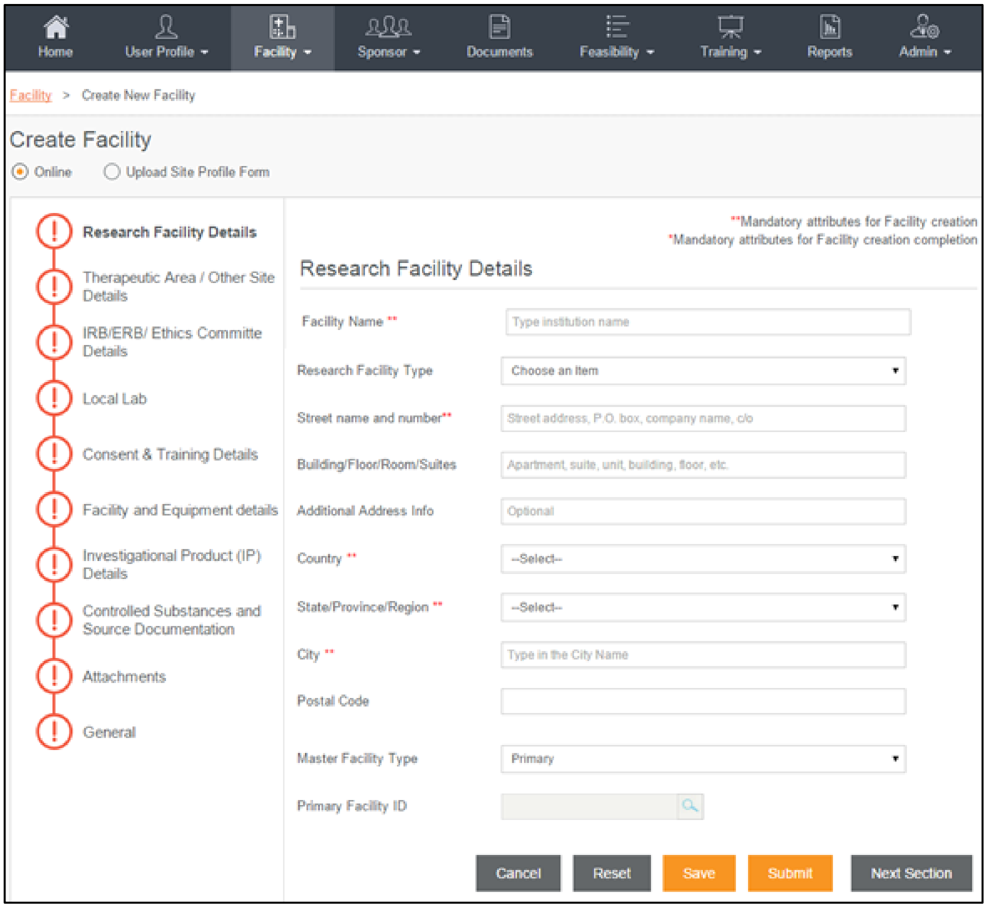


Figure 117. Create New Facility Page

When a new Facility Profile is created, a system check is run to check for duplicate Facilities based on Facility Name, Address, City, Country and ZIP Code.

When a duplicate Facility record is found, an error message is displayed to inform the Site User that a duplicate Facility Profile exists. The Facility Creator determines whether the Facility is already available (on the duplicates list). If yes, the Facility Creator can select that Facility. If it is not on the duplicates list, the Facility Creator can continue to create the new Facility.

3. On the left navigation pane, click the respective Facility option.
4. To save the entered details, click **Save**. The status of the Facility Profile is 'Draft' and you can proceed with entering the Facility Profile details.
5. To submit the record, click **Submit**.
6. In the confirmation message displayed, click **OK**. The status of the Facility Profile is ‘Active’ and available and it can be associated with the User Profile.
7. To go to the next section, click **Next Section**.

5.3.2.1. Add Research Facility Details

Facility information allows a Sponsor to identify the eligibility of a practitioner and associated Facility to participate in a specific clinical trial. The Sponsor evaluates whether a Facility has the appropriate equipment and access to potential clinical trials subjects to meet the trial requirements. The **Research Facility Details** page in the SIP system consists of details such as the Facility name, type, and address that are required other details required during the site identification and conduct of a clinical trial.

Only the Facility Profile Manager can edit the Facility details.

To add Research Facility details

1. On the left navigation pane of **Create Facility** page, click **Research Facility Details**. The **Research Facility Details** page is displayed.

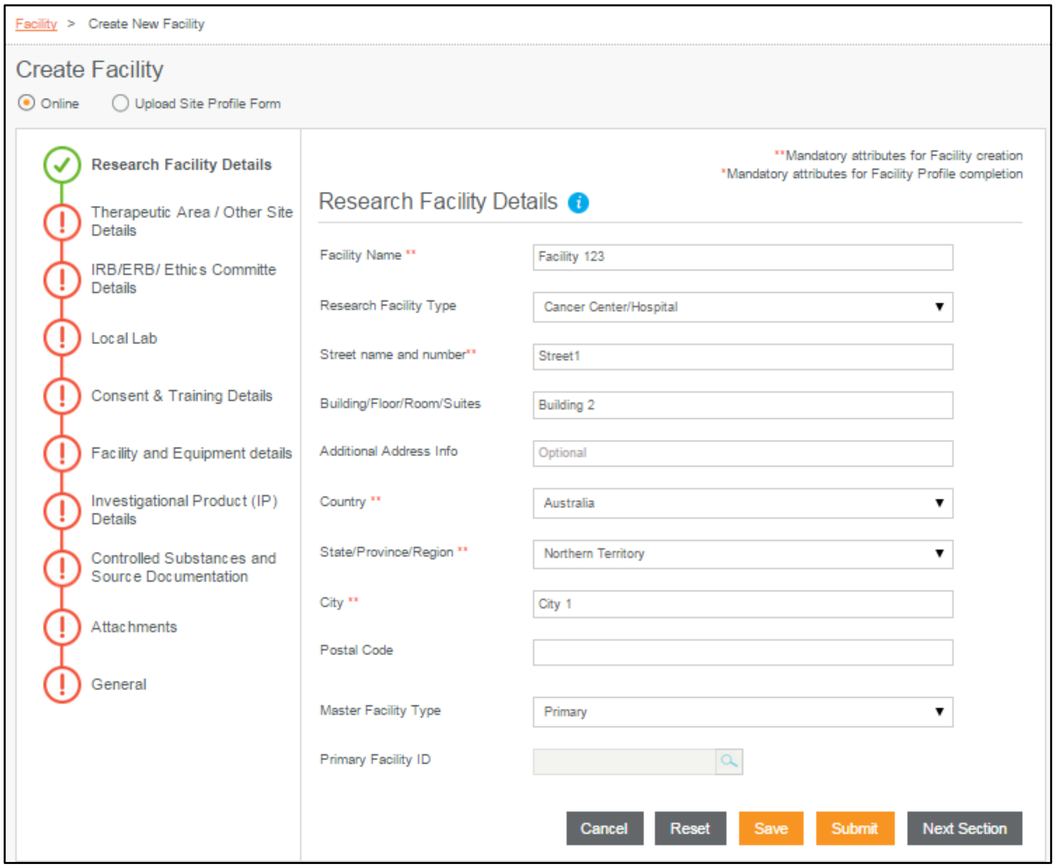


Figure 118. Research Facility Details Page

2. On the **Research Facility Details** page, enter or select the research Facility details. For Add Research Facility Details field descriptions, refer to Table 20.

3. To save the details, click **Save.** The entered details are now in Draft status and you can proceed with entering the Facility Profile details.
4. To submit the research Facility details for approval, click **Submit**.
5. In the confirmation message displayed, click **OK**. The entered details are now in 'Active' status.
6. To navigate to the next section of the Facility page, click **Next Section**. The Therapeutic Area page is displayed.

The following table provides the field descriptions for the Research Facility Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Facility Name**	Text box	This is a mandatory field.	Name of the Facility in which the study is conducted
Research Facility Type	Drop-down list	This is not a mandatory field.	Type of research Facility. For example, Academy and Clinical Research Unit, Primary Care Center.
Street Name and Number**	Text box	This is a mandatory field.	Name of the street and number in which the Facility is located. For example, Highway 51.
Building/Floor/Room/Suite	Text box	This is not a mandatory field.	Building or floor or room details of the Facility. For example, Building 3, Primary Care Center.
Additional Address info	Text box	This is not a mandatory field.	Additional address information of the Facility, if any.
Country**	Drop-down list	This is a mandatory field.	Name of the country in which the Facility is located. United States.
State/Province/Region**	Drop-down list	This is a mandatory field.	State, province, or region of the Site User's City (as specified in the City box). For example, California, Fransisco.
City**	Text box	This is a mandatory field.	Name of the city in which the Facility is located. For example, San Fransisco.
Postal Code	Drop-down list	This is not a mandatory field.	ZIP/Postal Code of the location
Master Facility Type	Text box	This is not a mandatory field.	Type of the Facility. • Primary (For example, Hospital and Clinic) • Secondary (For example, Department of Oncology in a Hospital)

Primary Facility ID	Search	This is not a mandatory field.	Primary Facility identification number Note: To run a quick search and filter the required primary Facility ID, click the Search icon.

Table 17. Field Descriptions for Add Research Facility Details

5.3.2.2. Add Therapeutic Area/Other Site Details

The Therapeutic Area or Other Site Details page allows the Site Users to enter other important information such as the Therapeutic Area, Trial Phase Capabilities, Facility Contact Type, and Other Site Details.

Site Users can add the following details in the therapeutic area section:

- Therapeutic area in which the study is conducted
- Trial phase capabilities of the study conducted
- Other site details such as patient population, ethnicity, and race

To add Therapeutic Area/Other Site details

1. On the **Create Facility** page, click **Therapeutic Area/Other Site Details**. The Therapeutic Area/Other Site Details page is displayed.

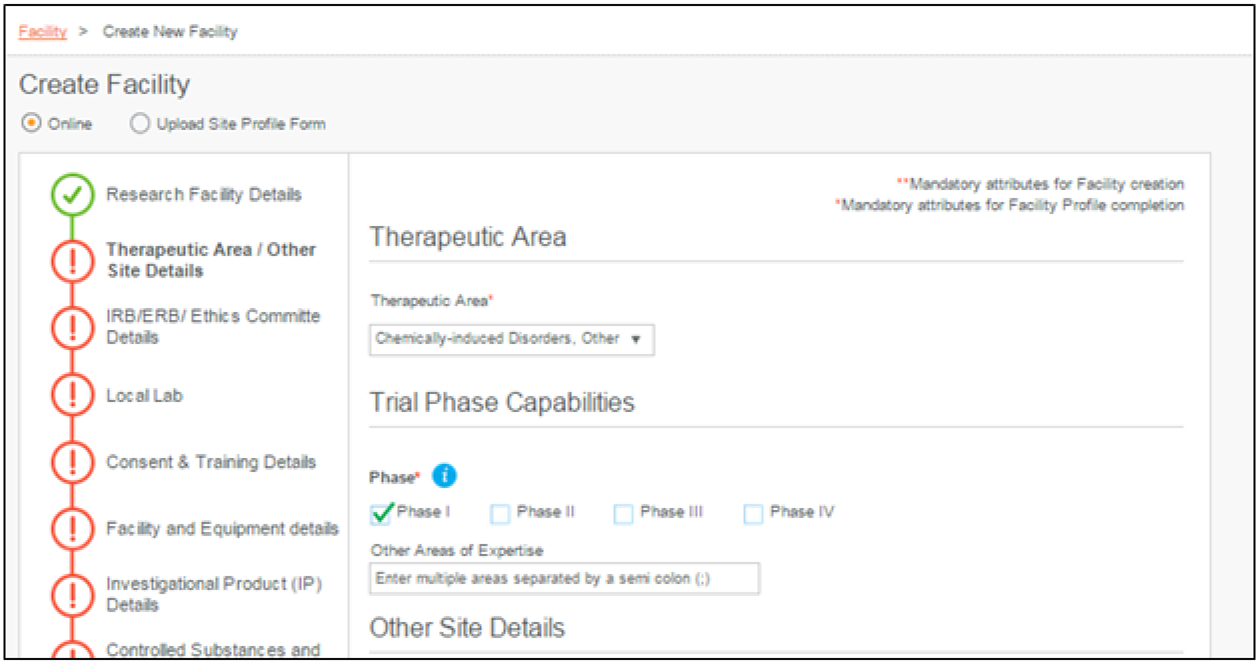


Figure 119. Therapeutic Area Page: Therapeutic Area and Trial Phase Capabilities Page

2. On the Therapeutic Area/Other Site Details page, enter the **Therapeutic Area**, **Trial Phase Capabilities**, **Facility Contact Type**, and **Other Site Details** sections. For Therapeutic Area or Other Site Details field descriptions, refer to Table 21.

3. In the **Therapeutic Area** section, select a check box next to a relevant Therapeutic Area.

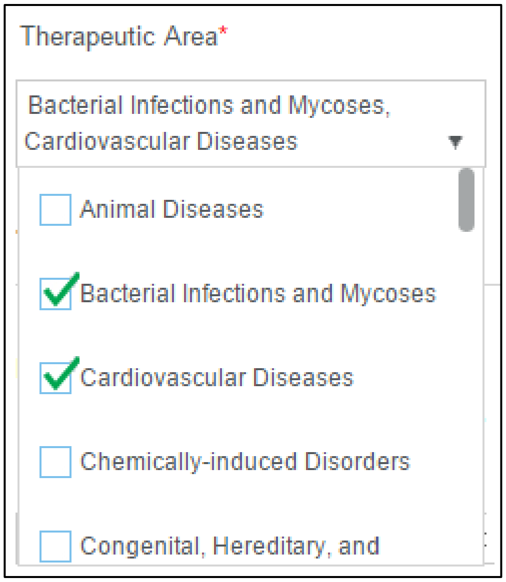


Figure 120. Therapeutic Area Page: Therapeutic Area Section

4. In the **Other Site Details** section, select or enter the required information.

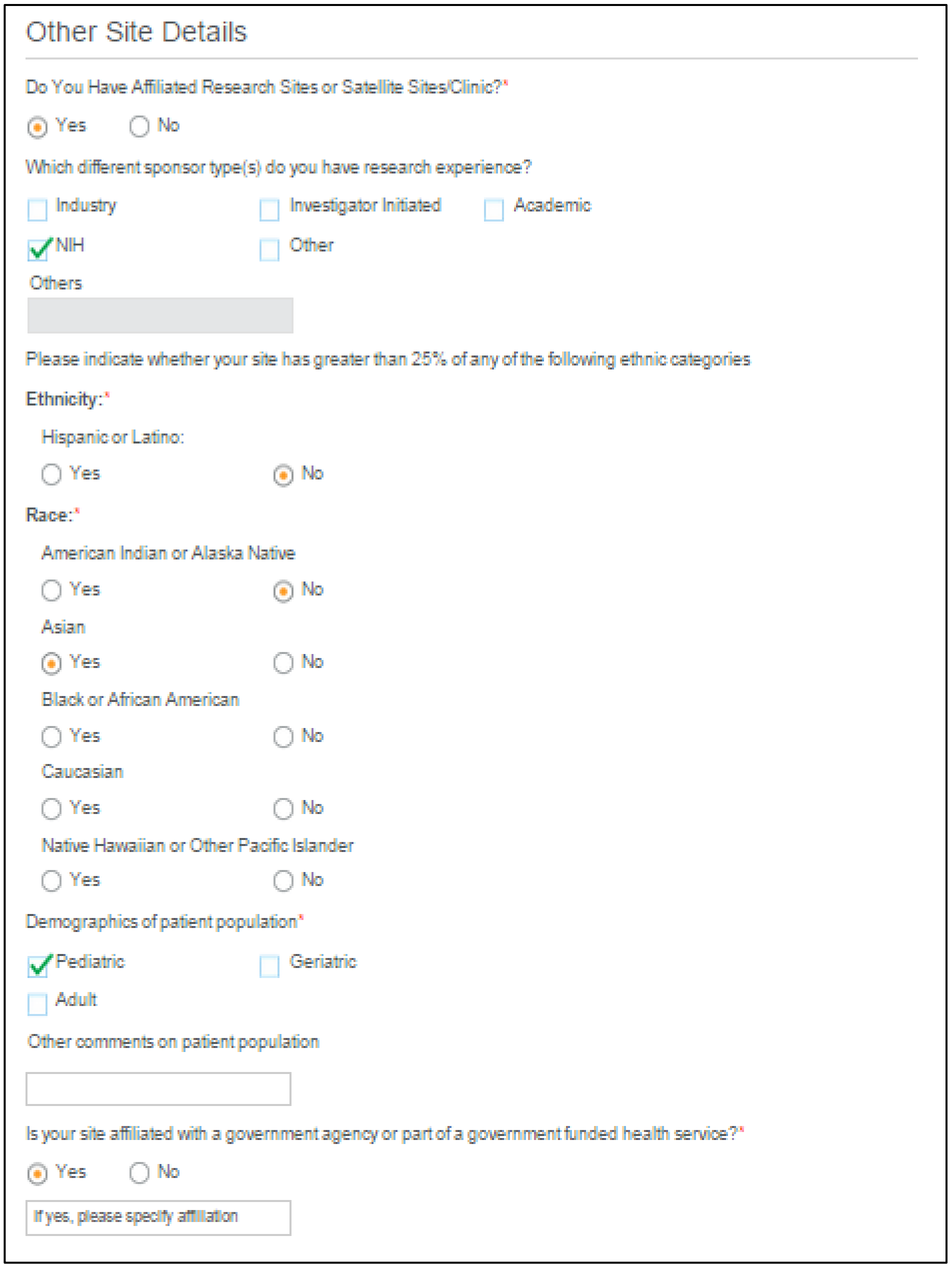


Figure 121. Therapeutic Area: Other Site Details Page

5. In the **Contact Types** section, enter the Facility Profile Manager details.

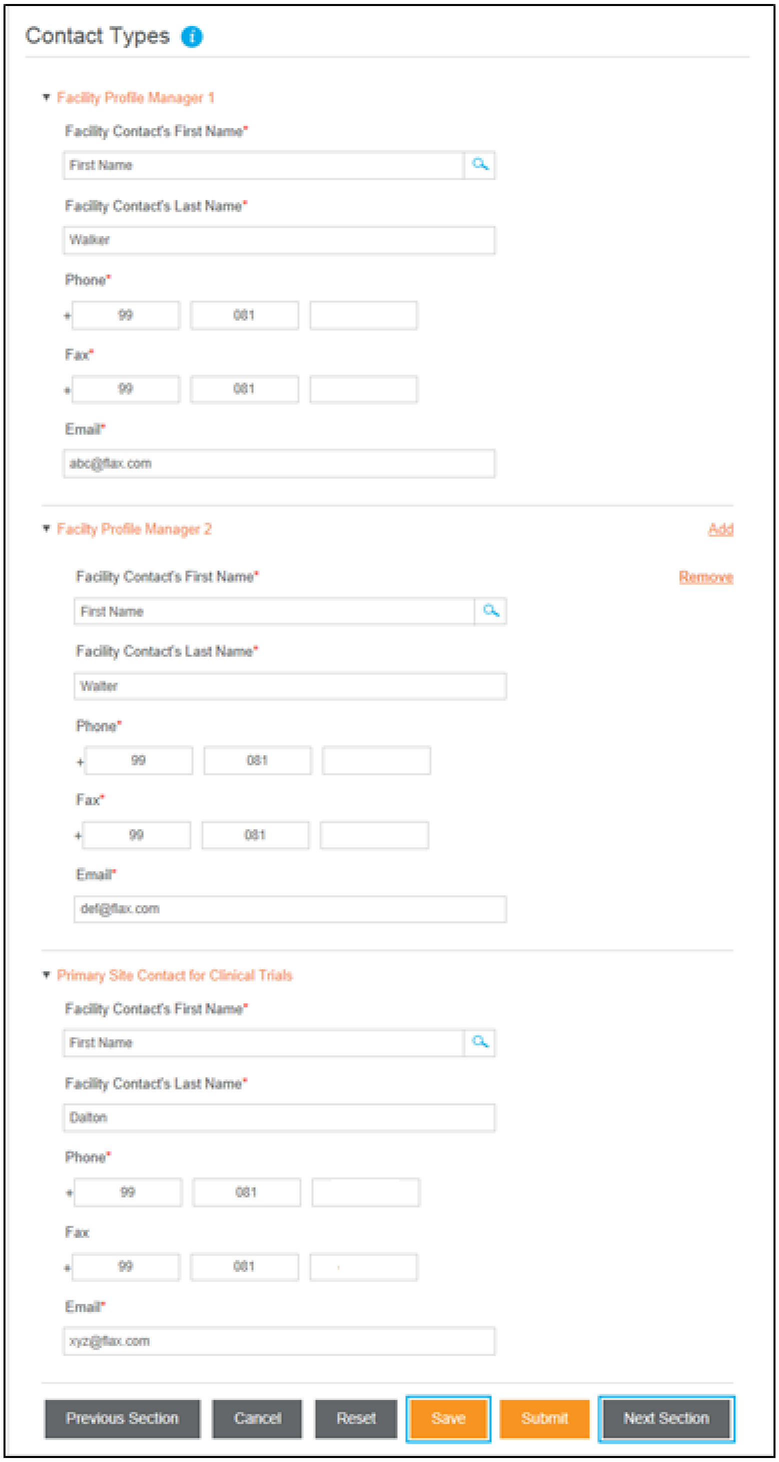


Figure 122. Therapeutic Area Page: Contact Types

6. Click **Save**. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.

7. To submit the details, click **Submit**.

8. In the confirmation message displayed, click **OK**. The status of the Facility Profile is 'Active' and available. Now it can be associated with the User Profile.

9. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the Therapeutic Area or Other Site Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Therapeutic Area			
Therapeutic Area*	Drop-down list	This is a mandatory field.	This is the area or field in which the Facility can conduct research. **Note** To specify another therapeutic area, in the **Therapeutic Area** section, click **Others**.
Trial Phase Capabilities			
Phase*	Check box	This is a mandatory field.	This is the trial phase capability of the Facility.
Other Areas of Expertise	Text box	This is not a mandatory field.	This is the other areas of expertise of a Facility. **Note** You can enter multiple areas separated by using a semi colon (;).
Other Site Details			
Do You Have Affiliated Research Sites or Satellite Sites/ Clinics? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Which Different Sponsor type(s) do you have research experience?	Check box	This is not a mandatory field.	This is the type of Sponsors with which the Facility has research experience. **Note** To specify another type of research experience, in the **Choose Different Sponsor Types Research Experience** drop-down list, click **Others**.
Others	Text box	This is not a mandatory field.	This refers to the other Sponsor types with which you have research experience.

Field	Field Type	Mandatory Field	Field Descriptions
Ethnicity*	Option button	This is a mandatory field.	This refers to each ethnicity that represents >25% of the overall patient population. Click **Yes** or **No** for each category. **Note** Hispanic refers to a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of the race.
Race*	Option button	This is a mandatory field.	This refers to each race that represents >25% of the overall patient population. Click **Yes** or **No** for each category.
Demographics of Patient Population*	Check box	This is a mandatory field.	This refers to the demographic details of the patient population including: pediatric and adult.
Other comments on patient population	Text box	This is not a mandatory field.	This refers to the other comments on demographics of patient population
Is Your Site Affiliated With a Government Agency or Part of a Government Funded Health Service? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Contact Types			
Facility Contact's First Name*	Search	This is a mandatory field.	This is the first name of the Facility Profile Manager, whom you can contact for any query regarding the Facility. The Facility Profile Manager is responsible for the entry and maintenance of the Facility Profile. Each site must have at least one Facility Profile Manager. Facility and maintenance of the Facility Profile information. **Note** To quickly search and view the required Facility Profile Manager for the Facility use the search icon.

Field	Field Type	Mandatory Field	Field Descriptions
Facility Contact's Last Name*	Text box	This is a mandatory field.	This is the last name of the Facility Profile Manager, whom you can contact for any query regarding the Facility. The Facility Profile Manager is responsible for the entry and maintenance of the Facility Profile. Each site must have at least one Facility Profile Manager.
Phone*	Text box	This is a mandatory field.	This is the phone number of the Facility Profile Manager. **Note** The phone number needs to be in the following format: Country Code, Area Code, and Phone Number.
Fax*	Text box	This is a mandatory field.	This is the fax number of the Facility Profile Manager
Email*	Text box	This is a mandatory field.	This is the email address of the Primary Site Contact.
Primary Site Contact for Clinical Trials			

Field	Field Type	Mandatory Field	Field Descriptions
Facility Contact's First Name*	Search	This is a mandatory field.	This is the first name of the Primary Site Contact, whom you can contact for any query regarding the Facility. The Primary Site Contact will receive copies of certain SIP notifications that are sent to the Facility. The Primary Site Contact can also act on those notifications. The following are some of the notifications: • Invitations to participate in pre-study evaluations • Invitations to participate in a study • Invitations to participate in a Sponsor Survey. This role is optional; sites can choose to designate a Primary Site Contact if desired. **Note** To quickly search and view the required Primary Site Contact for the Facility use the Search icon.
Facility Contact's Last Name*	Text box	This is a mandatory field.	This is the last name of Primary Site Contact, whom you can contact for any query regarding the Facility. A Primary Site Contact is the recipient at the site who receives additional copies of communications sent to that Facility by Sponsors. This role is optional; sites can choose to designate a Primary Site Contact if desired
Phone*	Text box	This is a mandatory field.	This is the phone number of the Primary Site Contact. **Note** The phone number needs to be in the following format: Country Code, Area Code, and Phone Number.
Fax*	Text box	This is not a mandatory field.	This is the fax number of the Primary Site Contact.

Field	Field Type	Mandatory Field	Field Descriptions
Email*	Text box	This is a mandatory field.	This is the email address of the Primary Site Contact.

Table 18. Field Descriptions for Therapeutic Area or Other Site Details

*To add an additional Primary Site Contact, click **Add**.*

*To remove a section, click **Remove**.*

5.3.2.3. Add IRB/ERB/Ethics Committee Details

An Institutional Review Board (IRB), also known as an Independent Ethics Committee (IEC), Ethical Review Board (ERB) or Research Ethics Board (REB), is a committee that is formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Site Users can use the IRB or Ethics Committee page on SIP to associate a committee to a Facility and also to add the committee details such as committee name and committee type. The user can add multiple IRBs to the Facility Profile.

To add IRB/ERB/Ethics committee details

1. On the left navigation pane of the **Create Facility** page, click **IRB/ERB/Ethics Committee Details**.
   The IRB/ERB/ethics Committee page is displayed.

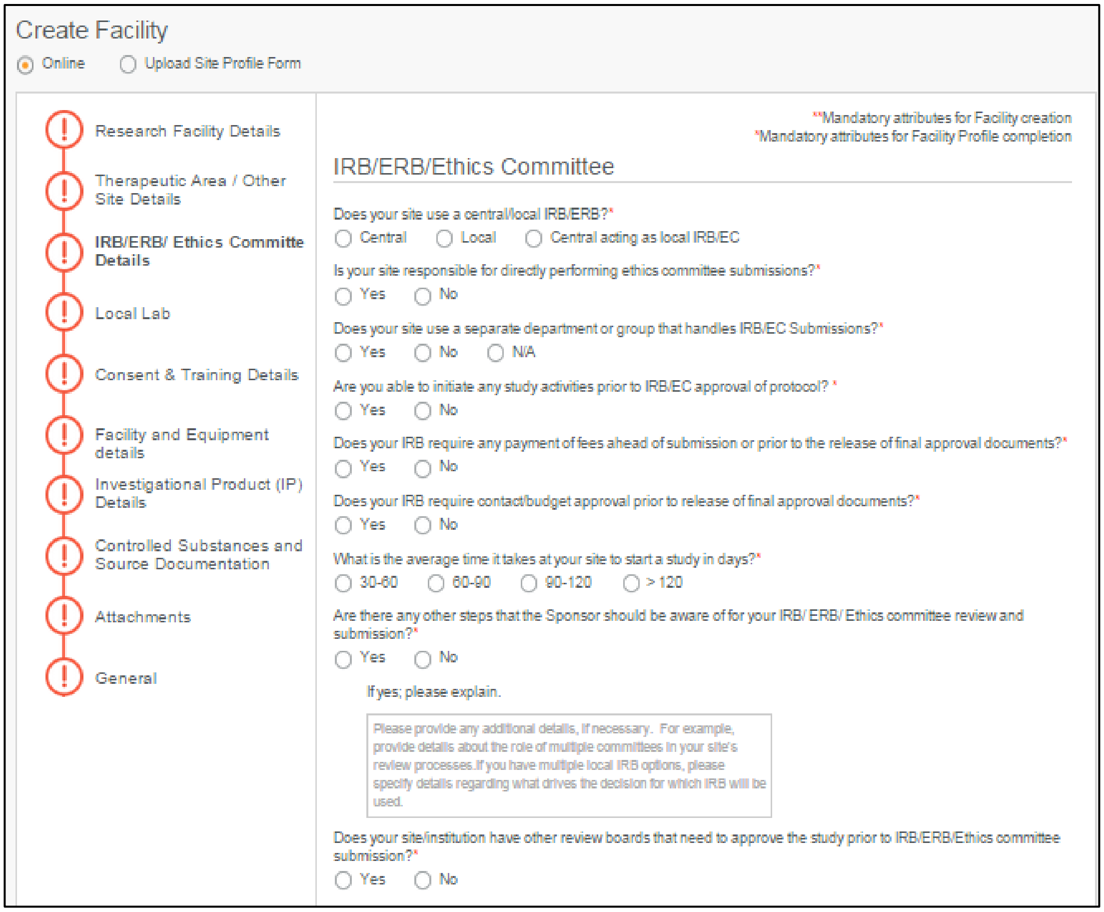


Figure 123. IRB/ERB/Ethics Committee Page

2. On the **IRB/ERB/Ethics Committee** page, enter the required committee details. For IRB/ERB/ethics Committee Details field descriptions, refer to Table 22.

3. To enter the specific contact details for the department responsible for IRB/EC submissions, click **Yes**.

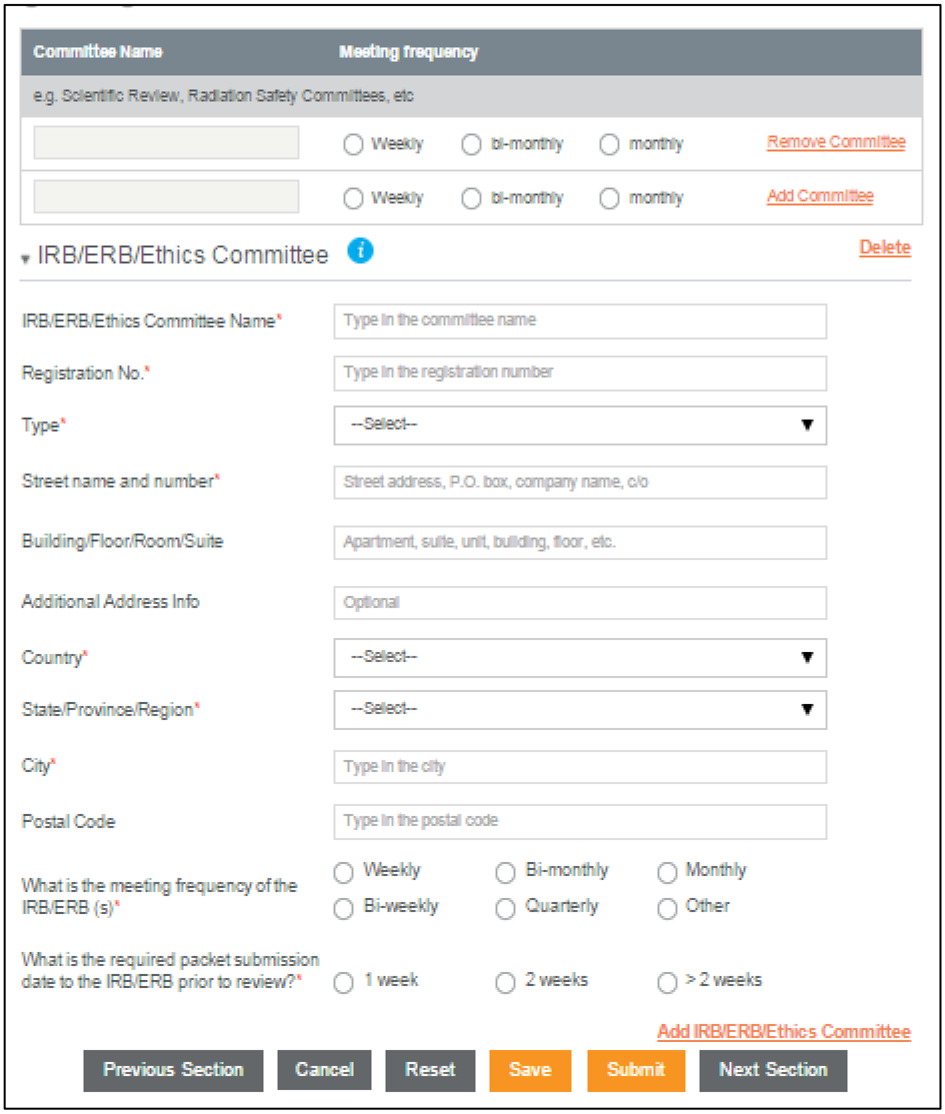


Figure 124. IRB/ERB/Ethics Committee Details Page

4. To save the IRB/ERB/ethics committee details and progress with entering the Facility Profile details, click **Save**. The Facility Profile is in the "Draft " status and you can proceed with entering the Facility Profile details.
5. To submit the IRB/ERB/ethics committee details, click **Submit**.
6. In the confirmation message displayed, click **OK**. The status of the Facility Profile is "Active" and can be associated with the User Profile.
7. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the IRB or ERB or Ethics Committee Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Does your site use a central/local IRB/ERB?*	Option button	This is a mandatory field.	This is a general inquiry to identify all IRB/EC types that this Facility may potentially use to conduct a study. Select all that apply among the following options: Central, Local and Central acting as local IRB/EC. If the IRB/EC type that the Facility can use is Local or Central acting as Local, the details of the committee (name or registration number.) must be provided in the section following the general questions. If only Central is selected, the remaining general questions regarding IRB/EC submissions become inactive.
Is your site responsible for directly performing ethics committee submissions?*	Option button	This is a mandatory field.	Click **Yes** or **No**.
Does your site use a separate department or group that handles IRB/EC submissions?*	Option button	This is a mandatory field.	Click **Yes, No**, or **N/A**.
Are you able to initiate any study activities prior to IRB/EC approval of protocol?*	Option button	This is a mandatory field.	Click **Yes** or **No**.
Does your IRB require any payment of fees ahead of submission or prior to the release of final approval documents?*	Option button	This is a mandatory field.	Click **Yes** or **No**.
Does your IRB require contact/budget approval prior to release of final approval documents?*	Option button	This is a mandatory field.	Click **Yes** or **No**.

Field	Field Type	Mandatory Field	Field Descriptions
What is the average time it takes at your site to start a study in days?*	Option button	This is a mandatory field.	Average time taken in days to start a study in the site.
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics committee review and submission?*	Option button	This is a mandatory field.	Click **Yes** or **No**. If Yes, explain the details in the box displayed.
Does your site/institution have other review boards that need to approve the study prior to IRB/ERB/Ethics committee submission?*	Option button	This is a mandatory field.	Click **Yes** or **No**. If Yes, provide the name and meeting frequency of the additional review board and click Add Committee. **Note** If Yes, in the **Committee Name**, type the name of the committee. In the **Meeting Frequency**, click one of the following: Weekly, Bi-Monthly, or Monthly. To add an additional Committee, click , or to remove the added option click .
Meeting Frequency	Option button	This is not a mandatory field	Select a meeting frequency option such as Weekly, Bi-monthly, or Monthly, Bi-weekly, Quarterly or Other.
IRB/ERB/Ethics Committee			
IRB/ERB/Ethics Committee Name*	Text box	This is a mandatory field.	This is the name of the IRB (Institutional Review board) or ERB (Ethical Review Board) or Ethics committee
Registration No.*	Text box	This is a mandatory field.	This is the registration number of the Site User in IRB or ERB or Ethic committee.
Type*	Drop-down list	This is a mandatory field.	This is the type of the committee. Options include Local, Central, and Central/Acts as Local.
Street Name and Number*	Text box	This is a mandatory field.	This is the name of the street and company. Fourth Avenue, 21, Medicare, P.O.

Field	Field Type	Mandatory Field	Field Descriptions
			21453.
Building/Floor/Room/Suite	Text box	This is not a mandatory field.	This is the building or floor or room details of the Facility. Building 3, 3rd floor, Suite 205.
Additional Address info	Text box	This is not a mandatory field.	This is the additional address information of the Facility, if any.
Country*	Drop-down list	This is a mandatory field.	This is the name of the country. United States.
State/Province/Region*	Drop-down list	This is a mandatory field.	This is the name of the State, province, or region. For example, California.
City*	Text box	This is a mandatory field.	This is the name of the city. For example, San Fransisco.
Postal Code	Text box	This is not a mandatory field.	This is the ZIP/Postal Code of the location. 23451.
What is the meeting frequency of the IRB/ERB(s)?*	Option button	This is a mandatory field.	This refers to the meeting frequency of the committee such as weekly, bi-monthly, or monthly.
What is the required packet submission date to the IRB/ERB prior to review?*	Option button	This is a mandatory field.	This refers to the required packet submission date such as 1 week, 2 weeks, or >2weeks.

Table 19 Field Descriptions for IRB/ERB/Ethics Committee Details

*To add an additional IRB/ERB/Ethics Committee, click **Add IRB/ERB/ Ethics Committee**.*

*To add an additional committee, click **Add Committee**.*

*To delete a committee, click **Remove Committee**.*

5.3.2.4. Add Local Lab Details

The Local Lab page allows the Site Users to enter the lab name, location, and lab Facility details.

To add local lab details

1. On the left navigation pane of the **Create Facility** page, click **Local Lab**. The Local Lab page is displayed.
2. On the **Local Lab** page, enter the lab details, and then browse to attach a relevant file. For Local Lab Details field descriptions, refer to Table 23.

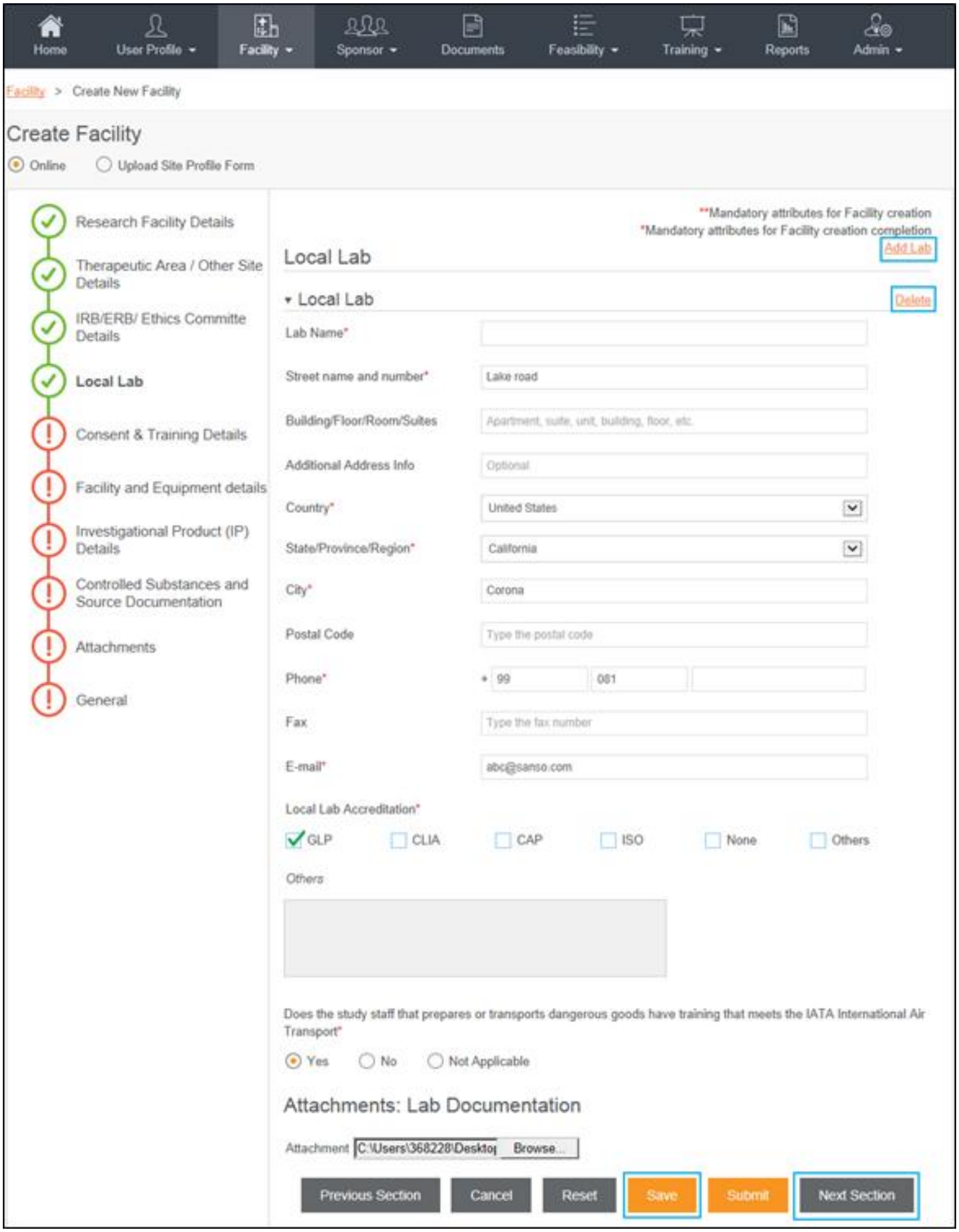


Figure 125. Local Lab Page

3. To save the details, click **Save**.

4. To submit the local lab details, click **Submit**.

5. In the confirmation message window that is displayed, click **OK**. The entered details are now in 'Active' status.

6. To navigate to the next section of the Facility page, click **Next Section**.

*To add an additional Local Lab section, click **Add Lab**.*

*To delete the additional Local Lab section, click **Delete**.*

The following table provides the field descriptions for the Local Lab Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Lab Name*	Text box	This is a mandatory field.	Name of the laboratory
Street name and number*	Text box	This is a mandatory field.	Name of the street and company
Building/Floor/Room/Suite	Text box	This is not a mandatory field.	Building or floor or room details of the Facility
Additional Address info	Text box	This is not a mandatory field.	Additional address information of the Facility, if any
Country*	Drop-down list	This is a mandatory field.	Name of the country
State/Province/Region*	Drop-down list	This is a mandatory field.	Name of the state, province, or region, where the laboratory is located
City*	Text box	This is a mandatory field.	Name of the city, where the laboratory is located
Postal Code	Text box	This is not a mandatory field.	ZIP/Postal Code of the location of the laboratory
Phone*	Text box	This is a mandatory field.	Phone number of the laboratory **Note** The phone number needs to be in the following format: Country Code, Area Code, and Phone Number.
Fax	Text box	This is not a mandatory field.	Fax number of the laboratory
Email ID*	Text box	This is a mandatory field.	Email address of the laboratory

Local Lab Accreditation*	Check box	This is a mandatory field.	Certification of the laboratory **Note** If the certification is different from the list of certifications displayed, select the **Others** check box and type the certification name in the Others box.
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport*	Option button	This is a mandatory field.	Click one of the following: **Yes**, **No**, or **Not Applicable**

Table 20. Field Descriptions for Local Lab Details

5.3.2.5. Add Consent and Training Details

The Consent and Training Details page consists of the status of the subject informed consent processes in place, consent language requirements, and training program details.

