Cognizant
Shared
Investigator
Platform

Table of Contents

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

Legal Notice

These materials have not been published and are not available to the public because they are proprietary to Cognizant and contain Cognizant confidential and/or trade secret information, including without limitation the descriptions of features, functions, methods, techniques, and technical concepts contained herein. These materials may also contain information covered by U.S. and/or foreign patents or patent applications. Use, distribution or copying of these materials, in whole or in part, is forbidden, except with Cognizant's express prior written permission.

The documentation is provided "as is" and all express or implied conditions, representations and warranties, including any implied warranty of merchantability, fitness for a particular purpose or non-infringement, are disclaimed, except to the extent that such disclaimers are held to be legally invalid. Cognizant shall not be liable for any incidental or consequential damages in connection with the furnishing, performance, or use of this documentation. The information contained in this documentation is subject to change without notice.

Cognizant® and Shared Investigator Platform are either registered trademarks or trademarks of Cognizant in the United States and other countries. Other trademarks referenced herein are the property of their respective owners.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **2** of **26**

Revision History

Version	Date	Author	Changes
1.1.0.22	04 Aug 2022	Cognizant Technology Solutions	Release 8.0 Updates

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **3** of **26**

1   What is a Facility Profile or Department Profile?

The Facility Module allows you to provide information about your Facility, by creating a profile for your Facility and Departments within the Facility. Facility and Department Profiles include detailed information about the physical location (for example, a hospital or a doctor's office) where a Principal Investigator conducts clinical research. In SIP, a unique Profile record is created for each location where an investigational product will be shipped. This includes any Primary Research location, which would be listed on Form 1572, or equivalent.

The information in a Facility Profile allows a Sponsor to identify the adequacy of Facility or Department to be used in conduct of a clinical trial. The Sponsor evaluates whether a Facility has the appropriate equipment and access to potential clinical trial subjects to meet the trial requirements. When a research facility or research department is selected for a clinical trial, the corresponding SIP Facility Profile and/or Department Profile is associated with the Study Workspace.

2   What information does a Facility/Department Profile include?

A Facility/Department Profile includes the following sections:

- ❖ **Facility Name & Address**— The primary address of the Facility/Department
- ❖ **Facility Contacts**— The individuals responsible for managing the profile in SIP and other contacts who will be copied on key SIP notifications and have access to view study information
- ❖ **Therapeutic Areas and Patient Population** — Details about the therapeutic area experience, study phase capabilities, and access to patient population
- ❖ **IRB/ERB/Ethics Committees** — Basic details about your ethics review process, the types of ethics committees your Facility works with, and the name and address of organizations that you work with on a regular basis
- ❖ **Local Labs** — Name, address, and accreditation of labs you commonly use on your studies
- ❖ **Consent and Training** — Basic details about your informed consent policies and procedures and the training provided to your site staff
- ❖ **Facility & Equipment** — Details about your facility capabilities, equipment, and computer capabilities available at the Facility
- ❖ **Investigational Product (IP) & Controlled Substances** — Names and addresses for IP Shipping and Storage Locations, storage equipment, policies and procedures, and controlled substance capabilities
- ❖ **Source Documentation & Remote Monitoring** — Details about paper or electronic records and equipment available to monitors
- ❖ **Additional Locations** – Details about additional addresses where patients are seen for procedures and lab services. These locations can be selected and added into a Study Site Profile.
- ❖ **Additional Information & Attachments** — Details about additional information or supporting documents for Facility/ Department.
- ❖ **Organization Affiliations** – Details about the affiliation requests to Facility/Departments in SIP from Organizations
- ❖ **Associated Site Users** - Details about the associated site users and pending site user association requests for a Facility.

3   Who can create a Department?

The following Site Users can create a Department under a facility in SIP:

- ❖ Facility Profile Manager(s) for the given facility
- ❖ Any Department Profile Manager(s) for the existing departments under the given facility
- ❖ Any Organization Profile Manager(s) for the organizations affiliated with the given facility

You can only edit a department profile if you are listed as a Department Profile Manager for the Department. If you are not the DPM and you need a Department Profile updated, send a message to the Department Profile Manager by clicking on the "Send Message to DPM" option in the actions column against the department record.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **4** of **26**

4	Who can be assigned as the Facility or Department Profile Manager?

For Facility Profile, when the first Site Staff member tries to add a facility to his/her User Profile – he/she will have the option to become the Primary FPM or assign another Site User.

Similarly, site users who create a Department is automatically assigned as the Primary Department Profile Manager and may assign the role to another site user and remove themselves as needed.

To assign an unregistered Site User send them a registration invitation. Once the individual is registered, you will need to search them again and then assign them as Primary FPM/DPM.

> *You can add multiple Facility Profile Managers from the Facility Contacts screen to maintain the Facility Profile.*

Facility Contacts

Facility Contacts

The following Facility Contact roles can be assigned at the Facility level.

1. Facility Profile Managers (FPM)
   - FPM have the ability to set-up, edit and maintain the Facility Profile.
   - Multiple FPMs can be added to maintain a Facility Profile, however only one individual can be selected as "Primary" FPM. The Primary FPM receives all of the Facility Profile related messages.
   - FPMs can create Departments under their Facility and assign applicable Department Profile Managers (DPM) to manage the Department Profile.
2. Facility Clinical Trial Contact (FCTC)
   - FCTC is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.
3. Head of Facility (HoF)
   - HoF is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.
   - HoF is added as the study site staff for the study sites associated to this Facility and its Departments and is given read-only access to view those study site profiles.
   - You need to add Head of Facility as a FPM / DPM in the Facility and Department(s) profile, if you wish to provide him or her with the access to edit the Facility/Department Profile.
   - The Head of Facility Delegate has the same rights as the Head of Facility.
4. Budget/Financial Contact
   - Budget/Financial Contact evaluates financial aspects of the pre-study contract with Sponsors, suggests and renders financial opinion.
   - Budget/Financial Contact is added as the study site staff for the study sites associated to this Facility and its Departments.
5. Regulatory Contact (Facility/Department)
   - Regulatory Contact (Facility/Department) role collects and submits all regulatory documents for IRB/IEC approval.
   - Regulatory Contact (Facility/Department) is added as the study site staff for the study sites associated to this Facility and its Departments.
6. Contract Manager
   - Contract Manager manages CDA, contract and amendments with Sponsors before study set up.
   - Contract Manager is added as the study site staff for the study sites associated to this Facility and its Departments.
7. Clinical Research Manager
   - Clinical Research Manager monitors operational feasibility of the institution for potential study set up.
   - Clinical Research Manager is added as the study site staff for the study sites associated to this Facility and its Departments.
8. Delegation Manager
   - Delegation Manager can assign or modify the following SIP delegates on behalf of any site users affiliated to the Facility: User Profile, Survey, Study Site Profile Maintenance, Safety Contact and Regulatory Contact (PI Delegate).
9. Contingency Contact - Business
   - Contingency Contact - Business is the primary contact for any Business Continuity Plan (BCP) of facility/departments. This role manages the processes during the crisis situations including any kind of major, minor or serious disruptions.
   - Contingency Contact - Business is added as the study site staff for the study sites associated to this Facility and its Departments.

