

Table of Contents

1	What is a User Profile and how is it used?4						
2	How can I update my User Profile?						
3	User Profile Menu						
4	How o	an I update my User Profile directly in SIP and generate my SIP CV?	5				
5	What	are the important features of the My Profile page?	5				
6	My Pr	ofile Page	6				
	6.1	Jpdate User Profile Option 1: Complete Online (Navigation and Important Features)	6				
	6.2	Jpdate User Profile Option 2: Upload SIP User Profile Form	11				
	6.3	Jpdate User Profile Option 3: Delegation	13				
	6.3.	Step 1: Assign a Delegate	13				
	6.3.	2 Step 2: Configuring User Profile Approval Settings (User Profile Owner)	16				
	6.3.	Step 3: Approve or Reject User Profile Updates (User Profile Owner)	16				
7	Facilit	y Details	17				
	7.1	Add Facility Contacts	21				
	7.2	Add Department to your User Profile	23				
	7.3	Remove Your Facility	24				
8	Previe	w SIP SIP CV	25				
9	Gene	ate & E-sign SIP CV	25				
	9.1	ogic for Records Displayed in SIP CV	25				
	9.1.	Basic Details	25				
	9.1.	Pacilities	25				
	9.1.	B Education	26				
	9.1.4	Professional Experience	26				
	9.1.	6 Research Experience	26				
	9.1.	GCP Training	26				
	9.1.	Zicense Details	26				
	9.2	To Generate the SIP CV	27				
10	CV Hi	story	28				
11	Expor	User Profile	29				
12	Expor	ed User Profile	30				
13	Uploa	d & Submit Non-SIP CV	31				
14	Histor	cal Study Information	32				
15	Deleg	ated User Profile - Update a User Profile Delegated to You	33				
16	Deleg	ates - Bulk Upload	35				
	16.1	Points to Remember for Bulk Upload by Delegates	35				
	16.2	Bulk Upload License Details	36				
	16.3	Bulk Upload Profile Attachments	39				
		Bulk Upload NON-SIP CV					
	16.4		42				
		Bulk Upload Training Credit Request					

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

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Revision History

Version	Date	Author	Changes
1.1.0.21	25 April 2022	Cognizant Technology Solutions	Release 7.1 Updates
1.1.0.22	01 Aug 2022	Cognizant Technology Solutions	Release 8.0 Updates

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What is a User Profile and how is it used?

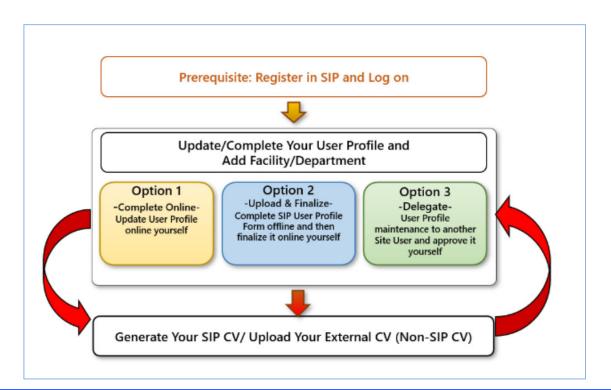
Your User Profile documents your affiliations, qualifications, research experiences, and Good Clinical Practice (GCP) training and can be used to generate your Curriculum Vitae (CV). Completing your User Profile makes your information searchable for all Sponsors running clinical trials in SIP. After registering in SIP, you must first complete your User Profile and generate your SIP Curriculum Vitae (CV).

2 How can I update my User Profile?

There are three options for updating your User Profile:

- Update User Profile Online: Enter the information directly in SIP on the User Profile >> My Profile page. To navigate from any section of the User Profile to the next section, click <Section Name> >. Alternatively, on the User Profile navigation pane on the left, click the relevant section name. For more information, refer to the User Profile Navigation Pane.
- Delegate: Assign your User Profile to another Site User (known as the Delegate) or to an Organization that is affiliated with your Facility/Department, who completes it on your behalf. You are required to review and approve the updates made by the Delegate or the Organization.
- Upload SIP User Profile Form: If you prefer to complete a form offline and then upload data into SIP, you can utilize the SIP User Profile Form. There are limitations to using the form, such as the form does not allow the user to add multiple records for certain sections and no attachments are possible via the form.

Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0



3 User Profile Menu

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The User Profile menu in SIP consists of the following:

- **My Profile** Update your User Profile and generate your CV.
- Delegated Profiles Update User Profiles delegated to you by other Site Users.
- Approve/Reject Update(s) Approve or reject updates made by the Delegates or Organization to your User Profile.

4 How can I update my User Profile directly in SIP and generate my SIP CV?

A Principal Investigator or Sub-Investigator should register as Investigator and all other roles as Clinical Research User. To navigate to the **My Profile** page, on the menu bar, click **User Profile** > **My Profile**. Depending on whether your role in SIP is **Investigator** or **Clinical Research User**, you are required to complete specific sections of the User Profile in order to generate your SIP CV. Each completed section is marked by a green checkmark. Incomplete sections are marked as half grey shaded circles. You can see the Last Modified Date for the User Profile on the My Profile page. For more information on User Profile sections, refer to the <u>SIP Site User Online Help</u>.