To add consent and training details

1. On the left navigation pane of the **Create Facility** page, click **Consent and Training Details**. The Consent and Training Details page is displayed.

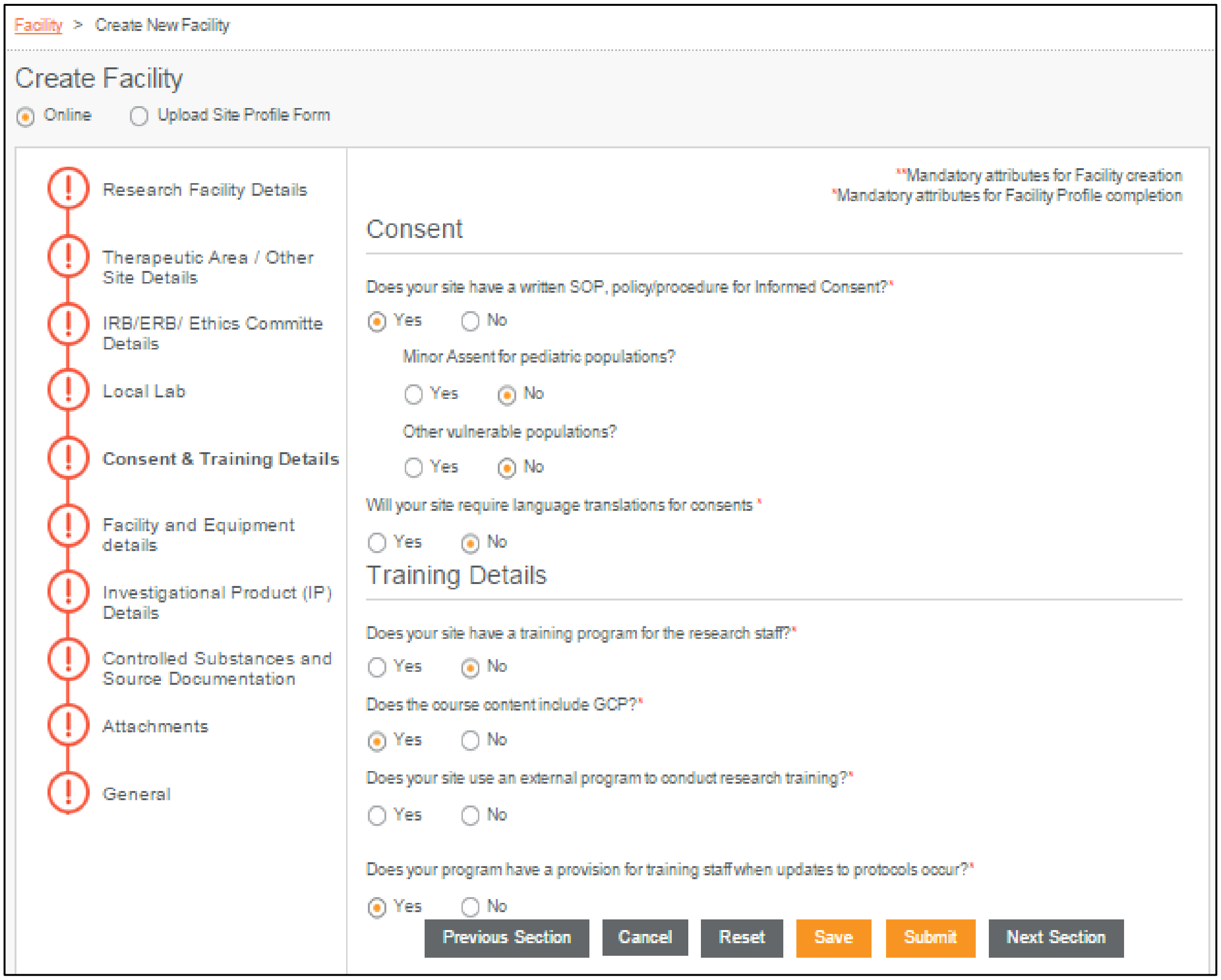


Figure 126. Consent and Training Details Page

2. On the **Consent and Training Details** page, enter the consent and training details. For Consent and Training Details field descriptions, refer to Table 24.

3. To save the details, click **Save**. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.

4. To submit the consent and training details, click **Submit**. In the confirmation message displayed, click **OK**. The entered details are now in ‘Active’ status.

5. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the Consent and Training Details page.

Field	Field Type	Mandatory Field	Field descriptions
Consent			
Does your site have a written SOP, policy/procedure for informed consent? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Minor assent for pediatric populations?	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Other vulnerable populations?	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Will your site require language translation for consents*	Option button	This is a mandatory field.	Click **Yes** or **No**. **Note** If Yes, specify the languages that are required.
Training Details			
Does your site have a training program for the research staff? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Does the course content include GCP? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Does your site use an external program to conduct research training? *	Option button	This is a mandatory field.	Click **Yes** or **No**. **Note** If Yes, specify the program course name
Does your program have a provision for training staff when updates to protocols occur? *	Option button	This is a mandatory field.	Click **Yes** or **No**.

Table 21. Field Descriptions for Consent and Training Details

5.3.2.6. Add Facility and Equipment Details

The Facility and Equipment Details page allows the Site Users to add the types of equipment, and computer and diagnostic capabilities.

To add Facility and equipment details

1. On the left navigation pane of the **Create Facility** page, click **Facility and Equipment Details**. The Facility and Equipment Details page is displayed.

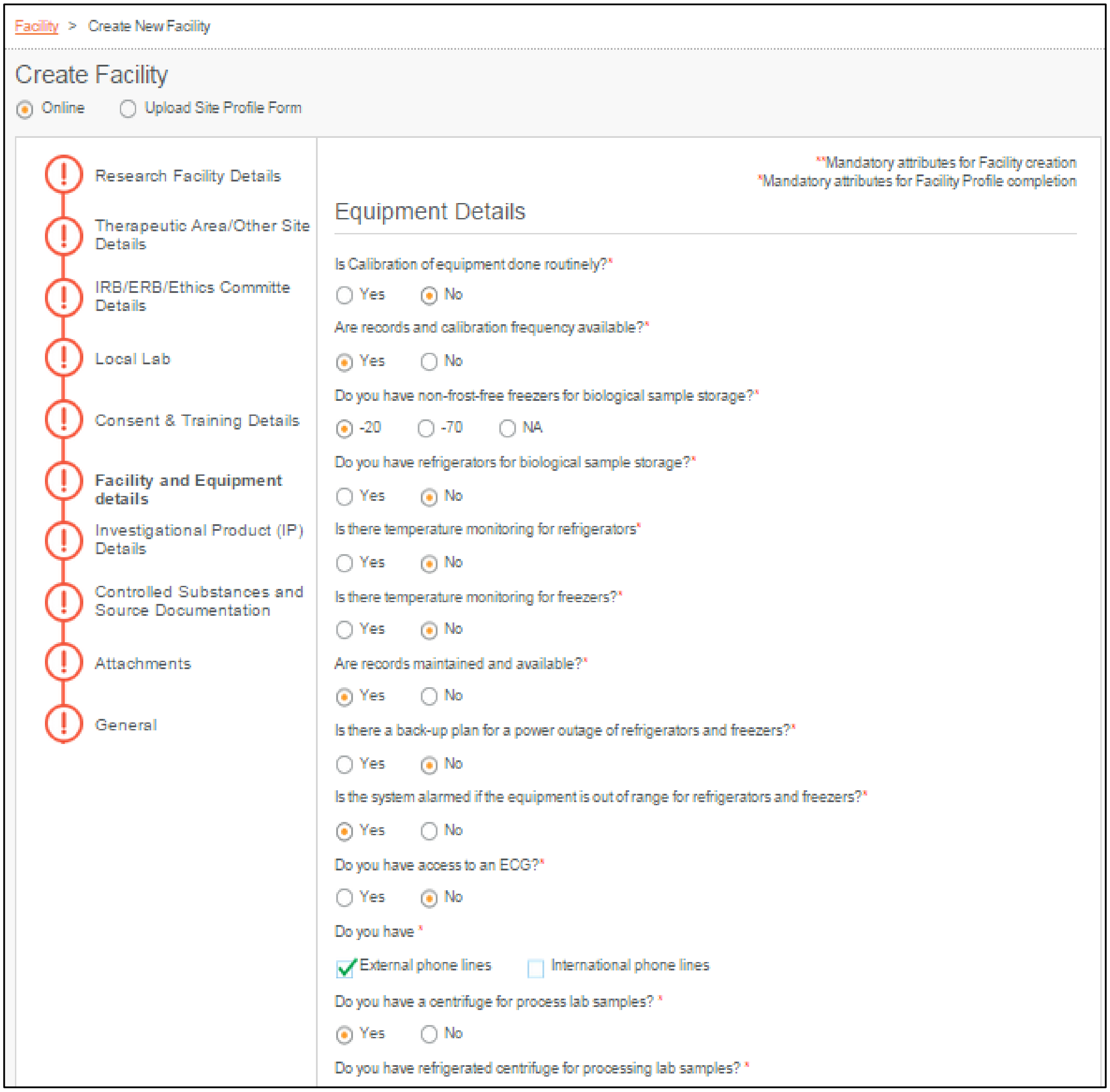


Figure 127. Facility and Equipment Details Page: Equipment Details

2. On the **Facility and Equipment Details** page, enter the **Equipment Details**, **Computer Capability**, **Digital Diagnostic Capabilities**, **Storage Facilities**, and Other details. For Facility and Equipment Details field descriptions, refer to Table 25.

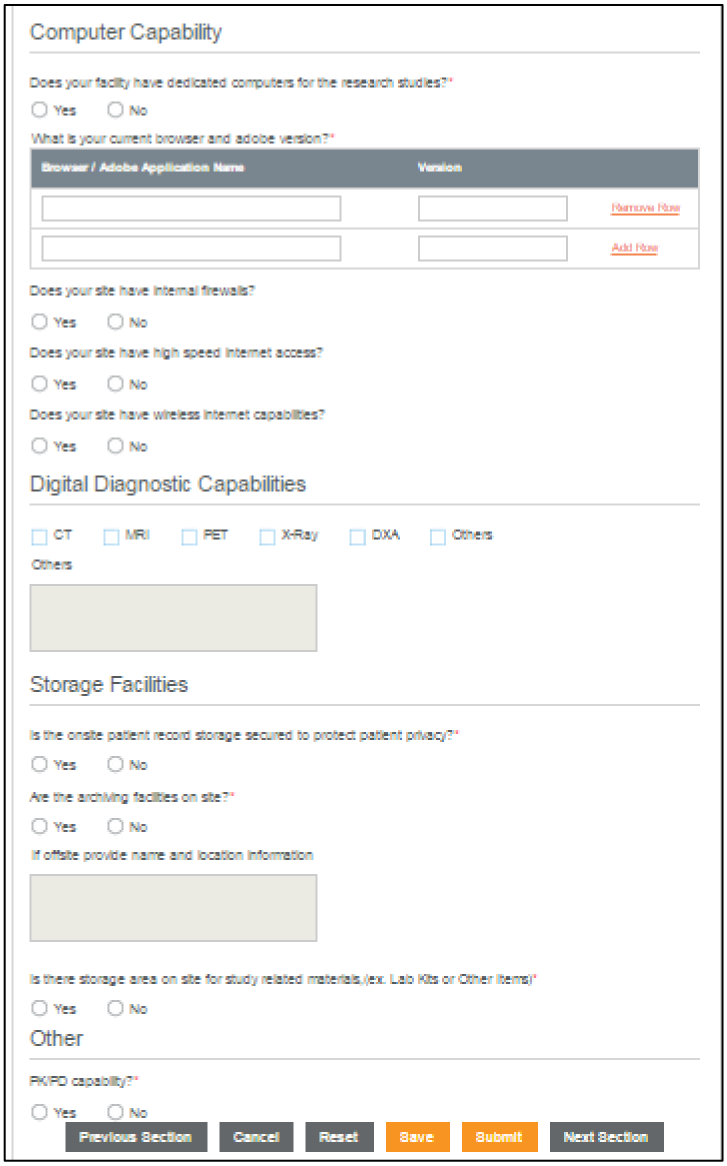


Figure 128. Computer Capability/ Digital Diagnostic Capabilities/Storage Facilities Page

3. To save the details, click **Save**. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.
4. To submit the Facility and equipment details, click **Submit**.
5. In the confirmation message displayed, click **OK**. The entered details are now in ‘Active’ status.
6. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the Facility and Equipment Details page.

Field	Field Type	Mandatory Field	Field descriptions
Equipment Details			
Is calibration of equipment done routinely? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Are records and calibration frequency available? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Do you have non-frost-free freezers for biological sample storage? *	Option button	This is a mandatory field.	A non-frost-free freezer for storing biological samples. Click multiple options: -20, -70, N/A. **Note**: You can click more than one option, if applicable.
Do you have refrigerators for biological sample storage? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is there temperature monitoring for refrigerators? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is there temperature monitoring for freezers? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Are records maintained and available? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is there a back-up plan for a power outage of refrigerators and freezers? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is the system alarmed if the equipment is out of range for refrigerators and freezers? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Do you have access to an ECG? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Do you have phone line? *	Option button	This is a mandatory field.	This is the phone line that is available such as external or international phone line.
Do you have a centrifuge for process lab samples? *	Option button	This is a mandatory field.	Click **Yes** or **No**.

Do you have refrigerated centrifuge for processing lab samples? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Computer Capability			
Does your site have dedicated computers for the research studies? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
What is your current browser and Adobe version? *	Option button	This is a mandatory field.	Click **Yes** or **No**. **Note** If Yes, do the following actions: In the **Browser/Adobe Application Name** drop-down list, click the application name. In the **Version** drop-down list, click the version number. To add an additional row in the Current Browser and Adobe Version section, click , or to delete the added row, click .
Does your site have internal firewalls?	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Does your site have high speed internet access?	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Does your site have wireless internet capabilities?	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Digital Diagnostic Capability			
Digital Diagnostic Capability	Check box	This is not a mandatory field.	This refers to the digital diagnostic capabilities that are available in the site. **Note** If you select **Others**, type the details of the device capabilities in the **Others** box.
Storage Facility			

Is the onsite patient record storage secured to protect patient privacy? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Are the archiving Facilities on site? *	Option button	This is a mandatory field.	Click **Yes** or **No**. **Note** If offsite, enter the name and location information in the box.
Is there storage area on site for study related materials*	Option button	This is a mandatory field.	Click **Yes** or **No**.
Others			
PK/PD capability? *	Option button	This is a mandatory field.	Click **Yes** or **No**.

Table 22. Field Descriptions for Facility and Equipment Details

5.3.2.7. Add Investigational Product Details

The Investigational Product Details page allows Site Users to add Investigational Product-Shipping Details, IP-Storage & Handling, Destruction of IP and IP Satellite Site details.

To add Investigational Product details

1. On the left navigation pane of the **Create Facility** page, click **Investigational Product (IP) Details**. The Investigational Product Details page is displayed.

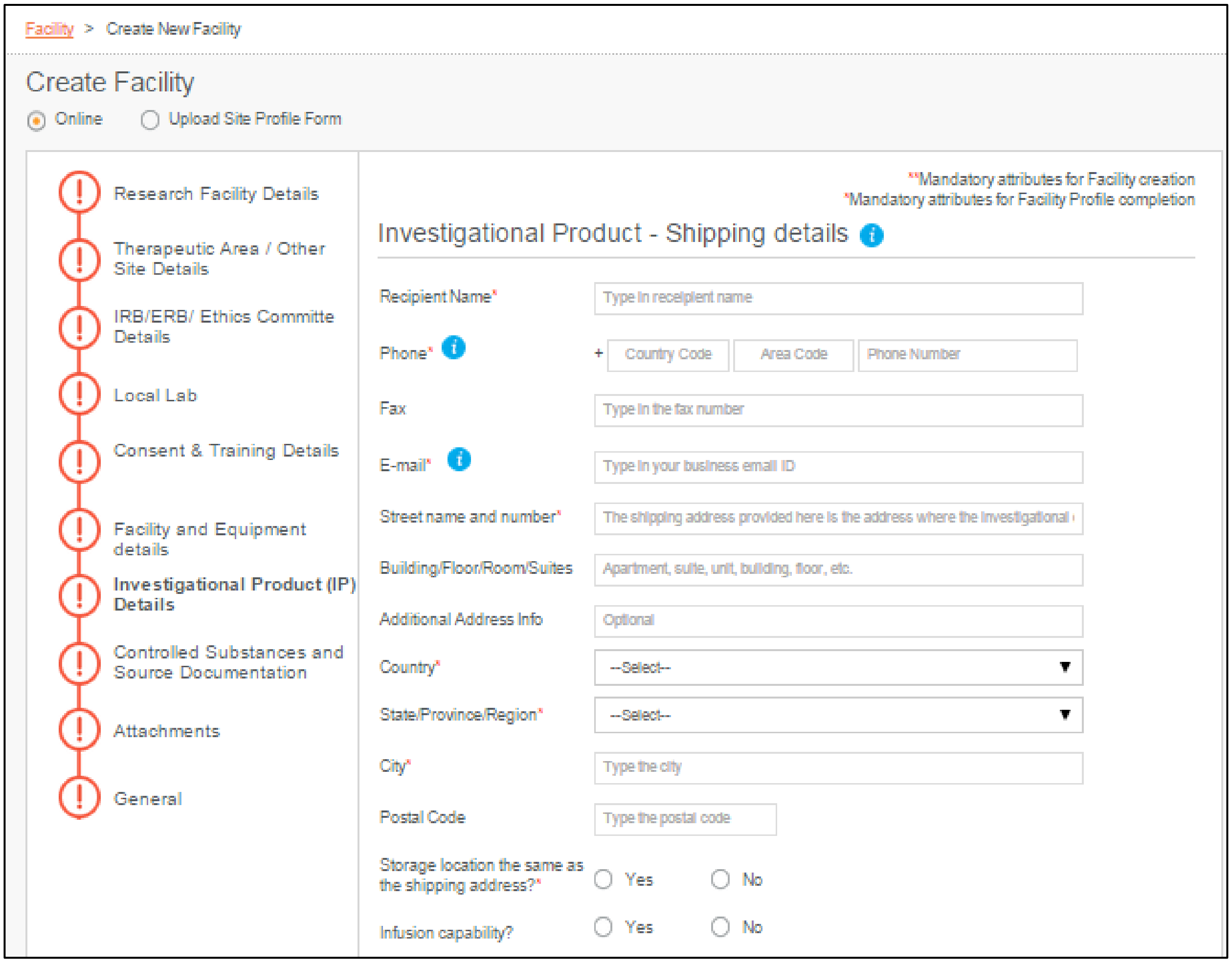


Figure 129. Investigational Product -Shipping Details Page

2. On the **Investigational Product Details** page, enter the Investigational Product-Shipping details, IP-Storage and Handling, Destruction of IP and IP Satellite Site details. For Add IP Details Field Descriptions, refer to Table 26.

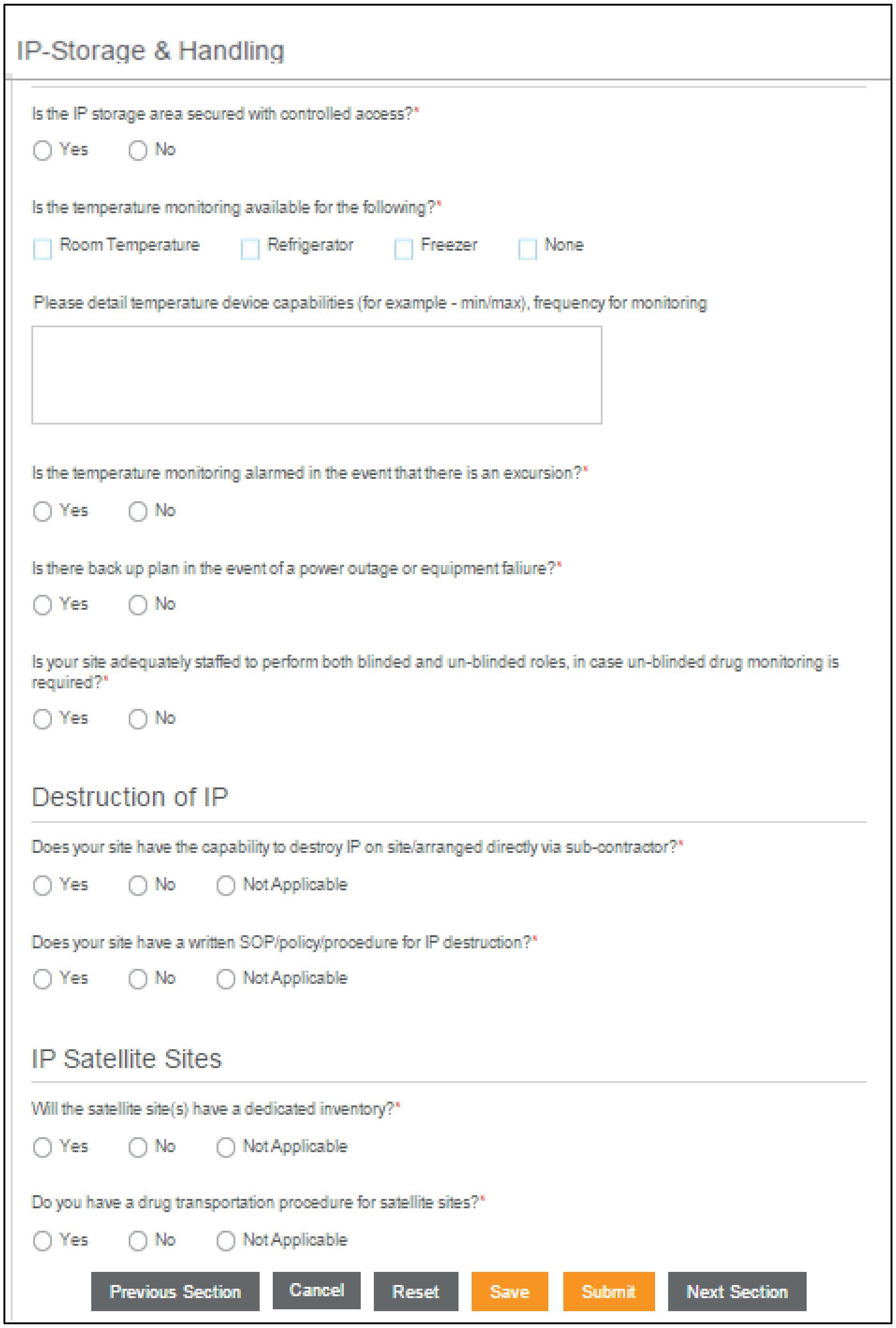


Figure 130. IP-Shipping Details Page: IP Storage and Handling, Destruction of IP, and IP Satellite Sites Sections

3. To save the entered details, click **Save**. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.

4. To submit the Investigational Product details, click **Submit**.

5. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the Investigational Product (IP) Details page.

Field	Field Type	Mandatory Field	Field Descriptions
Investigational Product - Shipping details			
Recipient Name*	Text box	This is a mandatory field.	This is the name of the recipient to receive Investigational Product.
Phone*	Text box	This is a mandatory field.	This is the phone number of the recipient. **Note** The phone number needs to be in the following format: Country Code, Area Code, and phone Number.
Fax	Text box	This is not a mandatory field.	This is the fax number of the recipient.
Email ID*	Text box	This is a mandatory field.	This is the email address of the recipient.
Street name and number*	Text box	This is a mandatory field.	This is the name of the street and company.
Building/Floor/Room/Suite	Text box	This is not a mandatory field.	This is the building or floor or room details of the Facility.
Additional Address info	Text box	This is not a mandatory field.	This is the additional address information of the Facility, if any.
Country*	Drop-down list	This is a mandatory field.	This is the name of the country.
State/Province/Region*	Drop-down list	This is a mandatory field.	This is the name of the state or province or region.
City*	Text box	This is a mandatory field.	This is the name of the city.
Postal Code	Text box	This is not a mandatory field.	This is the ZIP/Postal Code of the location.
Storage location the same as the shipping address? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Infusion capability	Option button	This is not a mandatory field.	Click **Yes** or **No**.
Storage Contact Name*	Text box	This is a mandatory field.	This is the name of the Facility Profile Manager associated with the storage location.

Address*	Text box	This is a mandatory field.	This is the address of the storage location.
Country*	Drop-down list	This is a mandatory field.	This is the name of the country in which the store is located.
State/Province/Region*	Drop-down list	This is a mandatory field.	This is the name of the state, province, or region in which the store is located.
City*	Text box	This is a mandatory field.	This is the name of the city in which the store is located.
Postal Code	Text box	This is not a mandatory field.	This is the ZIP/Postal Code of the location.
Infusion Capability? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
IP-Storage & Handling			
Is the IP storage area secured with controlled access? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is the temperature monitoring available for the following*	Check box	This is a mandatory field.	Click some of the following options: Room Temperature, Refrigerator, Freezer, and None. **Note** Specify the following details for the selected option: temperature details, device capabilities, and frequency for monitoring.
Is the temperature monitoring alarmed in the event that there is an excursion? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Is there a backup plan in the event of a power outage or equipment failure? *	Option button	This is a mandatory field.	Click **Yes** or **No**.

Is your site adequately staffed to perform both blinded and un-blinded roles, in case un-blinded drug monitoring is required? *	Option button	This is a mandatory field.	Click **Yes** or **No**.
Destruction of IP			
Does your site have the capability to destroy IP on site/arranged directly via sub-contractor? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
Does Your Site Have a Written SOP/Policy/Procedure for IP Destruction? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
IP Satellite Sites			
Will the satellite site(s) have a dedicated inventory*	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
Do you have a drug transportation procedure for satellite sites*	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.

Table 23. Field Descriptions for Investigational Product Details

5.3.2.8. Controlled Substances and Source Documentation

The Controlled Substances and Source Documentation page allows Site Users to enter the handling and storage details of controlled substances, source document information and experiences with electronic data capture systems.

To add controlled substances and source documentation

1. On the left navigation pane of the **Create Facility** page, click **Controlled Substances and Source Documentation**. The Controlled Substances and Source Documentation page is displayed.
2. Enter the Controlled Substances and Source Documentation/CRFS/Site Monitoring details. For Controlled Substances and Source Documentation field descriptions, refer to Table 27.

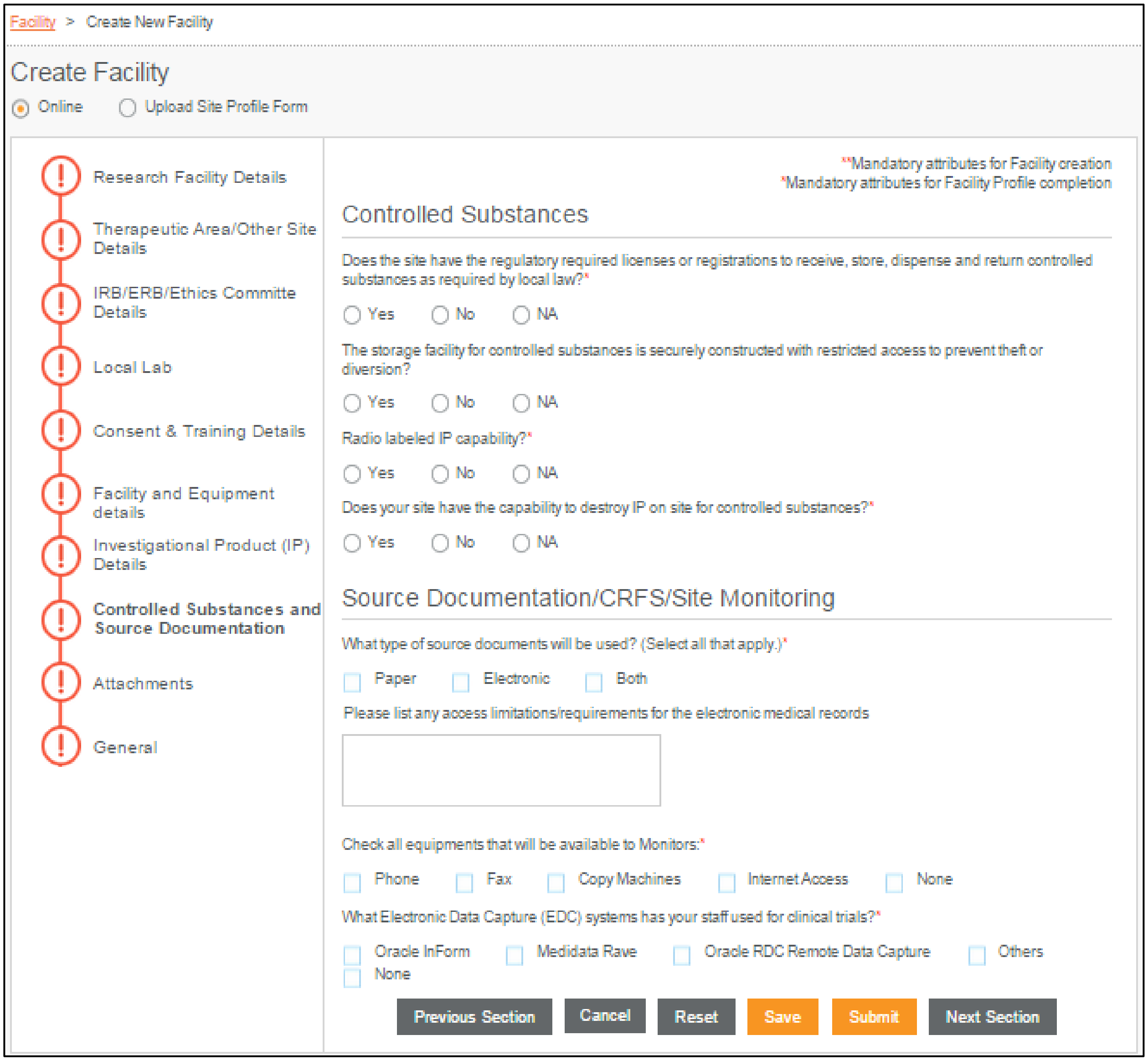


Figure 131. Controlled Substances and Source Documentation Page

3. To save the details, click **Save**. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.
4. To submit the controlled substances and source documentation details, click **Submit**.
5. In the confirmation message displayed, click **OK**. The entered details are now in ‘Active’ status.
6. To navigate to the next section of the Facility page, click **Next Section**.

The following table provides the field descriptions for the Controlled Substances and Source Documentation page.

Field	Field Type	Mandatory Field	Field Descriptions
Controlled Substances			
Does the site have the regulatory required licenses or registrations to receive, store, dispense and return controlled substances as required by local law? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
The storage Facility for controlled substances is securely constructed with restricted access to prevent theft or diversion? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
Radio labeled IP capability? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
Does your site have the capability to destroy IP on site for controlled substances? *	Option button	This is a mandatory field.	Click one of the following options: **Yes**, **No**, **Not Available**.
Source Documentation/CRFS/Site Monitoring			
What type of source documents will be used*	Check box	This is a mandatory field.	This is the type of the source document. **Note** Specify the access limitations or requirements for electronic media record in the box, if any.
Check all equipment that will be available to Monitors*	Check box	This is a mandatory field.	Select some of the following devices for the monitors: phone, fax, copy machines, internet access, and none.

What electronic data capture (EDC) systems has your staff used for clinical trials? *	Check box	This is a mandatory field.	This is the electronic data capture system that the staff uses for clinical trials. **Note** If Other is selected, specify the EDC Vendor and Product in the box.

Table 24. Field Descriptions for Controlled Substances and Source Documentation

5.3.2.9. Add Attachments

The Attachments page allows Site Users to upload supporting documentation about their Facilities.

To attach a file

1. On the left navigation pane of the **Create Facility** page, click **Attachments**. The attachments page is displayed.

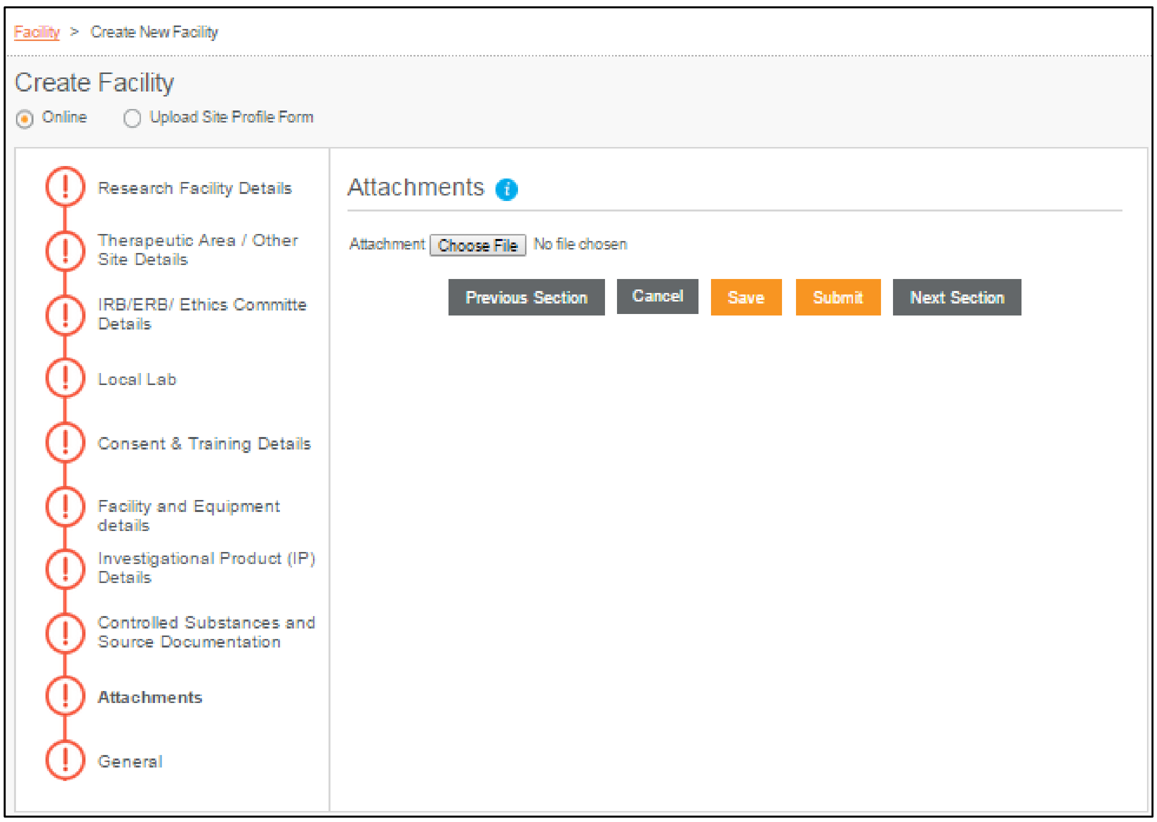


Figure 132. Attachments Page

2. On the **Attachments** page, click **Choose File**.

3. In the **Choose File to Upload** dialog box, browse to the location of the file, and then click **Open**.

4. To save the attachment, click **Save.** The attachment is now in Draft status and you can proceed with entering the Facility Profile details.
5. To submit the attachment, click **Submit**.
6. In the confirmation message displayed, click **OK**. The attachment is now in 'Active' status.
7. To navigate to the next section of the Facility page, click **Next Section**.

*To close the page, click **Cancel**.*

*To navigate to the previous section of the Facility page, click **Previous Section**.*

5.3.2.10. Add General Details

The General page allows Site Users to enter additional information in the free text field; enter the information that has not been mentioned in the previous sections.

To add general details

1. On the left navigation pane of the **Create Facility** page, click **General**. The General page is displayed.
2. In the box, enter the details. The entered details are now in Draft status and you can proceed with entering the Facility Profile details.
3. To save the details, click **Save**.

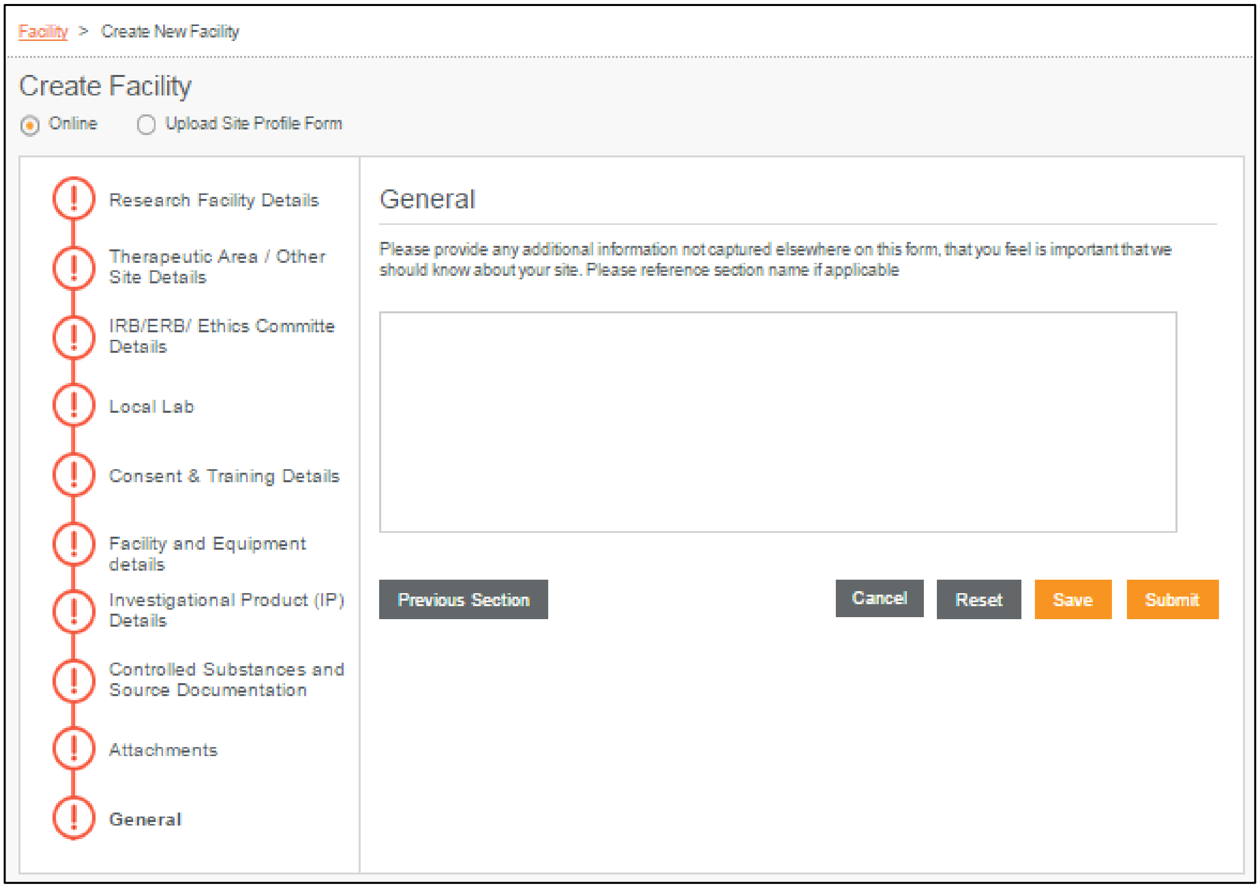


Figure 133. General Details Page

4. To submit the Facility Profile, click **Submit**. The following confirmation message is displayed.

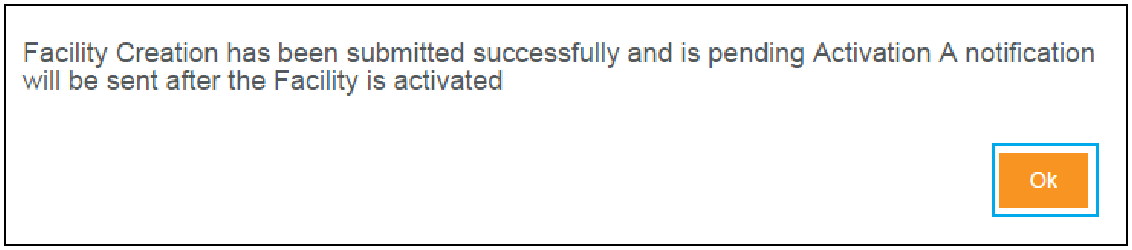


Figure 134. Facility Creation Confirmation Message

5. To acknowledge the message, click **OK**. The status of the Facility Profile is 'Active' and available and it can be associated with the User Profile.

6 Manage Study Workspace

The Study Workspace feature allows Principal Investigators and their Delegates to manage Study Staff and Study Sites used to conduct a particular clinical trial. Study Site is the combination of a Principal Investigator and Facility assigned to a specific study. For each Study Site, the Principal Investigator or his/her Delegate must define the Study Site Profile and Study Site Staff on the SIP Study Site page.

Principal Investigator: *A Principal Investigator directs the research activities at the site and has overall responsibility for the conduct of the clinical trial.*

Designated Study Site Contact: *A Designated Study Site Contact receives all communications that are sent to the Study Site in terms of notifications in the SIP system and an email. Designated Site Contact only receives Study Site communications and there are no other privileges.*

Principal Investigators and their Delegates can perform the following tasks:

Add or Edit Study Site Profile

Add or Edit Study Site Staff

All Site Users can exchange Study-level Documents securely, view, and launch study-level trainings by using the Study Workspace feature.

Search for a Study Document

View Assigned and Completed Trainings

6.1 Study-Specific Home Page

The Study-Specific Home page allows the Site User to view the study tasks or activities specific to the User who has currently logged on. It displays the news and the links related to a study.

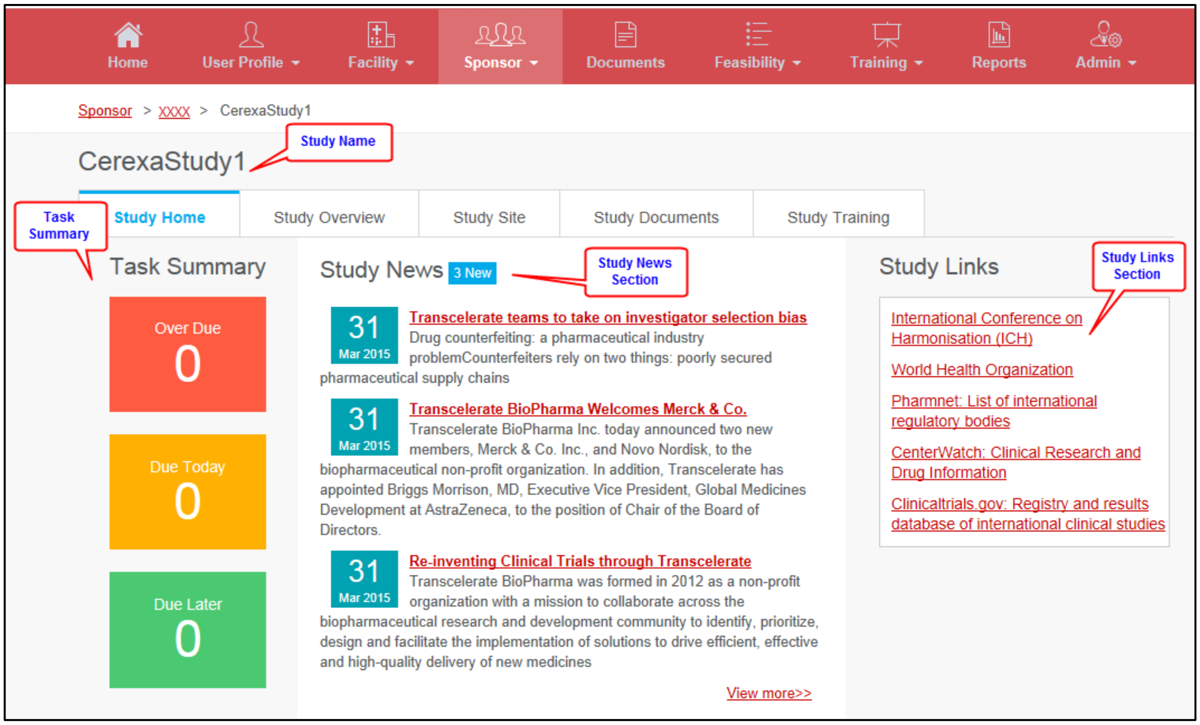


Figure 135. Study Home Page

- To view the task summary, under **Task Summary**, click one of the following options: **Overdue**, **Due Today**, or **Due Later**.
- To view any news related to the study, in the **Study News** section, click the required link.
- To navigate to one of the study links, in the **Study Links** section, click the required link.