The Facility Contact roles added at the Facility level are:

❖ **Facility Profile Managers** (FPM) – Set-up, edit, and maintain Facility Profile.
❖ **Head of Facility** (HoF) – Is copied on all Survey and Study invitation notifications.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

The Head of Facility Delegate has the same rights as the Head of Facility.

❖ **Facility Clinical Trial Contact** (FCTC) – Is copied on all Survey and Study invitation notifications that are sent to the Principal Investigator assigned to that Facility/Department:

    ❖ Invitations to participate in Pre-Study evaluations

    ❖ Invitations to participate in a Study

    ❖ Invitations to participate in a Feasibility Survey

❖ **Budget/Financial Contact** - Evaluates financial aspects of the pre-study contract with Sponsors, suggests and renders financial opinion, added as the study site staff for the study sites associated to this Facility and its Departments and is given read-only access to view those study site profiles).

❖ **Regulatory Contact** (Facility/Department) - Collects and submits all regulatory documents for IRB/IEC approval, added as the study site staff for the study sites associated to this Facility and its Departments and is given read-only access to view those study site profiles).

❖ **Contract Manager** - Manages CDA, contract and amendments with Sponsors/CROs before study set up, added as the study site staff for the study sites associated to this Facility and its Departments).

❖ **Clinical Research Manager** - Monitors operational feasibility of the institution for potential study set up, added as the study site staff for the study sites associated to this Facility and its Departments).

❖ **Delegation Manager** - Set up and manage delegates for User Profile, Survey, Study Site Profile Maintenance, Safety Contact and Regulatory Contact (PI Delegate) on behalf of site users affiliated to the facility.

❖ **Contingency Contact - Business** - Manages the Business Continuity Plan (BCP) of the facility and its Departments. Users with this role are added as the study site staff for the study sites associated to a Facility and its Departments.

5	**What are the Roles and Responsibilities of a Facility Clinical Trial Contact?**

A Site has the option to assign an additional Site Contact for clinical trials called Facility Clinical Trial Contact (FCTC). This individual receives the following notifications sent to the Facility/Department Profile:

    ❖ Invitations to participate in pre-Study evaluations

    ❖ Invitations to participate in a Study

    ❖ Invitations to participate in a Feasibility survey

6	**How can I set up my Facilities and Departments?**

You should follow a centralized approach to setting up Facilities and Departments. This eliminates the risk of creating duplicates and ensures consistency.

    ❖ Search for your Facility, to ensure that it is not already set up.

    ❖ If you do not find your facility in the system, contact the SIP Helpdesk to create it for you.

    ❖ After the facility is created for you, you will be prompted to complete the entire profile yourself or assign someone else (Site Staff Member or an Organization) to complete the profile. In case you would not like to continue as the Primary Facility Profile Manager, you can assign someone else.

    ❖ In order to assign someone else to become the Facility Profile Manager, that person should be a registered SIP user so that he/she comes up in the search results when you try to search him/her using their email address or last name/first name.

    ❖ After the assignment is complete, the assigned user will get a notification and the facility will get added to his/her User Profile in SIP. He/she can then complete the remaining sections of the Profile.

    ❖ You can create all the Departments within your Facility that shall be used for conduct of studies in a similar manner.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **6** of **26**

7	How can I set up Delegation Managers for a Facility or Department?

SIP allows the Facility Profile Manager (FPM), Department Profile Manager (DPM), or Organization Profile Manager (OPM) to assign Delegation Manager roles to site users who are always affiliated with the facility or department. The FPM/DPM can select a site user in the **Facility Contacts** page and assign the Delegation Manager role.

For more information on how to assign Delegation Manager for a facility or department, refer to the Delegation Manager Job Aid.

Delegation Managers can set up and manage delegates (for User Profile, Survey, Study Site Profile Maintenance, Safety Contact and Regulatory Contact (PI Delegate) on behalf of site users affiliated to the same facility or department. The Delegation Managers can also assign themselves as delegates.
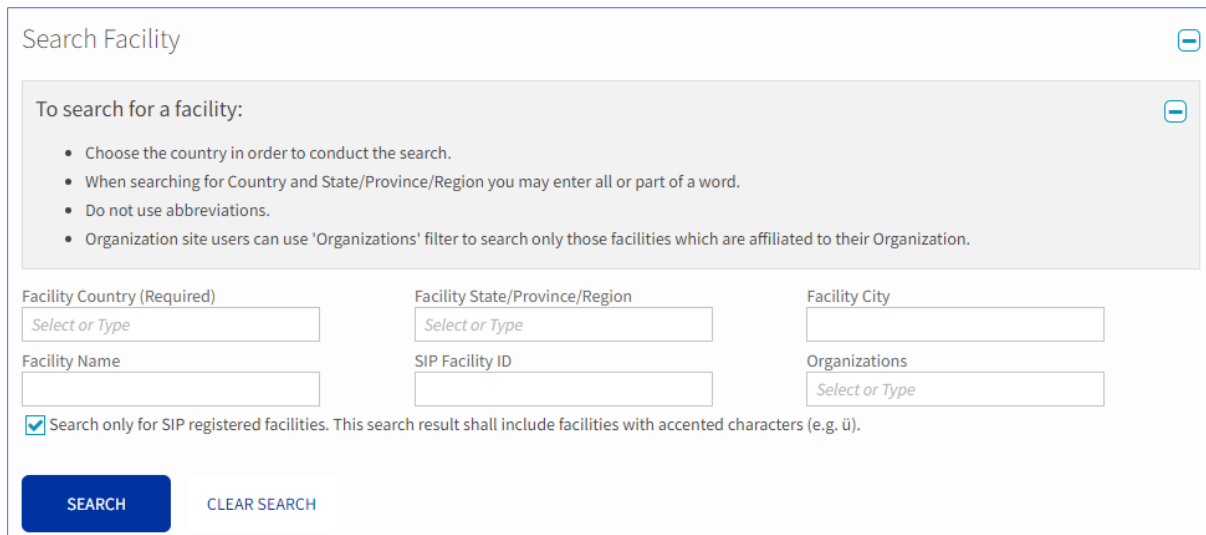
The availability of a Delegation Manager for a facility or department is indicated by an asterisk on the affiliated facility or department in the **My Facilities** screen.

8	How do I search for a Facility?

You can use the **Search Facility** page to search for Facility Profiles available in SIP.