*To view all tasks, click the **View more** link.*

6.2 Study Overview

The Study Overview page provides a view of the study details such as Study ID, Compound, Indication, Protocol Title, and Protocol Short Description. It also displays the study milestone details such as Planned First Subject First Visit and Planned First Subject Last Visit.

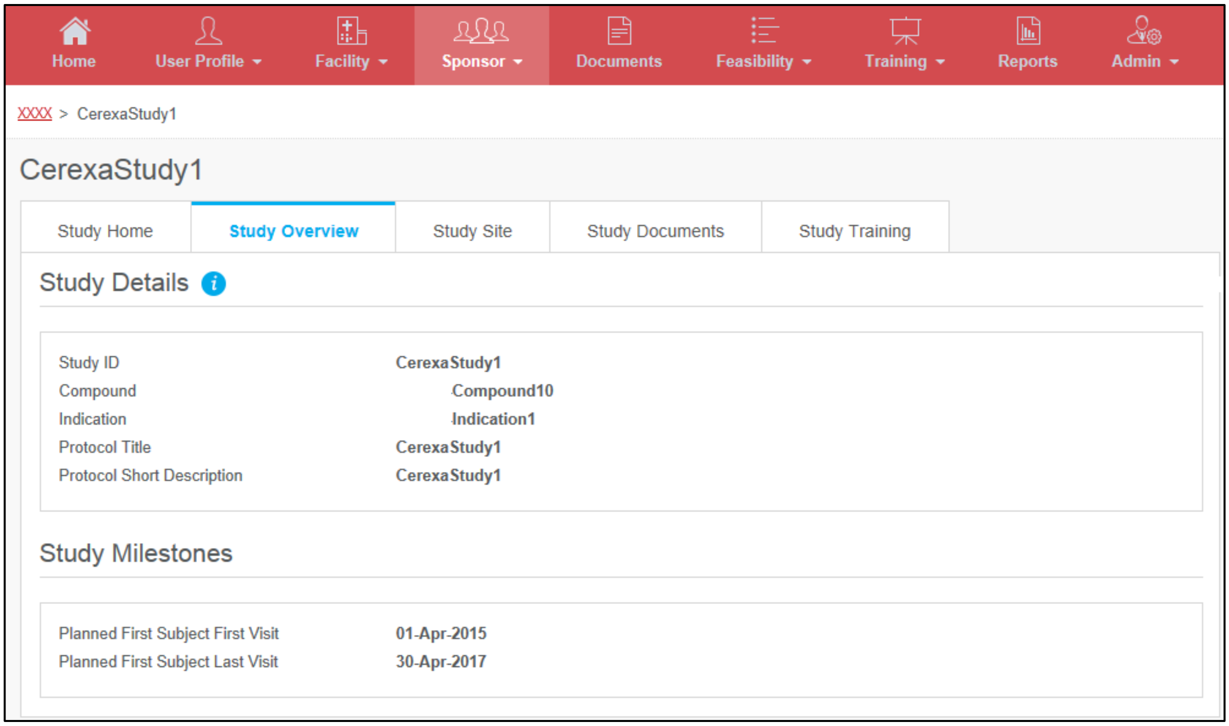


Figure 136. Study Overview Page

6.3 Study Site

Study Site is the combination of a Principal Investigator and Facility assigned to a specific study. For each Study Site, the Principal Investigator or his or her Delegate must define Study Site Profile and Study Site Staff following on the SIP Study Site page.

The Study Site consists of the following options:

- Study Site Profile
- Study Site Staff

6.3.1 Manage Study Site Profile

The Study Site Profile feature allows the Principal Investigator and his or her Delegate to provide the Sponsor with detailed information regarding site conduct of the study, including:

- Confirmation of Facilities/locations to be used
- Shipping addresses for study supplies and Investigational Product
- IRB/ERB/Ethics Committee
- Local Lab

The Principal Investigator and his or her Delegate need to update the Study Site Profile as needed throughout the conduct of the study. This is to ensure that accurate information is available to the Study Sponsor.

Only a Principal Investigator and his or her Delegate can edit the Study Site Profile details.

To add or edit Study Site Profile details

1. On the **Sponsor** menu of the SIP User Landing Page, click a required study.
2. On the Study page, click the **Study Site** tab.
3. In the **Study Site** drop-down list, click a required Study Site. The following Study Site Profile is displayed.

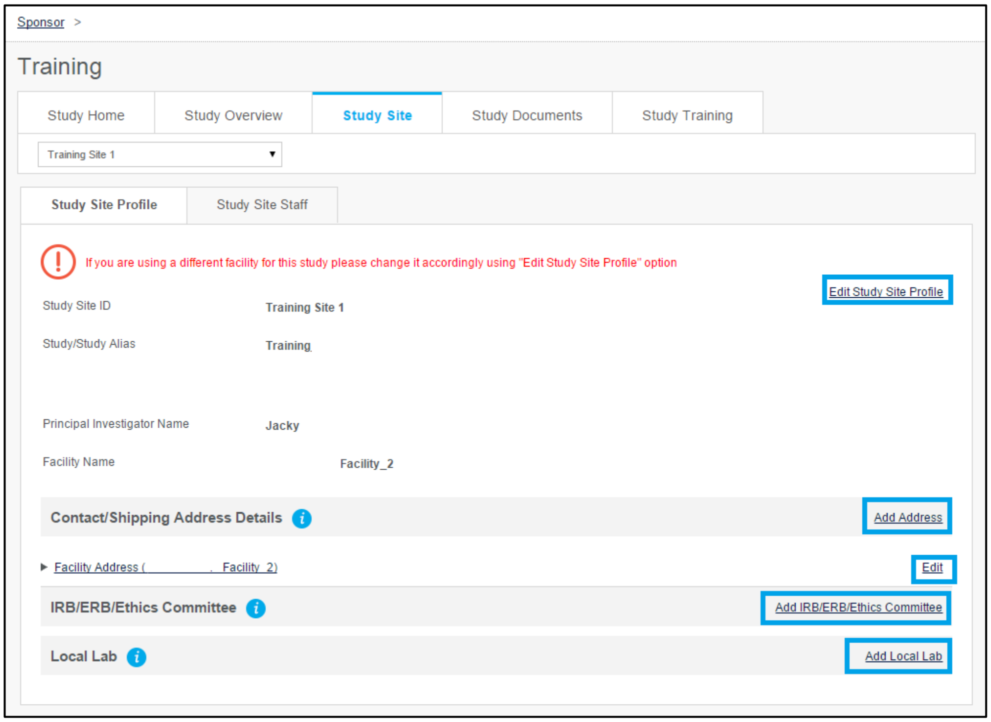


Figure 137. Study Site Page

4. To edit the Study Site details, click **Edit Study Site Overview**. The following confirmation message is displayed.

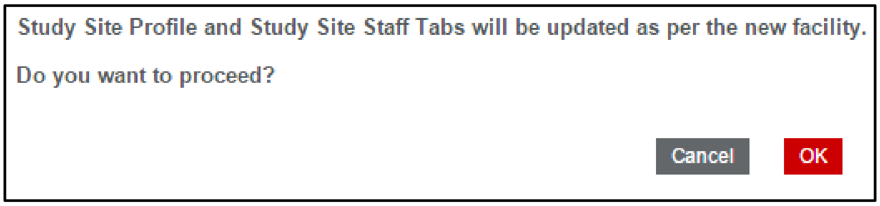


Figure 138. Edit Study Site Profile – Confirmation

5. Click **OK**. The Facility Name field is enabled.

6. Edit the Facility name by using the search option. For Search for Facility field descriptions, refer to Table 11.

A Study Site Research Facility can be replaced only with Facilities that are associated with the Principal Investigator in the User Profile.

7. To save the changes, click **Save**.

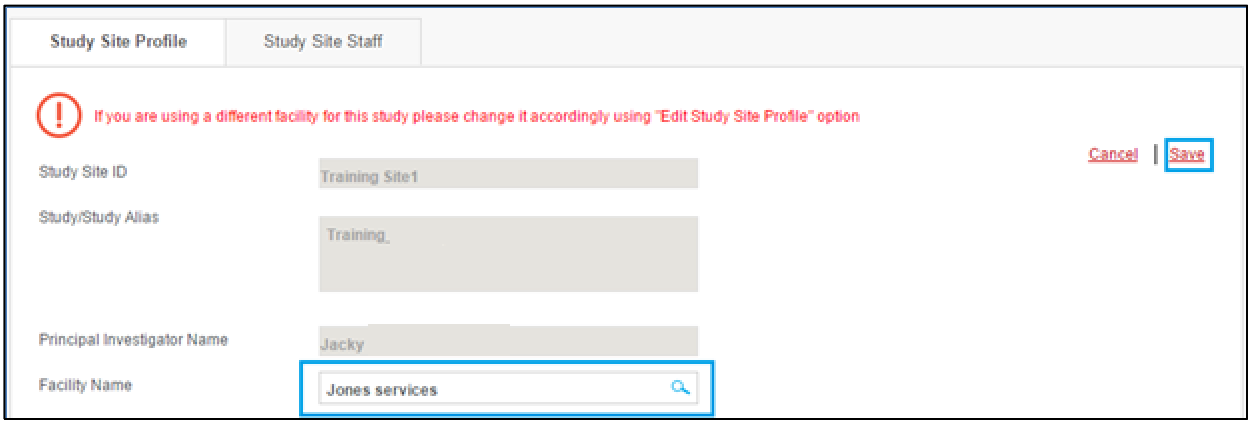


Figure 139. Edit Study Site Overview

6.3.1.1. Add or Edit Contact or Shipping Address Details

The Add or Edit Contact Details feature allows Site Users to add or edit the contact or shipping details. This section will display data from the Facility Profile by default. However, Site User can modify the data as required. The Facility Profile Manager will receive a notification that Facility information has been updated at the Study Site level.

To add or edit contact or shipping address details

1. To add contact or shipping address, in the **Contact/Shipping Address Details** section, click **Add Address**. The **Add Address** page is displayed.

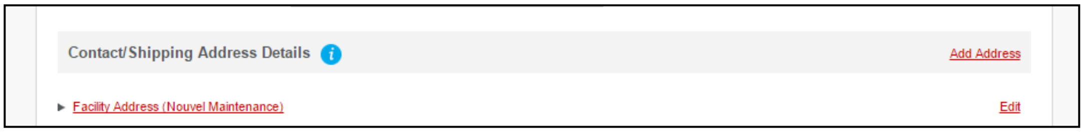


Figure 140. Contact/Shipping Address Details: Add Address Page

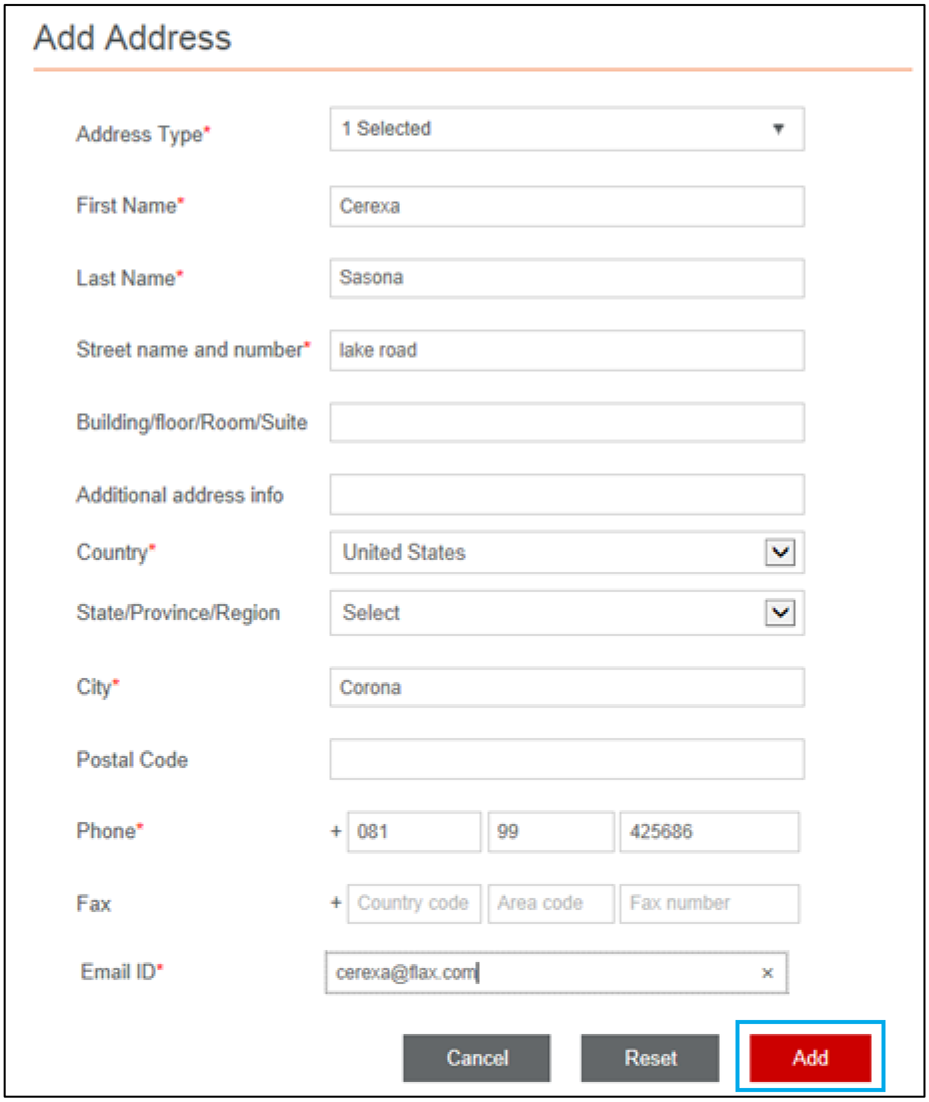


Figure 141. Add Address Window

2. On the **Add Address** page, enter the address details. For Add Address field descriptions, refer to Table 28.
3. To add the address, click **Add**.
4. To edit the address details, in the **Facility Address** section, click **Edit**.
5. Edit the required details. For Edit Address field descriptions, refer to Table 28.
6. To save the changes, click **Save**.

Figure 142. Edit Facility Address

The following table provides the field descriptions for all the fields on the Add Address window:

Field	Field Type	Mandatory Field	Field Descriptions
Address Type*	Drop-down list	This is not a mandatory field.	Type of Facility address **Note** You can click any one or all of the options.
First Name*	Text box	This is a mandatory field.	First name of the Site User
Last Name*	Text box	This is a mandatory field.	Last name of the Site User
Street Name and Number*	Text box	This is a mandatory field.	Name of the street and number in which the Facility is located. For example, Park Avenue, 45.
Building/Floor/Room/Suite	Text box	This is not a mandatory field.	Building or floor or room details of the Facility. For example, Apex Complex, 3^{rd} floor, Suite 31.
Additional Address info	Text box	This is not a mandatory field.	Additional address information of the Facility, if any
Country*	Drop-down list	This is a mandatory field.	Name of the country in which the Facility is located. For example, United States.
State/Province/Region	Drop-down list	This is not a mandatory field.	Name of the State, province, or region in which the Facility is located. For example, Texas.
City*	Text box	This is a mandatory field.	Name of the city in which the Facility is located. For example, Dallas.
Postal Code	Text box	This is not a mandatory field.	ZIP/Postal Code of the location. For example, 345124.

Phone*	Text box	This is a mandatory field.	Phone number of the Facility Note: The phone number needs to be in the following format: Country Code, Area Code, and Phone Number. 044-213-45612
Fax	Text box	This is not a mandatory field.	Fax number of the Facility **Note** The fax number needs to be in the following format: Country Code, Area Code, and Fax Number. 891-234-34562
Email ID*	Text box	This is a mandatory field.	Email address of the user. For example, xxx @pharma.com

Table 25. Field Descriptions for Add/Edit Address

6.3.1.2. Add or Edit IRB/ERB/Ethics Committee Details

SIP allows the Site Users to add or edit the IRB/ERB/Ethics committee details. This section will display data from the Facility Profile by default; however, Site User can modify the data as required. The Facility Profile Manager will receive a notification that Facility information has been updated at the Study Site level.

To add or edit IRB/ERB/Ethics committee details

1. On the **IRB/ERB/Ethics Committee** section, click **Add IRB/ERB/Ethics Committee**.
2. In the **Add IRB/ERB/Ethics Committee** window, enter the committee details. For Add IRB/ERB/Ethics Committee field descriptions, refer to Table 22.
3. To add the details, click **Add**.

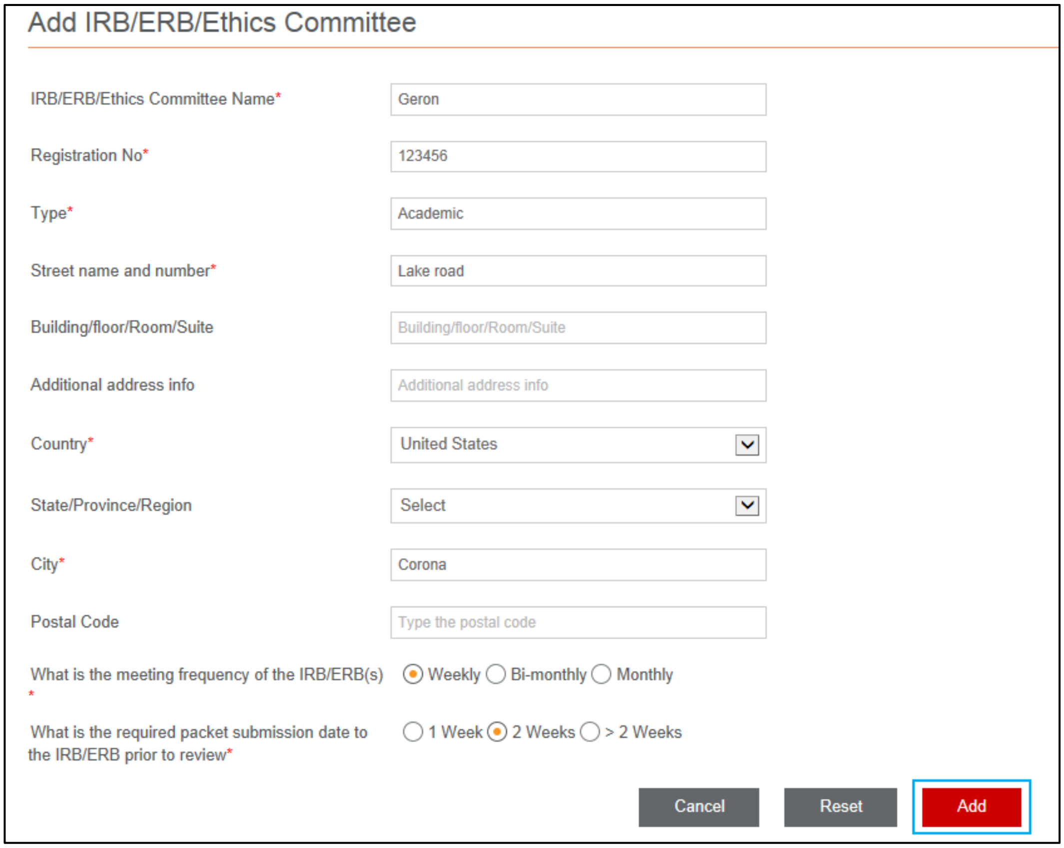


Figure 143. Add IRB/ERB/Ethics Committee Window

4. To edit the committee details, in the **IRB/ERB/Ethics Committee** section, click **Edit**.
5. Edit the required details.
6. To save the changes, click **Save**.

6.3.1.3. Add or Edit Local Lab Details

SIP allows the Site User to add or edit the local lab details. This section will display data from the Facility Profile by default. However, Site User can modify the data as required. The Facility Profile Manager will receive a notification that Facility information has been updated at the Study Site level.

To add or edit local lab details

1. In the **Local Lab** section, click **Add Local Lab**.
2. On the **Add Local Lab** page, enter the lab details. For Add Local Lab field descriptions, refer to Table 23.
3. To add the details, click **Add**.

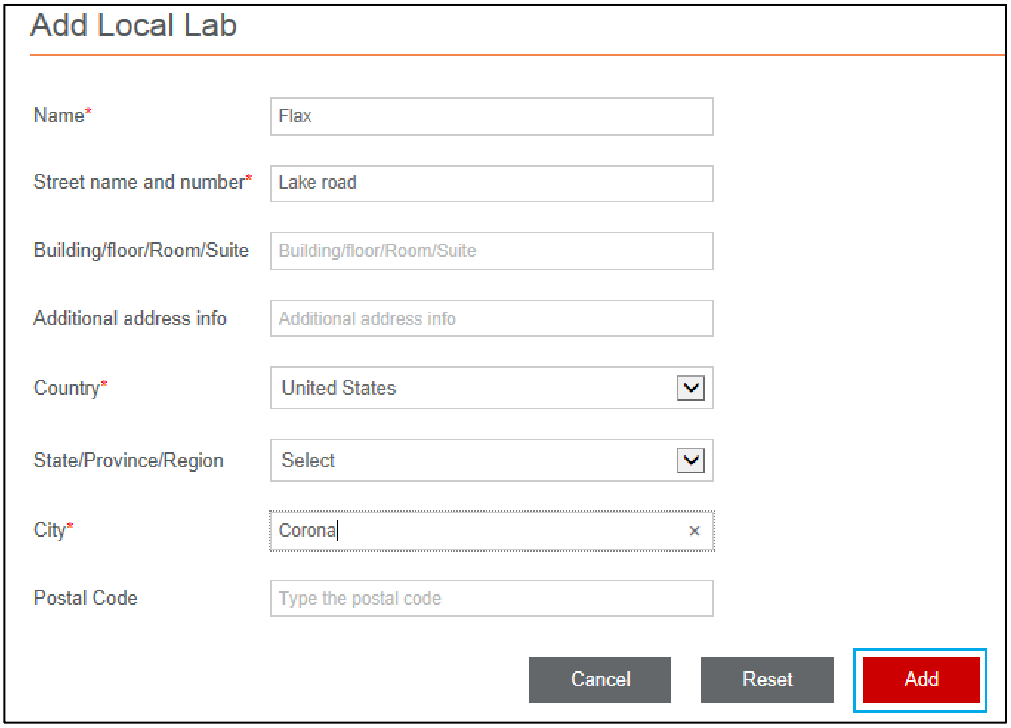


Figure 144. Add Local Lab Window

4. To edit the local lab details, in the **Local Lab** section, click **Edit**.
5. Edit the required details.
6. To save the changes, click **Save**.

6.3.2 Manage Study Site Staff Details

The Study Site Staff feature allows the Site Users to add a Site Staff who works on the study. This is to ensure that staff has the system access needed to fulfill study-related activities. This feature is required to inform Sponsor of site personnel assigned to key roles required for study conduct. For example, Sub-investigators, Study Coordinator, and Pharmacist.

Sponsor use the information on this page to assign study-specific training, grant appropriate system access (for example, EDC) and manage communications with the site. For this reason, the PI/Delegate need to update the data entered here, as needed throughout the study. This is to ensure accuracy.

To add Study Site Staff details

1. On the **Sponsor** menu of the SIP User Landing Page, click a required study.
2. On the Study page, in the **Select Study Site** drop-down list, click a Study Site, and then click the **Study Site Staff** tab.

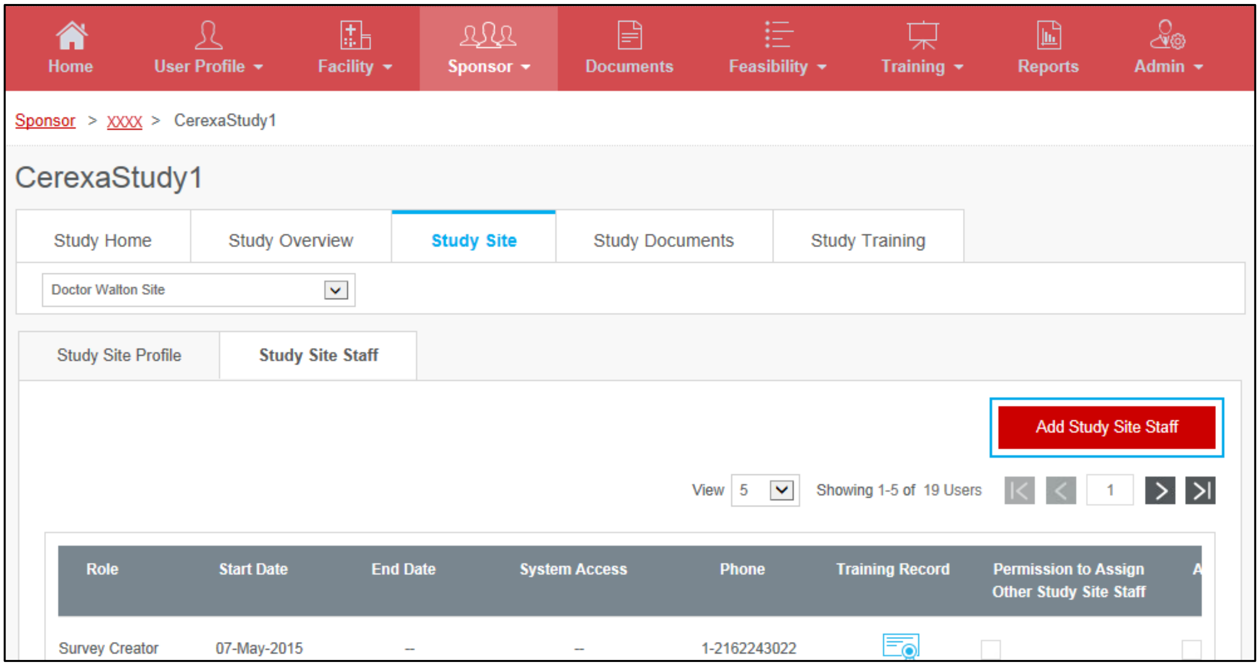


Figure 145. Study Site Staff Page

3. On the **Study Site Staff** page, click **Add Study Site Staff**. For Study Site Staff field descriptions, refer to Table 29. The Add Study Site Staff page is displayed.
4. Enter the relevant details and click **Search**.

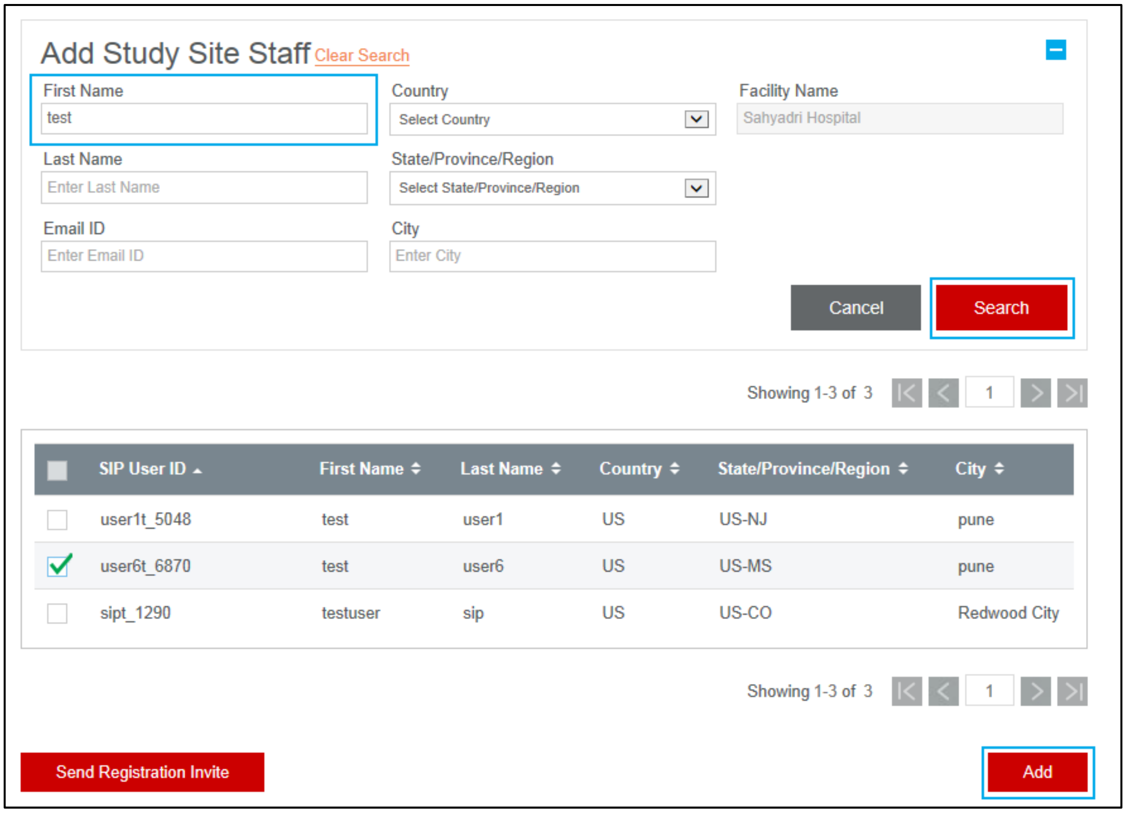


Figure 146. Add Study Site Staff Dialog Box

5. In the list of users displayed, select a user who needs to be assigned as a Study Site Staff.

The Search option is restricted only to the Site Users who have the Study Site Facility associated with their User Profile. If the search results does not display the relevant Site User, you need to invite the Site User to the Study Site. Refer to section: Send a registration Invite.

6. Click **Add**.

To edit Study Site Staff details

1. To edit a Study Site Staff record, on the **Study Site Staff** page, in the **Actions** column, click . The options including Role, Start Date, End Date, Permission to Assign Other Study Site Staff, and Assign as Designated Site Contact fields are enabled.

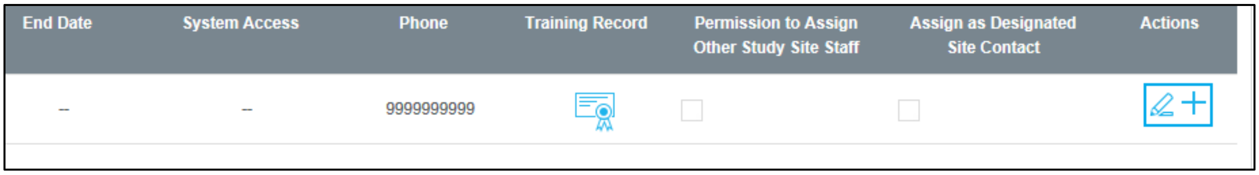


Figure 147. Edit Record Option

2. In the **Role** drop-down list, click a role for the Study Site Staff.

3. Click the date picker and then click a Start and End Date.

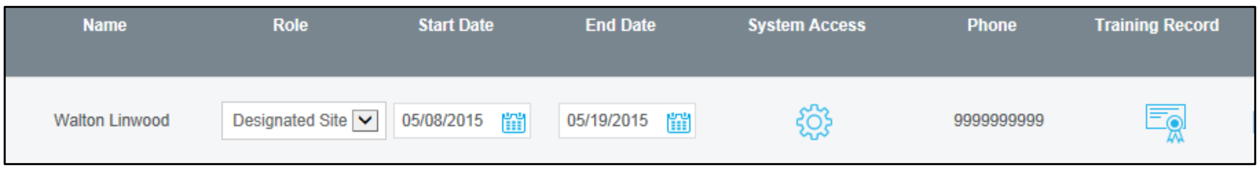


Figure 148. Edit Study Site Staff Details

4. To provide the rights to assign other Study Site Staff, in the **Permission to Assign Other Study Site Staff** column, select the check box.
5. To assign a staff member as a Designated Site Contact, in the **Assign as Designated Site Contact** column, select the check box.

Principal Investigator provides the permission to assign other Study Site Staff to a site.

Designated Site Contact receives all the communications that are sent to the Study Site, such as notifications in the SIP system and email. Designated Site Contact only receives Study Site communications and there are no other privileges.

---

6. To save the changes, click .

7. To add another role to existing Study Site Staff, in the **Actions** column, click **Add Role**. A new row with the user name is added. The options, Role, Start Date, and End Date fields are enabled.
8. Enter the details and click **Save**.

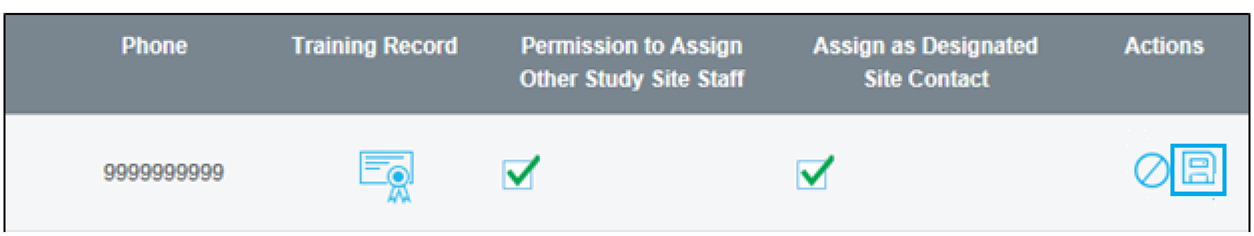


Figure 149. Save Option

To cancel the changes, click .

The following table provides the field descriptions for all the fields on the Study Site Staff page.

Field	Field Type	Mandatory Field	Field Descriptions
First Name	Text box	This is not a mandatory field.	First name of the Study Site Staff
Last Name	Text box	This is not a mandatory field.	Last name of the Study Site Staff
Email ID	Text box	This is not a mandatory field.	Email address of the Study Site Staff
Country	Drop-down list	This is not a mandatory field.	Name of the country in which the Study Site Staff resides. For example, United States.
State/Province/Region	Text box	This is not a mandatory field.	Name of the state or province or region in which the Study Site Staff resides. For example, California.
City	Text box	This is not a mandatory field.	Name of the city in which the Study Site Staff resides. For example, San Fransisco.
Facility Name	Text box	This is not a mandatory field.	Name of the Facility in which the Study Site Staff resides. For example, Primary Medicare Center.

Table 26. Field Descriptions for Study Site Staff

6.3.2.1. Send a Registration Invite

The Send Registration Invite feature allows the Site Users to invite other Site Users who are not yet registered in the SIP application.

To send a registration invite

1. On the **Add Study Site Staff** dialog box, click **Send Registration Invite**.

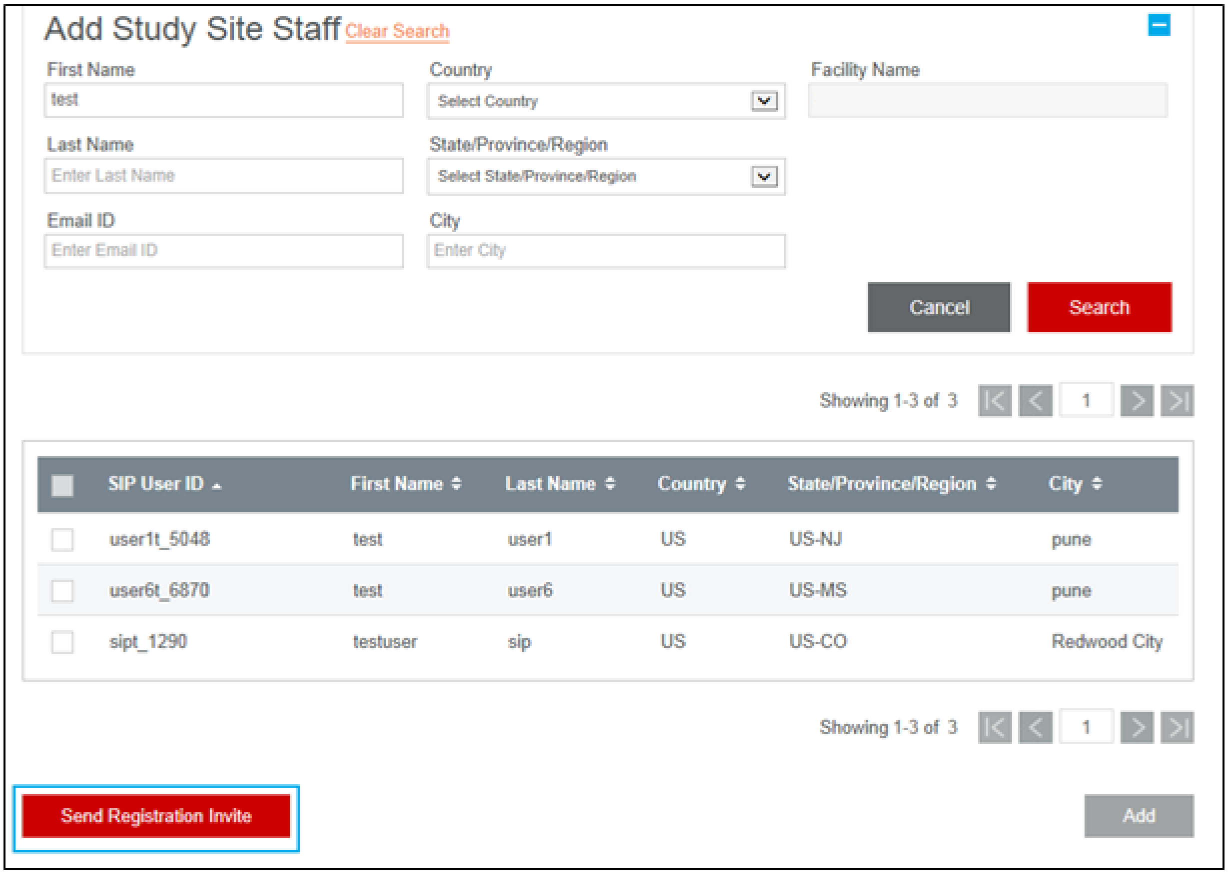


Figure 150. Add Study Site Staff Dialog Box: Send Registration Invite

2. In the **Email ID** box, enter the email address.

CAUTION *The Email ID box is a mandatory field.*

3. To send the invite, click **Send Invite**. A notification is sent to the Site User.

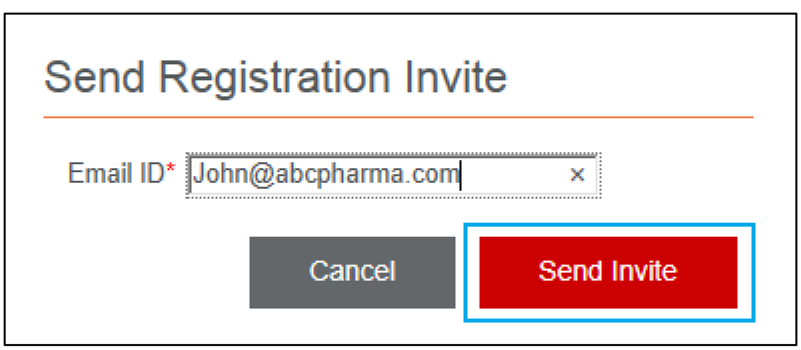


Figure 151. Send Registration Invite Dialog Box

4. If the Site User is already a registered SIP user but is not associated to the Study Site's Research Facility, the following message is displayed.

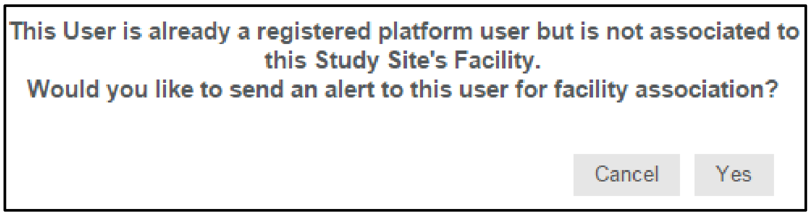


Figure 152. Facility Association Message Dialog Box

1. Click **Yes**. A notification is sent to the Site User.

6.4 Study-Specific Documents

The Study-specific Documents feature allows Site Users to receive Sponsor-generated Study-specific documents and submit requested site documents to Sponsors in support of site startup as well as throughout the study conduct. Site Users can Search for documents of interest and perform multiple Document Exchange Actions (such as. Send Message and Download) Study-specific documents include reference documents on clinical investigations, approved informed consent form templates, and delegation of authority logs.

Patient-specific documents should not be exchanged through SIP.

6.4.1 Upload a Study-Specific Document

The Upload a Study Document feature allows the Site Users to post Study-specific documents such as lab reference documents, Ethical Review Board Approvals, IRB/IEC Approval, Local Lab Certification, and the Protocol Signature page.

To upload a Study-specific document

1. On the **Document Search** page, click **Upload New Document**.

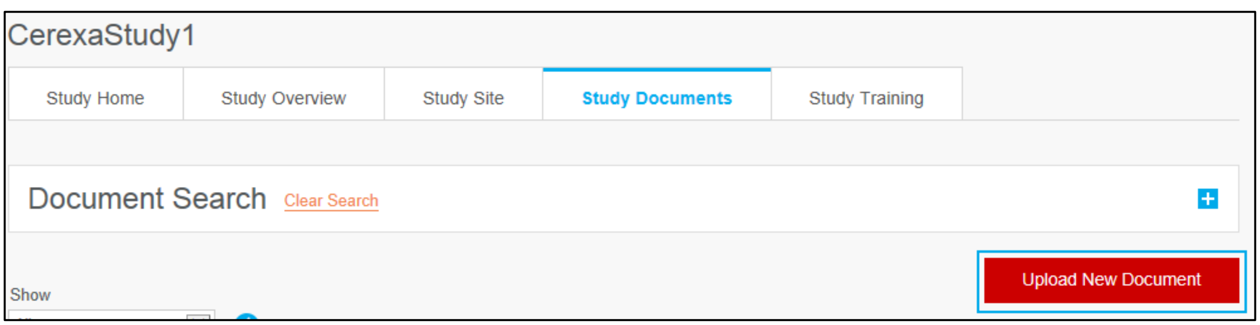


Figure 153. Upload New Document

2. On the **Upload New Document** page, enter the document details, For Upload New Document field descriptions, refer to Table 32.

3. In the **Choose a File** section, click **Browse**.
4. In the **Choose File to Upload** dialog box, browse to the location of the document, and then click **Open**.
5. To upload the document, on the **Upload New Document** page, click **Upload**.

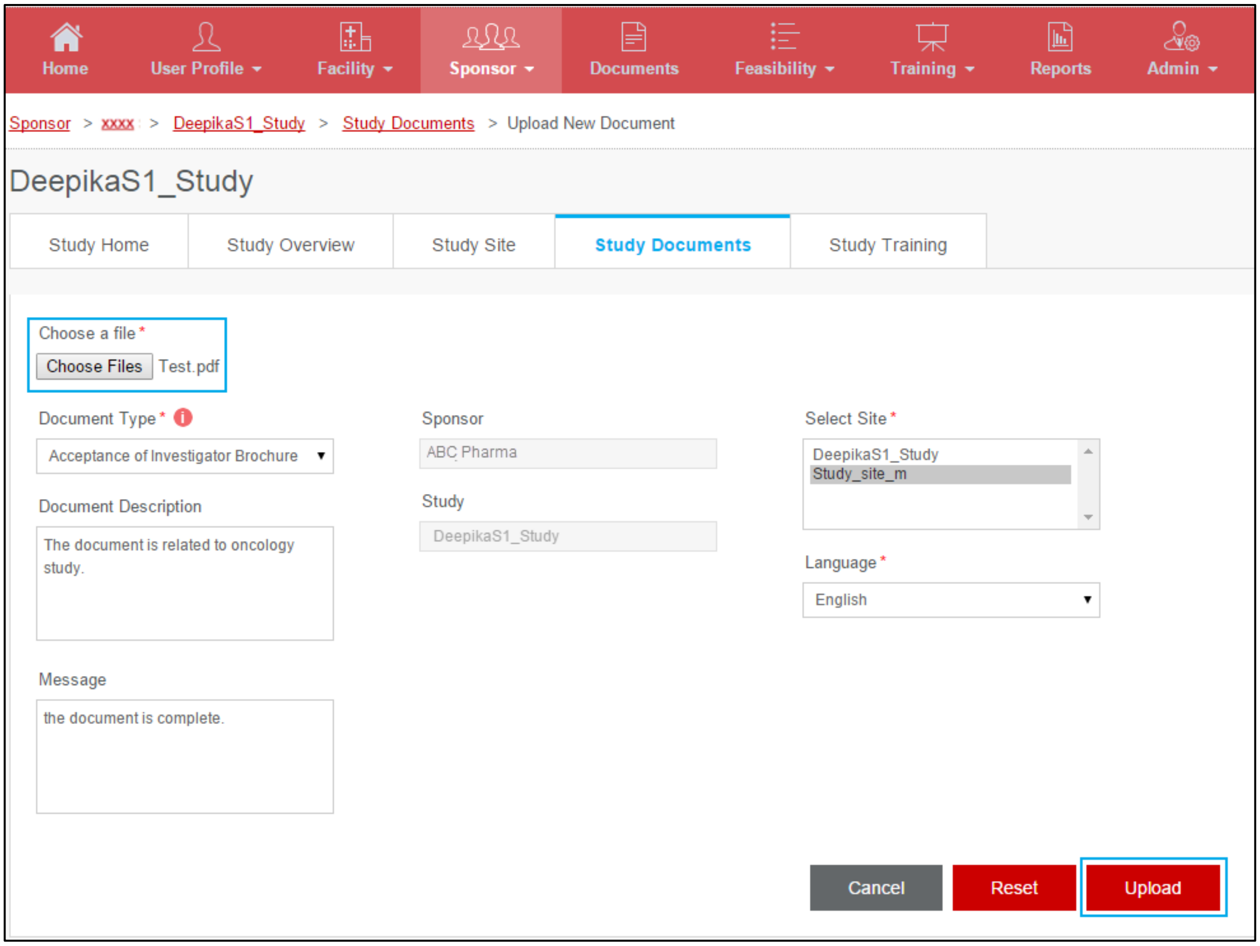


Figure 154. Upload New Documents Page

The following table provides the field descriptions for all the fields on the Upload a New Document page.

Field	Field Type	Mandatory Field	Field Descriptions
Choose a file*	Button	This is a mandatory field.	Click Choose a file button. Browse for and select the relevant file. Click Open and then click Upload.

Document Type*	Drop-down list	This is a mandatory field.	This is the type of the document. Examples are Study Protocol, Investigator's Brochure and Financial Disclosure.
Document Descriptions	Text box	This is not a mandatory field.	This is a brief note on the objective or content of the document.
Language *	Drop-down list	This is a mandatory field.	This is the language of the document uploaded.
Select Site*	Text box	This is a mandatory field.	This refers to the name of the Study Site associated with the document.
Message	Text box	This is not a mandatory field.	This is the message that needs to be sent to the document recipient.

Table 27. Field Descriptions for Upload New Document

6.4.2 Search for a Study-Specific Document

The Search feature allows the Site Users to search for and select a clinical research document based on search parameters such as Document Title, Document Type, Document Package, Study Name, Country, Document Uploaded By, From and To Date, and Site. Also the Advanced Search feature allows the Site Users to search for and select a clinical research document based on the search parameters such as User, Original File Name, and Metadata Last Modified by, Metadata Modified Date, Status, File Format, Viewed, and Language.

To search for a study document

1. On the Study page, click the **Study Documents** tab.

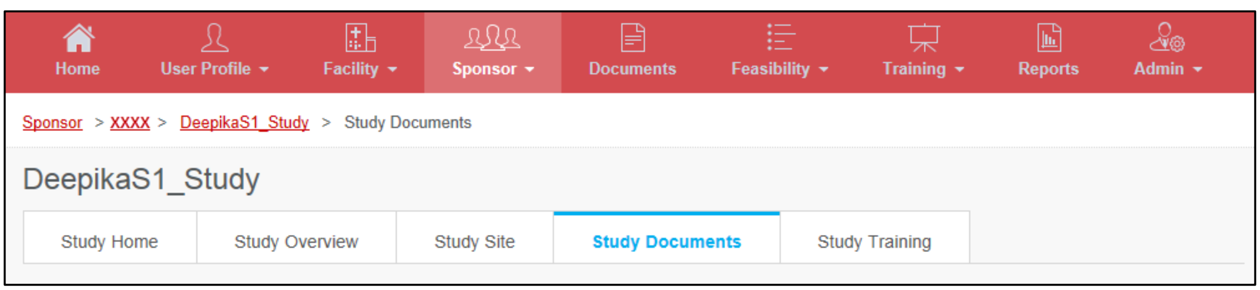


Figure 155. Study Documents Tab

2. In the **Document Search** section, click . The search fields are displayed.
3. To search for a document, in the relevant fields, enter or click any or all of the required search criteria. For Search for Document field descriptions, refer to Table 30.

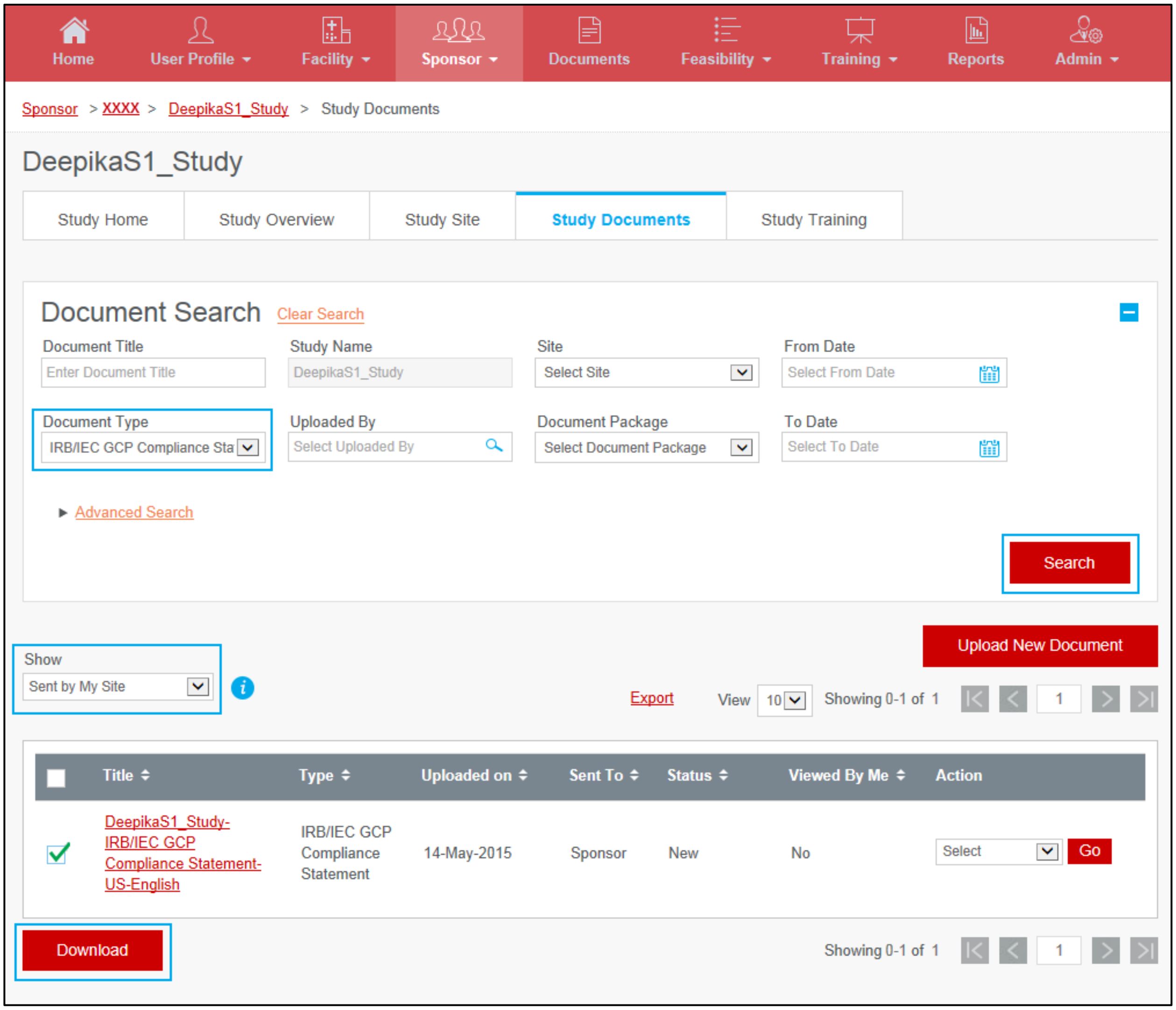


Figure 156. Study Document Search Page

4. Click **Search**. The search results are displayed.

5. To filter the search results further, perform the following action:

   a. In the **Show** drop-down list, click one of the options:

      - **Sent to Site**

        All documents sent to the Study Site associated to the Site User are displayed

      - **Sent by My Site**

        All documents sent by any Study Site that the Site User is associated with are displayed.

      - **Sent to Me**

        - All documents sent to the Site User are displayed.

6. To download a study document, in the search results displayed, select a document that you want to download, and then click **Download**. The document is downloaded to the local drive of the system.
7. To export the document search results, on the **Document Search** page, click **Export**.
8. On the **Export** dialog box, in the **Choose Format** section, click a format, and then click **OK**. The relevant document is displayed.

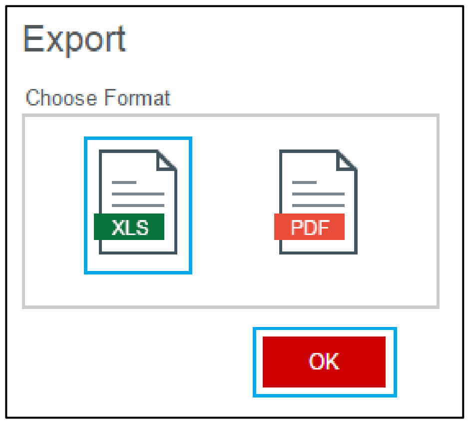
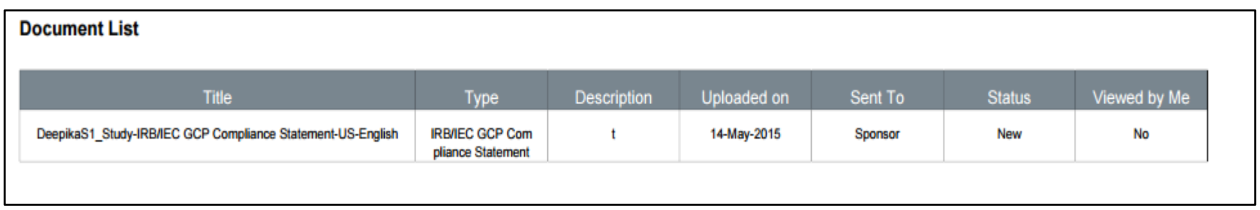


Figure 157. Search for a Document: Export Dialog Box



Document List

Title	Type	Description	Uploaded on	Sent To	Status	Viewed by Me
DeepikaS1_Study-IRB/IEC GCP Compliance Statement-US-English	IRB/IEC GCP Compliance Statement	t	14-May-2015	Sponsor	New	No

Figure 158. Document Search Results Exported

The following table lists the descriptions for all the fields displayed on the Document Search page.

Field	Field Type	Mandatory Field	Field Descriptions
Document Title	Text box	This is not a mandatory field.	This is the title of the document.
Document Type	Drop-down list	This is not a mandatory field.	This is the type of the document. For example, Study Protocol, Investigator’s Brochure, Financial Disclosure, and Reference Document.
Document Package	Drop-down list	This is not a mandatory field.	This is the type of the Document Package that a Sponsor User uses, while uploading the document.

Study Name	Drop-down list	This is not a mandatory field.	This is the protocol number of the study.
Site	Drop-down list	This is not a mandatory field.	This is the name of the Facility in which the study was conducted.
From Date	Date picker	This is not a mandatory field.	This date refers to the date of upload of the document. Documents uploaded prior to this date are not returned in the search results.
To Date	Date picker	This is not a mandatory field.	This date refers to the date of upload of the document. Document uploaded after this date is not returned in the search results.
Uploaded By	Search	This is not a mandatory field.	This is the Site User who has uploaded the document.

Table 28. Field Descriptions for Search for Document

To search for a study document by using advanced search option

1. In the **Document Search** section, click **Advanced Search**. The advanced search fields are displayed.

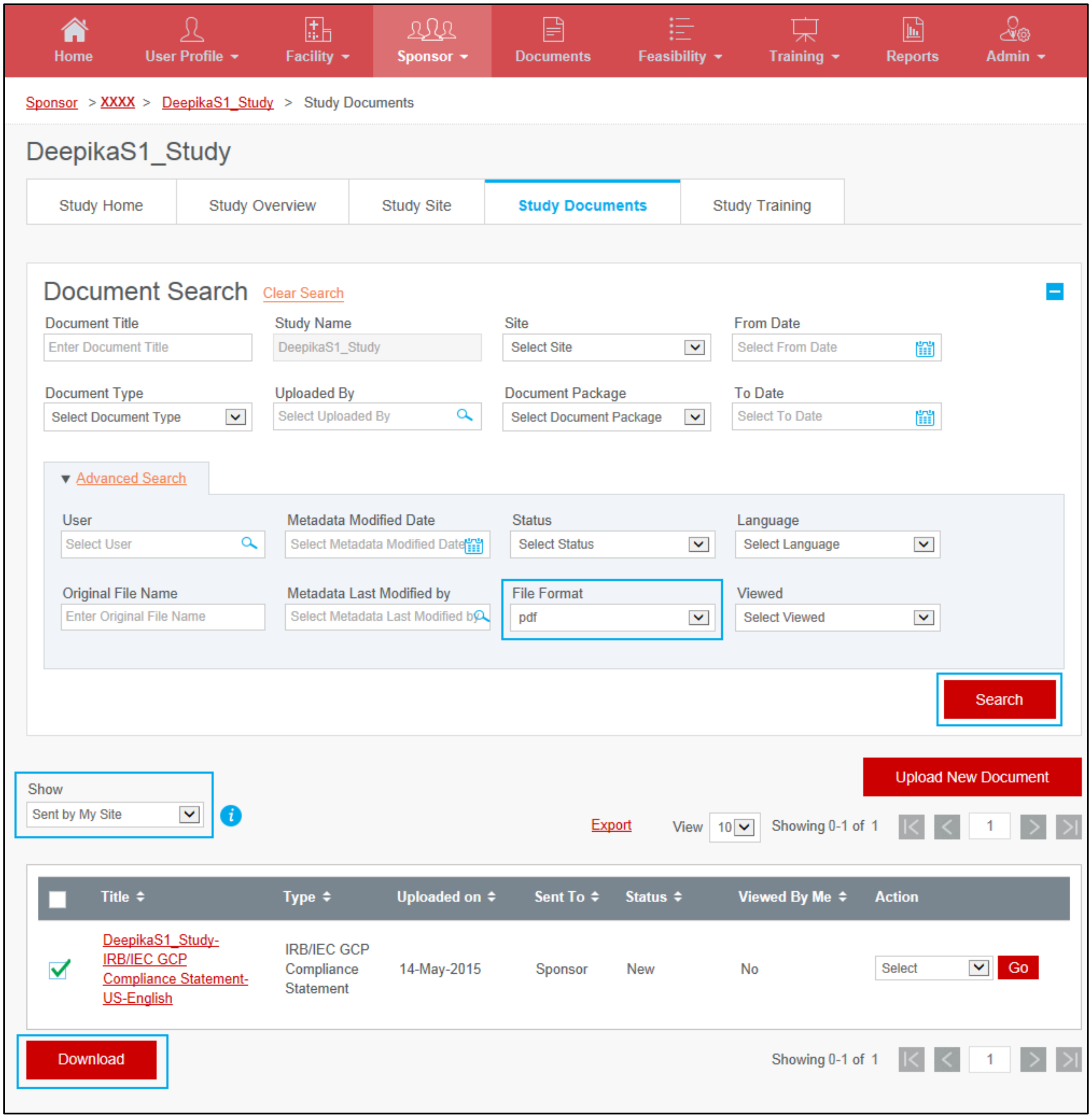


Figure 159. Advanced Search for a Study Document

2. To search for a document, in the relevant fields, enter the required search criteria. For Advanced Search for Document field descriptions, refer to Table 31.

3. Click **Search**. The search results are displayed.

4. To filter the search results further, perform the following action:

   a. In the **Show** drop-down list, click one of the options:

      - **Sent to Site**

All documents sent to the Study Site associated to the Site User are displayed.

- **Sent by My Site**

  All documents sent by any Study Site that the Site User is associated with are displayed.

- **Sent to Me**

  All documents sent to the Site User are displayed.

5. To export the document search results, on the **Document Search** page, click **Export**.
6. On the **Export** dialog box, in the **Choose Format** section, click a format, and then click **OK**. The relevant document is displayed.

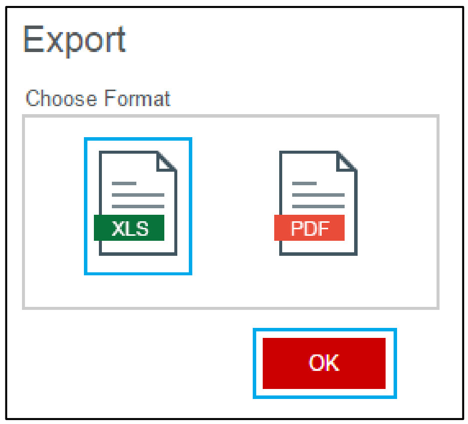


Figure 160. Search for a Document: Export Dialog Box

Document List

Title	Type	Description	Uploaded on	Sent To	Status	Viewed by Me
DeepikaS1_Study-IRB/IEC GCP Compliance Statement-US-English	IRB/IEC GCP Com pliance Statement	t	14-May-2015	Sponsor	New	No

Figure 161. Document Search Results Exported

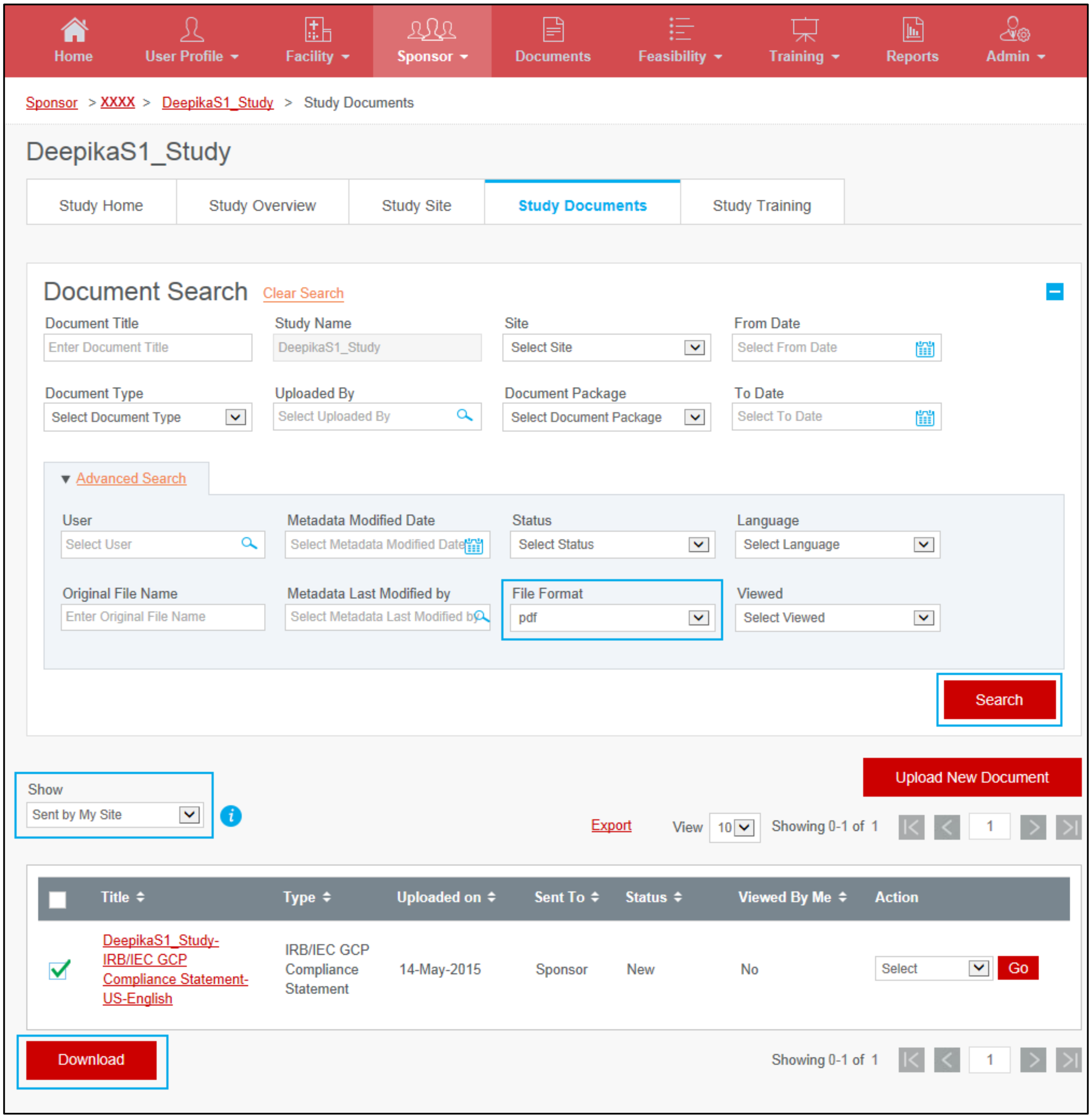


Figure 162. Advanced Search for a Study Document

The following table lists the descriptions for all the fields displayed for the Advanced Search for a Document section.

Field	Field Type	Mandatory Field	Field Descriptions
User	Search	This is not a mandatory field.	This is the name of the Site User to whom the document was sent.
Original File Name	Text box	This is not a mandatory field.	This is the name of the document uploaded by the Sponsor User or Site User.
Metadata Last Modified By	Text box	This is not a mandatory field.	This is the name of the Site User who last modified the metadata.
Metadata Modified Date	Date picker	This is not a mandatory field.	This is the latest date on which the metadata of the document was modified.
Status	Drop-down list	This is not a mandatory field.	This is the status of the document.
File Format	Drop-down list	This is not a mandatory field.	This is the file format of the uploaded document.
Viewed	Drop-down list	This is not a mandatory field.	If the document is viewed, click **Yes**. Otherwise, click **No**.
Language	Drop-down list	This is not a mandatory field.	This is the language of the uploaded document.

Table 29. Field Descriptions for Advanced Search for Document

6.4.3 Document Exchange Actions

You can use SIP to perform the following actions on the documents:

- **Send Message**
  The Site User can send a message to a Sponsor User with respect to the document for clarifications. After sending a message, the recipient will receive an email and a notification.

- **Download**
  The Site Users can download a document.

- **View Details**
  The Site Users can view the metadata of the document. They can view the document details such as Document Type, Document Description, Study Site, Sponsor, and Language details.

- **Edit**
  There is an Edit option available in the **Action** drop-down list. The Site Users can edit a few attributes of the document: Document Type, Document Description, Language, and Site. Not all attributes are editable.

- **History**
  Site Users can view the document history. You can use this feature to view the document history and Site User access details. The Site User can use this option to identify the User ID and the document modified date. Site Users can view the changes made to the metadata of the document. You can view all associated information, which include the last modified date and name of the Site User who last modified the document, metadata pertaining to a document, and access records of the document.

- **Delete**
  Site Users can delete a document uploaded by them by using the delete option. A document cannot be deleted after the Sponsor User or a Site User has accessed the document for the first time. After you click delete, you need to confirm that you want to delete the document from SIP.

6.4.3.1. Send Message

The Send Message feature allows the Site Users to send a message to the Sponsor User about a document. A sample message is as follows: Document is signed by the Principal Investigator as instructed.

To send a message to a Sponsor User

1. In the search results displayed, in the **Action** drop-down list, corresponding to the document you want to send, click **Send Message**, and then click **Go**.

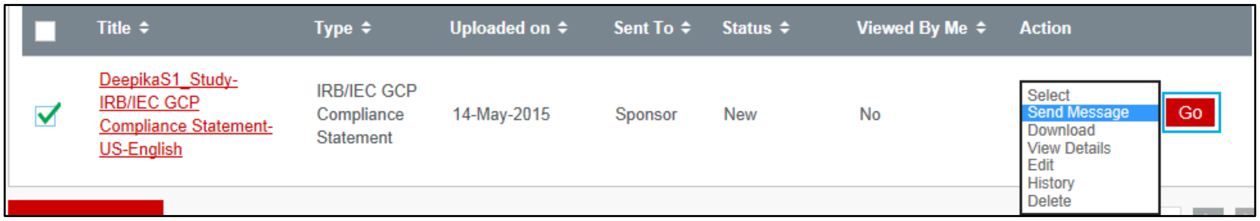


Figure 163. Action List: Send Message

2. In the **Send Message To** window, enter any or all of the search criteria such as First Name, Last Name, and Study Name. Click **Search**.

3. To filter the search results further, perform one or both of the following actions:

    a. In the **Show** drop-down list, click the name of the required country. The results are filtered to display the list of Sponsor Users who belong to that country.

    b. In the **Users** drop-down list, click the required Sponsor User type. The results are displayed in accordance with your filter criteria.

    c. If you clicked both the drop-down lists, the selected Sponsor Users of the selected country are displayed.

4. In the displayed search results, select the check box corresponding to the name of the Sponsor User to whom you want to send the message.

5. In the **Message** box, enter the message that needs to be sent. The message can contain information on the action expected from the recipient or the intended purpose of sending the document, even if no action is warranted.

6. To send the message, click **Send Message**.

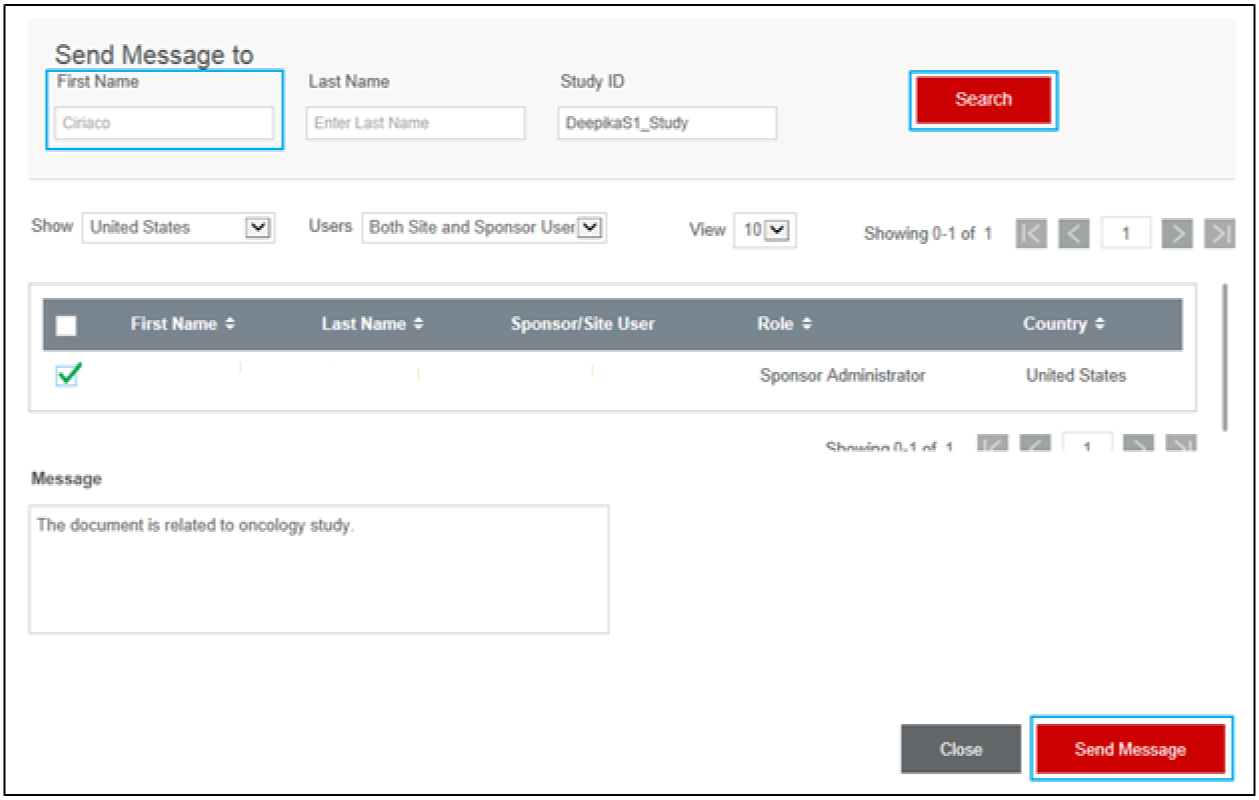


Figure 164. Send Message To Window

6.4.3.2. *Download a Document*

The Download feature allows the Site User to download a document. In the Study Documents tab, all documents are displayed.

You can download a document in the **Action** drop-down list.

To download a document

1. In the search results displayed, in the **Action** drop-down list, corresponding to the document that you want to download, click **Download**, and then click **Go**.

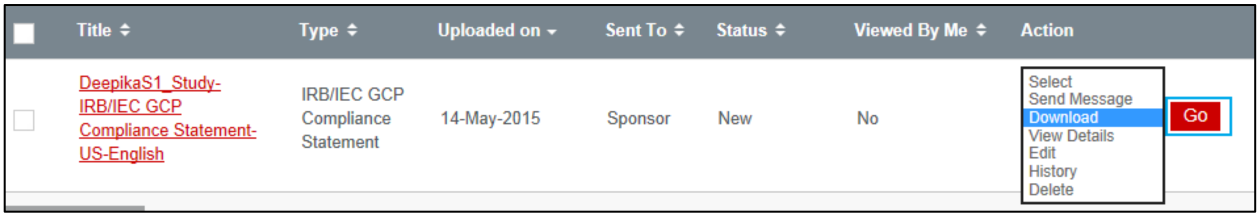


Figure 165. Action List: Download

Or,

Alternatively, to download more than one document at a time, select the check boxes next to the documents that you want to download. Now, click **Download**.

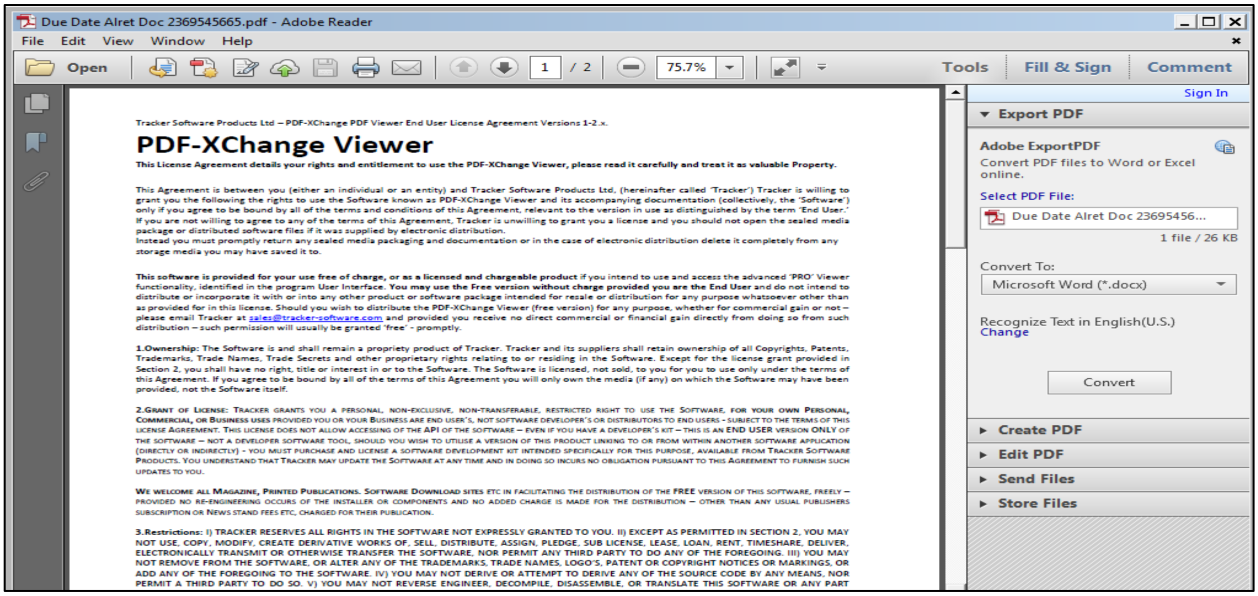


Figure 166. Downloaded Document

When multiple documents are downloaded together, a zip file containing all the selected documents is generated. The zip file is named "document.zip". The files inside the zip file will have the original file names of uploaded documents.

6.4.3.3. View Document Details

The View Document Details feature allows the Site User to view the document metadata.

To View document details

1. In the search results displayed, in the **Action** drop-down list, corresponding to the document whose details you want to view, click **View Details**. Click **Go**. The View Document details page is displayed.

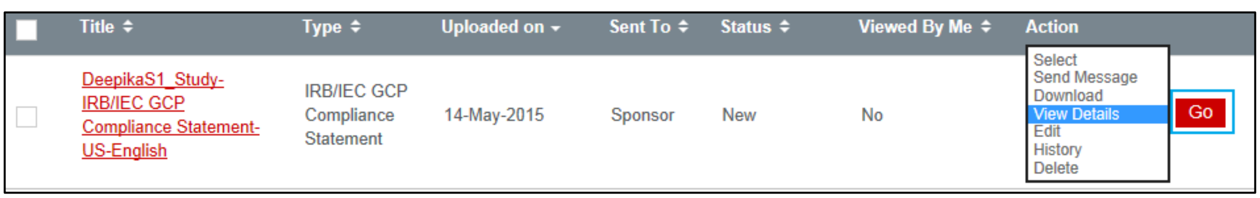


Figure 167. Action List: View Details

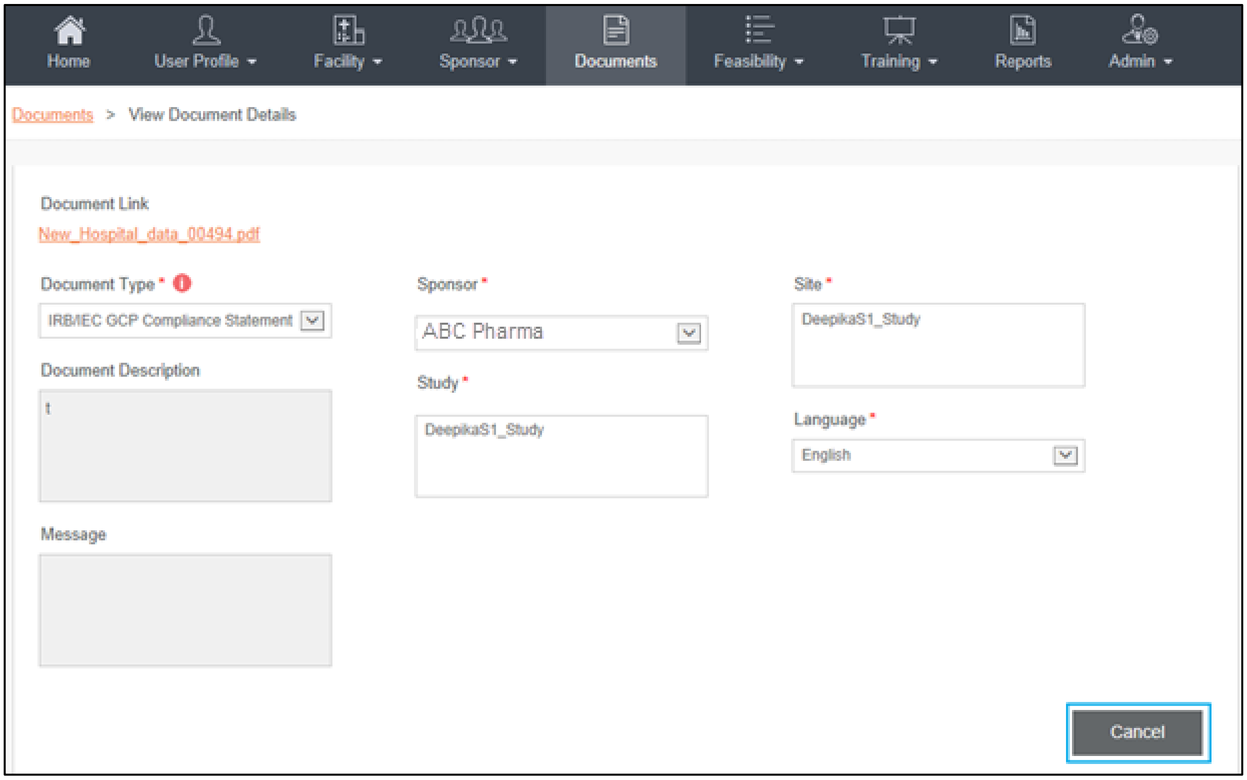


Figure 168. View Details Page

6.4.3.4. *Edit Document Details*

The Edit Document Details feature allows the Site User to edit the details describing the document, also known as metadata. Site Users can edit the metadata of documents that they uploaded. Sponsor and study details cannot be edited. When the changes are saved, the recipient will receive a notification on the updates to the document metadata.

To edit the document metadata

1. In the search results displayed, in the **Action** drop-down list corresponding to the document you want to edit, click **Edit**, and then click **Go**.

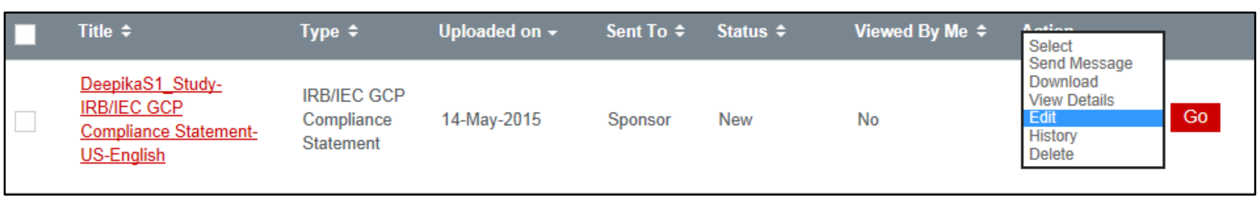


Figure 169. Action List: Edit

2. On the **Edit** page, edit any or all of the following details:

   a. In the **Document Type** drop-down list, click a document type.

   b. In the **Document Description** box, enter the description.

   c. In the **Message** box, enter the message.

   d. In the **Select Site** drop-down list, click an appropriate site.

   e. In the **Language** drop-down list, click a required language.

3. To save the changes, click **Save**.

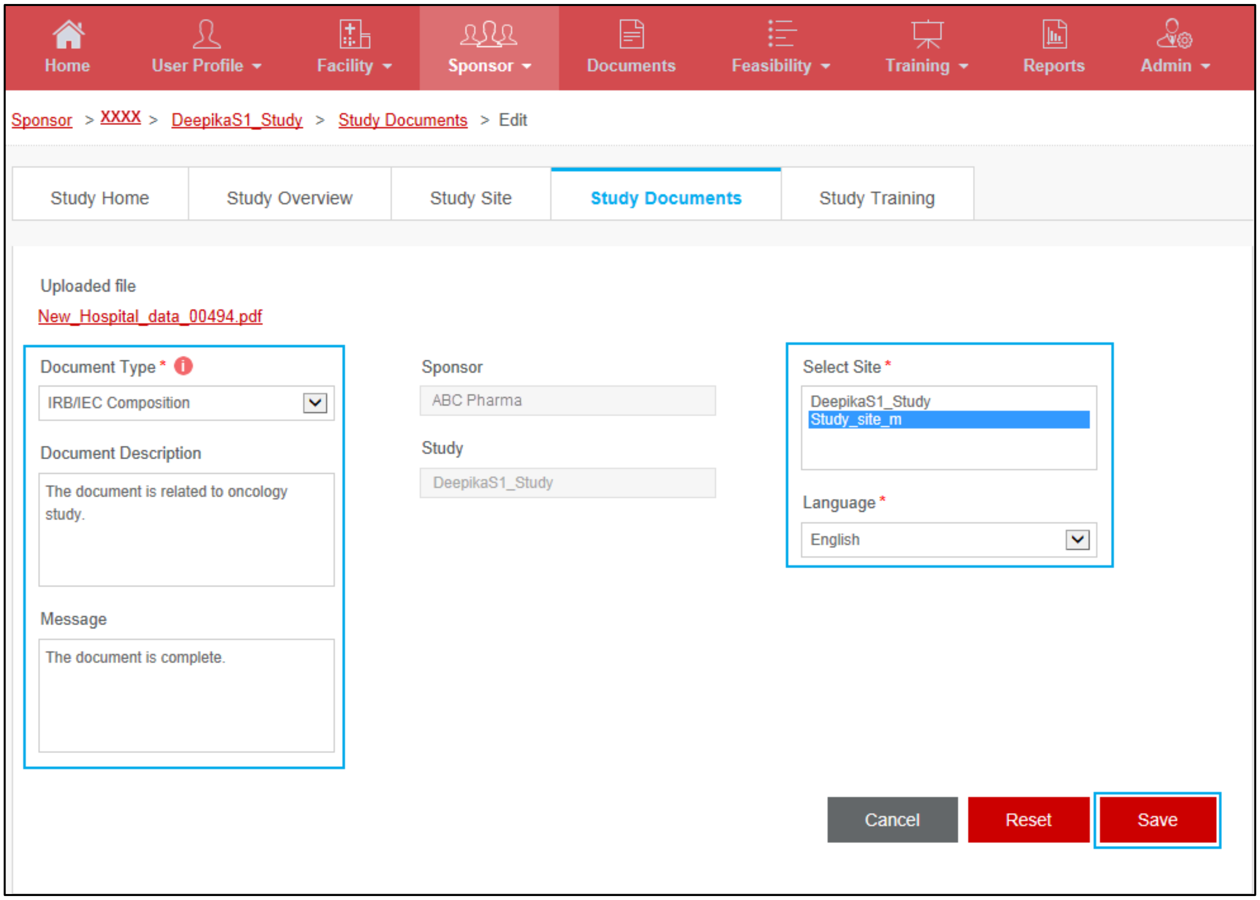


Figure 170. Edit Document Details Page

6.4.3.5. View Document History

The History feature allows the Site User to view and export the document history details.