To Search for a Facility:

1. On the menu bar, click **Facility** > **Search Facility.** The **Search Facility** screen appears.

- ❖ *You can also perform a search by clicking the **User Profile** menu, selecting **My Profile**, selecting **Facilities** in the left navigation and then clicking **Add Facility**.*
- ❖ *You can search for a Facility by selecting the country in which the Facility is located and by selecting the SIP Facility ID.*
- ❖ *You can use accented characters in the **Facility Name** and **City** fields when performing a search.*

2. In the **Search Facility** section, enter or select the search criteria, and then click **Search**.

The search results display only up to 200 facility records.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

Select	Facility Name ⌃	Address	City ⇕	State/Province/Region ⇕	SIP Facility ID	Contact FPM	FPM Approval Required?	Delegation Manager Available?	Organization Name
○	!@#	Testa Place, Fairfield County	Norwalk	Connecticut	FC0816201813222 11017	✉	No	No	View
○	"FAcility R"	"10 Main Street"	"Main City"	American Samoa	FC0924201919550 92180	✉	Yes	No	View
○	123	1220, U.S. 22, Somerset County	Bridgewater	New Jersey	FC0905201819481 61074	✉	No	No	View
○	123	123, Meadow Lane, Montgomery County	Coffeyville	Kansas	FC0913201807483 91082	✉	No	No	View
○	15825 Laguna Canyon Road	1 Main Road	Irvine	California	FC0430201819165 40703	✉	No	No	View
○	21st Century Oncology	7340 East Thomas Road	Scottsdale	Arizona	FC0508201814103 50728	✉	No	No	View
○	21st Century Oncology	8946 77th Terrace East	Lakewood Ranch	Florida	FC0629201819355 50799	✉	No	No	View
○	21st Century Oncology	7341 Gladiolus Drive	Fort Myers	Florida	FC0516201816454 00738	✉	No	No	View
○	21st Century Oncology	350 North West 84th Avenue	Plantation	Florida	FC0514201820215 00735	✉	No	No	View
○	\ /:*?|USA Eye Center\ /:*?|Facility\ /:*?|	1900 Street, Southeastern,, NA	Salem	Virginia	FC1209202007343 53466	✉	No	No	View

Showing 1 to 10 of 1,937 entries   Show 10 ⌄ entries   Page 1   of 194 > >|

ADD FACILITY TO YOUR USER PROFILE   CANCEL

Users can view the details of the organization by clicking the View option.

Organization Details for Abbott Research

Organization Name	Affiliation Type
Org_Check*01	Always

OK

*You can search for facilites without restrictions by selecting the **Search only for SIP registered facilites** checkbox in the **Search Facility** screen. When this option is selected, only the Facilities registered in SIP with a Facility Profile Manager (FPM) are displayed in the search results.*

8.1 Add an existing Facility to your User Profile

1. If the Facility is an existing Facility, in the **Select Facility** section, select the Facility. Click **Add Facility to your User Profile**.
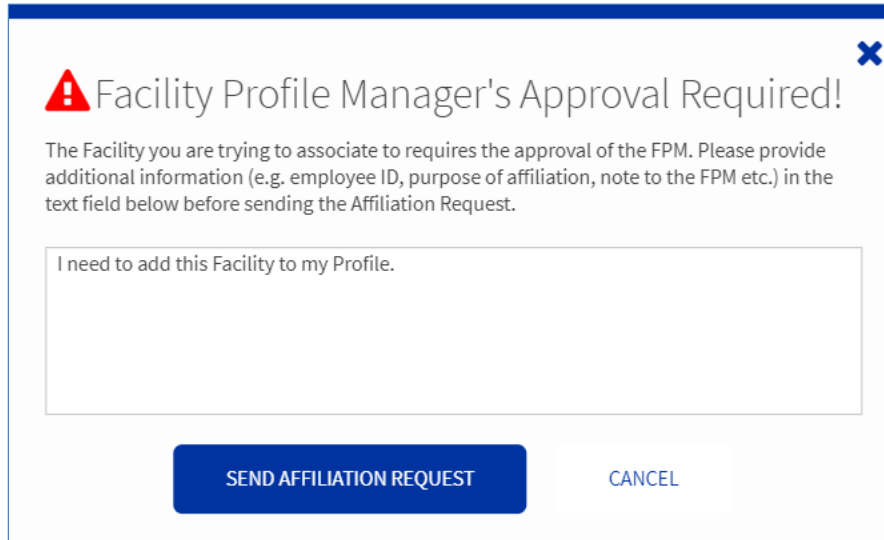
For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

If the required Facility is not displayed in the Select Facility section, contact the Helpdesk to add the Facility.

If you select a facility that has the Contact FPM message icon unavailable, then a message informing you that an FPM needs to be identified is displayed. It also provides you with the option of either maintaining the facility profile by yourself or assigning it to some delegate.

*If you select a Facility that requires the FPM's approval for user association, the **Facility Profile Manager's Approval Required!** pop-up screen appears.*

⚠️ Facility Profile Manager's Approval Required!

The Facility you are trying to associate to requires the approval of the FPM. Please provide additional information (e.g. employee ID, purpose of affiliation, note to the FPM etc.) in the text field below before sending the Affiliation Request.

I need to add this Facility to my Profile.

SEND AFFILIATION REQUEST   CANCEL

❖ *Click **Send Affiliation Request** to send the request after entering the details.*

2. On the **Add Department(s)** page, select the required departments from the list of departments in that Facility.
   ❖ Click **Add Departments to your User Profile**. If the department does not exist, click Create New Department for the selected Facility.
   ❖ If you do not want to add departments, click **No Department**.
   ❖ Alternatively, DPM/FPM can add or create a department within a facility by clicking on the "Add department" option in the actions column against a facility record in **My facilities** section of User Profile.

*In the **Facilities** page of your User Profile, you can view all the facilities/departments added to your user profile. In the **Actions** column, click [⚙]. The following options are displayed:*
   ❖ *Add Department*
   ❖ *Export Department Profile*
   ❖ *Remove Department*
   ❖ *Send Message to DPM*
   ❖ *Export Facility Profile*
   ❖ *Remove Facility*
   ❖ *Send Message to FPM*
   ❖ *Assign Profile Manager: This option will be available only when a facility or a department is assigned to an ongoing study and as the FPM or DPM will not be assigned to such facility or department.*

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk
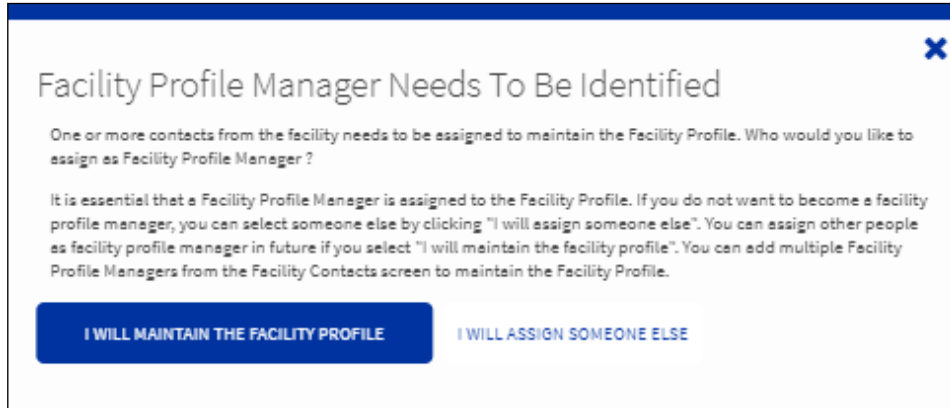
8.2   How do I update a Facility Profile?

To create a new Facility, you need to contact the SIP Helpdesk.

To Update a Facility Profile

1. In **My Facilities** page, click the name of the Facility and complete the Facility Profile details.
2. In the **Facility Name & Address details** section, enter or select the required Facility details.
3. Click **Save**.

The following pop-up screen appears if the facility has no FPM assigned.