To view the document history

1. In the search results displayed, in the **Action** drop-down list corresponding to the applicable document, click **History**, and then click **Go**. The history of that document is displayed.

   The following are the key information highlighted on this page:

   - Date document was uploaded and the identity of the Site User who uploaded it.
   - Details about all the Site Users who have accessed the document till date

- Document status
- Last modified date
- Deletion record of the document, if applicable

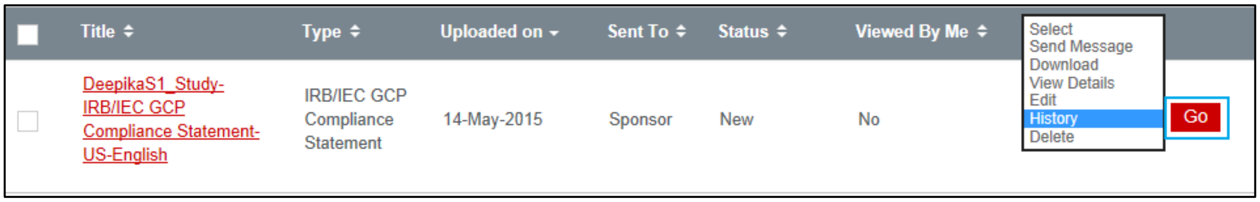


Figure 171. Action List: History

To close the window, click **Close Window**.

2. To export the document history details, in the **History** window, click **Export**.

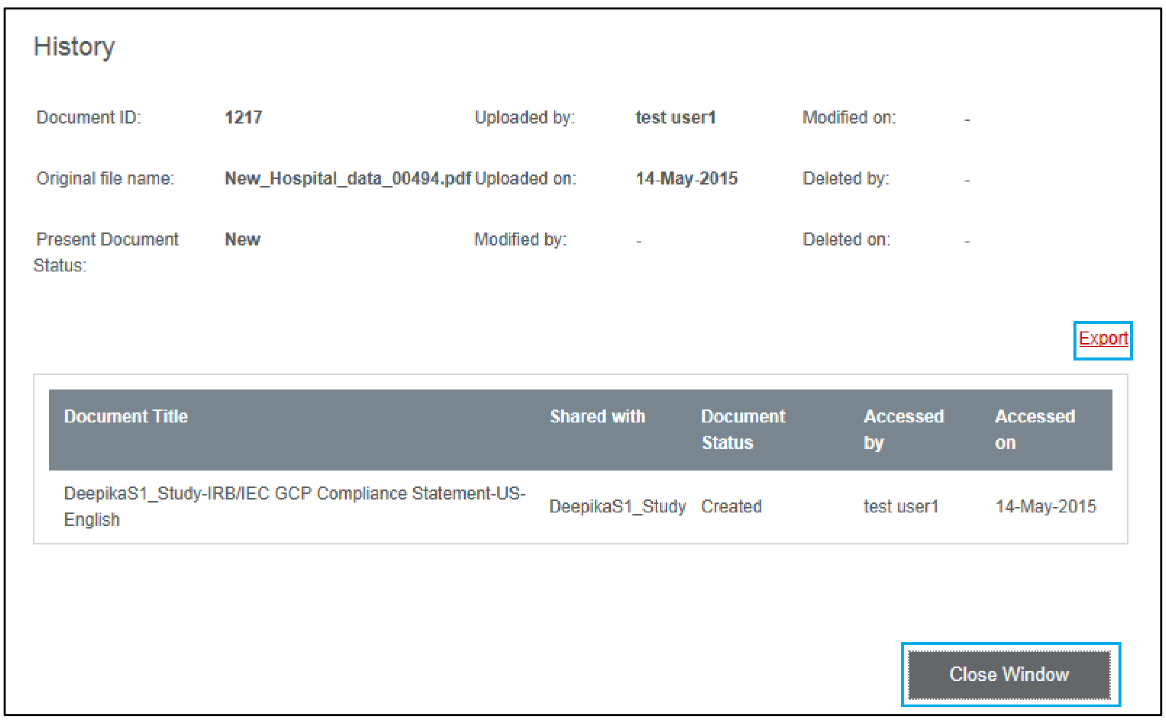


Figure 172. Document History Window

3. In the **Export** dialog box, in the **Choose Format** section, click a required format, and then click **OK**. The relevant document is displayed.

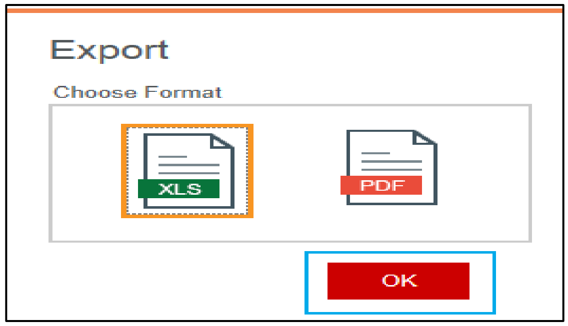
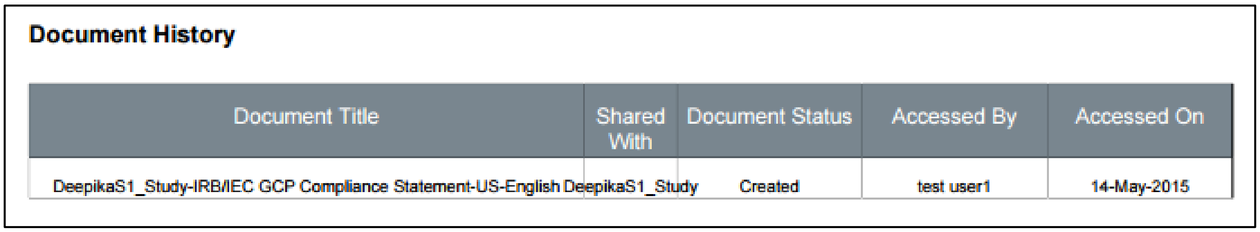


Figure 173. Document History: Export Dialog Box



Document History

Document Title	Shared With	Document Status	Accessed By	Accessed On
DeepikaS1_Study-IRB/IEC GCP Compliance Statement-US-English	DeepikaS1_Study	Created	test user1	14-May-2015

Figure 174. Document History Exported

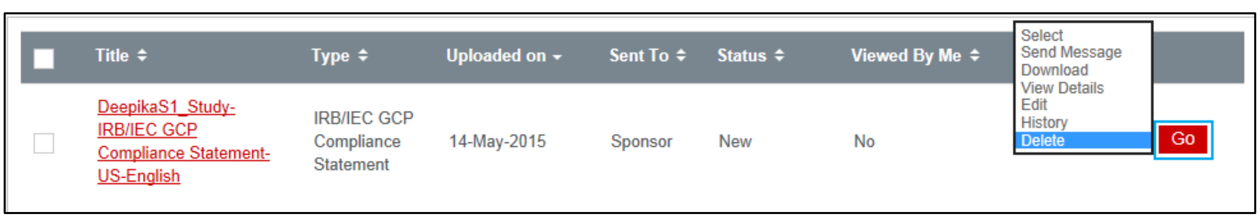
6.4.3.6. Delete a Document

Site Users can delete only the documents that they uploaded. A document cannot be deleted after a Sponsor User or a Site User has accessed the document.

If a document is uploaded in error and has been accessed by another Site User, the Sponsor can request the deletion of the document through a request to the SIP Help desk.

To delete a document

1. In the search results displayed, in the **Action** drop-down list corresponding to the document you want to delete, click **Delete.** Now click **Go**.



	Title	Type	Uploaded on	Sent To	Status	Viewed By Me	
	DeepikaS1_Study-IRB/IEC GCP Compliance Statement-US-English	IRB/IEC GCP Compliance Statement	14-May-2015	Sponsor	New	No	Select / Send Message / Download / View Details / Edit / History / Delete — Go

Figure 175. Action List: Delete

1. In the **Do you Want to Delete This Document** dialog box displayed, click the **Reasons** drop-down list and select the reason/s for the deletion. Now, click **OK**.

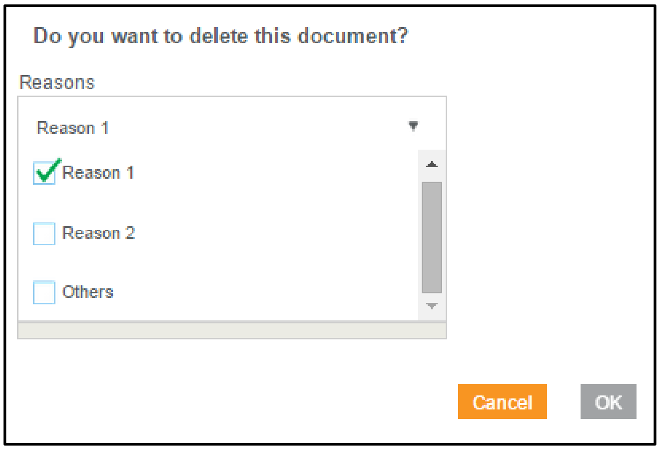


Figure 176. Delete Document: Confirmation Message

6.5 Study Training

The Study Training feature allows Site Users to launch assigned study-specific trainings as well as view the completion certificate for any completed study-specific courses.

Each Sponsor may have their own training course, which may be mutually recognized across multiple Sponsors. For example, Global clinical Practice (GCP) training. However, the Site User needs to complete only one such assigned course to receive credit from multiple Sponsors. After the completion of a course, the Site User need not take the same course again when another Sponsor assigns it.

Site Users can perform the following tasks:

- Search for Assigned and Completed Courses
- Launch Training Courses

6.5.1 Assigned Training

The Assigned Training feature allows Site User to view the Assigned Training records. Site Users can also access self-assigned courses from My Training.

To launch a assigned training course

1. In the **Training** menu of the SIP User Landing Page, click a required study.
2. On the Study page, click the **Study Training** tab.
3. In the **Search** section of the **Assigned Training** tab, enter or select any or all of the search criteria, and then click **Search**. For Search for Course field descriptions, refer to Table 33.

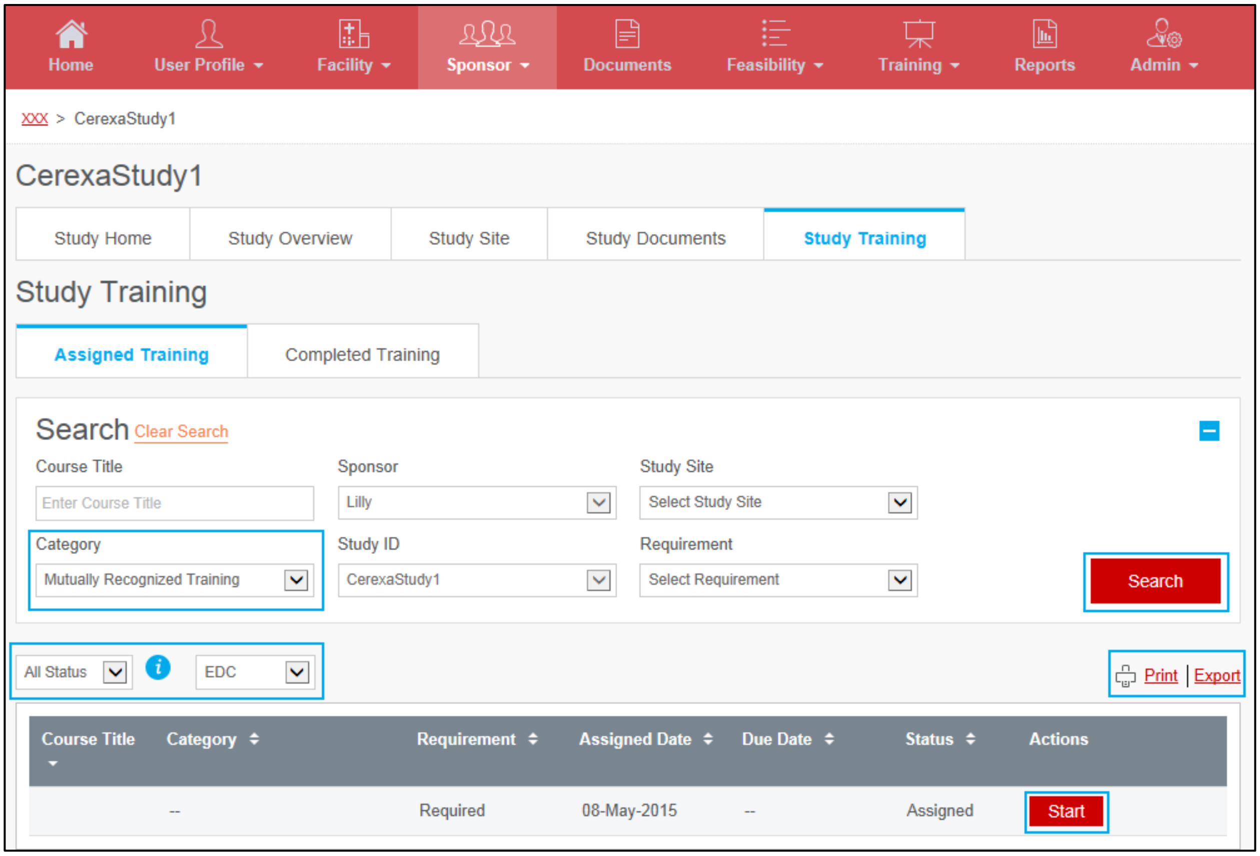


Figure 177. Search an Assigned Training Course

4. To filter the search results further, perform one or both the following actions:

   a. In the **All Status** drop-down list, click one of the options:

      - **Assigned**

        Displays assigned courses that the Site User has not yet accessed

      - **In-progress**

        Displays assigned courses that were started, but not completed

      - **Overdue**

        Displays courses that have not yet been completed as of the published Due Date

      - **Registered**

        Displays courses that were self-assigned by the Site User in the Find a Course feature and are yet to be completed. Self-assigned courses are not assigned a Due Date and will remain on the Assigned Training page until completed.

   b. In the **Type** drop-down list, click an option.

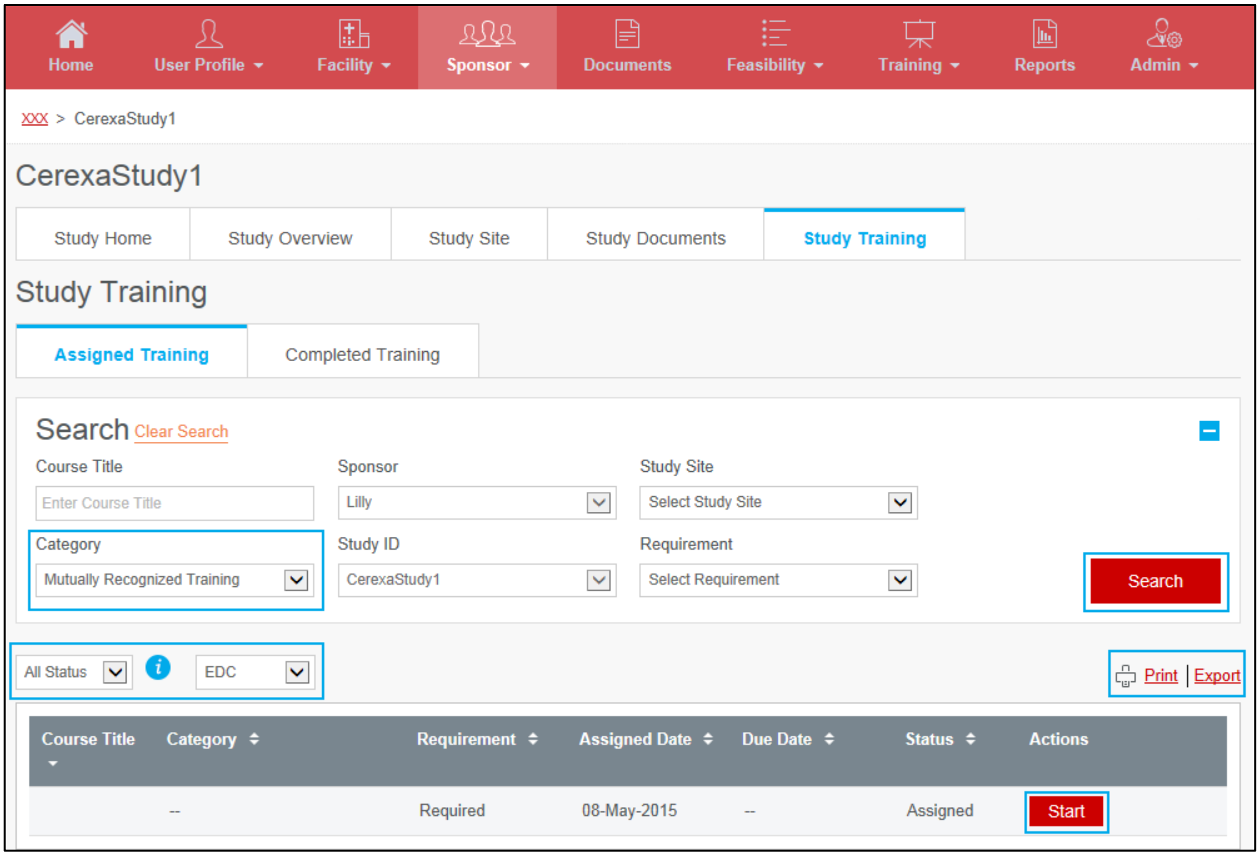


Figure 178. Search an Assigned Training Course

5. To print the assigned training details, on the **Assigned Training** page, click **Print**.

6. To launch a course, in the search results displayed, in the **Actions** column, click **Start**. The selected course page is displayed.

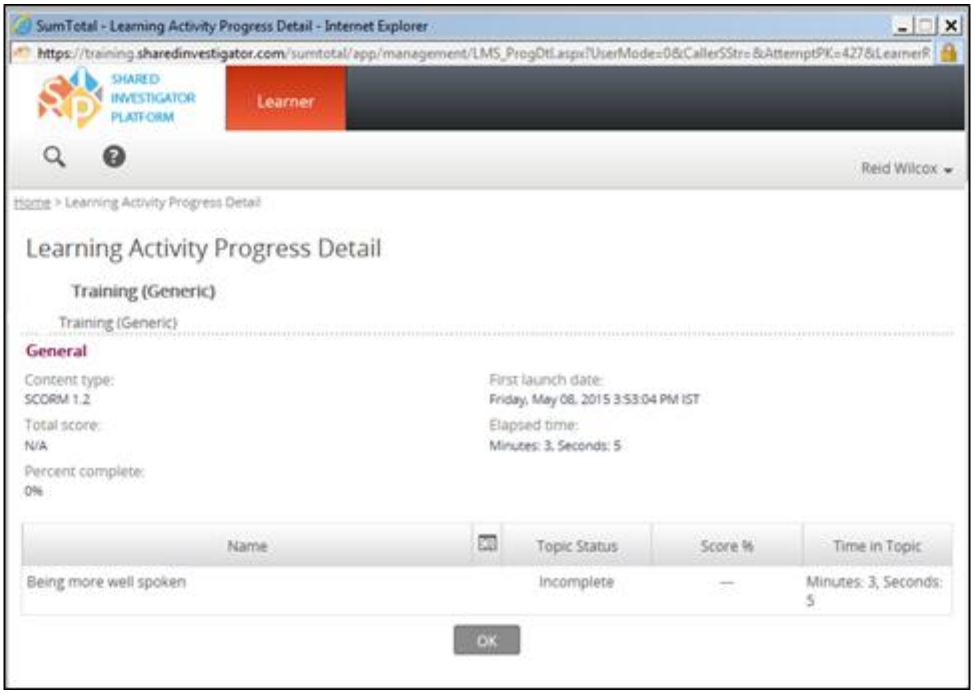


Figure 179. Learning Course Page

7. To export the assigned training details, on the **Assigned Training** page, click **Export**. The following dialog box is displayed.

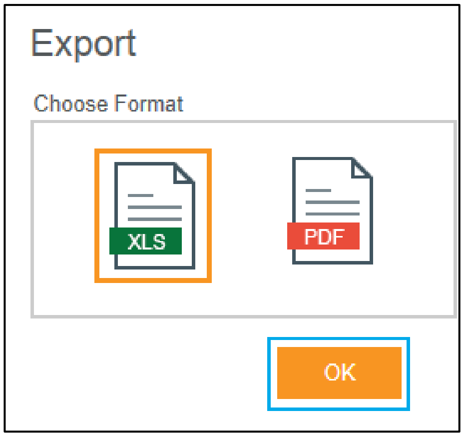


Figure 180. Export Assigned Training Course Dialog Box

8. On the **Export** dialog box, in the **Choose Format** section, click a required format, and then click **OK**.

6.5.2 Completed Training

This feature allows the Site Users to view and re-launch all completed trainings.

To search a completed training course

1. On the Study page, click the **Study Training** tab.

2. On the **Search** section of the **Completed Training** tab, enter or select any or all of the search criteria, and then click **Search**. For Search for Course field descriptions, refer to Table 35.

To filter the search results further:

1. In the **Type** drop-down list, click a required option.

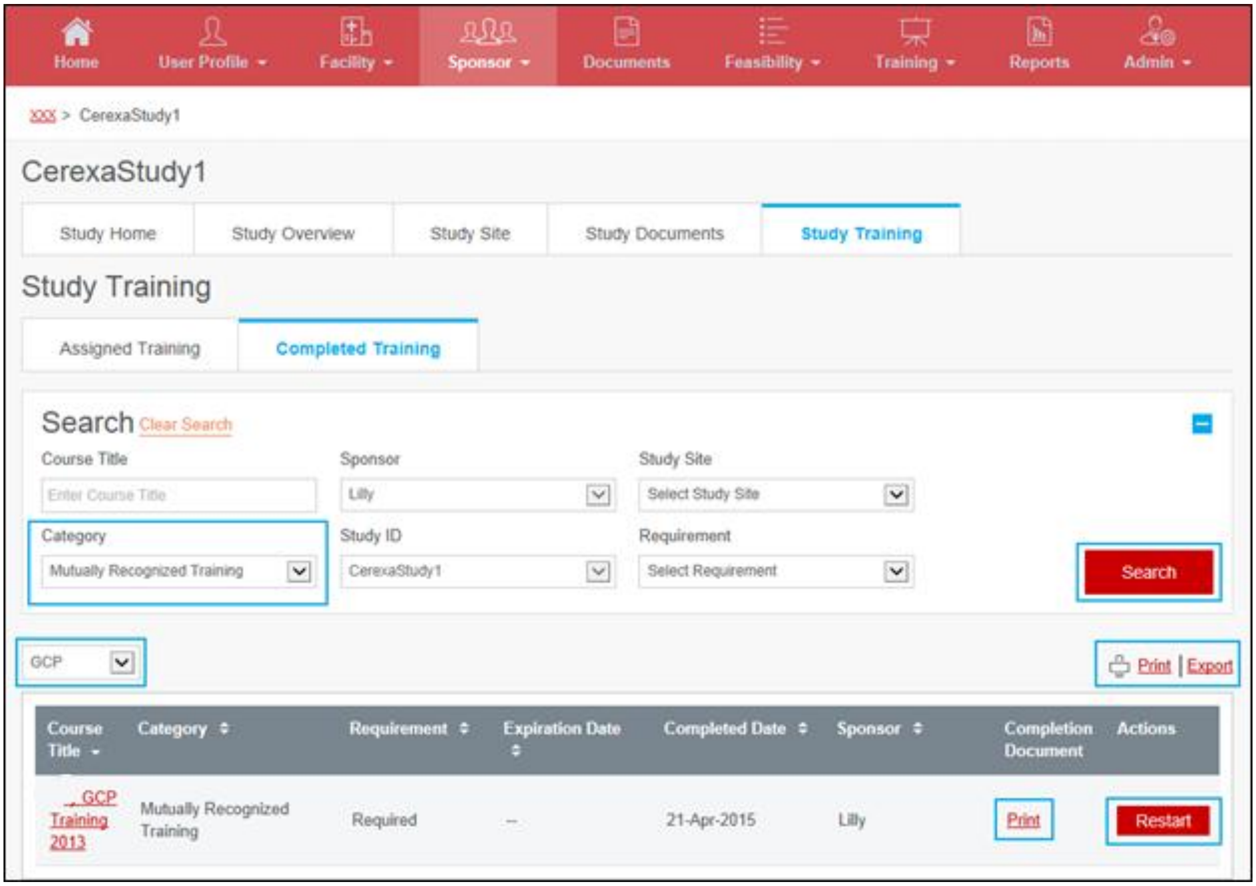


Figure 181. Search a Completed Training Course Page

2. To print the completed training details, on the **Completed Training** page, click **Print**.

3. To print the completion documents or certificates, in the **Completion Document** column corresponding to the course that you want a certificate, click **Print**.

4. To re-launch a course, in the **Actions** column of the search results displayed, click **Restart**. The selected course page is displayed.

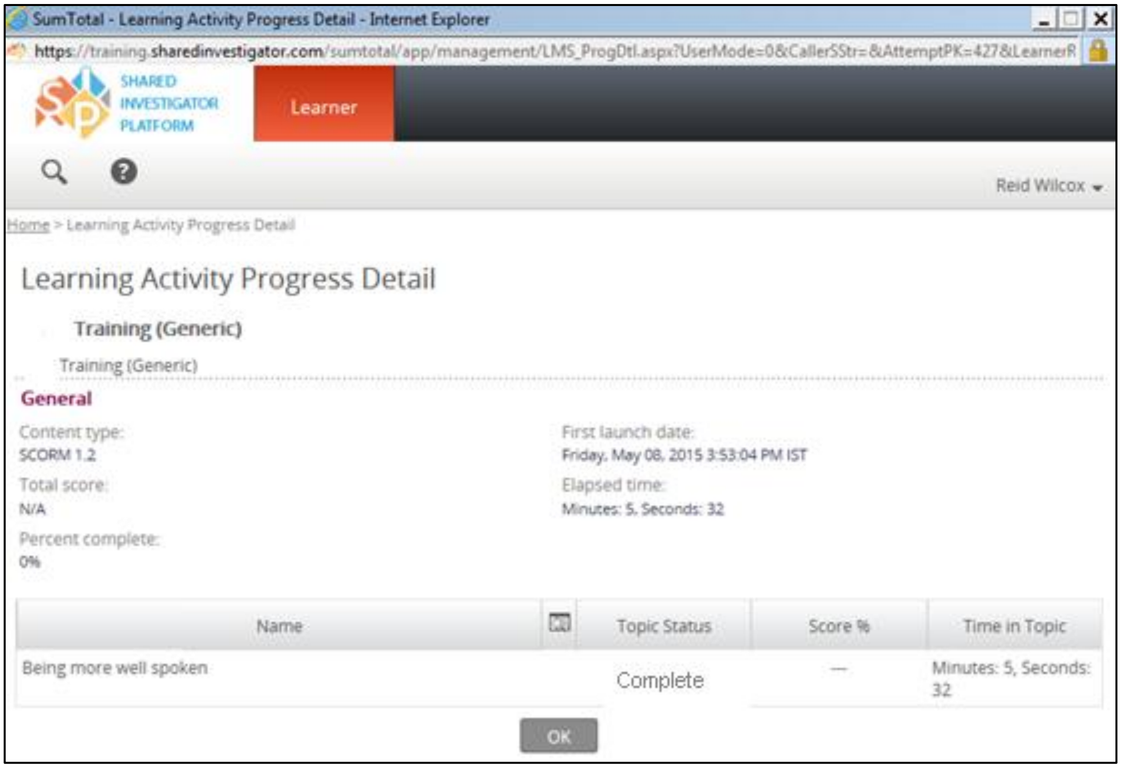


Figure 182. Learning Course Page

5. To export the completed course details, click **Export**. The following dialog box is displayed.

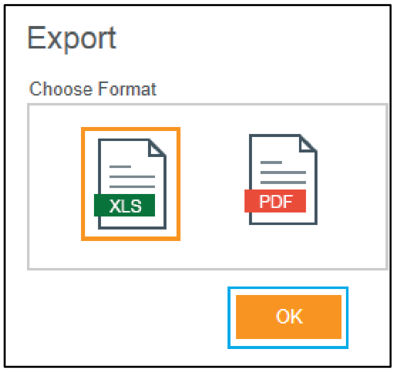


Figure 183. Export Completed Training Course Dialog Box

6. In the **Export** dialog box, click a required format: **XLS** or **PDF**, and then click **OK**.

7 Manage Documents Exchange

Site Users can use the Document Exchange feature to exchange information securely. This feature allows Site Users to exchange non–study-specific documents. Site Users can upload, edit, view, and delete non–study-specific documents.

SIP is not intended to be the Investigative Site File. All documents must be downloaded, printed and filed appropriately at your site. Patient-specific documents should not be exchanged through SIP.

Site Users can exchange documents by using the following modules:

- **Workspace Module**: Study-specific documents
- **Documents Module**: Non–study-specific documents

Study Site is the combination of a Principal Investigator and Facility assigned to a specific study. For each Study Site, the Principal Investigator or his/her Delegate must define the Study Site Profile and Study Site Staff on the SIP Study Site page: Site Users can perform the following tasks in the Documents module:

- Search for a Document
- Upload a New Document

7.1 Search for a Document

The Search feature allows the Site Users to search for and select a document. There are two levels of search:

- Basic
- Advanced

The Search feature allows Site Users to search for a document based on the list of shared documents that are displayed in the task list. The Site Users are given access to documents for studies in which they are associated with in the Study Workspace. Also, the Advanced Search feature allows Site Users to search for and select a Clinical Research document based on the search parameters such as Original File Name, Created By, User, Role, Metadata Last Modified By, Metadata Modified Date, Status, File Format, Viewed, and Language.

To search for a document by using the basic search option

1. On the SIP User Landing Page, click **Documents**. The Document Search page is displayed.

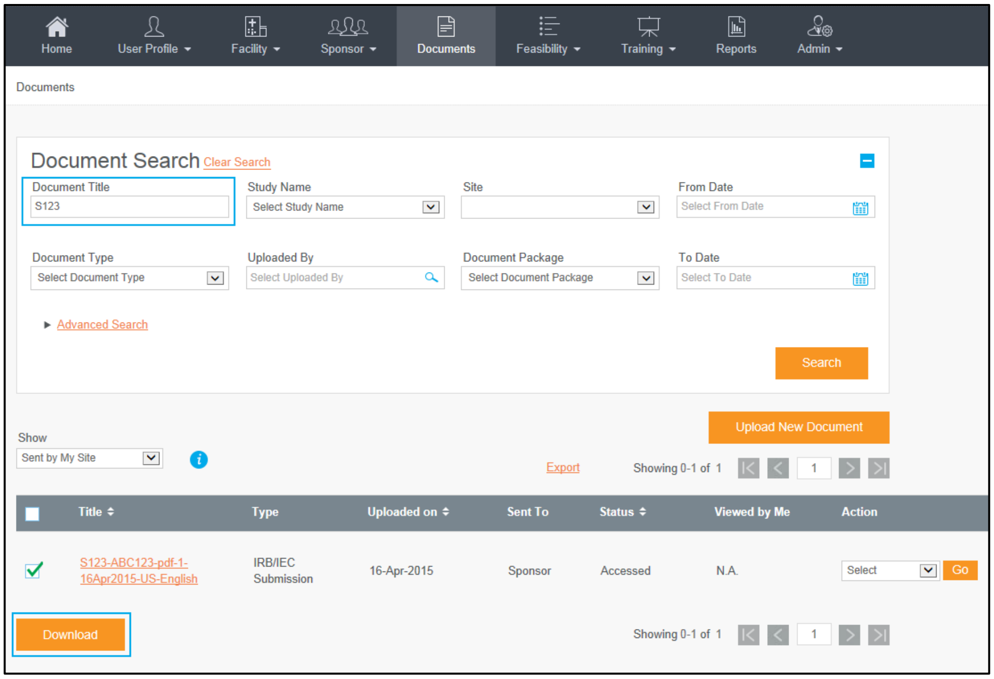


Figure 184. Document Search Page

2. In the **Document Search** section, click . The search fields are displayed.

3. To search for a document, in the relevant fields, enter or click any or all of the required search criteria. For Search for Document field descriptions, refer to Table 30.

4. Click **Search**. The search results are displayed.

5. To filter the search results further, perform the following action:

   a. In the **Show** drop-down list, click one of the options:

      - **Sent to Site**

        If you click **Sent to Site**, all documents sent to the Study Site of the Site User are displayed.

      - **Sent by My Site**

        If you click **Sent by My Site**, all documents sent by any site with which the Site User is associated with are displayed.

      - **Sent to Me**

        If you click **Sent to Site**, all documents sent to the Site User are displayed.

6. To download a document, in the search results displayed, select a document, and then click **Download**.

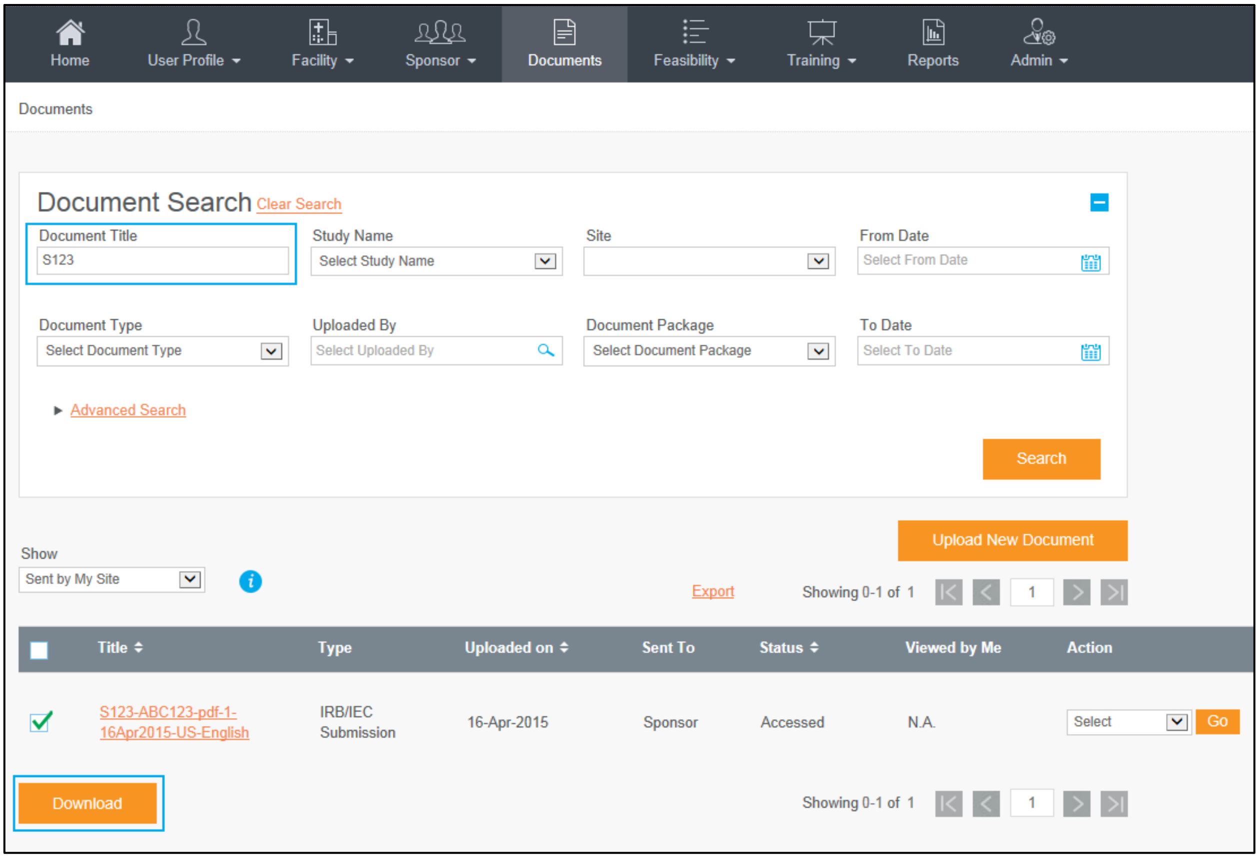


Figure 185. Document Search Page

Advanced Search for a Document

To search for a document by using the advanced search option

1. In the **Document Search** section, click **Advanced Search**. The advanced search fields are displayed.
2. To search for a document, in the relevant fields, enter or select any or all of the search criteria. For Advanced Search for Document field descriptions, refer to the following Table 31.
3. Click **Search**. The search results are displayed.
4. To filter the search results further, perform the following action:
   a. In the **Show** drop-down list, click one of the options:
      - **Sent to Site**

        If you click **Sent to Site**, all documents sent to the Study Site of the Site User are displayed.
      - **Sent by My Site**

If you click **Sent by My Site**, all documents sent by any site that the Site User is associated with are displayed.

- **Sent to Me**

If you click **Sent to Site**, all documents sent to the Site User are displayed.

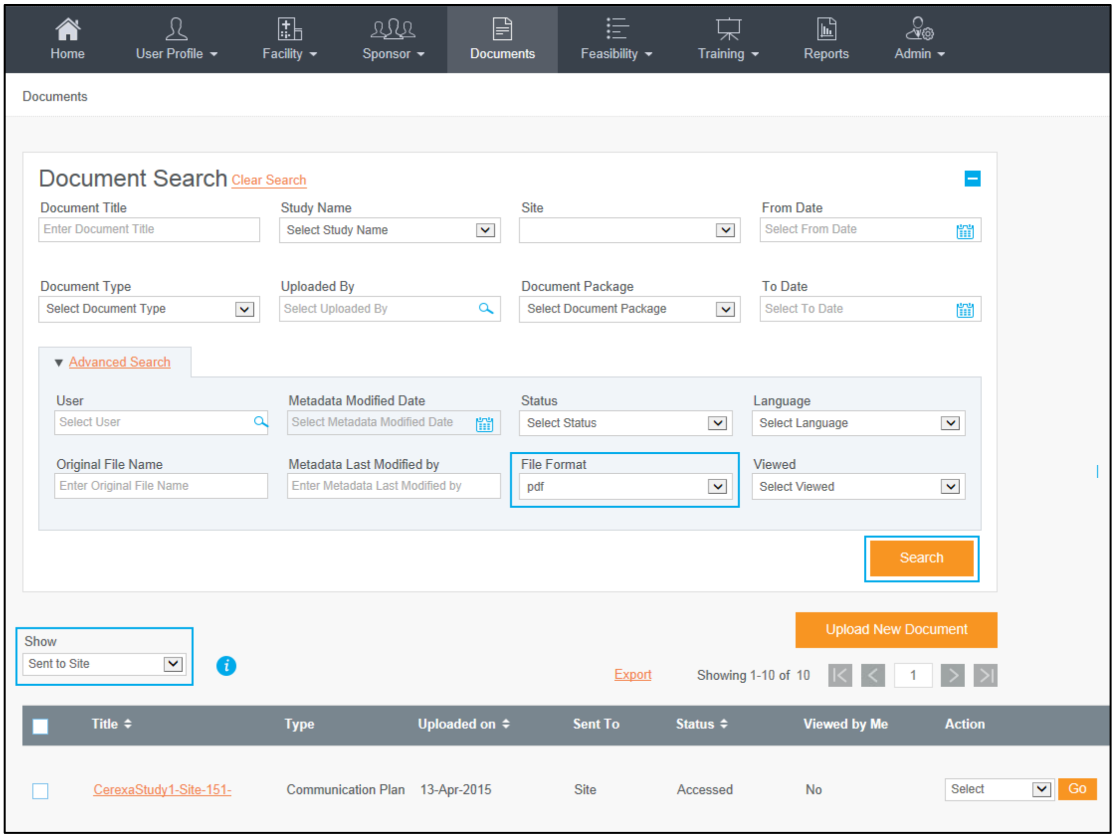


Figure 186. Advanced Search for a Document

7.2 Document Exchange Actions

Site Users can perform the following actions with the documents:

- Send a message with a document
- Download a document
- Edit metadata of an uploaded document
- View the history of a document
- Delete a document that you have uploaded if it has not been accessed by another Site User

1. To send a message, in the document search results displayed, in the **Action** column, click **Send Message,** and then click **Go**. For Send Message, refer to Section 6.4.2.1.
2. To download a document, in the document search results displayed, in the **Action** column, click **Download,** and then click **Go**. For Download document, refer to Section 6.4.2.2.
3. To view document details, in the document search results displayed, in the **Action** column, click **View Details**, and then click **Go**. For Edit Document Details, refer to Section 6.4.2.3.
4. To edit document details, in the document search results displayed, in the **Action** column, click **Edit**, and then click **Go**. For View Details, refer to Section 6.4.2.4.
5. To view document history, in the document search results displayed, in the **Action** column, click **History**, and then click **Go**. For Document History, refer to Section 6.4.2.5.
6. To delete a document, in the document search results displayed, in the **Action** column, click **Delete**, and then click **Go**. For Delete Document, refer to Section 6.4.2.6.

7.3 Upload a Non–Study-Specific Document

The Upload a Document feature allows the Site Users to share the clinical study documents with other Site or Sponsor Users. The Site User provides the document details and uploads the file.

To upload a new document

1. On the SIP User Landing Page, click **Documents**.

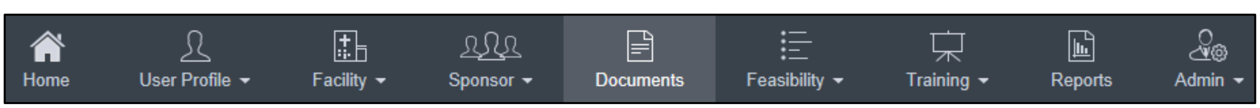


Figure 187. Documents Menu

2. On the **Document** page, click **Upload New Document**.

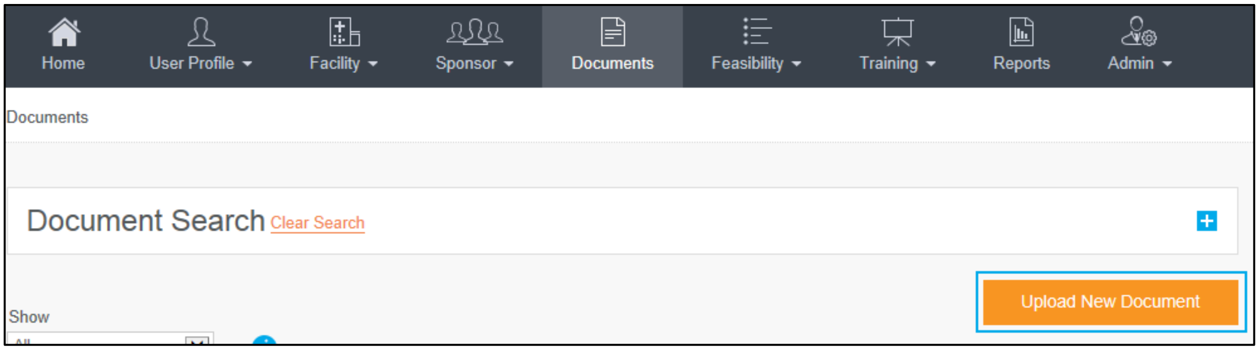


Figure 188. Upload New Document Option

3. On the **Add a New Document** page, enter or select the document details. For Add a New Document field descriptions, refer to Table 33.