Facility Profile Manager Needs To Be Identified

One or more contacts from the facility needs to be assigned to maintain the Facility Profile. Who would you like to assign as Facility Profile Manager ?

It is essential that a Facility Profile Manager is assigned to the Facility Profile. If you do not want to become a facility profile manager, you can select someone else by clicking "I will assign someone else". You can assign other people as facility profile manager in future if you select "I will maintain the facility profile". You can add multiple Facility Profile Managers from the Facility Contacts screen to maintain the Facility Profile.

I WILL MAINTAIN THE FACILITY PROFILE   I WILL ASSIGN SOMEONE ELSE

*Click **I Will Create/Maintain The Facility Profile** or **I will assign someone else**.*

4. In the **New Facility Created/Identify Contact** dialog box, click **I WILL CREATE/MAINTAIN THE FACILITY PROFILE**.
5. To continue updating the Facility Profile, in the confirmation message displayed, click **CONTINUE UPDATING THIS FACILITY**.
6. In the **Populate Facility Profile** page, you get two options:
   ❖ Enter Facility Profile Manually
   ❖ Upload SIP Facility Profile Form

8.3   How do I complete a Facility Profile?

A Facility/Department Profile is maintained in SIP and the information will be used as follows:
   ❖ **Potential Investigator Search -** Sponsors will use this information to find Investigators who are added to Facilities that have the research capabilities they seek.
   ❖ **Feasibility Survey -** Rather than asking Facility-related questions in Feasibility Surveys, Sponsors can pull Facility Profile information directly into their survey.

You can create a new Facility Profile by one of the following methods:
   ❖ Complete Facility Profile: Online—You can complete the Facility Profile by entering the details directly in SIP. The advantage of manually entering the Facility details is that you get to see validation messages instantly wherever mandatory data needs to be entered. In addition, you can upload attachments in the relevant sections of the profile from the user interface.
   ❖ Complete the Facility Profile by using a Completed Site Profile Form—You can complete the Facility Profile by uploading the completed Facility Profile Form.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **10** of **26**

8.4   How do I enter Facility or Department Details manually?

Any Site User who has created the Facility or who has been assigned the role of Facility Profile Manager can enter the following details of a Research Facility in multiple sections of the Facility Profile online:

- ❖ Facility Contacts
- ❖ Therapeutic Areas & Patient Population
- ❖ IRB/ERB/Ethics Committee (IRB number is optional)
- ❖ Local Lab
- ❖ Consent & Training
- ❖ Facility & Equipment
- ❖ Investigational Product (IP) & Controlled Substances
- ❖ Source Documentation & Remote Monitoring
- ❖ Additional Locations
- ❖ Additional Information & Attachments
- ❖ Organization Affiliations
- ❖ Associated Site Users

> ❖ *The questions mentioned in the below table are mandatory for the respective sections.*
> ❖ *There are also other optional questions in the mentioned sections that can be filled in by the user for additional information about their facility.*
> ❖ *All questions are mandatory for the **Study Phase Capabilities** section names in Therapeutic Areas & Patient Population.*

The following fields are mandatory for the completion of a facility profile:

Mandatory Fields for Facility Profile Completion
Therapeutic Areas & Patient Population
Therapeutic Area(s)
Add Therapeutic Area
Study Phase Capabilities
All questions are mandatory
Other Facility Details
Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects, usually this is the same investigator who sees subjects at the primary site location.
What study types does your Facility have experience with?
Is your Facility affiliated with a government agency or part of a government funded health service?
IRB/ERB/Ethics Committee
General Questions

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

Mandatory Fields for Facility Profile Completion
What is the average time (in days) to start a study once you have received the regulatory package?
Does your Facility perform IRB/ERB/Ethics Committee submissions?
Does your Facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions?
Is your Facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?
What types of IRB/ERB/Ethics Committee does your Facility use?
Does your institution and/or local regulation mandate the distribution of safety reports [e.g., Development Safety Update Report (DSUR), suspected unexpected serious adverse reaction (SUSAR)] to a local Review only IRB/ERB/Ethics Committee?
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics committee review and submission?
Local IRB/ERB/Ethics committee
IRB/ERB/Ethics Committee Name
Street Name and Number
Country
State/Province/Region
City
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?
How long before IRB/ERB/Ethics Committee review is the Submission Packet required?
Review ONLY IRB/ERB/Ethics Committee
IRB/ERB/Ethics Committee Name
Street Name and Number
Country
State/Province/Region
City
Other Review Boards
Review Board Name

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

Mandatory Fields for Facility Profile Completion
Street Name and Number
Country
State/Province/Region
City
Local Lab
Lab Name
Street Name and Number
Country
State/Province/Region
City
Local Lab Accreditation
Consent & Training
Consent
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?
Will your Facility require language translations for consents?
If located in the US, has your Facility used or are you able to use the informed consent short form?
Training
Does your Facility have a training program for the research staff?
Does the course content include GCP?
Does your Facility use an external program to conduct research training?
Do you have a process or program in place to retrain research staff when a protocol is amended?
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?
Facility & Equipment
Facility Capabilities

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

| |
|---|
| **Mandatory Fields for Facility Profile Completion** |
| Does your study staff have sufficient English knowledge to understand communications in English? |
| Does your Facility have access to translator and translation support for study conduct (e.g. consent, study specific instruction)? |
| Does the Facility have storage space for Study-Related materials, (e.g. Lab Kits, Patient Materials, etc.)? |
| Does your Facility have the ability to collect and store PK/PD specimens? |
| **General Equipment** |
| Does your Facility have the necessary equipment to treat medical emergencies (i.e. code cart)? |
| **Computer Capabilities** |
| Does your Facility have computers which are dedicated to research studies? |
| Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research? (e.g. web portals to submit documents to sponsors or CROs) |
| Does your Facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)? |
| **Business Continuity Plan** |
| Does your facility have Business Continuity Plan (BCP) to protect essential business operations which describes how those processes will be performed during a crisis at your facility? |
| **Investigational Product (IP) & Controlled Substances** |
| **Investigational Product Shipping Details** |
| IP Recipient Name |
| Street Name and Number |
| Country |
| State/Province/Region |
| City |
| Phone Number |
| Fax Number |
| Email Address |
| **Investigational Product Storage Location** |

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

Mandatory Fields for Facility Profile Completion
IP Storage Location Name
Street Name and Number
Country
State/Province/Region
City

Investigational Product Storage & Handling
Is the Investigational Product Storage Room secured with controlled access?
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?
Does the Investigational Product Storage Room have back-up power?
Does the Investigational Product Storage Room have a temperature alarm?
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?

Controlled Substances
Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?
Does the Facility have the ability to handle radio-labeled Investigational Product?
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?
Source Documentation & Remote Monitoring

Source Documents
Does your Facility have secure storage for patient records?
Does your Facility have patient record archiving on-site?

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **15** of **26**

Once the above questions are answered, the facility profile completion status is marked as completed with a green tick mark.

On the **Upload SIP Facility Profile Form** option on the **Populate Facility Profile** page, you can use an offline form to upload the Site Profile details. On the **Upload SIP Facility Profile Form** page, click **Download SIP Facility Profile Template** and complete the form with Facility information.
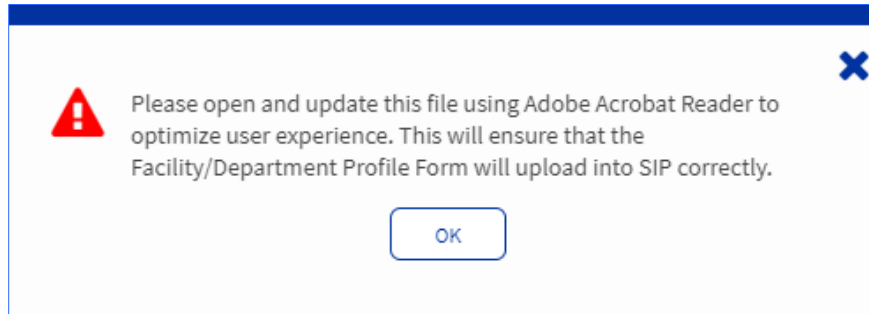
1. Click **Browse** (or **Choose File)** based on your browser type.
2. In the **Choose File to Upload** dialog box, browse to your local location of the completed Site Facility Profile Form, and then click **Open**.
3. Click **Upload Document**. Click **OK**. Successfully uploaded forms will be processed in 15-20 minutes after which the Facility Profile details will be available in SIP.

> *The upload workflow may vary based on the browser (Google® Chrome or Microsoft® Internet Explorer) being used. When using IE, in the **Choose File to Upload** dialog box, click **Open**. When using Chrome, in the **Open** dialog box, click **Open**.*

8.6   How do I manage Orphan Facilities Using Customer Service Accounts?

SIP Support Team can use the Customer Service Account to get associated to all orphan Facilities within SIP. If a site user gets incorrectly associated with a facility and is tagged as the Facility Profile Manager, the site user can disassociate themselves from the incorrect facility.

In order to allow the site user to disassociate from incorrect facility, SIP Support Team Member will have the ability to be the Facility Profile Manager with email ID as TemporaryFPM@cognizant.com and name as Temporary FPM to add the facility to Customer Service Account.

9   How do I add Shipping locations as IP Storage locations?

In the Investigational Product (IP) & Controlled Substances section, in the **IP Storage Locations** section, select any one of the IP shipping Address from the drop-down list to add as an IP Storage location.

9.1   How to add IP Recipients?

Facility Profile (FPM) or Department Profile Manager (DPM) can search the facility or department and select registered site users as IP Recipients. The address and contact details of the selected IP recipient are auto-populated from the User Profile. Users can manually add non-SIP site users as IP Recipients.

10   What is included in the Facility Contacts section?

In the **Facility Contacts** section, you can search for an existing Facility Contact in your Facility or Department or select any Site User as your Facility Contact.

You can also assign Facility roles, such as Facility Profile Manager(s), Facility Clinical Trial Contacts, Head of Facility, Head of Facility Delegate, Budget/Financial Contact, Clinical Trial Manager, Contract Manager, Delegation Manger and Regulatory Contact (Facility/Department) for the selected Facility.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **16** of **26**

> *The following users/roles can click the site user name in the **Facility Contacts** page to view site user's profile in read only mode:*
> ❖ *Any Sponsor User*
> ❖ *FPM/DPM of the given facility/department*
> ❖ *OPM of the organization affiliated to the given facility/department*

10.1   How do I add Facility Contacts?

To Add a Facility Contact:

1. On the menu bar, click **Facility → My Facilities**.
2. In the **Facilities** section, in the row corresponding to the required Facility, click the Facility name for the facility to which you want to add or update Facility Contacts. The **Facility Name and Address** section is displayed.
3. Click **Facility Contacts** in the left navigation. The **Facility Contacts** section appears.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **17** of **26**

Liz Plummer Cancer Centre

Last Modified Date :31-Jan-2022

- ✔ Facility Name & Address
- ✔ **Facility Contacts**
- ✔ Therapeutic Areas & Patient Population
- ✔ IRB/ERB/Ethics Committee
- ✔ Local Lab
- ◑ Consent & Training
- ◑ Facility & Equipment
- ◑ Investigational Product (IP) & Controlled Substances
- ◑ Source Documentation & Remote Monitoring
- Additional Locations
- Additional Information & Attachments
- Organization Affiliations
- Associated Site Users

Facility Contacts

Facility Contacts   ⊟

The following Facility Contact roles can be assigned at the Facility level.

1. Facility Profile Managers (FPM)
   - FPM have the ability to set-up, edit and maintain the Facility Profile.
   - Multiple FPMs can be added to maintain a Facility Profile, however only one individual can be selected as "Primary" FPM. The Primary FPM receives all of the Facility Profile related messages.
   - FPMs can create Departments under their Facility and assign applicable Department Profile Managers (DPM) to manage the Department Profile.
2. Facility Clinical Trial Contact (FCTC)
   - FCTC is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.
3. Head of Facility (HoF)
   - HoF is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.
   - HoF is added as the study site staff for the study sites associated to this Facility and its Departments and is given read-only access to view those study site profiles.
   - You need to add Head of Facility as a FPM / DPM in the Facility and Department(s) profile, if you wish to provide him or her with the access to edit the Facility/Department Profile.
   - The Head of Facility Delegate has the same rights as the Head of Facility.
4. Budget/Financial Contact
   - Budget/Financial Contact evaluates financial aspects of the pre-study contract with Sponsors, suggests and renders financial opinion.
   - Budget/Financial Contact is added as the study site staff for the study sites associated to this Facility and its Departments.
5. Regulatory Contact (Facility/Department)
   - Regulatory Contact (Facility/Department) role collects and submits all regulatory documents for IRB/IEC approval.
   - Regulatory Contact (Facility/Department) is added as the study site staff for the study sites associated to this Facility and its Departments.
6. Contract Manager
   - Contract Manager manages CDA, contract and amendments with Sponsors before study set up.
   - Contract Manager is added as the study site staff for the study sites associated to this Facility and its Departments.
7. Clinical Research Manager
   - Clinical Research Manager monitors operational feasibility of the institution for potential study set up.
   - Clinical Research Manager is added as the study site staff for the study sites associated to this Facility and its Departments.
8. Delegation Manager
   - Delegation Manager can assign or modify the following SIP delegates on behalf of any site users affiliated to the Facility: User Profile, Survey, Study Site Profile Maintenance, Safety Contact and Regulatory Contact (PI Delegate).
9. Contingency Contact - Business
   - Contingency Contact - Business is the primary contact for any Business Continuity Plan (BCP) of facility/departments. This role manages the processes during the crisis situations including any kind of major, minor or serious disruptions.
   - Contingency Contact - Business is added as the study site staff for the study sites associated to this Facility and its Departments.