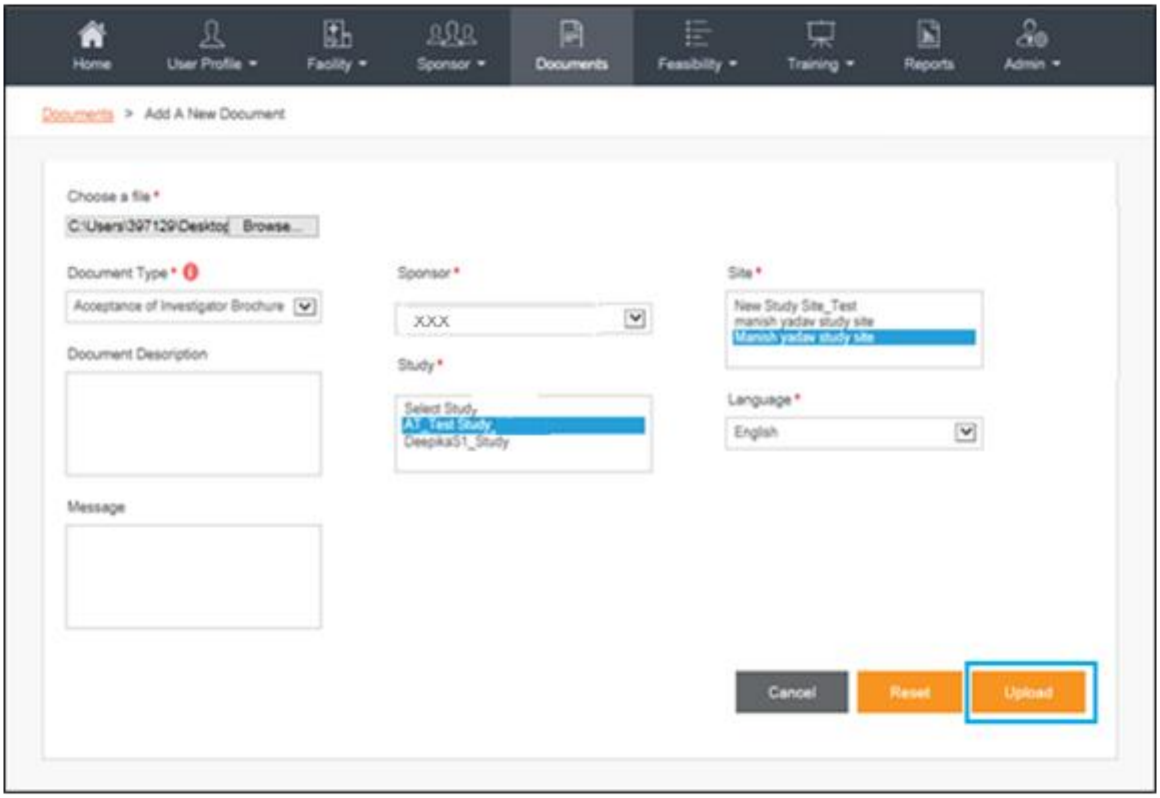


Figure 189. Add a New Document Page

4. To upload a file in the **Choose a File** section, click **Browse**. The Choose File to Upload dialog box is displayed.

The Choose a File feature in the Upload a New Document page is a mandatory field.

The upload process workflow may vary with the browser (Google® Chrome or Microsoft® Internet Explorer) being used.

5. Browse to the location of the file, and then click **Open**.

6. To upload a document, click **Upload**. The confirmation message is displayed.

7. To accept the confirmation message, click **OK**.

The following table lists the descriptions of the fields displayed on the Add a New Document page.

Field	Field Type	Mandatory Field	Field Descriptions
Document Type*	Drop-down list	This is a mandatory field.	This is the type of the document. For example, Study Protocol, Investigator's Brochure, and Financial Disclosure.
Document Description	Text box	This is not a mandatory field.	This is a brief note on the objective or content of the document.
Message	Text box	This is not a mandatory field.	This is the message that needs to be sent to the document recipient.
Sponsor	Drop-down box	This is not a mandatory field.	This is the name of the Sponsor.
Study	Drop-down box	This is not a mandatory field.	This is the title of the study.
Site	Drop-down box	This is not a mandatory field.	This refers to the name of the Study Site associated with the document.
Language*	Drop-down box	This is a mandatory field.	This is the language of the document uploaded.

Table 30. Field Descriptions for Add New Document

8 Manage Surveys

When a Sponsor User sends a survey to a site, the Survey Recipient receives an email and a task in the Tasks section of the Site User Landing Page. The Survey Recipients can open the Feasibility section to view, respond to, decline or delegate a survey to another member of the same Study Site.

The Survey Recipient can delegate completion of a survey question, section, or the entire survey to another Study Site Staff member. In that case, the Delegate must be registered to enter the survey responses. Site Users cannot delegate surveys to Sponsor Users.

Site Users can perform the following tasks:

- Delegate a Survey
- View Open Surveys
- Respond to a Survey
- View Completed Surveys

8.1 Respond to a Survey

This feature allows Survey Recipients to respond to a survey.

To respond to a survey

1. On the **Feasibility** menu of the Site User Landing Page, click **Survey List**.

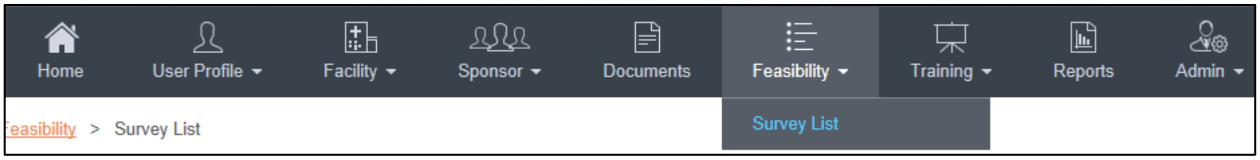


Figure 190. Feasibility: Survey List

2. On the **Survey List** page, click the **Open Surveys** tab. The list of surveys is displayed.

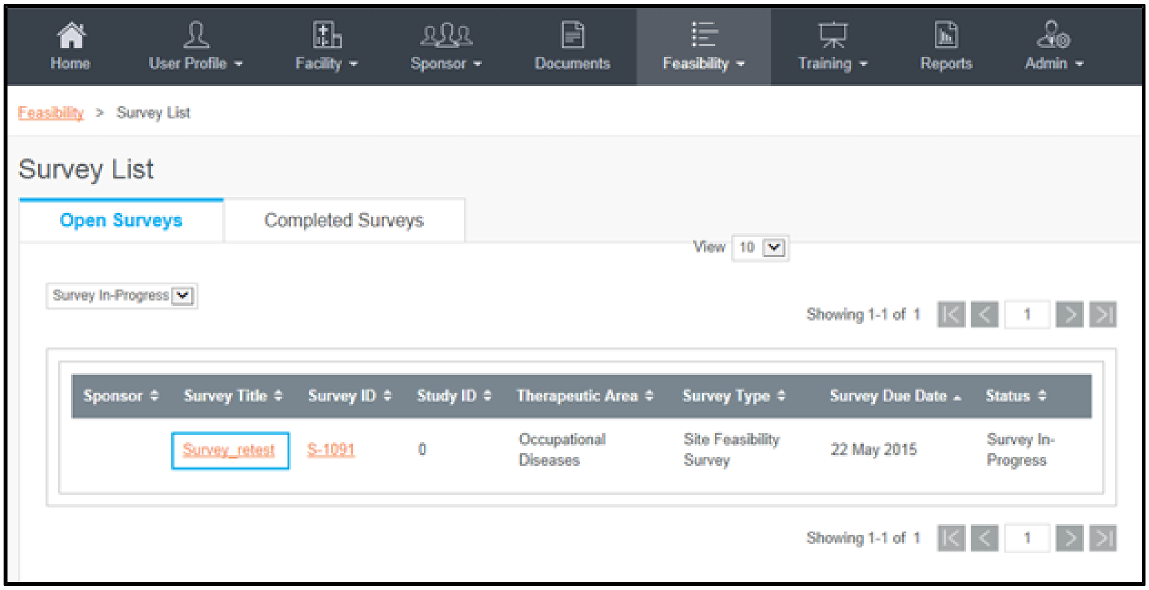


Figure 191. Survey List Page

3. Click the survey title to which you need to respond. The **Respond to Survey** page is displayed.

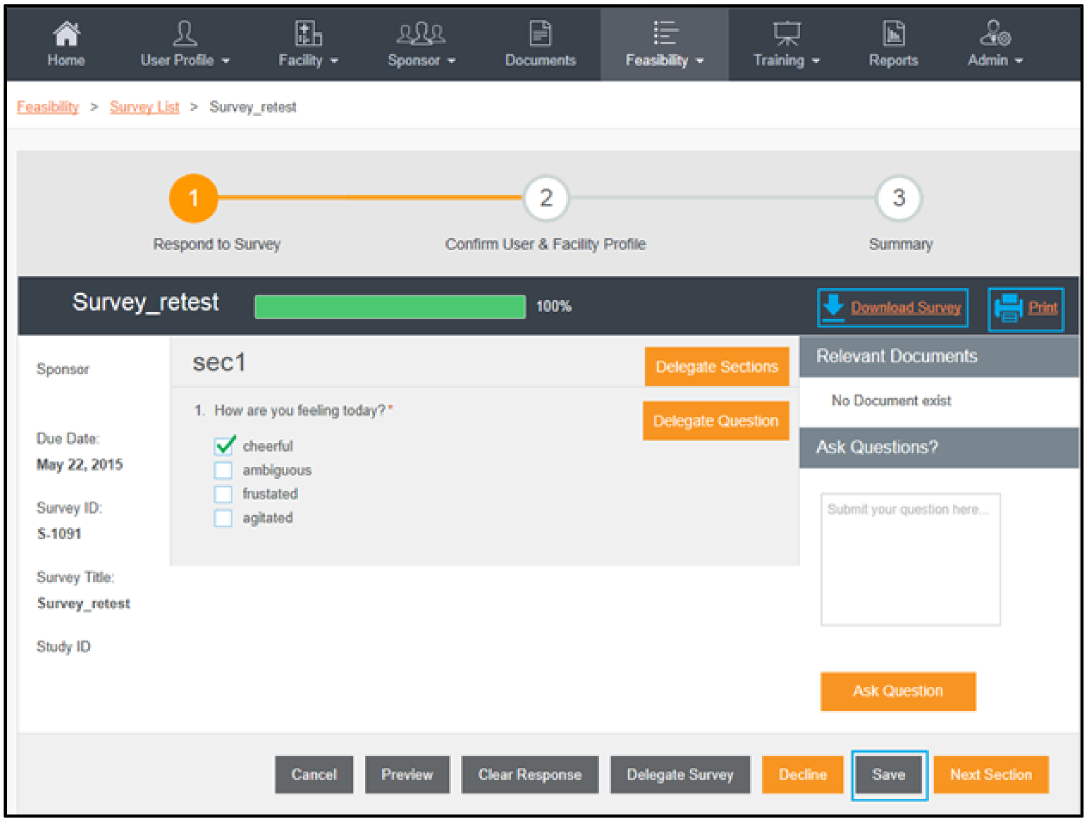


Figure 192. Respond to Survey Page

4. Enter your response to the survey questions.

5. To save the responses, click **Save**.

6. When the confirmation message displays, click **OK**.

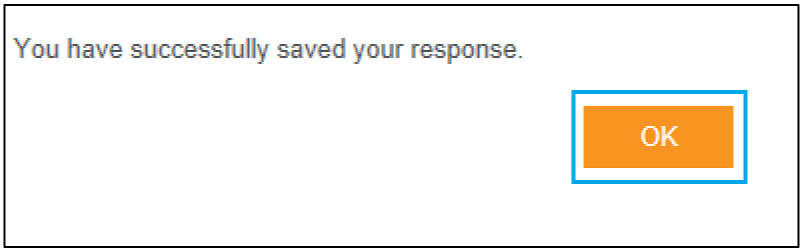


Figure 193. Save Responses: Confirmation Message

7. To decline the survey, click **Decline**. When the confirmation message displays, click **OK**.

8. To clear the response, click **Clear Response**.

9. To preview the survey, click **Preview**. The **Preview** dialog box is displayed.

Figure 194. Preview Dialog Box

10. To print a survey, on the **Respond to Survey** page, click **Print**.

11. After responses to all survey questions have been entered, the Site User must review and confirm the information in his or her SIP User Profile and the Facility Profile. To navigate to the next section, on the **Respond to a Survey** page, click **Next Section**. The **Confirm User and Facility Profile** page is displayed after all sections are completed.

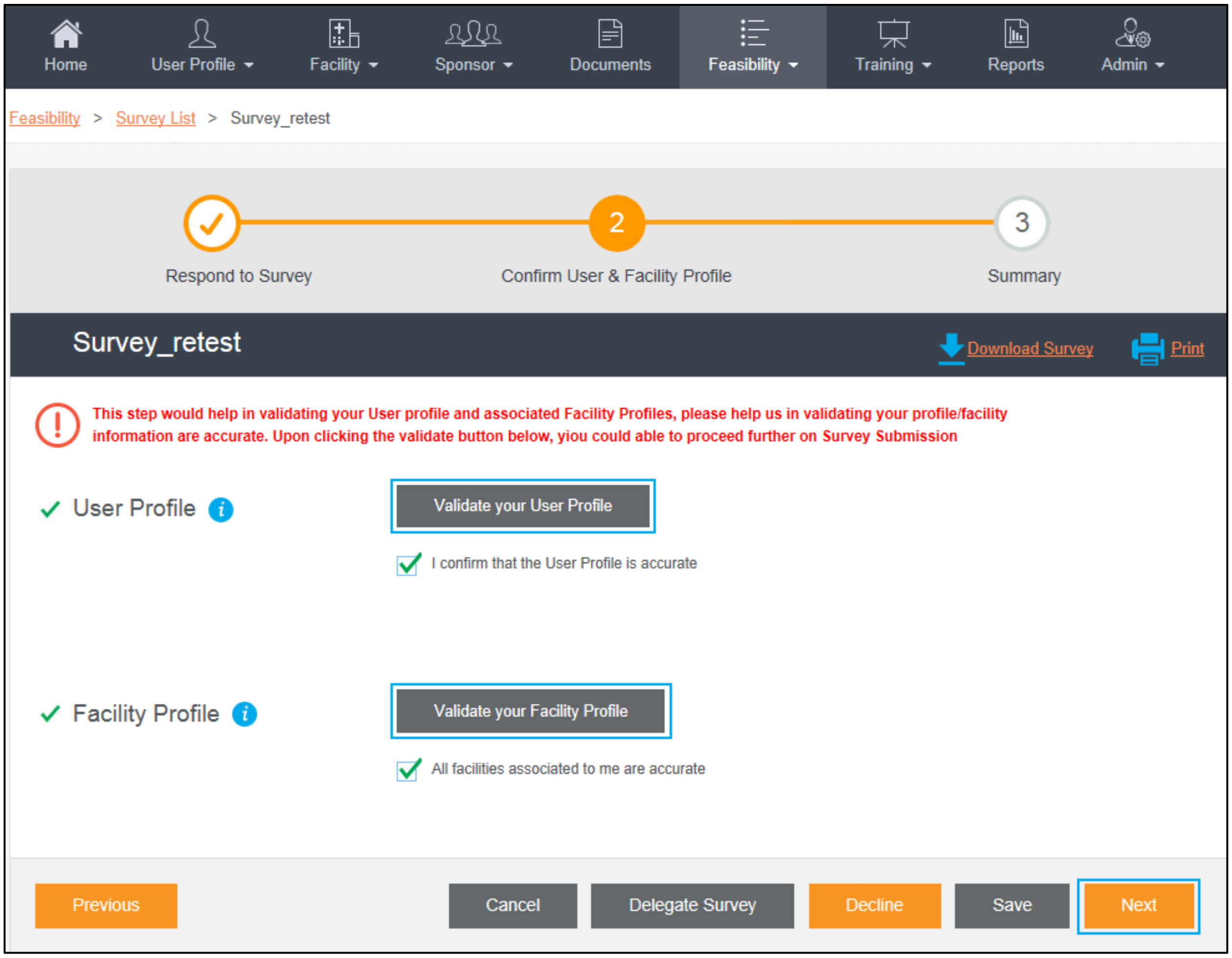


Figure 195. Confirm User and Facility Profile Page

12. Review the information in your User Profile, and make any updates or complete any missing information. On the **Confirm User and Facility Profile** page, click **Validate your User Profile**.

*To confirm, select the **I confirm that the User Profile is accurate** check box.*

13. Review the information in your Facility Profile. If there is any missing or inaccurate information, have the Facility Profile Owner make these updates. On the **Confirm User and Facility Profile** page, click **Validate your Facility Profile**.

*To confirm, select the **I confirm that the Facility Profile information is accurate** check box.*

14. Click **Next**. The Summary page is displayed.

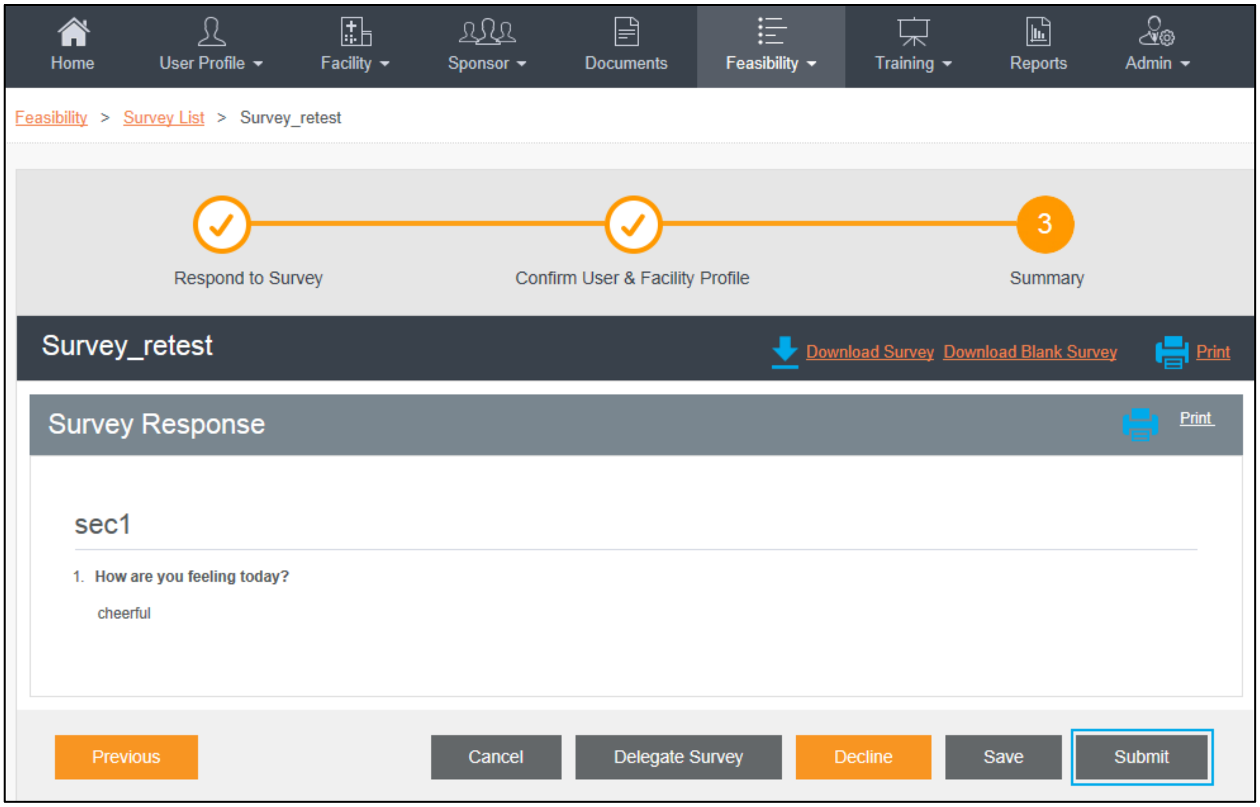


Figure 196. Summary Page

15. To save the response, click **Save**.
16. To submit the survey, on the **Summary** page, click **Submit**. A confirmation message is displayed.
17. To accept the confirmation message, click **OK**. The survey is submitted and is now displayed in the list of completed surveys.

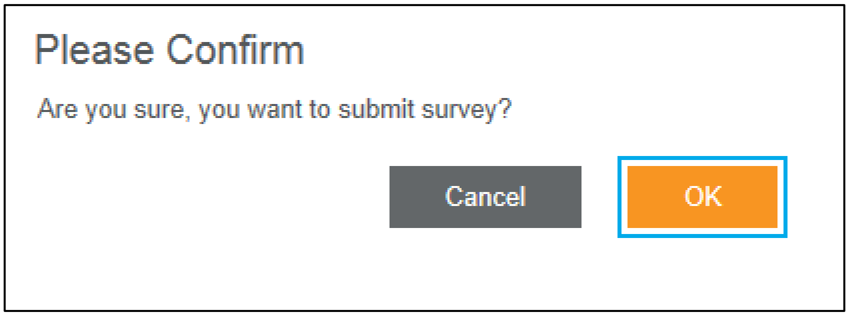


Figure 197. Submit Survey: Confirmation Message

While responding to the survey, if the Survey Recipients have a question about the survey, they can enter their question in the ***Ask Sponsor A Question?*** *box and click* ***Ask Question****. The Sponsor will receive the question and can respond.*

18. To save a copy of a completed survey, click **Completed Survey** tab in the **Survey List** page, select the desired survey and click **Download Survey**. The survey document gets downloaded to the local drive of the Site User.

8.2 View Open Surveys

The Open Survey feature allows the Site Users to view their surveys and the status of the survey:

- Survey Not Started
- Survey In-Progress
- Survey Abandoned
- Survey Delegated

To view the open surveys

1. On the **Feasibility** menu of the Site User Landing Page, click **Survey List**.

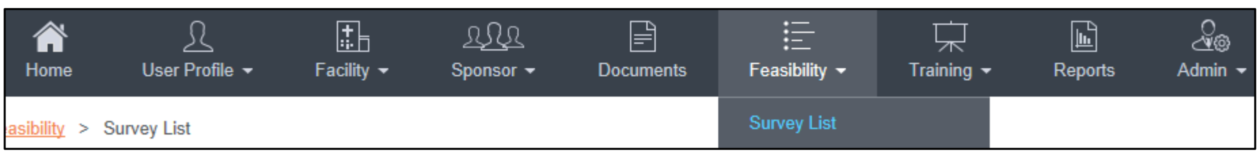


Figure 198. Feasibility: Survey List

2. On the **Survey List** page, click the **Open Surveys** tab. The following page is displayed.

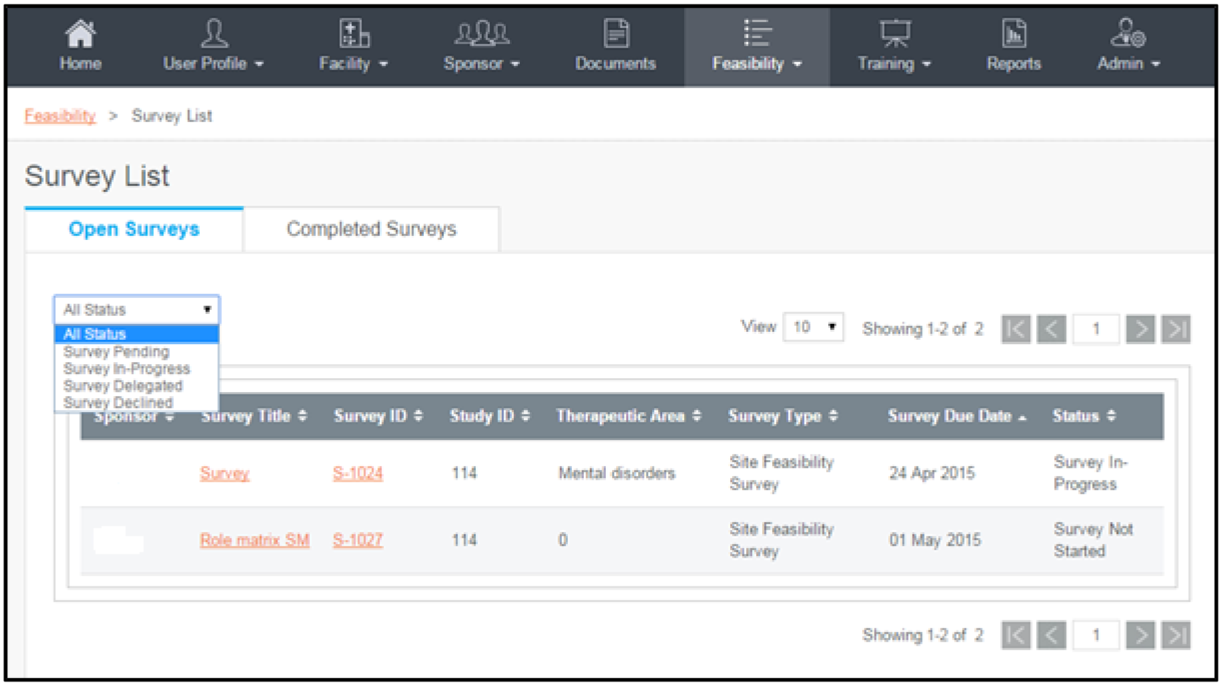


Figure 199. Open Survey Page

3. In the **All Status** drop-down list, you can view surveys by status if you click a required status such as **Survey Not Started**, **Survey In-Progress**, **Survey Abandoned** and **Survey Delegated**. The list of open surveys is displayed.

8.3 View Completed Surveys

The Completed Survey feature allows the Site User to view the completed surveys and the status of the survey:

- Survey Response Submitted
- Survey Declined

To view the completed surveys

1. On the **Feasibility** menu of the Site User Landing Page, click **Survey List**.

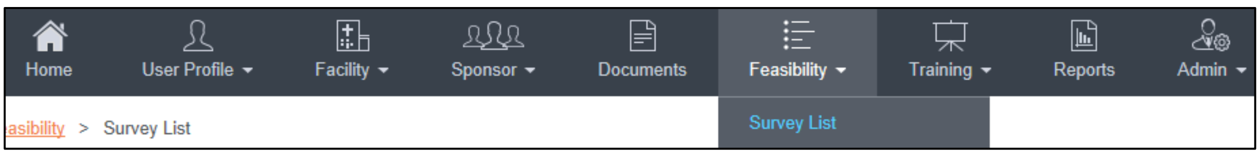


Figure 200. Feasibility: Survey List

2. On the **Survey List** page, click the **Completed Surveys** tab. The following page is displayed.

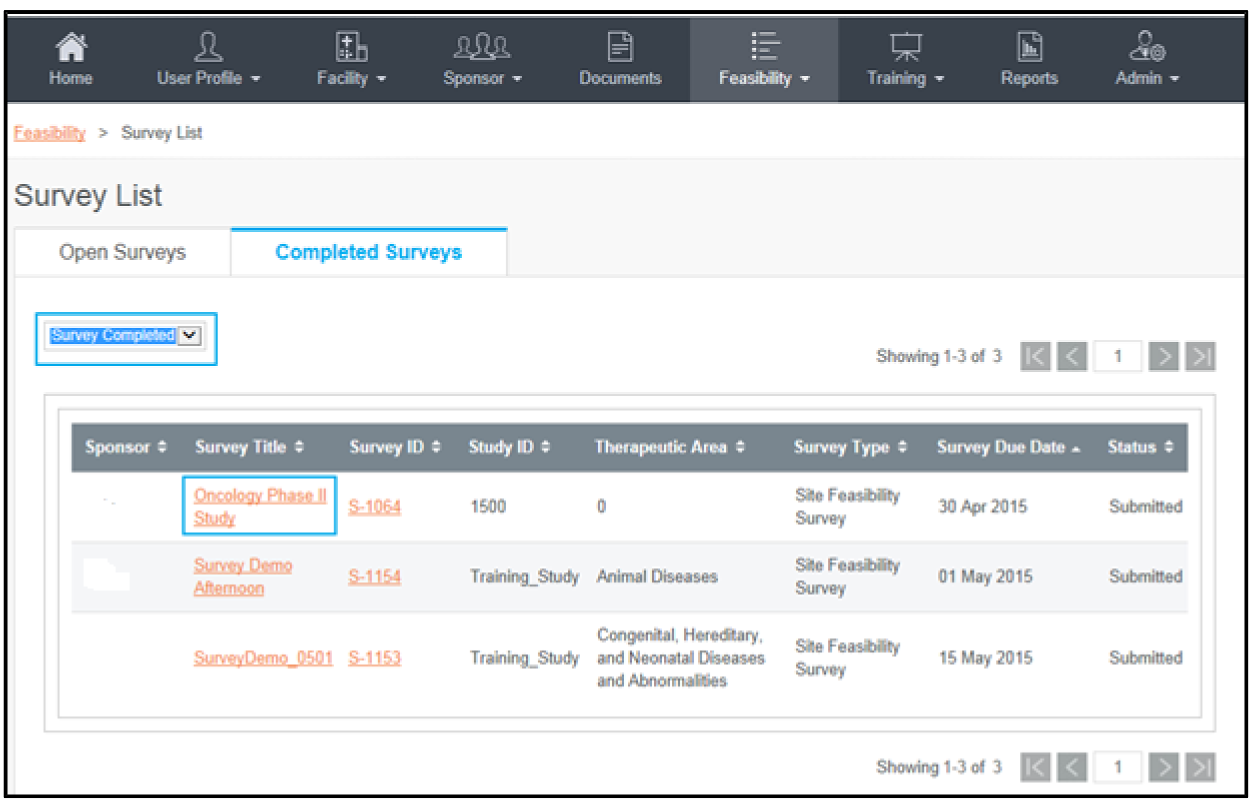


Figure 201. Survey List Page: Completed Surveys

3. In the **All Status** drop-down list, you can view surveys by status if you click a required status: **Survey Response Submitted** and **Survey Declined**. The list of completed surveys is displayed.

4. To view a completed survey, click the required Survey Title or the Survey ID.

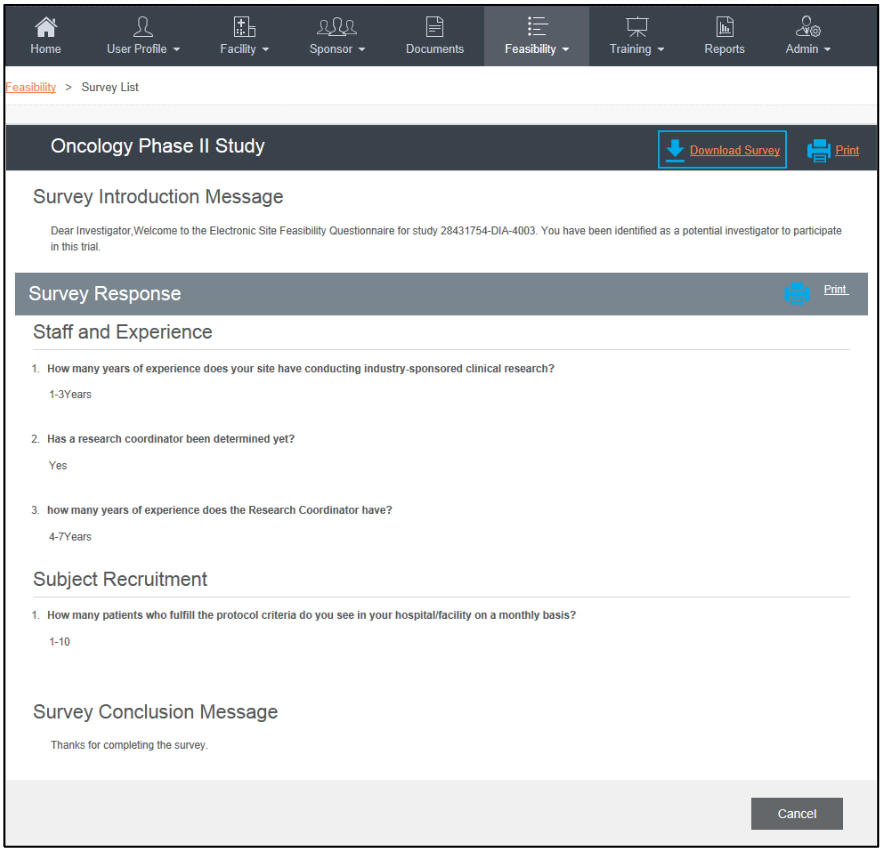


Figure 202. Survey Page

1. To save a copy of a completed survey, click the desired survey and click **Download Survey**. The survey document is downloaded to the local drive of the Site User.

05-11-2015 **Oncology Phase II Study** Survey response

Staff and Experience

1. How many years of experience does your site have conducting industry-sponsored clinical research?

○ <1Year
● 1-3Years
○ 4-7Years
○ >7 Years

Figure 203. Survey Response Document

8.4 Delegate a Survey

This section describes how a Survey Recipient can delegate completion of a survey question, section or the entire survey to other Site Users. After the Survey Recipient selects the Survey from the list of Open Surveys, the Survey Recipient identifies the portions of the survey to be delegated. The Survey Recipient also identifies the Delegates to whom it will be delegated. The Survey Recipient can delegate different questions or sections to different Delegates. After the Delegate(s) complete the data entry of the responses, the Survey Recipient must review their entries and perform the final steps for survey submission. The Survey Recipient can delegate the following:

- Specific survey questions to another Site User
- Specific sections of a survey to another Site User
- The entire survey to another Site User

The Survey Recipient can delegate different questions or sections to different Delegates. After the Delegate completes the data entry of the responses, the Survey Recipient must review their entries and perform the final steps for survey submission.

To delegate specific survey questions to another Site User

1. On the **Feasibility** menu, click **Survey List**.

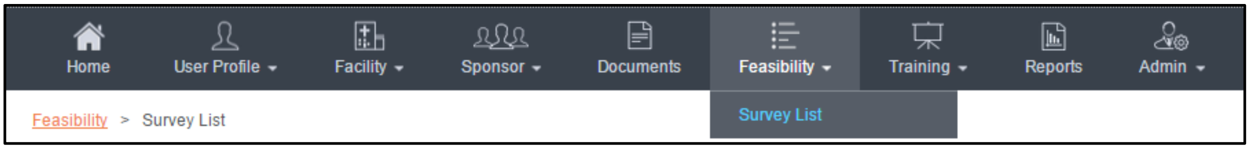


Figure 204. Feasibility: Survey List

2. On the **Survey List** page, click the **Open Surveys** tab. The list of surveys is displayed.

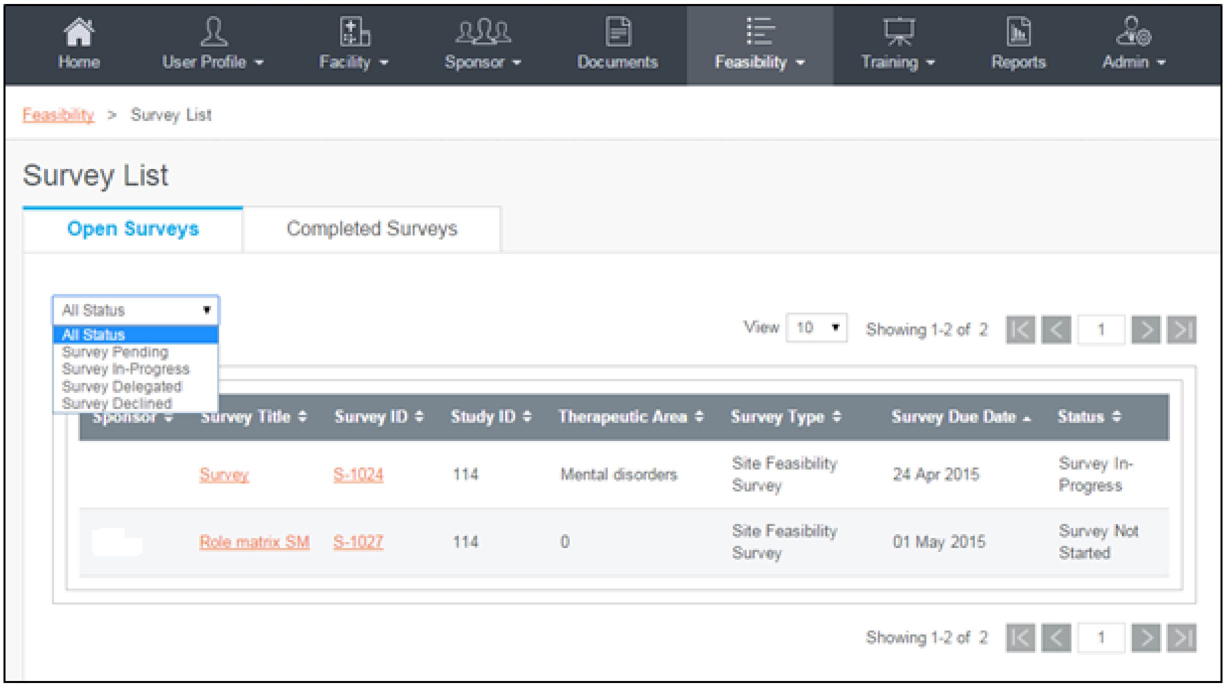


Figure 205. Open Survey Page

3. Click the survey title that requires a response. The **Respond to Survey** page is displayed.

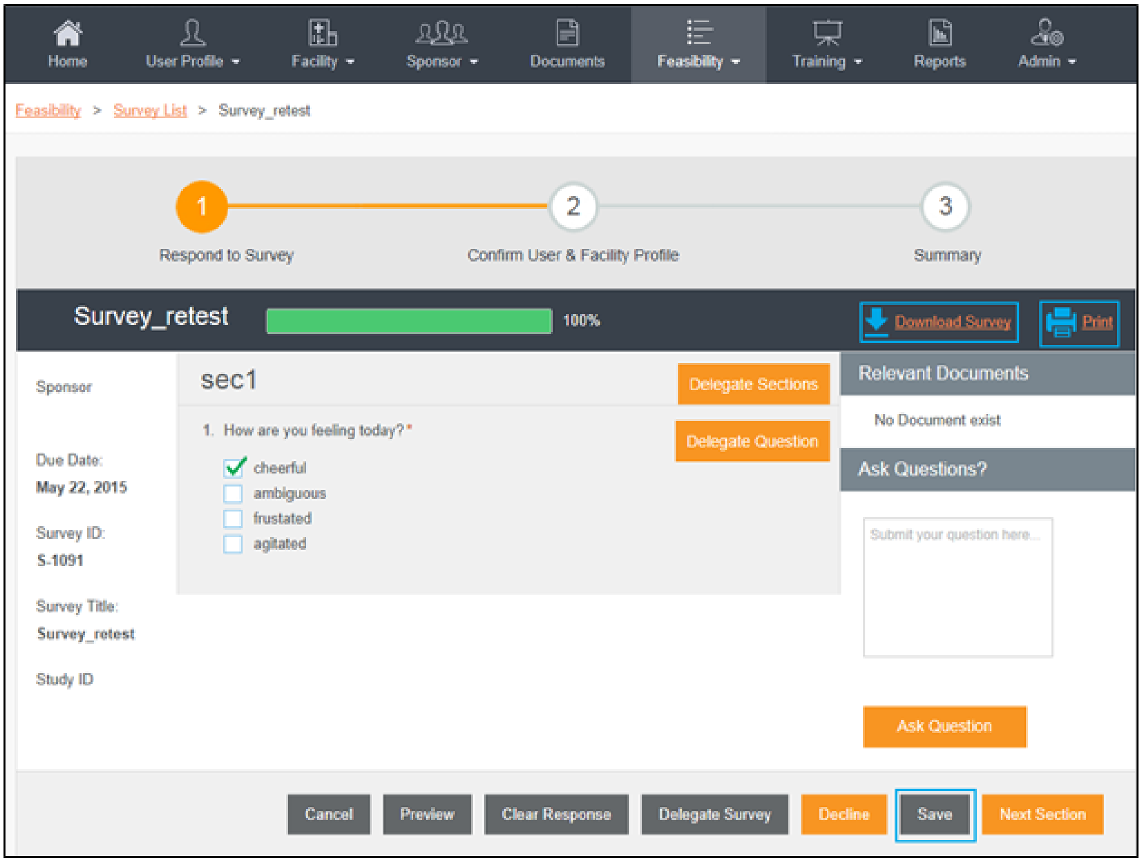


Figure 206. Respond to Survey Page

4. To delegate a question, on the **Respond to Survey** page, identify the question that you need to delegate and click **Delegate Question** next to the identified question. The Delegate Survey dialog box is displayed.

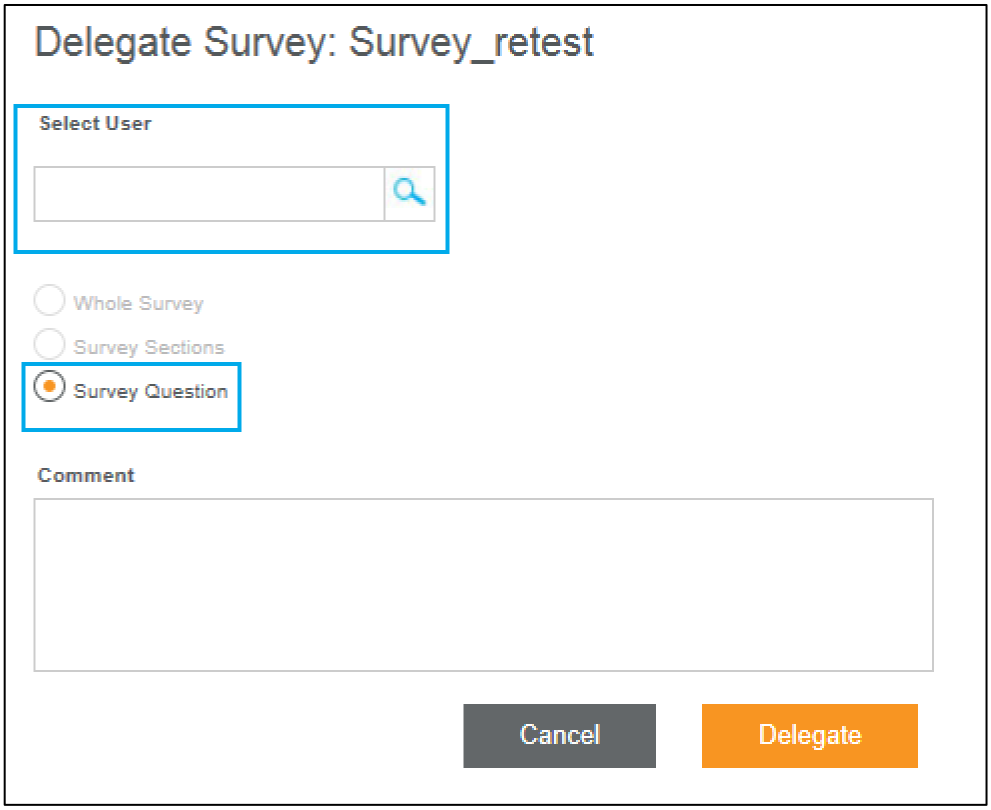


Figure 207. Delegate Question Dialog Box

5. To search for a Site User Delegate, in the **Select User** section, click .
6. In the **Search Delegate User** window, enter any or all of the search criteria, and then click **Search**. For Search Delegate User field descriptions refer to Table 34.
7. In the displayed search results, find your desired Delegate, select the check box corresponding to the Delegate's name. Now, click **Add**.

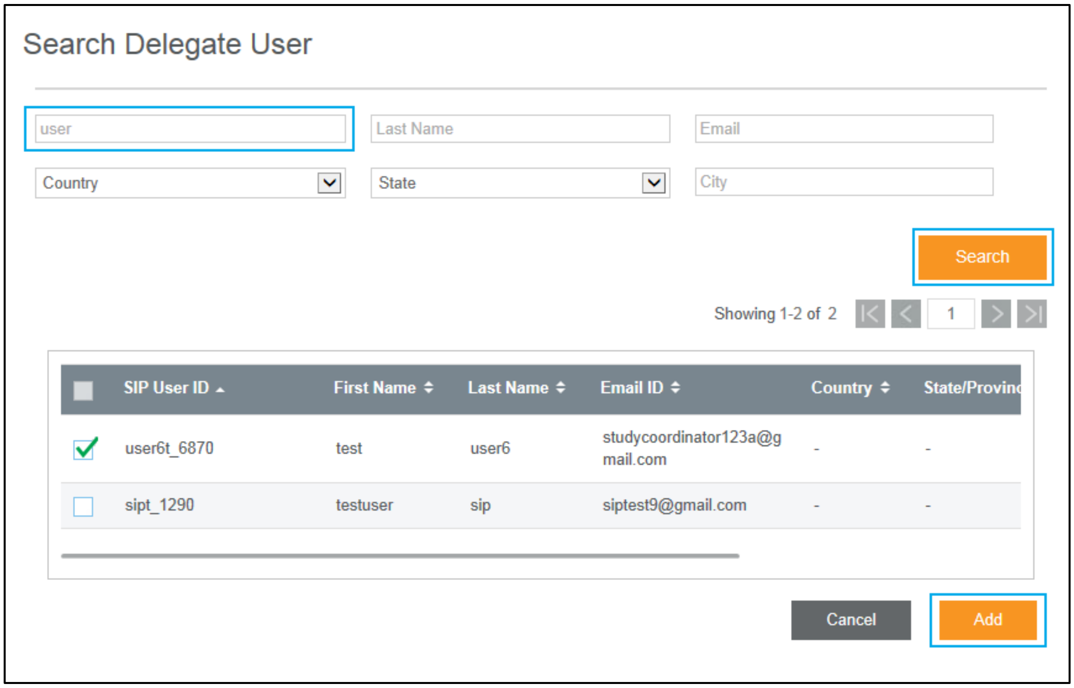


Figure 208. Search Delegate User window: Delegate a Question

8. In the **Comment** box, enter any instructions or additional information for the Delegate, if any.

9. To delegate the survey, click **Delegate**. The delegated record is displayed as a task in the **Tasks** section of the Delegate's Site User Landing Page.

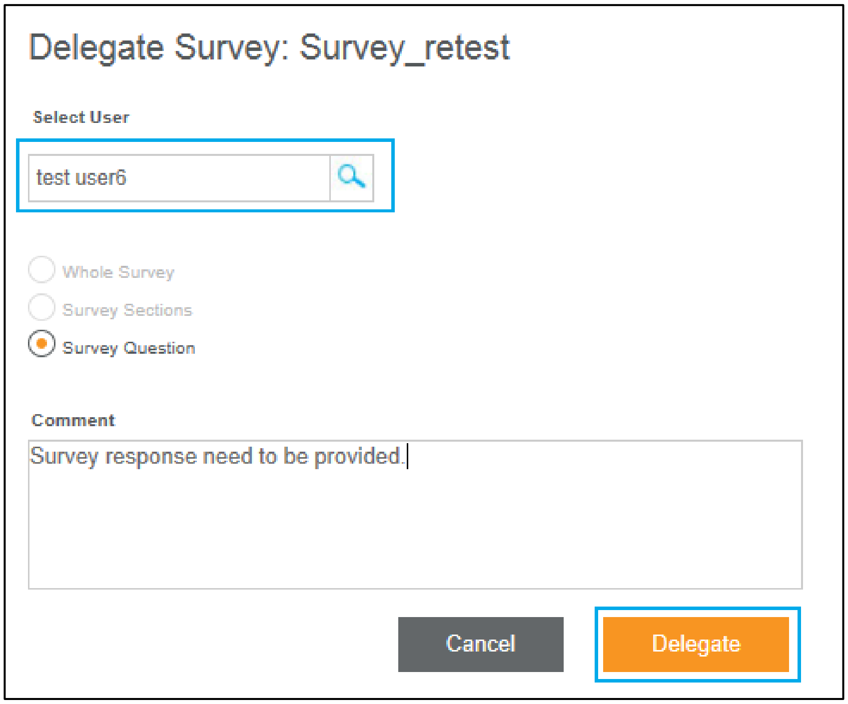


Figure 209. Delegated Question Dialog Box

To delegate specific sections of a survey to another Site User

1. To delegate a survey section, go to the **Respond to Survey** page, identify the section you need to delegate, click **Delegate Section**. The Delegate Survey dialog box is displayed.

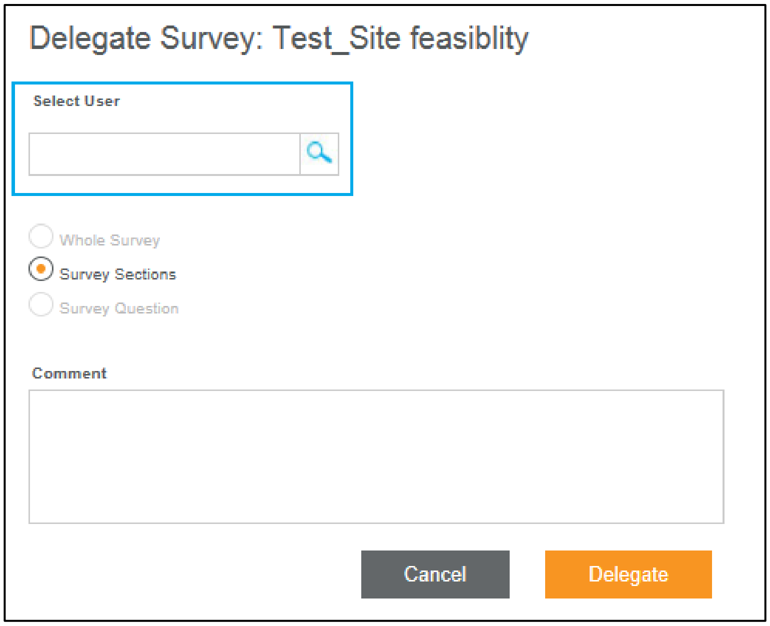


Figure 210. Delegate section Dialog box

2. To search for the Site User Delegate, in the **Select User** section, click .

3. In the **Search Delegate User** window, enter any or all of the search criteria, and then click **Search**. For Search Delegate User field descriptions refer to Table 34.

4. In the displayed search results, find your desired Delegate, select the check box corresponding to the Delegate's name. Now, click **Add**.

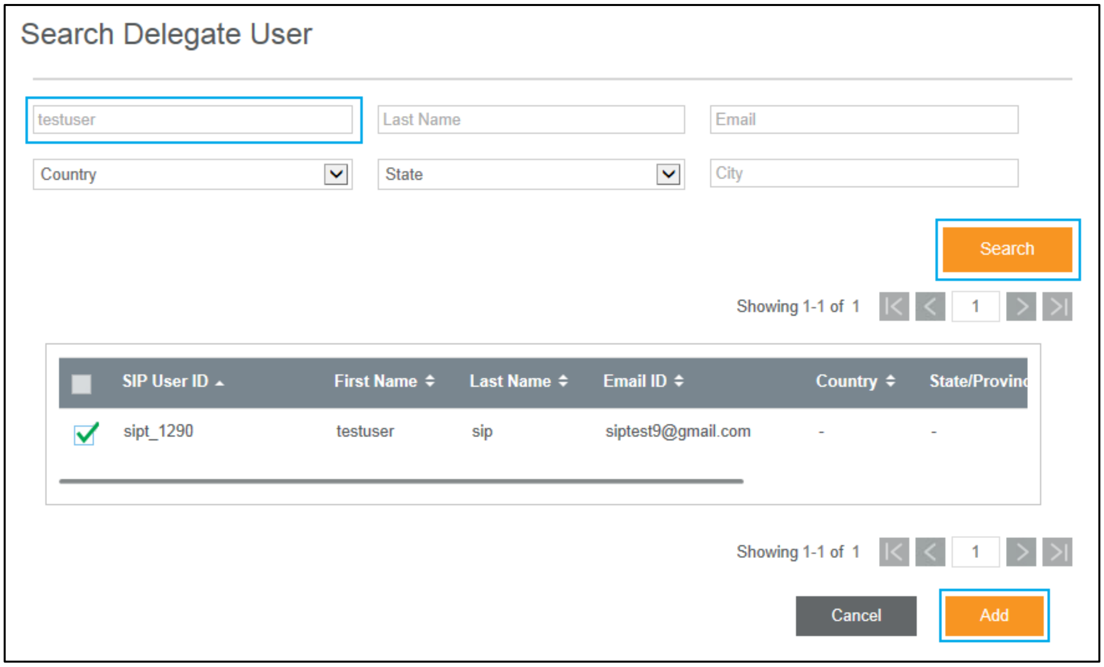


Figure 211. Search Delegate User Window: Delegate a Section

5. In the **Comment** box, enter any instructions or additional information for the Delegate, if any.

6. Click **Delegate**.

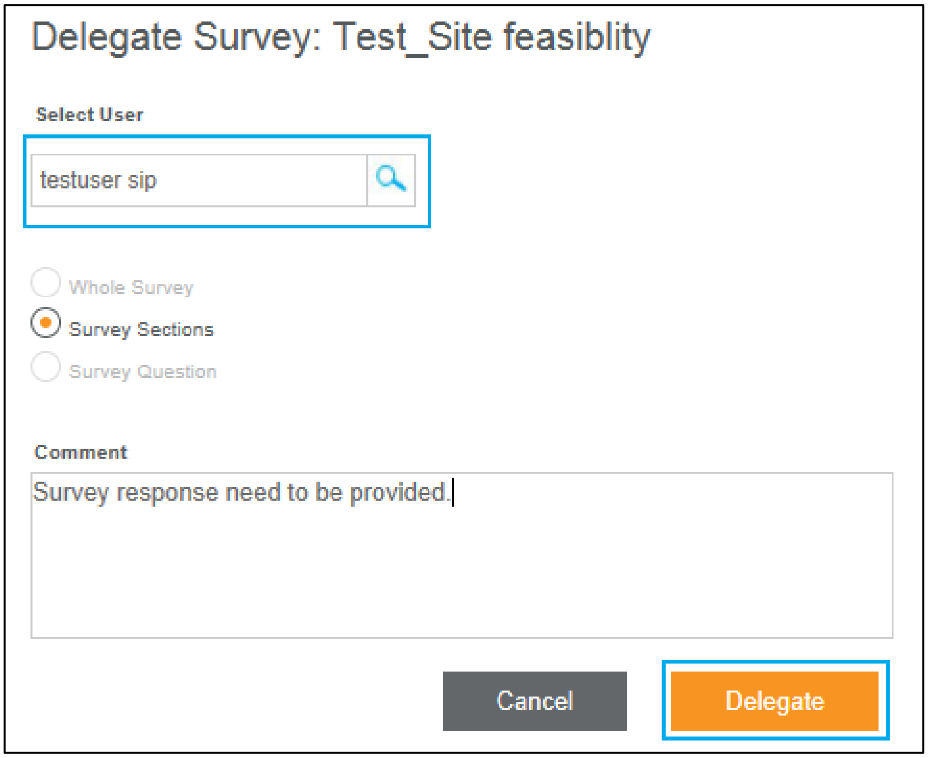


Figure 212. Delegated section Dialog box

To delegate the entire survey to another Site User

1. To delegate a survey, on the **Respond to Survey** page, click **Delegate Survey**. The Delegate Survey dialog box is displayed.

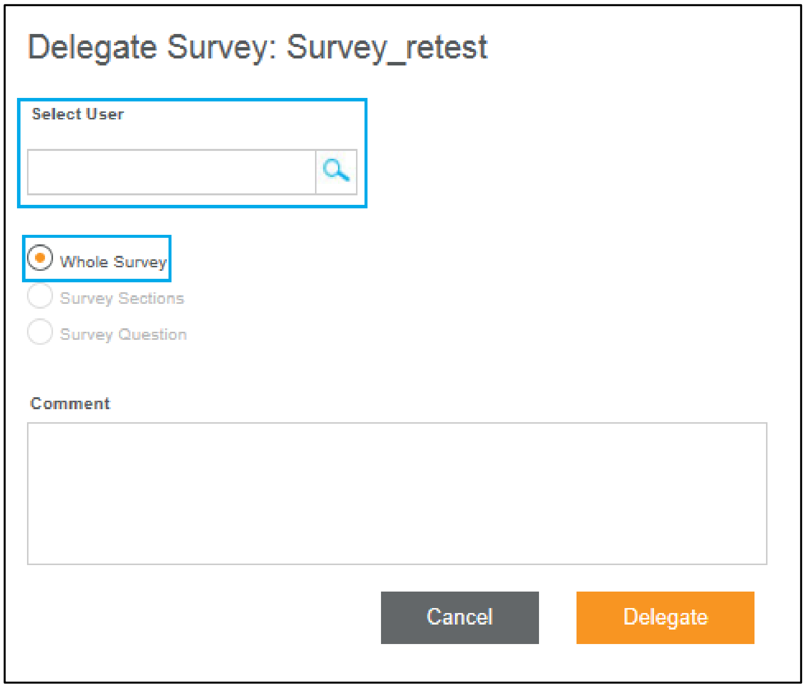


Figure 213. Delegate Survey Dialog Box

2. To search for a Site User Delegate, in the **Select User** section, click .
3. In the **Search Delegate User** window, enter any or all of the search criteria, and then click **Search**. For Search Delegate User field descriptions refer to Table 34.
4. In the displayed search results, find your desired Delegate, select the check box corresponding to the Delegate's name. Now, click **Add**.

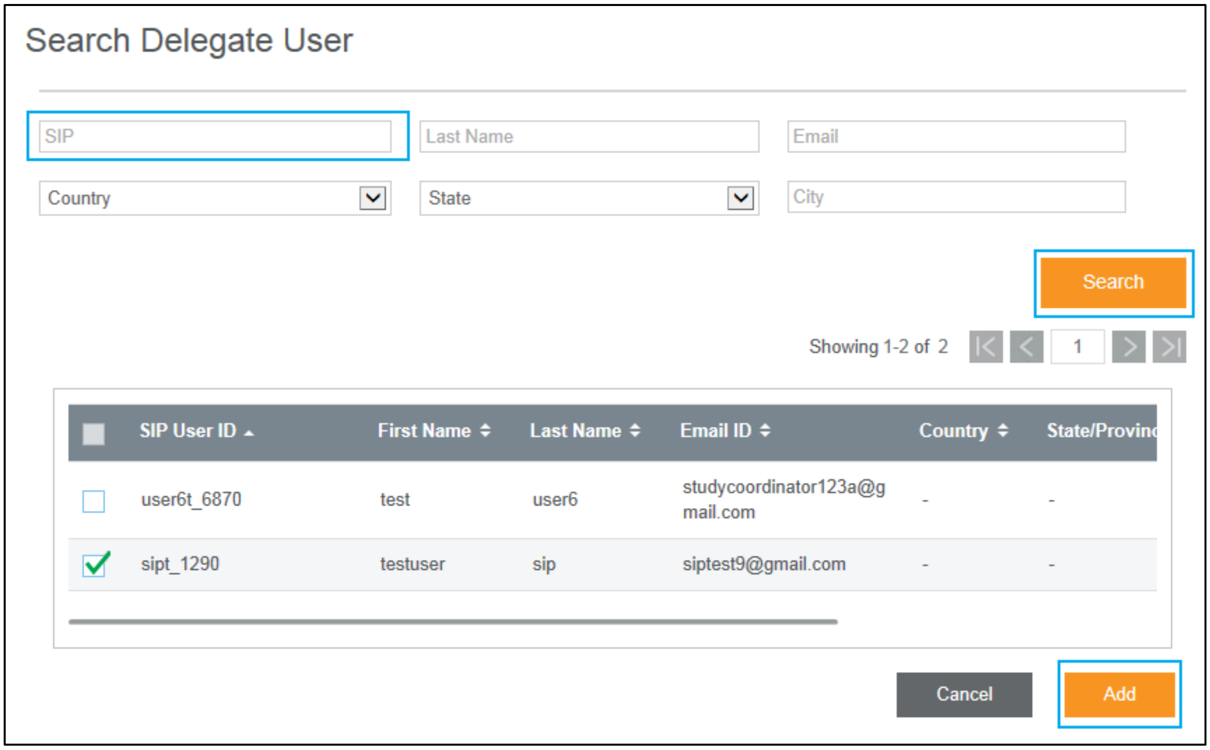


Figure 214. Search Delegate User: Delegate a Survey

5. In the **Comment** box, enter any instructions or additional information for the Delegate.

6. To delegate the survey, click **Delegate**. The delegated record is displayed as a task in the **Tasks** section of the Delegate's Site User Landing Page.

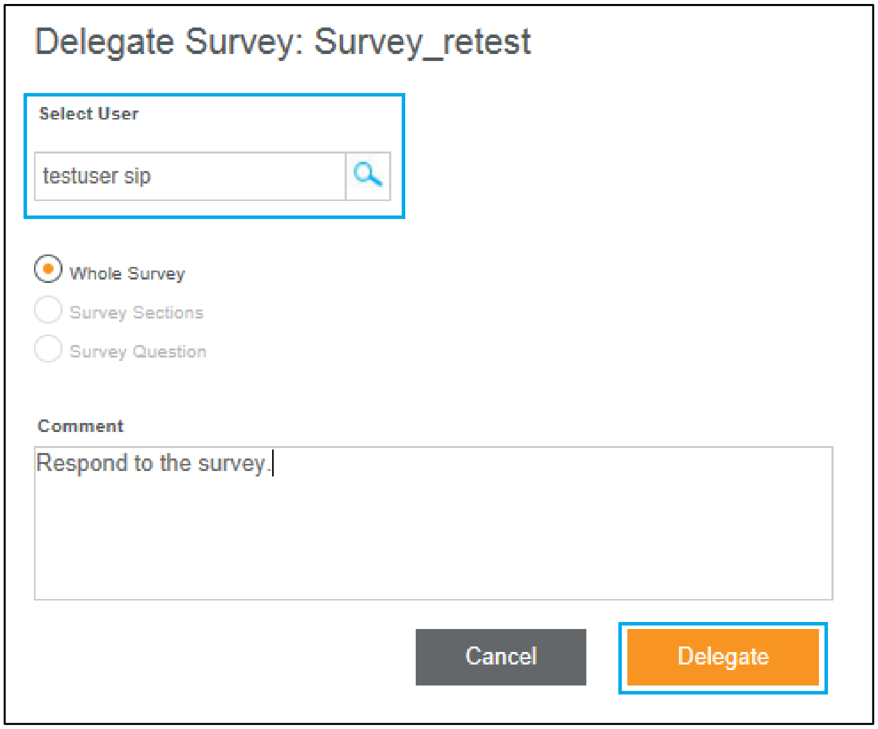


Figure 215. Delegated Survey Dialog Box

The following table provides the field descriptions for the Search Delegate User window.

Field	Field Type	Mandatory Field	Field Descriptions
First Name	Text box	This is not a mandatory field.	First name of the Site User
Last Name	Text box	This is not a mandatory field.	Last name of the Site User
Email	Text box	This is not a mandatory field.	Email address of the Site User
Country	Drop-down list	This is not a mandatory field.	Name of the country where the Site User resides.
State	Drop-down list	This is not a mandatory field.	Name of the state where the Site User resides
City	Text box	This is not a mandatory field.	Name of the city where the Site User resides.

Table 31. Field Descriptions for Search Delegate User

9 Manage Training

The Training feature allows the Site Users to manage training assignments across their multiple studies and Sponsors in a consolidated view. Similarly, SIP also provides Site Users with a history of completed training in a single view. Site Users can complete assigned training, print documentation of training completion, request credit for courses completed outside SIP and even find courses of interest and self-assign them.

Site Users can also request credit for already completed courses. Each Sponsor may have their own training course(s), which may be mutually recognized across multiple Sponsors that is GCP Training. However, the Site User needs to complete only one such assigned course to receive credit from multiple Sponsors. On completion of a course, the Site User need not take the same course again when assigned by another Sponsor.

SIP manages two categories of training courses:

- Mutually Recognized Training (MRT) for which all participating member companies will grant training credit
- Sponsor/Study-specific training for which training credit is limited to a single Sponsor or study

MRT may be provided by training vendors (Provider MRT) or Sponsors (Sponsor MRT) whose courses meet the established criteria for mutual recognition. Credit for review of TransCelerate Informational Materials that are also available in the SIP system is also mutually recognized across all participating member companies.

*Site Users can access trainings under the **My Training** tab of the **Training** menu.*

Site Users can perform the following tasks in the Training module:

- Search for an Assigned Training Course
- Search for a Completed Training Course
- Find a Course
- Request for Credit for yourself
- Request for Credit on Behalf of Another User

9.1 My Training

The My Training page displays all of the Site User's training assignments and completion history in a single view, regardless of course category.

Mutually Recognized Training (MRT) is a training course that Member Companies have approved.

9.1.1 Assigned Training

The Assigned Training feature allows the Site User to view their training assignments and completed courses based on the additional information provided such as Due Date. Training notifications will remind Site Users when assigned required training is overdue or training credit is expiring in addition to notifications as new training is assigned. Management of GCP training assignments via SIP allows Sponsors to apply past training credit for mutually recognized GCP courses to new studies as applicable. This eliminates the need for Site Users to repeat GCP training except as credit expires every three years.

To search for an assigned training course

1. On the **Training** menu of the SIP User Landing Page, click **My Training**.

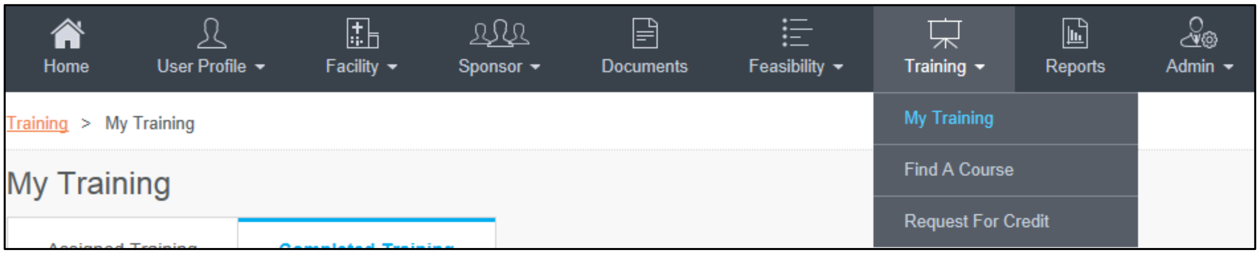


Figure 216. Training: My Training

2. On the **My Training** page, click the **Assigned Training** tab.

3. In the **Search** section, enter or click any or all of the search criteria, and then click **Search**. For Search for Course field descriptions, refer to [Table 35.](#)

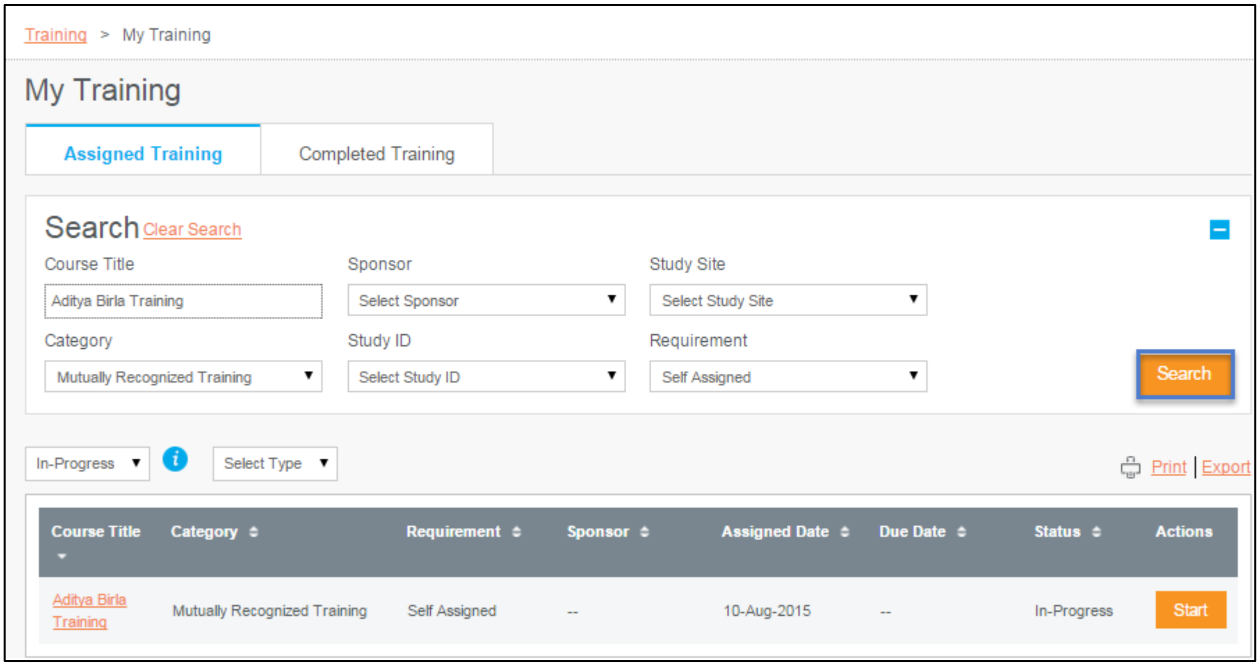


Figure 217. Training: Assigned Training

4. To filter the search results further, perform one or both the following actions:

   a. In the **All Status** drop-down list, click one of the options:

      - **Assigned -** Displays assigned courses that the Site User has not yet accessed

        If you click **Assigned**, all the assigned courses are displayed.

      - **In-progress -** Displays assigned courses that the Site User has not yet accessed

        If you click **In-progress**, all the courses that are in-progress are displayed.

      - **Overdue -** Displays courses that have not yet been completed as of the published Due Date

        If you click **Overdue**, all the courses that are overdue are displayed.

      - **Registered -** Displays courses that were self-assigned by using the Find a Course feature and are not yet complete. Self-assigned courses are not assigned a Due Date and will remain on the Assigned Training page until completed.

        If you click **Registered**, all the courses that are registered under a curriculum or the self-registered courses are displayed.

   b. In the **Type** drop-down list, click an option.

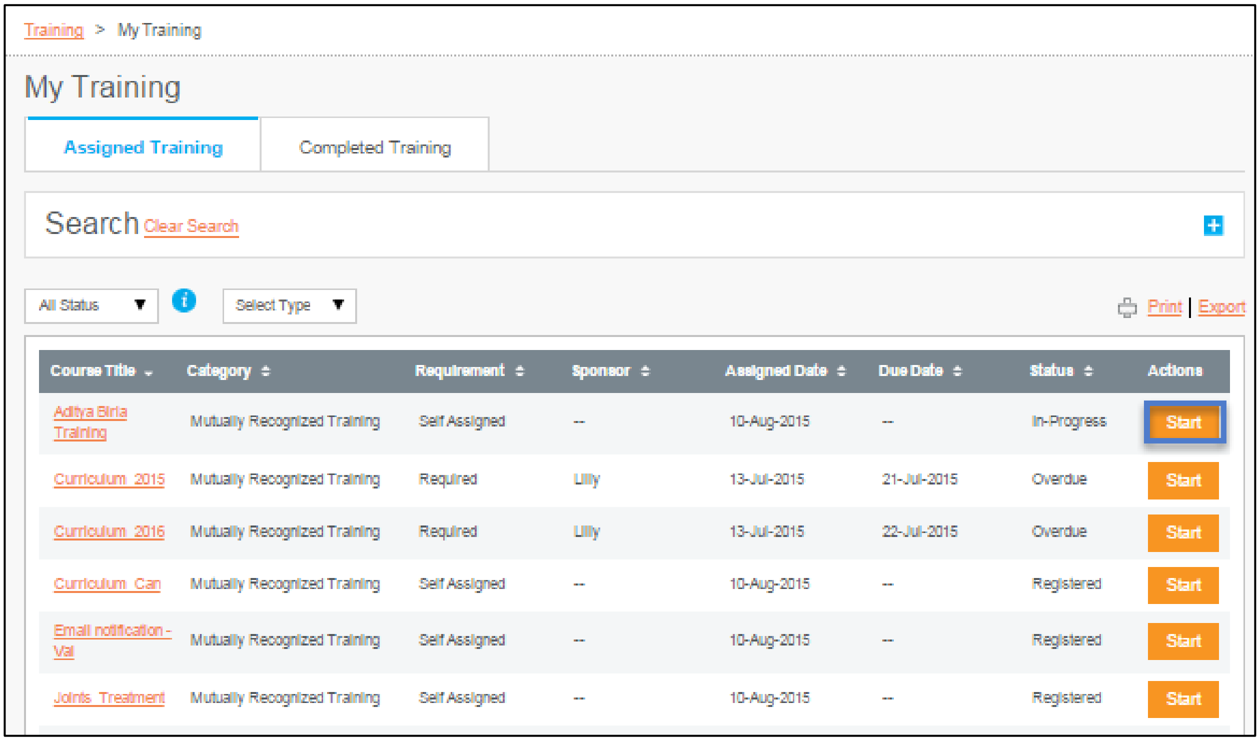


Figure 218. Search an Assigned Training Course

5. To print the assigned training details, on the **Assigned Training** page, click **Print**.
6. To launch the course, in the search results displayed, in the **Actions** column, click **Start**. The following page is displayed.
7. When the course is downloaded, the selected course is displayed.

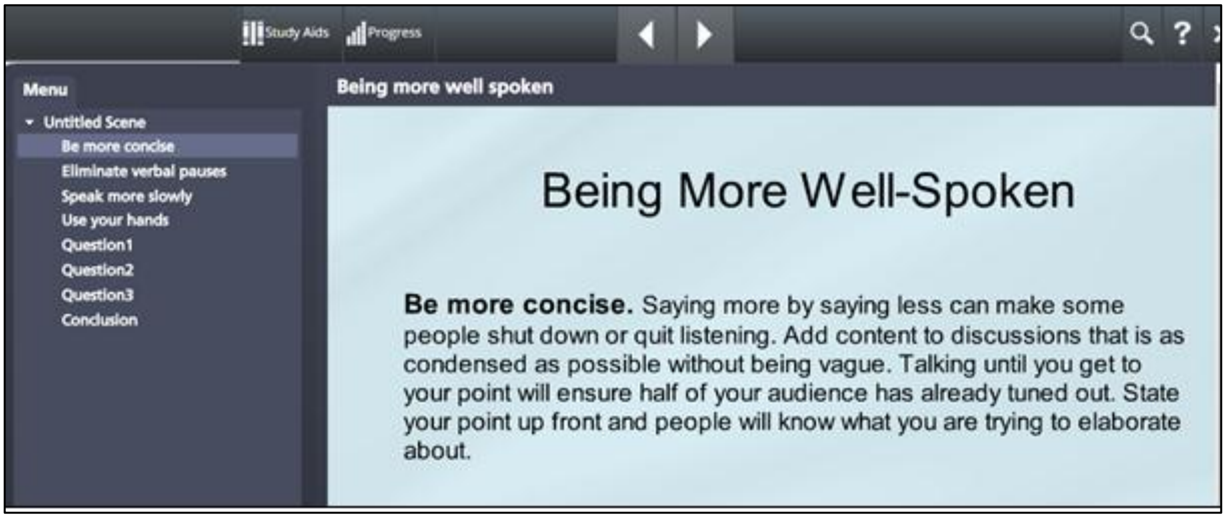


Figure 219. Learning Course Page

2. Use the Navigation button ▶ to navigate to the consecutive pages.

3. On completion of the course, click icon. The status of the training course is displayed.

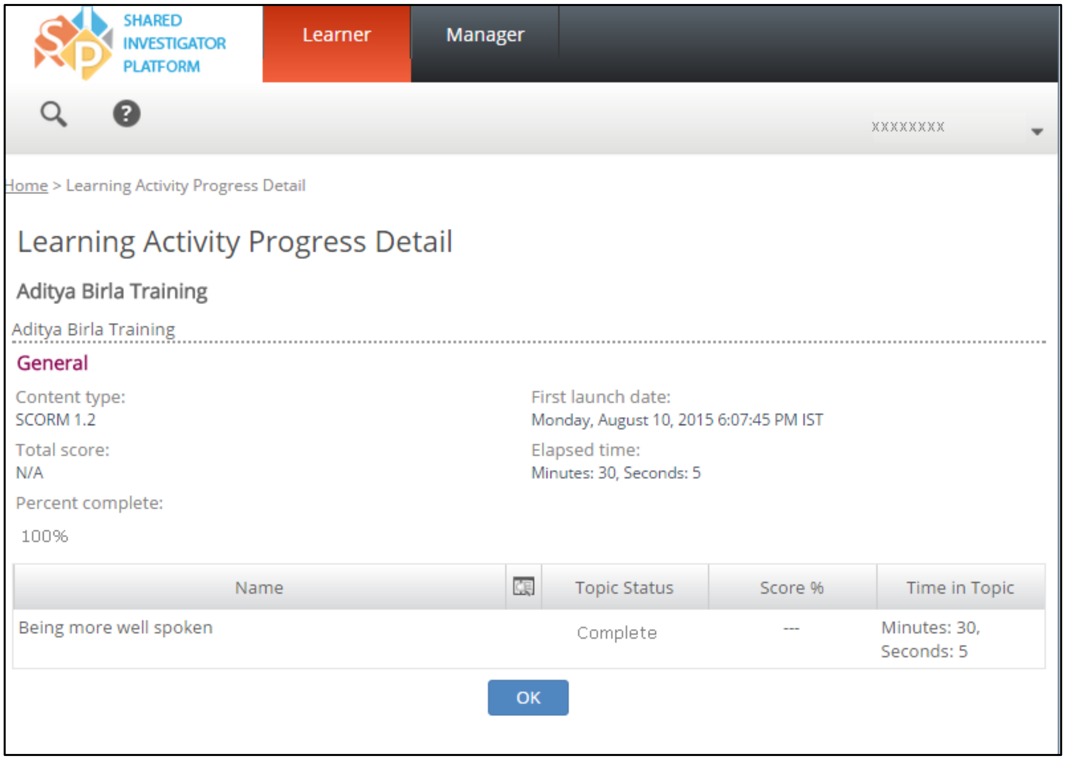


Figure 220. Learning Course Status Page

4. Click **OK**. The Completed Training tab with the current status of training course is displayed as Completed.

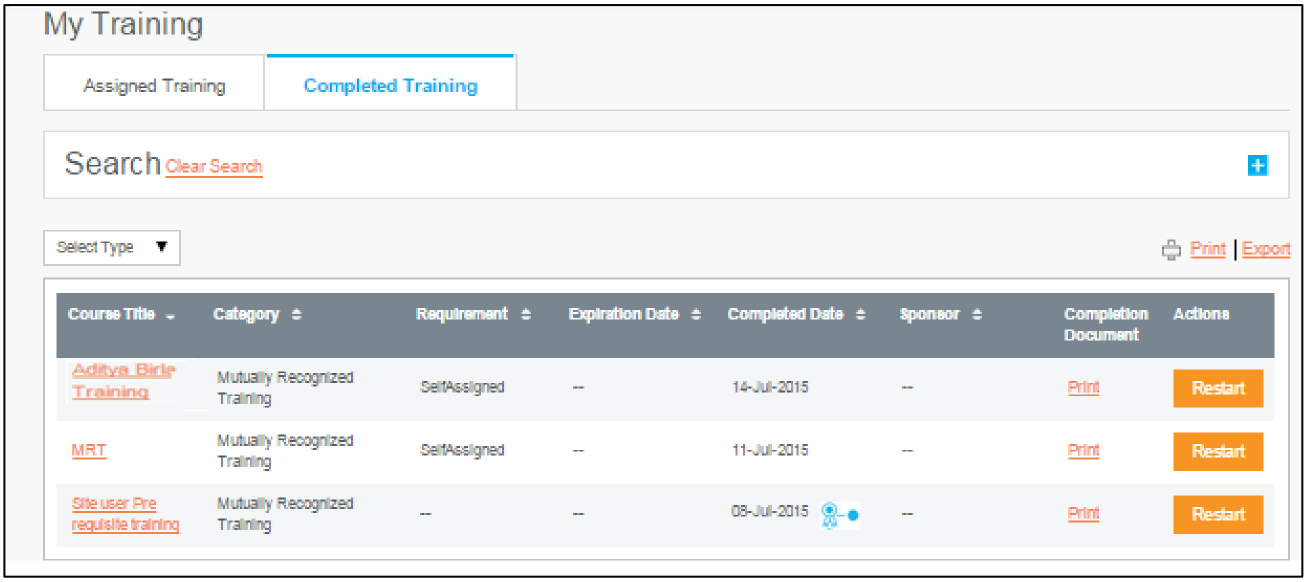


Figure 221. Learning Course: Completed Training Page

5. To export the assigned training details, click **Export**. The following dialog box is displayed.

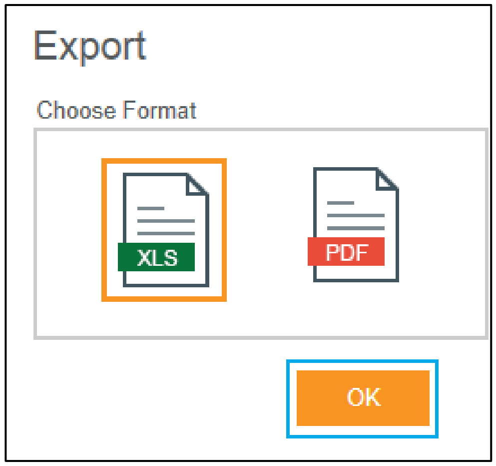


Figure 222. Export Assigned Training Course Dialog Box

8. In the **Export** dialog box, click a required format: **XLS** or **PDF**, and click **OK**.

9.1.2 Completed Training

This feature allows the Site Users to view, relaunch, and export course details for all the completed trainings. Site Users can restart a training course as a refresher.

To search for a completed training course

1. On the **My Training** page, click the **Completed Training** tab.
2. In the **Search** section, enter or select any or all of the search criteria, and then click **Search**. For Search for Course field descriptions, refer to Table 35.

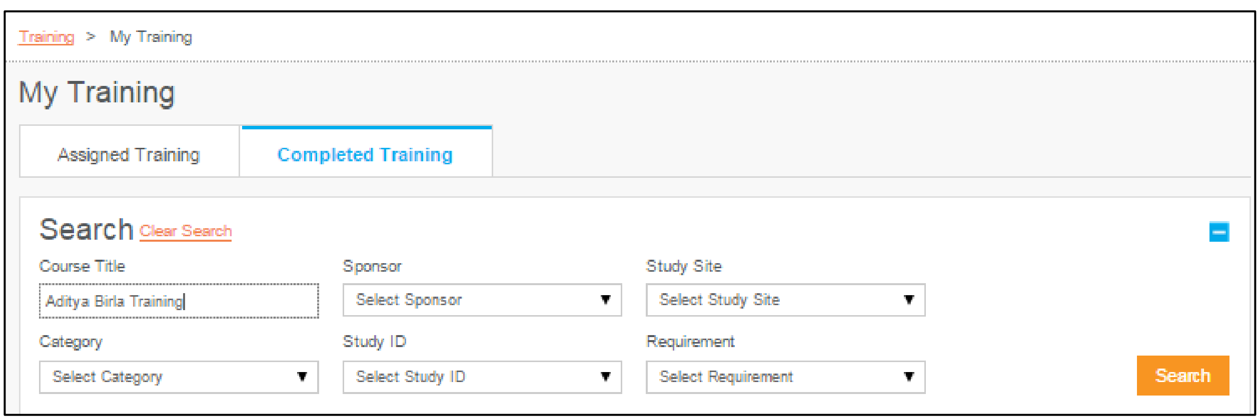


Figure 223. Completed Training: Search Course Page

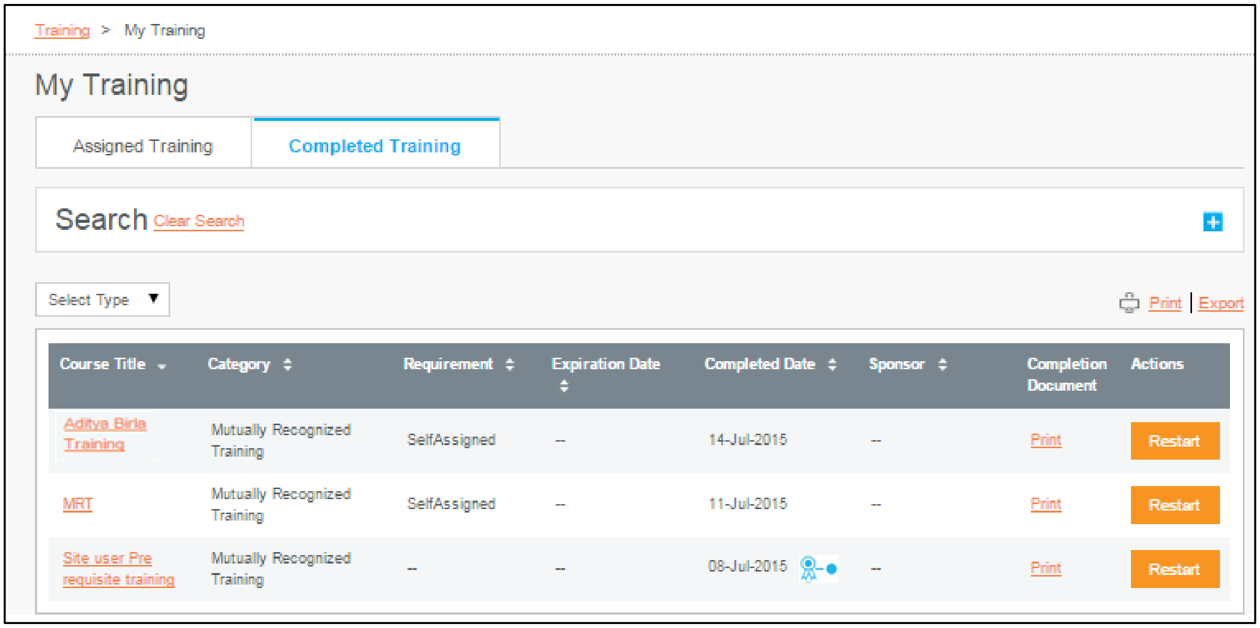


Figure 224. Completed Training: Course Search Results Page

3. To print the completed training course details, click **Print**.
4. To print the completed training certificate, in the **Completion Document** column, click **Print**.
5. To export the completed training course details, click **Export**.
6. To re-launch the training course as a refresher, in the **Actions** column, click **Restart**. The selected course page is displayed. You need to follow the same procedure to launch the training course again as specified in Assigned Training.