Select Primary FPM	Name	E-mail Address	Roles	Actions
★	Shetty, Rohit	sandip911@protonmail.com	Facility Profile Manager	✎ ✕
☆	Bose, Rahul	sandiptest12@yahoo.com	Facility Profile Manager Contingency Contact - Business	✎ ✕

[Add Facility Contact]

4. Click **Add Facility Contact**. The Search for Facility Contact section is displayed.
   - ❖ To search for Site Users within the Facility, in the **By Facility/Department** section, enter the relevant search criteria.
   - ❖ To search for Site Users who do not belong to your Facility, in the By Email Address section, type their email address.
5. Click **Search**. The **Site Users Search Results** section is displayed.
6. Select the user to whom you want to assign a Facility role. If the user does not appear, you can search again or search by email address.
7. Click **Select Facility Contact**. The **Add Facility Roles For <site user>** dialog box is displayed.
8. Select the role to be assigned to the user.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

**SIP Help Desk** Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **18** of **26**

9. Click **Save**. The **Facility Contacts** section is displayed with the name of the user and the role you assigned.

> ❖ *If you are the FPM/DPM of a Facility/ Department, you can also add Facility Contacts from the Manage Delegation Page under the Admin Menu.*
> ❖ *In the Manage Delegation Page, click on "Facility/Department Profile" from the left menu.*
> ❖ *Against the Facility/Department record, click on the edit icon. This will take you to the Search for **Facility Contacts** page in step 4 above.*

> *The Head of Facility and Head of Facility Delegate roles cannot be assigned to the same user.*

11   How do I add multiple Shipping locations to a Facility or Department Profile?

In the Investigational Product (IP) & Controlled Substances section, enter the Shipping location details and click **Save**. To continue adding another shipping location, click **Add Shipping Location**. You can add any number of shipping locations to a Facility Profile.

12   How can I add a New Department?

If you do not find the Department that you would like to add to your User Profile, you can create a New Department.

> *Following site users shall be able to create a Department under a facility in SIP:*
> ❖ *Facility Profile Manager(s) for the given facility*
> ❖ *Any Department Profile Manager(s) for the existing departments under the given facility*
> ❖ *Any Organization Profile Manager(s) for the organizations affiliated with the given facility.*

To create a new Department:

1. On the menu bar, click **Facility** > **My Facilities**.
2. In the **Facilities** section, in the row corresponding to the required Facility, click the Facility name.
3. In the **Departments in <Facility Name>** section, the list of departments is displayed.
4. Click **Add Department**.
5. To create a new Department, in the **Add Department(s)** section, click **Create New Department**. The **Department Name & Address** section is displayed.
6. Enter the Department Name choose the Department Type from the drop-down list and click **Save**.
   - ❖ Each Department Type can only be selected once.
   - ❖ If there is no good match for the Department you are trying to create, or if you need to split the existing Department Type, choose a Department Type that is not being used within your facility. This allows your staff to start using the Department.
7. Department Type is displayed in the read only mode and cannot be modified by the Site Staff. They will only see the Department Name. Sponsors to search for Departments in your Facility use department Type. To request a change to the Department Type list, contact the SIP Help Desk.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **19** of **26**
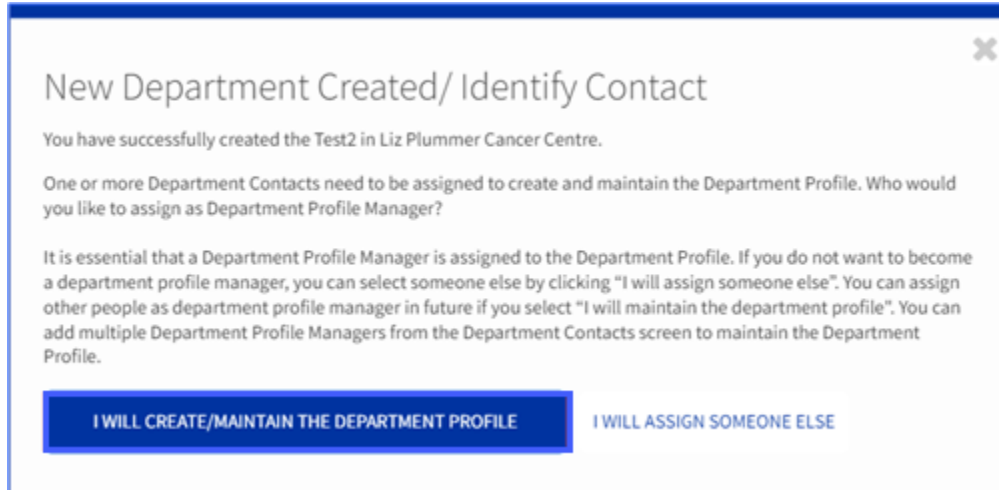
8. In the **New Department Created/Identify Contact** dialog box, click **I WILL CREATE/MAINTAIN THE DEPARTMENT PROFILE**.
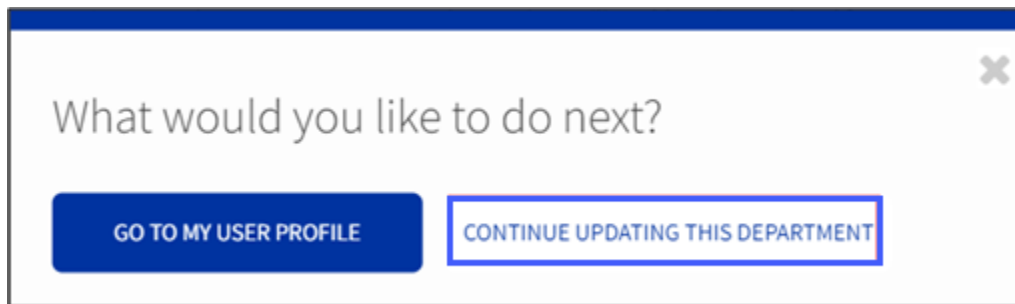
9. To continue updating the Department Profile, in the **What would you like to do next** dialog box, click **Continue Updating This Department**.
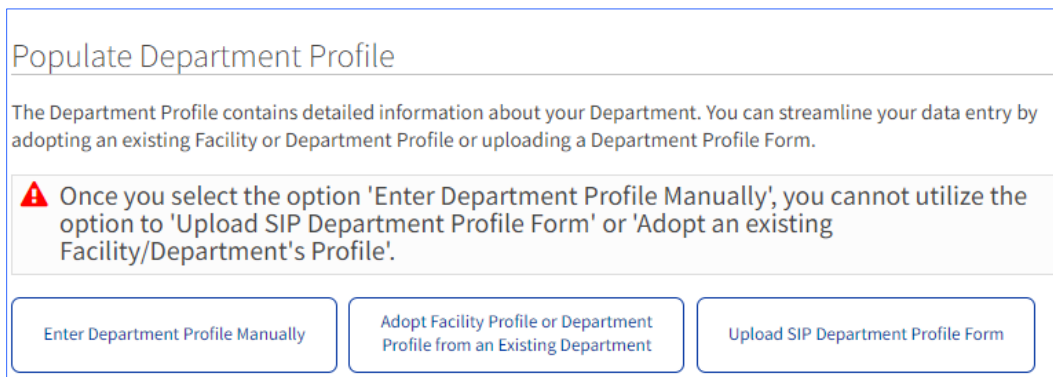
10. In the **Populate Department Profile** section, there are three options:
    ❖ **Enter Department Profile Manually** - manually update the department profile.
    ❖ **Adopt Facility Profile or Department Profile From an Existing Department** - adopt a Department/Facility profile from an existing Facility/Department in SIP and update the details in the Department Profile.
    ❖ **Upload SIP Department Profile Form** - to upload the department profile details.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **20** of **26**

> ⚠️ Please open and update this file using Adobe Acrobat Reader to optimize user experience. This will ensure that the Facility/Department Profile Form will upload into SIP correctly.
>
> [OK]
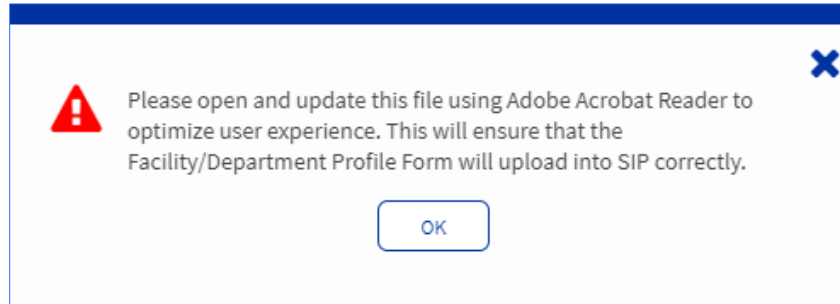
11. Click **Enter Department Profile Manually**.
12. Enter the following details in the respective sections:
    - Department Contacts
    - Therapeutic Areas & Patient Population
    - IRB/ERB/Ethics Committee
    - Local Lab
    - Consent & Training
    - Facility and Equipment
    - Investigational Product (IP) & Controlled Substances
    - Source Documentation
    - Additional Locations
    - Additional Information and Attachments
    - Organization Affiliations
    - Associated Site Users

12.1 How can I add Department Contacts?

You can use the **Department Contacts** section to search for an existing Department Contact in your Facility or Department or select any Site User as your Department Contact. The Department Contact roles added at the Department level are:

- **Department Profile Managers** (DPM) – Set-up, edit, and maintain Department Profile
- **Department Clinical Trial Contact** –Get copied on all Survey and Study Invitation notifications
- **Budget/Financial Contact** - Get copied on all survey and study invitation notifications
- **Regulatory Contact (Facility/Department)**- Collects and submits all regulatory documents for IRB/IEC approval.
- **Contract Manager** - Get copied on all survey and study invitation notifications
- **Clinical Research Manager** - monitors operational feasibility of the institution for potential study set up.
- **Delegation Manager** - Set up and manage delegates for User Profile, Survey, Study Site Profile Maintenance, Safety Contact and Regulatory Contact (PI Delegate) on behalf of site users affiliated to the department
- **Contingency Contact - Business** - the primary contact for any Business Continuity Plan (BCP) of the department. Users with this role are added as the study site staff for the study sites associated to a Facility and its Departments.

> *The following users/roles can click the site user name in the Department Contact section to view site user's profile in read only mode:*
> - *Any Sponsor User*
> - *FPM/DPM of the given facility/department*
> - *OPM of the organization affiliated to the given facility/department*

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **21** of **26**

To Assign Another Registered Site User as Department Profile Manager:

1. On the menu bar, click **Facility** > **My Facilities**.
2. Navigate to the concerned Department > Department Contacts section.
3. Click **Add Department Contact**.
4. Select or enter the search criteria and click **Search**.
5. In the **Site User Search Results** section, click the user to whom you want to assign a role, and then click **Select Department Contact**.
6. To select the roles assigned to the selected Department Contact, in the **Add Department Roles For <site user>** dialog box, select the Department roles.
7. Click **Save**. The details of the user and their role are displayed on the **Department Contacts** section.

13 How to edit/update my Facility or Department Profile?
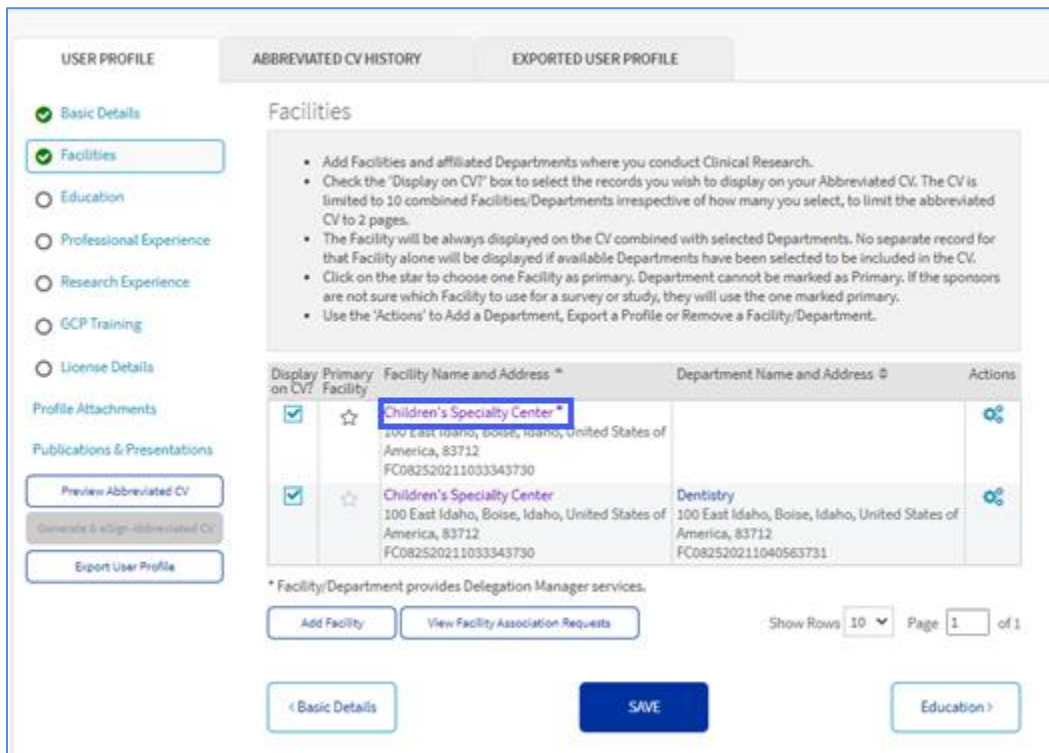
After you have created a Facility/Department, or selected an existing Facility/Department, you can complete or edit details on the remaining pages of the Facility/Department Profile.

The **Facilities** section of your User Profile displays all the Facilities added to your User Profile. You can edit Facility Profiles for which you are the Facility/Department Profile Manager.

> *In order to update the Department Type, you must contact the SIP Help desk.*

The availability of a Delegation Manager in a facility or department is indicated by an asterisk on the facility or department name in the **Facilities** section.

To edit a Facility or Department Profile:

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **22** of **26**

1. On the menu bar, click **Facility** > **My Facilities**.
2. To edit the details of a Facility Profile, in the **Action** column, click the **Edit Facility Profile** icon. To edit the details of the Department Profile, click the Department name and in the **Actions** column, click the **Edit Department Profile** icon. You will see an Edit icon only for those records where you have been assigned as a Facility Profile Manager.
3. Navigate through the sections of the Facility Profile using the left navigation, and update the required details and click **Save**.
4. Click **OK**.

13.1 How can I remove Facility/Department Contact Roles?

To remove Facility/Department Contact Roles:

1. To remove a Facility/Department Contact, on the **Facility (or Department) Contacts** page, in the **Actions** column, click the **Delete** icon.
2. Click **OK** on the confirmation dialog box.