The following table lists the field descriptions for the search for a course section.

Field	Field Type	Mandatory Field	Field descriptions
Course Title	Text box	This is not a mandatory field	This is the title of the course.
Category	Drop-down list	This is not a mandatory field	This is the course category.
Sponsor	Drop-down list	This is not a mandatory field	This is the name of the Sponsor User.
Study ID	Drop-down list	This is not a mandatory field	This is the identification number of the study.
Study Site	Drop-down list	This is not a mandatory field	This is the name of the Study Site.
Requirement	Drop-down list	This is not a mandatory field	Click one of the following options: Required, Assigned, or Recommended.

Table 32. Field Descriptions for Search for a Course

9.2 Find a Course

The Find a Course feature in the Training module helps Site Users search for courses of interest for self-assignment.

Courses are made available for self-assignment at the discretion of each Sponsor. Only courses of the Category Mutually Recognized Training are mutually recognized for credit across all participating sponsors. The Site Users can access the training course, only if they have registered for the course.

To find a course

1. On the **Training** menu of the SIP User Landing Page, click **Find a Course**.

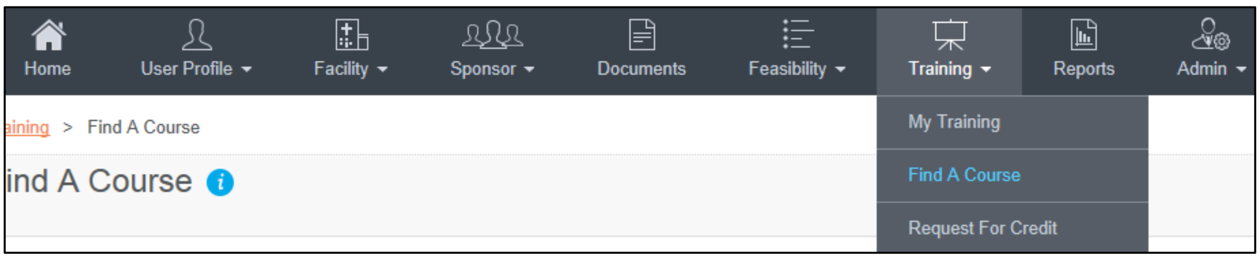


Figure 225. Training: Find a Course

2. On the **Search Courses** section, enter or click any or all of the search criteria, and then click **Search**. For Find a Course field descriptions, refer to Table 36.

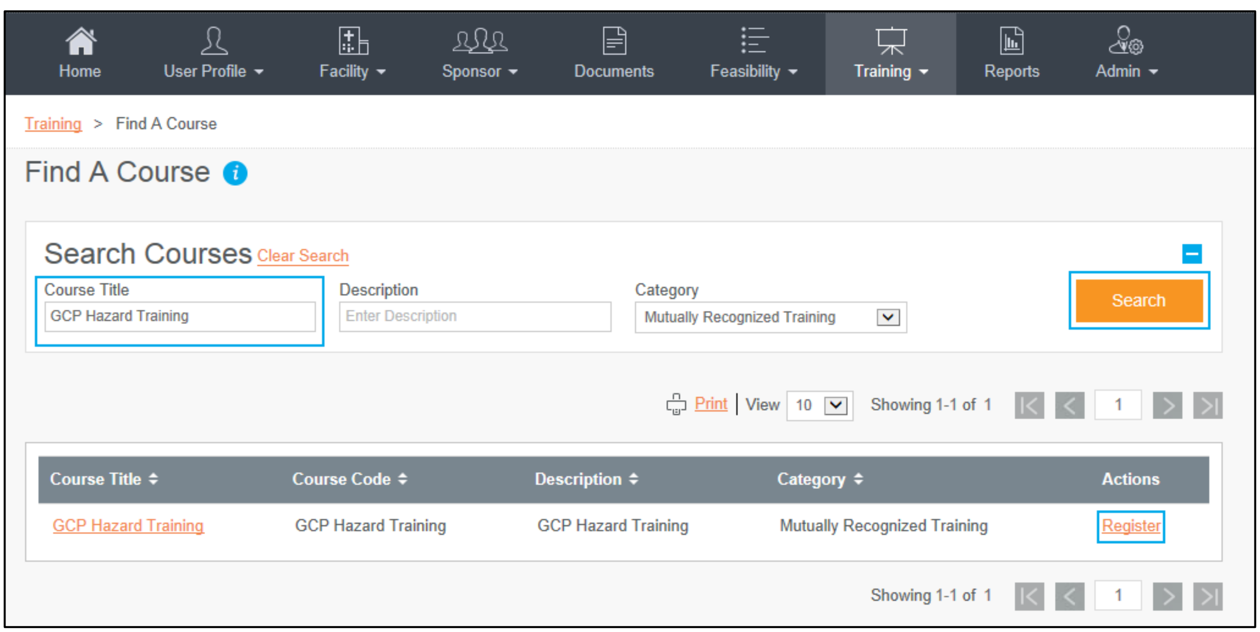


Figure 226. Find a Course page

3. To print the course details, on the **Find a Course** page, click **Print**.

To register for a course

1. To register for a course, in the search results displayed, in the **Actions** column, click **Register**. The following confirmation message is displayed.

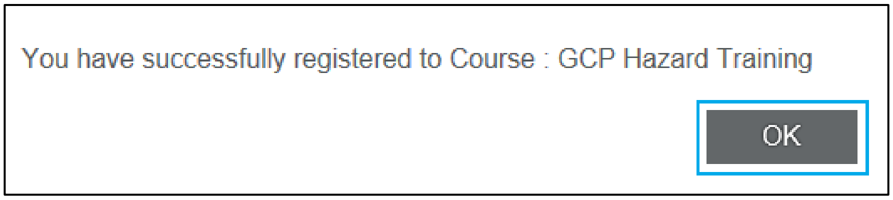


Figure 227. Course Registration: Confirmation Message

2. To accept the confirmation message, click **OK**.

The following table lists the field descriptions for the Find a Course section.

Field	Field Type	Mandatory Field	Field Descriptions
Course Title	Text box	This is not a mandatory field	Title of the course
Category	Drop-down list	This is not a mandatory field	Category of the course
Description	Text box	This is not a mandatory field	Brief description of the course

Table 33. Field Descriptions for Find a Course Section

9.3 Request for Credit

The Request for Credit feature allows the Site Users to request credit for courses completed outside SIP. The designated PI/Site Contact can request credit on behalf of other Study Site Staff if both Site Users are associated with that Study Site.

To view list of requests for credit

1. On the **Training** menu of the SIP User Landing Page, click **Request for Credit**.

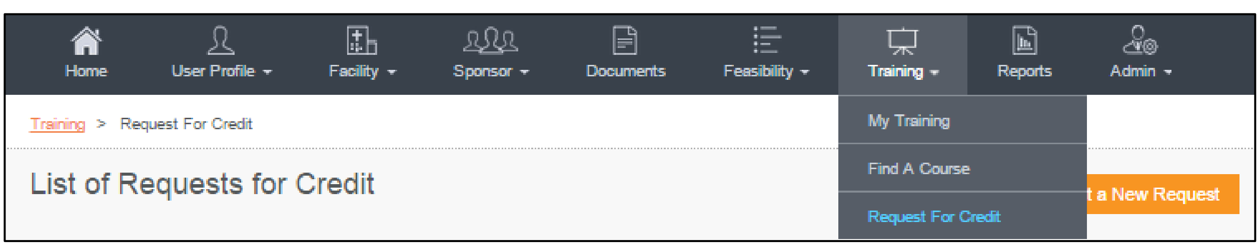


Figure 228. Training: Request for Credit Page

2. In the **All Status** drop-down, click a status of the course: **Sent for Approval**, **Approved**, or **Rejected**. The courses with the selected status are displayed.

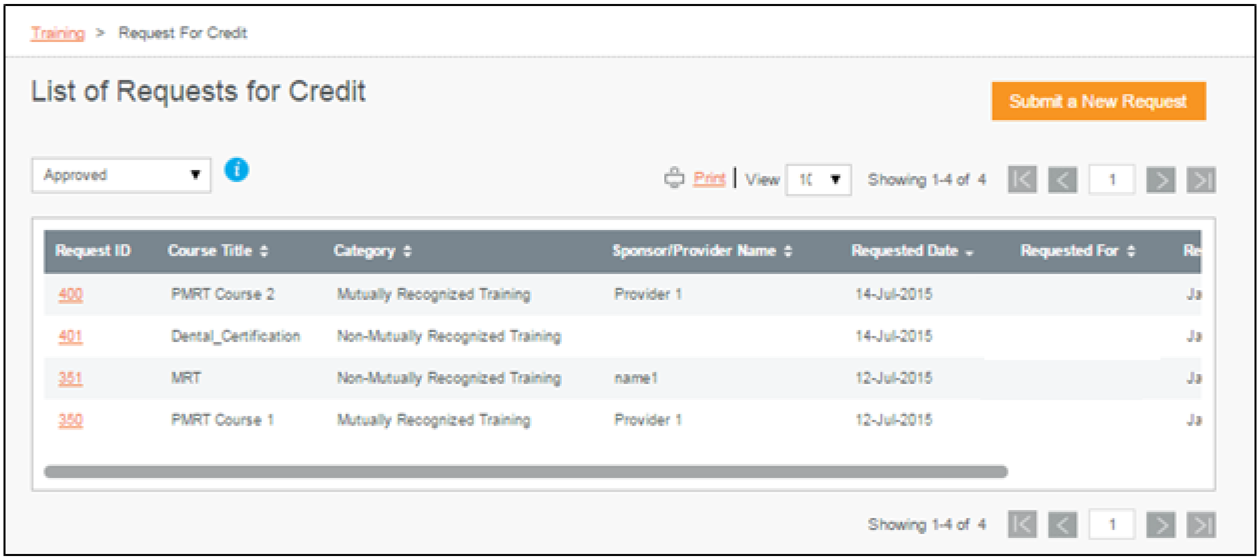


Figure 229. List of Requests for Credit Page

6. To print the requests for credit, on the **List of Requests for Credit** page, click **Print**.

9.3.1 Request for Credit for Yourself

The Request for Credit feature allows you to place a request for credit for training courses that you completed.

To request for credit for yourself

1. On the **List of Requests for Credit** page, click **Submit a New Request**.

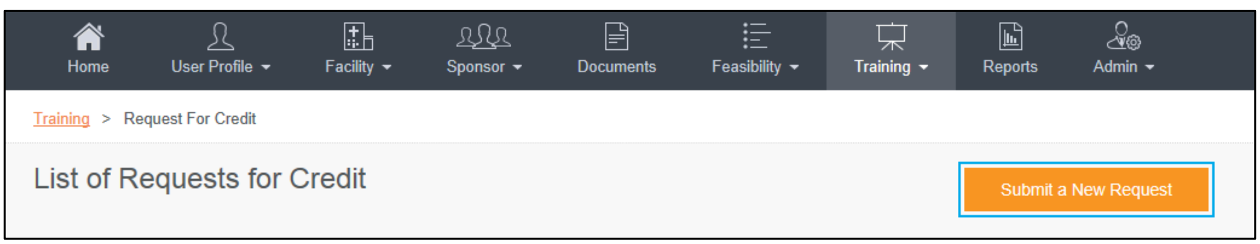


Figure 230. Submit a New Request Option

2. On the **Submit a New Request** page, in the **Request Credits for** section, click **Myself**.
3. In the **Select Course Title** drop-down list, click the required course.
4. Click the date picker, and then click date of completion.
5. In the **Comments** box, enter the comments for the designated Principal Investigator or the Designated Site Contact, if any.

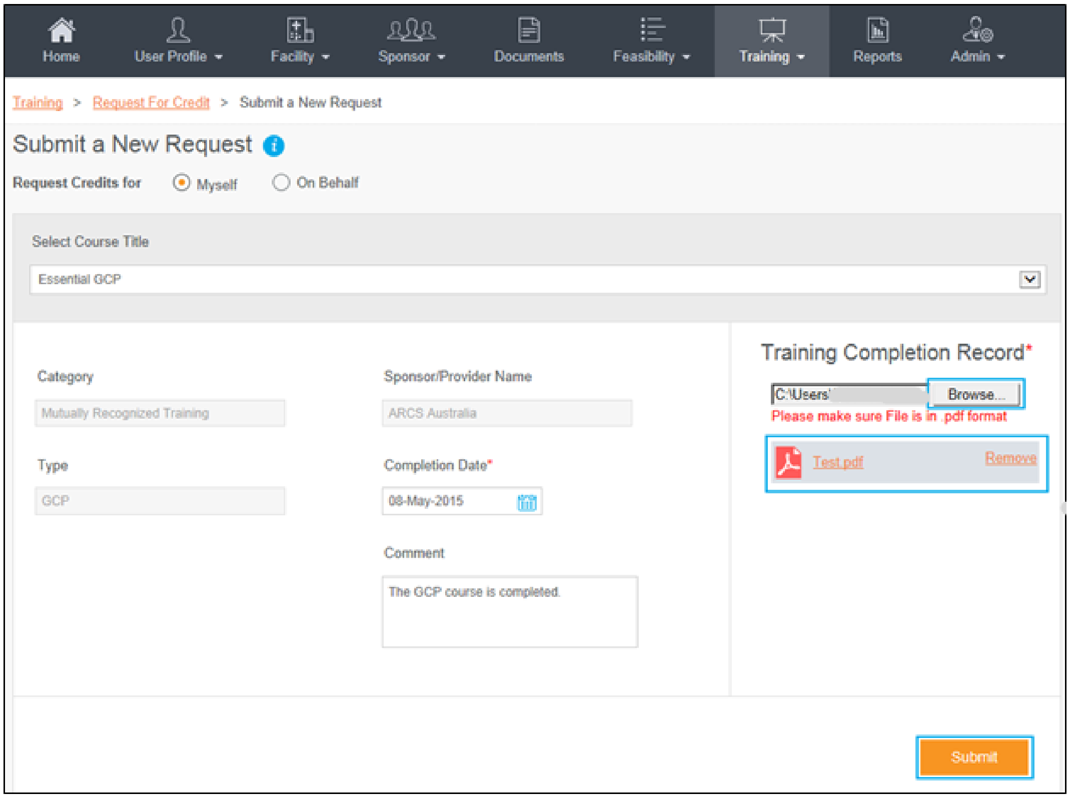


Figure 231. Request Credits: Self

6. To add a file, in the **Training Completion Record** section, click **Browse**. The Choose File to Upload dialog box is displayed.

7. Browse to the location of the file, and then click **Open**.

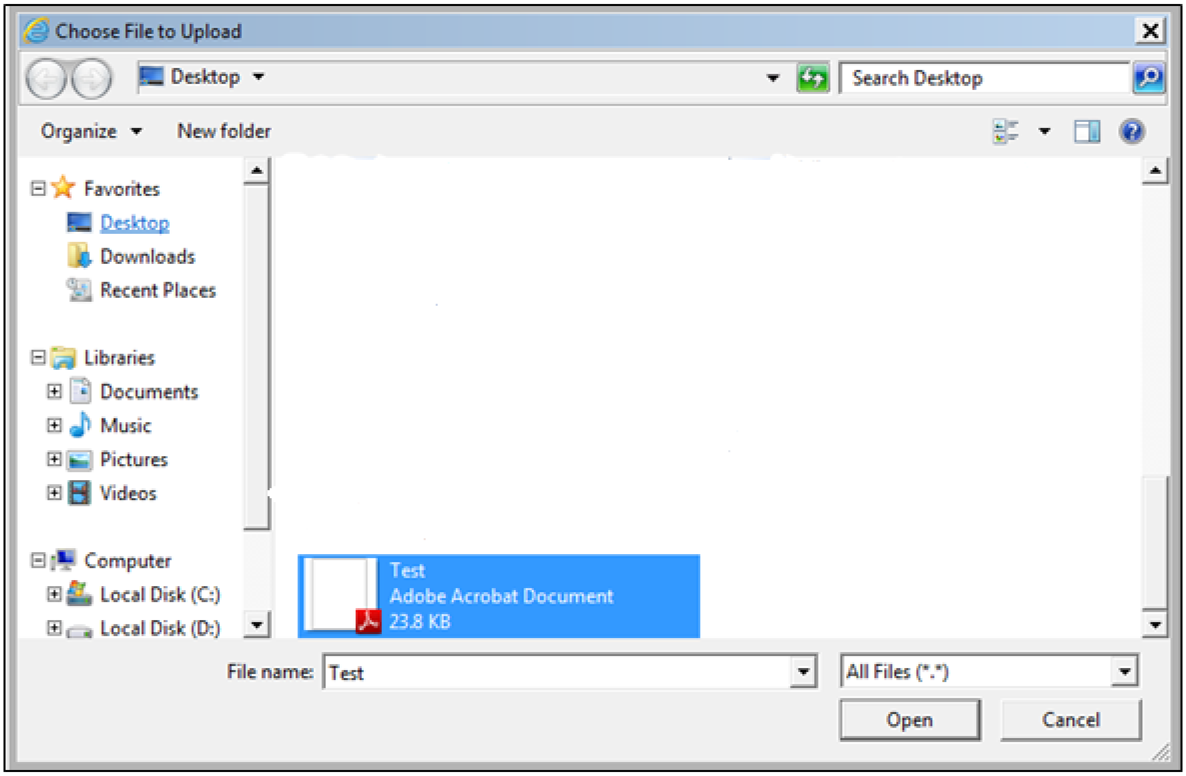


Figure 232. Choose File to Upload Dialog Box

8. To submit the request, click **Submit**. A confirmation message is displayed.

9. To accept the confirmation message, click **OK**. The request is sent to the Sponsor (Training Credit Approver) and the credit is awarded when the request is approved.

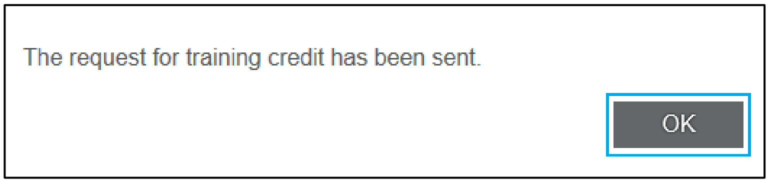


Figure 233. Request for Training Credit: Confirmation Message

The Training Completion Record is a mandatory section. In the Training Completion Record section, it is mandatory to attach the training completion records. The file attached in the Training Completion Record section needs to be a PDF. The request is sent to the Sponsor for approval.

9.3.2 Request for Credit on Behalf of Another User

The Request for Credit feature allows the Site Users such as a Principal Investigator or designated Site contact to place a request for credit on behalf of other Study Site Staff. This is possible only if both Site Users are associated with that Study Site (that is assigned to the same Study Workspace).

To request for credit on behalf of another user

1. On the **List of Requests for credit** page, click **Submit a New Request**.
2. On the **Submit a New Request** page, click **On Behalf**.

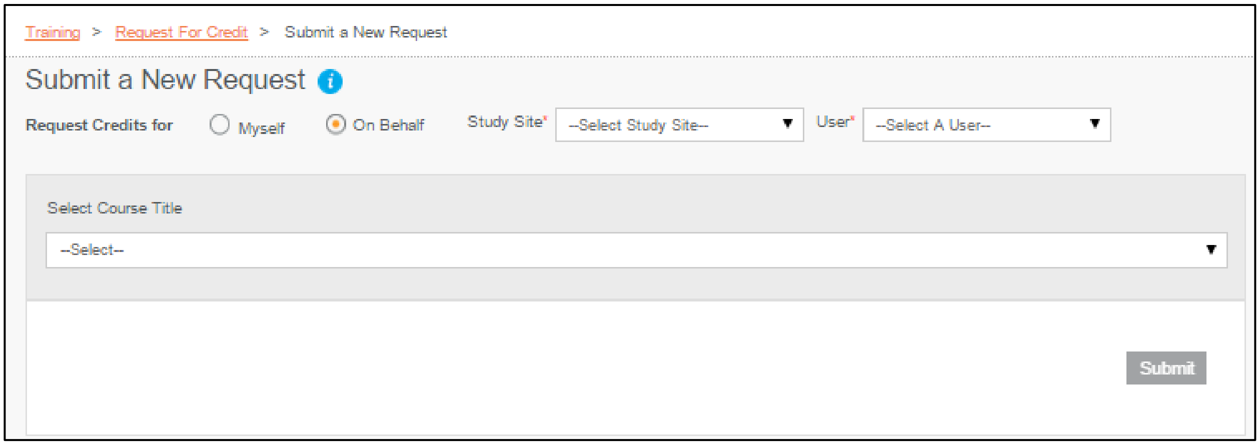


Figure 234. Submit a New Request page

The following mandatory fields are displayed: Study Site and User.

3. In the **Study Site** drop-down list, click the required Study Site.
4. In the **User** drop-down list, click the Site User for whom the credits request need to be raised.
5. In the **Select Course Title** drop-down list, click the course title. The additional information that needs to be filled out before submitting the request.

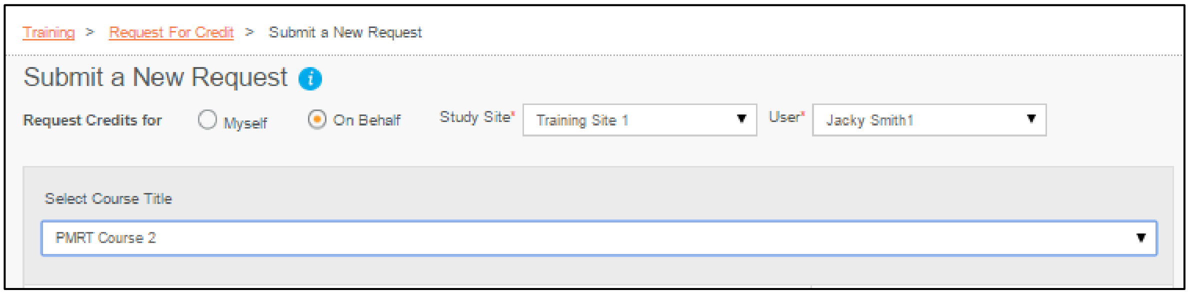


Figure 235. Submit a New Request: Select Course Title page

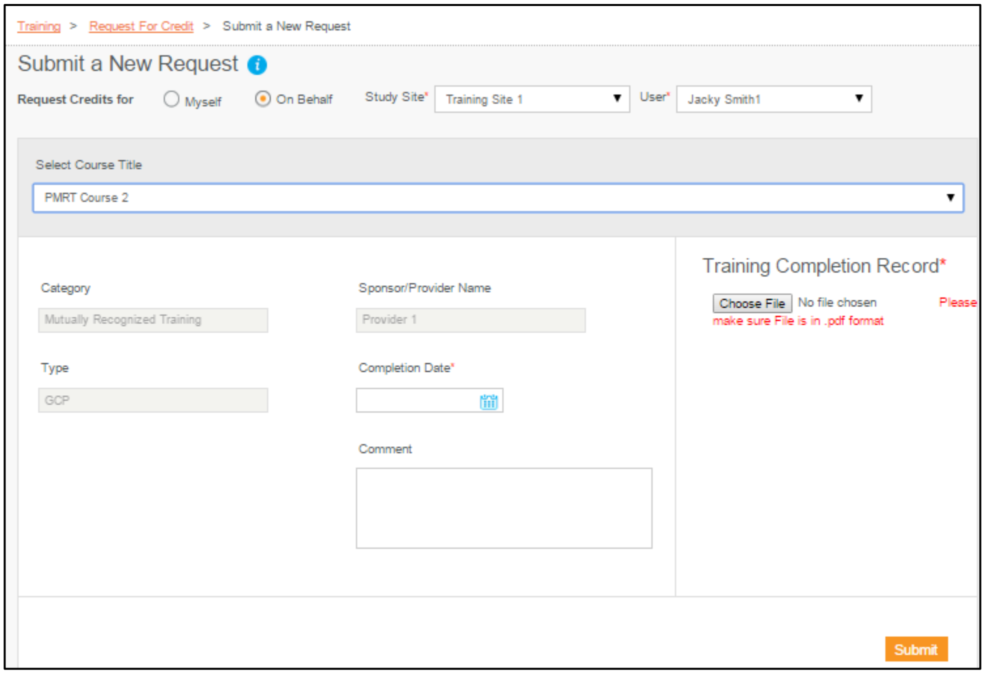


Figure 236. Submit a New Request: Additional Information page

6. In the **Completion Date** field, click the date picker icon, and then click a date of completion.
7. In the **Comments** box, enter the comments for the designated Principal Investigator or the Designated Site Contact, if any.
8. To add a file, in the **Training Completion Record** section, click **Browse**.
9. In the **Choose File to Upload** dialog box, browse to the location of the file, and then click **Open**.

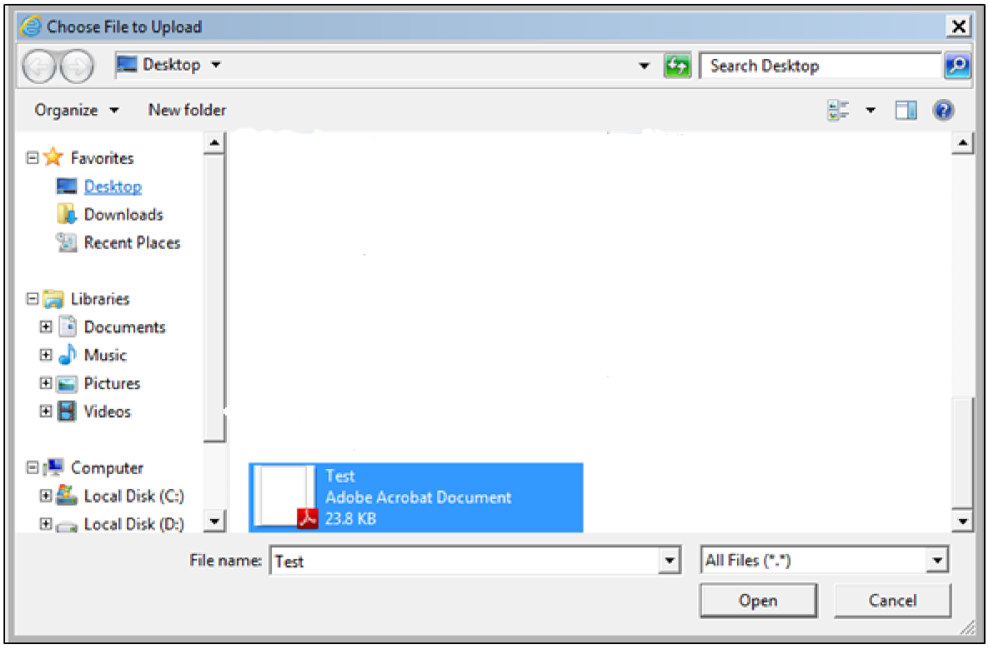


Figure 237. Choose File to Upload Dialog Box

10. To submit the request, click **Submit**. A confirmation message is displayed.

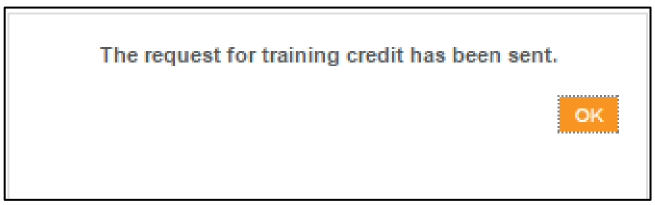


Figure 238. Request for Training Credit: Confirmation Message

11. To accept the confirmation message, click **OK**. The request for training credit is sent as a notification to the Principal Investigator or the Designated Site Contact.

In the Training Completion Record section, it is mandatory to attach the training completion records.

The file attached in the Training Completion Record section needs to be a PDF. The request is sent to the Sponsor for approval.

10 Manage Reports

A Site User who is either a Principal Investigator or a Delegate can generate the Training Status Report.

If a Site User other than the Principal Investigator or a Delegate tries to access this report section, the following error message is displayed: 'You do not have permissions to view this section'.

Permission to Assign Other Study Site Staff can be checked under the Sponsor Study Site Staff tab for a Study Site. This gives the Delegate the permission to assign other Site Staff to the Study Workspace as well as run the Training Status report.

Site Users can perform the following task in the Reports module: Generate Training Status Report.

10.1 Generate Training Status Report

The Training Status Report displays the status of all trainings assigned to the Study Site Staff. The Site User can filter the report data by using the filter criteria, such as Study ID, Study Site ID, Status, Study Site Role, Country, Training Type, Site Staff, and the time taken to complete the training.

The 'Export with user records' option allows the Site User to export the Excel sheet (similar to 'Export') and associated training certificates in a zip file. Site Users can export the report in one of the four formats: .xls, .csv, .pdf, and .xml.

To generate a report

1. On the Site User Landing Page, click **Reports**.

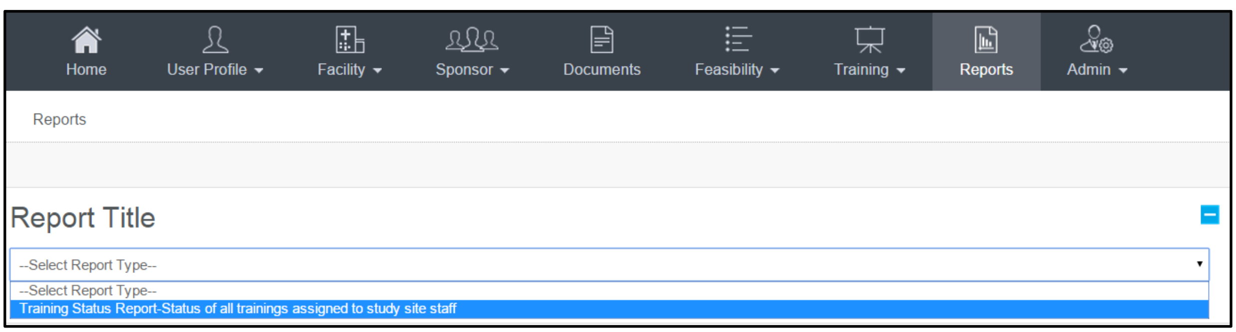


Figure 239. Report Title Drop-Down List

2. In the **Report Title** drop-down list, click **Training Status Report-Status of all Trainings Assigned to Study Site Staff**.

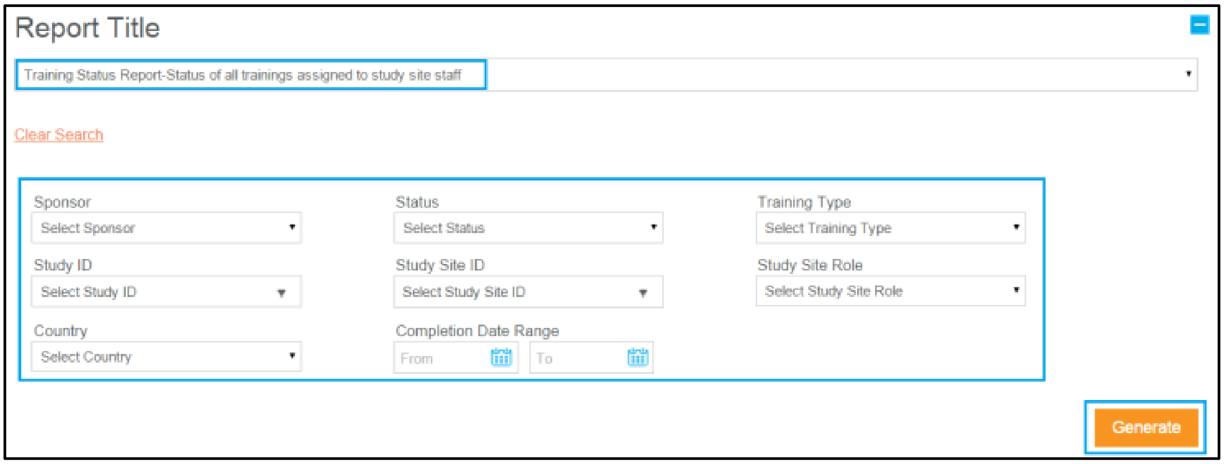


Figure 240. Training Status Report: Filter Criteria

3. Select or enter the required filter criteria. For Training Status Report field descriptions, refer to Table 37.

4. Click **Generate**. The Training Status report is displayed.

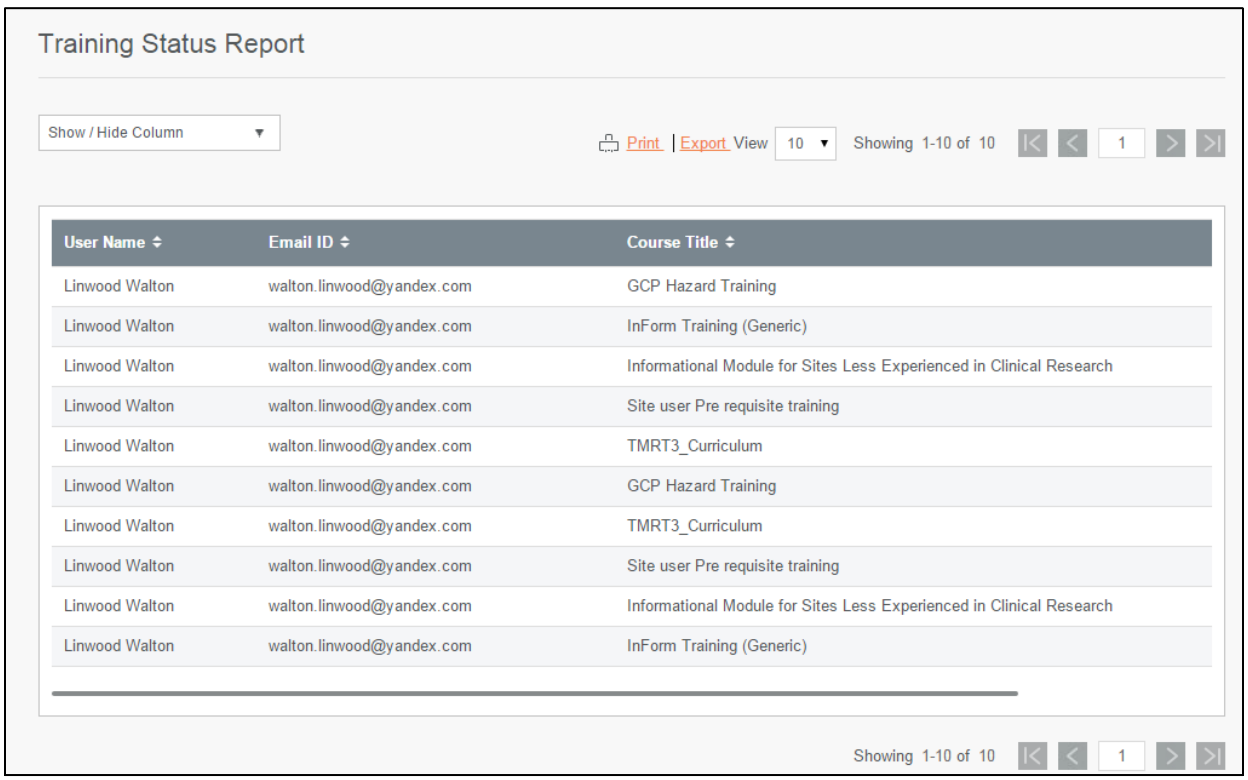


Figure 241. Training Status Report

To select the report columns, click the Show/Hide Column drop-down list. Select the required check box and click Apply. The selected report details are displayed.

*To print the report, click **Print**.*

*To export the report, click **Export**. The Export Report Response window is displayed.*

*To export the report in Microsoft® Excel format, in the Export Report Response window, click , and then click **Export**.*

*To download the report as PDF, in the Export Report Response window, click and then click **Export**.*

*To export the report data in .CSV format, in the Export Report Response window, click and then click **Export**.*

*To export the report data in XML format, in the Export Report Response window, click and then click **Export**.*

*To cancel the activity, click **Cancel**.*

*To directly export the report in Microsoft® Excel format, click **Export with User Records**.*

The following are the output parameters of the Training Status Report:

- User Name
- Email ID
- Course Title
- Sponsor
- Status
- Completion Certificate
- Completion Date
- Due Date
- Category
- Study ID
- Study Site ID
- SIP User ID

Training Status Report Field Descriptions

The following table provides the field descriptions for all the fields in the filter criteria.

Field	Field Type	Field Descriptions
Sponsor	Drop-down list	Name of the Sponsor User
Study ID	Drop-down list	This is the protocol number of the study for the selected compound and program Note Displays all the studies to which the Sponsor User is associated.
Study Site ID	Drop-down list	Name of the Study Site Note The Study Site ID values are displayed based on the selected study ID.
Status	Drop-down list	Status of the training
Study Site Role	Drop-down list	Role of the Study Site Staff
Country	Drop-down list	Name of the country
Training Type	Drop-down list	Type of the training
Site Staff	Search	Name of the Study Site Staff
Completion Date Range	Date picker	From and To date range of the completed training

Table 34. Field Descriptions for Training Status Report

11 Appendix

11.1 Global Helpdesk Numbers

US Toll Free Number: 1-855-770-2615

US Toll Number: 1-951-821-2630

US Toll Number: 1-347-817-7874

You need to enter the Customer Code as 1234

The following are the phone numbers for all countries:

Country	Toll - Free Access Number	Toll or Local Access Number City #1	Toll or Local Access Number City #2
Argentina	08004449878	541159842045	543424134922
Australia	1800856878	61261112046	61280730159
Austria	0800297498	431253021591	4326822059317
Bahamas	18003890656	-	-
Bahrain	80004803	97316198748	97316198753
Belgium	080078308	3228948355	3228948356
Brazil	08008922468	552127306917	552127306918
Bulgaria	008001181122	35924916052	35932570144
Chile	12300206733	5625994738	5625994723
China	108007141749 108001401779	864001201489	-
Colombia	018005181945	-	-
Costa Rica	08000111245	-	-
Croatia	0800805967	-	-
Cyprus	80097406	35722022637	35726022683
Czech Republic	800700458	420225986561	420587439896
Denmark	80250475	4532727759	4532727760
Dominican Republic	18887514925	18299478907	18299478908

Country	Toll - Free Access Number	Toll or Local Access Number City #1	Toll or Local Access Number City #2
El Salvador	8006904	-	-
Estonia	8000100373	3726226555	3726226572
Finland	0800915543	358931582265	358341089328
France	0800914548	33170918693	33488921892
Germany	08001844796	4969255114427	4969255114428
Greece	0080016122069878	302111980217	302721128014
Hong Kong	800908733	85258082879	85258082907
Hungary	0680019767	3614088966	3652808054
Iceland	8009393	-	-
India	0008001008258	-	-
Indonesia	0078030199878 0018030199878	-	-
Ireland	180094722five	35315260093	35315260094
Israel	1809459878	97225609355	97237217952
Italy	800788009	390645230485	390230410460
Japan	00531161240	81350505377	81350505378
Latvia	80004341	37166013631	37166013644
Lithuania	880031463	37052055472	37052055489
Luxemburg	80026983	35220881798	35227860001
Malaysia	1800816027	-	-
Malta	80062266	-	-
Mexico	0018005149878	525547772354	528112477645
Monaco	80093842	-	-
Netherlands	08000227909	31207946722	31207946723
New Zealand	0800452821	6449094650	6499291855
Norway	80069928	4721075084	4775803201

Country	Toll - Free Access Number	Toll or Local Access Number City #1	Toll or Local Access Number City #2
Panama	008002269878	5078366149	5078366148
Peru	0800five4968	5117071241	5117071278
Philippines	180011101353	-	-
Poland	008001124371	48222953580	48814635045
Portugal	800827765	-	-
Romania	0800895859	40215293996	40215293905
Russia	88001009602	74952216665	
Singapore	8001012655	6531582502	6531582526
Slovakia	0800606594	421233215507	421412302907
Slovenia	080081091	38618888199	38658888103
South Africa	0800999123	27218311909	27115898328
South Korea	00798142069878	-	-
Spain	900866970	34917699713	34960473328
St Kitts And Nevis	18003002063	-	-
Sweden	020791641	46850513595	46850513596
Switzerland	0800563073	41225927650	41434569582
Taiwan	00801127362	-	-
Thailand	0018001562069878	-	-
Trinidad	18002069878	-	-
Turkey	00800142074718	-	-
UAE	800035702329	-	-
UK	08006351260	442034639190	441214110947
UK Virgin Islands	18773957761	-	-
Uruguay	00040190562	-	-
Ukraine	800500724	-	-

Country	Toll - Free Access Number	Toll or Local Access Number City #1	Toll or Local Access Number City #2
Venezuela	08001029696	-	-
Vietnam	18004836	-	-
US / Canada	18774089578	13237812748	13103434990
Alaska, Puerto Rico, American Samoa, Guam, Mariana Islands, Saipan & US Virgin Islands	18774089578	13237812748	13103434990

11.2 Glossary

The following table lists the terms and definitions used in this manual.

Term	Definition
Dashboard	A graphical view of key performance indicators relevant to a specific role. Data includes Standard TCB information and Sponsor specific information.
Delegate	A Site User identified on behalf of another Site User to perform SIP-related tasks (e.g. User Profile completion or survey completion).
Exostar	User Profile data is uploaded to SIP
Facility	A facility is the physical location (for example, hospital or doctor's office) where the investigators perform clinical research. This facility is associated with the study workspace at the time when the facility is selected for a clinical trial.
Facility Profile Manager	The Facility Profile Manager is responsible for the entry and maintenance of the facility profile. Each site needs to have at least one Facility Profile Manager.
Landing Page	First page viewed when logging on. It contains an aggregation of various portlets based on roles (for example, alerts, and dashboards).
IRB/EC/ERB	IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects in US and EC is the group designated to review and monitor biomedical research involving human subjects outside US. Note: In this document IRB, Ethics Committee (EC) and Ethical Review Board (ERB) has been used interchangeably.

Term	Definition
FAQ	FAQs is the list of most frequently asked questions and answers that help Site Users learn important task-specific information and concepts involved in all the SIP modules.
Primary Site Contact	A site has the option to assign a Primary Site Contact for SIP clinical trials; this role can be assigned in the Facility Profile. The Primary Site Contact will receive copies of certain SIP notifications that are sent to the facility. The Primary Site Contact can also act on those notifications. These notifications include: Invitations to participate in pre-study evaluations Invitations to participate in a study Invitations to participate in a Sponsor Survey
Study Site	Study site is the combination of a Principal Investigator and Facility assigned to a specific study. For each study site, the PI or his/her delegate must define the following on the SIP Study Site page: Study Site Profile and Study Site Staff..
Module	Segments of a training course.
Notification	A communication in writing that gives notice that could be delivered via a dashboard, email, text, or other medium.
POC	Point of Contact
Site User	A Site User is any individual who is based at a research site and participated in the conduct of a clinical trial, for example, Investigator, site coordinator, and study nurse. This individual is registered to utilize the platform, and manages their own profile data including credentials.

Table 35. Glossary

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