> *Only FPM/DPMs can add/remove facility/department contacts from the profile. If they want to remove a site user who has added their facility/department profiles to their User Profiles, the respective FPM/DPM must reach out to SIP HelpDesk to initiate the process.*

13.2 How can I communicate with the Facility or Department Profile Manager?

To communicate with the Facility Profile Manager:

1. On the menu bar, click **Facility** > **My Facilities**.
   OR
   On the menu bar, click **User Profile** > **My Profile** > **Facilities**.
2. In the row corresponding to the required Facility, click **Send Message to the Primary Profile Manager**.
3. In the **Message to Profile Manager** dialog box, type the message for the Primary Profile Manager.
4. Click **Send Message**.
5. On the confirmation dialog box, click **OK**.

To communicate with the Department Profile Manager:

1. On the menu bar, click **Facility** > **My Facilities**.
   OR
   On the menu bar, click **User Profile** > **My Profile** > **Facilities**.
2. In the row corresponding to the Facility with which the Department is associated, click the **View Departments** icon.
3. In the row corresponding to the required Department, click **Send Message to the Primary Profile Manager**.
4. In the **Message to Profile Manager** dialog box, type the message for the Department Profile Manager.
5. Click **Send Message**.
6. On the confirmation dialog box, click **OK**.

13.3 How can I Confirm/Decline Organization Affiliations?

If an Organization wants to help the Facility or Department maintain SIP, the Primary FPM/DPM will receive a task requesting that the organization affiliation be confirmed. Any FPM or DPM can confirm or decline the request.

> *The steps to confirm/decline organziation affiliations for a facility is the same as confirming or declining organization affiltitions for a department.*

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

To confirm or decline an organization affiliation request:

1. From any section of a Facility Profile or Department Profile, click **Organization Affiliation** on the **Department Profile** navigation pane.
   OR
   On the **Additional Information & Attachments** page, click **Organization Affiliations**>.
   OR
   Click on the hyperlink in the org affiliation task that you have received.

2. In the **Organization Affiliations** page, select the affiliation request status from All Affiliation Statuses.
   ❖ **Select All**—to view all the affiliation requests
   ❖ **Confirmed**—to view only those organization affiliation requests that have been accepted
   ❖ **Declined**—to view only those organization affiliation requests that have been rejected
   ❖ **Pending**—to view only those organization affiliation requests that have not yet been accepted or rejected.

> *The table will display "No records" when there are no Organization affiliations with the Facility or any pending affiliation requests.*

3. In the **Actions** column against records with pending status, click [icon]. The options to either Confirm/Decline Affiliation or Send Message to OPM are displayed.

4. Click **Confirm/Decline Affiliation**. The **Confirm/Decline Organization Affiliation** message is displayed.

5. Select **I always work with this Organization** or **I sometimes work with this Organization**, and click **Confirm Affiliation**. The Organization is now affiliated with the Department and the updated details can be viewed on the **Organization Affiliations** page.

> *To decline an Organization affiliation, click **Decline Affiliation**.*

14   How can I enable or disable the review process for site user association requests for a facility?

Facility Profile Managers (FPM), Department Profile Managers DPM, and Organization Profile Managers (OPM) can enable or disable the review process for facility association requests from site users at a Facility.

To enable or disable site user association request reviews for a Facility:

1. From any section of a Facility Profile, click **Associated Site Users** on the navigation pane.
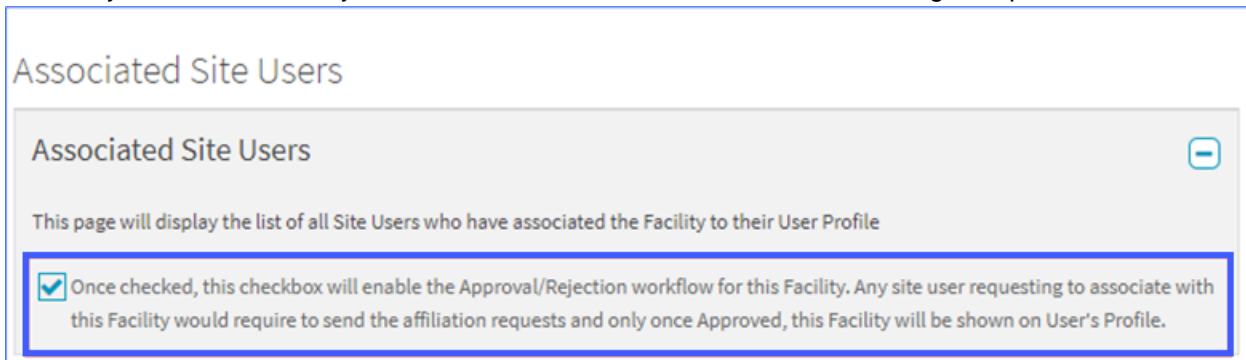
2. Click the checkbox to enable the review process for site user association requests for a Facility.

The review process for site user association requests is now enabled for the Facility.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

14.1   How to approve or decline site user association requests?

The Facility Profile manager can view, approve or decline the site user association request as necessary.

To approve or decline site user association request for a Facility:

1.   From any section of a Facility Profile, click **Associated Site Users** on the navigation pane.
2.   Click the checkbox of the pending site user request to approve or decline in the **Site User Association Requests** section.
3.   Click **Approve Affiliation or Decline Affiliation** to confirm or decline the selected site user association request as necessary.

Users can also view the declined site user association requests by using the filter in the **Site User Association Requests** section.

14.2   How to remove an existing site user associated to a facility?

The Facility Profile manager can remove a previously associated site user from a Facility.

To remove an existing site user associated to a Facility:

1.   From any section of a Facility Profile, click **Associated Site Users** on the navigation pane.
2.   Click the checkbox of the necessary site user to remove from the **ASSOCIATED/CONFIRMED SITE USERS** section.
3.   Click **Remove User** to remove association of the selected site user from the Facility.

The associated site user is now removed from the facility.

14.3   When a site user cannot be removed from a Facility/Department?

1.   Site users who are the only FPM/DPM for a Facility/Department cannot be removed.
2.   Study Site Staff/Principal Investigators with assignments to a study site under a Facility/Department cannot be removed.
3.   Study Site Staff/PI assigned to an ongoing study in a study site under a Facility/Department cannot be removed.
4.   Site users with one or more department associations under a Facility cannot be removed.
5.   Centralized Delegates associated with the Facility/ Department of the PI cannot be removed from the Facility/Department unless the PI undelegated the user.
6.   Principal Investigators who have assigned centralized delegates for a Facility/Department cannot be removed.
7.   Site users listed as the Facility/Department contacts cannot be removed.

14.4   How can site users view their pending facility association requests?

The site users can view their pending facility association requests in the **Facilities** section of the **User Profile** page.

To view pending facility association requests:

1.   Go to **User Profile** >**My Profile >Facilities**. The Facility details are displayed.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk

©2022 Cognizant Technology Solutions U.S. Corporation. All rights reserved.   Page **25** of **26**

2. Click **View Facility Association Requests** to view the pending Facility/Department association requests for the site user.

For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: *See* Help Desk