5 What are the important features of the My Profile page?

The **My Profile** page allows Site Users to view, maintain, and share information such as their name, phone number, email address, training, experience, and research area of interest with Sponsors. For more information, refer to the <u>My</u> <u>Profile</u> section.

The My Profile page has the following tabs:

- Solution CV. User Profile—Update the various sections of your User Profile and generate your CV.
- CV History—View all versions of your CV that you have generated and the access records of your CV by Sponsor Users to date.
- Exported User Profile—View exported User Profile.

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6 My Profile Page

	My Profile					Last Modif	ied Date 27-Jan-2022
	Las vega 89655	JONES s , Nevada 2861 uroshan.sundaresan@4		sk PI to add you to	o an active stu	udy	Delegated To :
SIP User Profile	SIP Us	er Profile Form			Ask PI to add me	e to a Study	Undelegate
Form							
Update your User Profile by uploading	USER PROFILE	CV HISTORY	EXPORTED USER	RPROFILE		sections of	f your User
the completed SIP User Profile Form.	🕑 Basic Details	Basic Details	S		Profile to a	another Si	te User.
	♥ Facilities			pdating user profile in SIP. lum Vitae, FDA Form 1572,			ed on
	Seducation			ind phone number as enter		ccessible via Clini	icalTrials.gov
User Profile •	Professional Experience			being conducted at the fac be able to edit this section		ept for your email	l address.
Navigate through the sections of your User	Research Experience	NAME & CRITICAL	CONTACT DETAILS				
Profile to update.	GCP Training		Title		Edit	•	Edit
	License Details		First Name	Rohit		tions of th	e User
Preview	Profile Attachments		Middle Name Last Name	Shetty	Profile.		
Fieview	Publications & Presentations		Suffix	Snetty		Email	
Preview your CV before			Initials			Business	email ID is
generation.	Preview SIP Abbreviated CV		Phone	437623812		preferred	
Export	Generate & eSign SIP Abbreviated CV		Email Address	sandip911@protonmai	il.com		luring SIP
	Export User Profile	JOB TITLE & ROLE	E			registration details ca	
Export User Profile in PDF	Upload & Submit Non-SIP CV			Dester		modified	
or Word Format.	PI Study History	J	ob Title/Profession Role	Ooctor ● Investigator ○ Clin	ical Pesearch User	can be u	
Upload & Submit Non-SIP CV			KOle		ical Research Oser	5	e Exostar
Upload a non-SIP generated CV		PRIMARY BUSINES	SS ADDRESS			page.	
PI Study View PI study history details.		Enter your primary or equivalent.	y business address. Fo	r Investigators, this should	be the address you	would include o	n the Form 1572
details.		Compan	y/Institution Name	SIP Private Institute			
Profile Complete - Generate & e-Sign Abbreviated CV			Name and Number	No.91, Jalan Kertajaya	I		
Generate your CV using the		, in the second s	/Floor/Room/Suite	Kota Surabaya			
details from your User		Addi	itional Address Info				
Profile.			Country	United States of Ameri	ica		
		Sta	te/Province/Region	Nevada			

6.1 Update User Profile Option 1: Complete Online (Navigation and Important Features)

To navigate to the My Profile page, on the menu bar, click User Profile > My Profile.

After you update each section of the User Profile, you can navigate to the next section by clicking **Section Name>**. Navigating to other sections by clicking the **Next Section Name>** or **Previous Section Name** buttons, will also save the User Profile details. Alternatively, on the **User Profile** navigation pane, click the relevant section name. The User Profile details will also be saved when you navigate to other sections from the left navigation pane.

You can also save your changes at any point of time by clicking **Save**. In the following table, Sections and Fields specified as **required** for your Role are needed to generate your CV. Optional fields provide Sponsors with additional

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information, but are not required for the CV. You can mark sections or fields as **Not Applicable** if warranted, based on their relevance to your role. The Security questions (also called Challenge questions) allow you to secure your User ID and password. You can update these questions and answers.

Section	Description	Investigator	Clinical Research User
Profile Picture	Upload your recent picture in JPG, GIF, PNG, or BMP format. Maximum permissible dimensions are 100 x 110 pixels.	Optional	Optional
	 Name and Critical Contact Details View your basic personal details, including the details that you had entered during registration. Basic details include: Title or prefix of your name. For example: Mr., Ms., Prof, and Dr. First Name Middle Name Last Name Suffix: For example: Senior, Junior, I, and II. Initials Mobile/Cell Phone (This number may be made publicly available on regulatory authority portal) Email address (Users can update email in SIP by clicking on the Edit icon present right next to the email address present at top right of the page .) Job Title & Role Job Title/Profession—The Job Title or Profession at the Facility (or Facilities) you are associated with. Role—Your role at the Facility (or Facilities) you are associated with. You cannot select multiple roles. The available options include: 	Required	Required
Basic Details	 Investigator Clinical Research User – This is a non-Investigator role in SIP. If you select Clinical Research User, an additional drop-down list is displayed, where you can select the type of role within the Clinical Research User category. The list includes the following roles: Budget/Financial Contact Laboratory Contact Legal Contact National Coordinating Investigator Nurse Other Pharmacist Pharmacy staff Recruitment/Retention Contact Safety Contact Site Administrator Site Data Manager Study Coordinator If the type of role is not listed, select Other. Primary Business Address For Investigators, this is the address you include on FDA Form 1572 or equivalent: Company or Institution Name 		

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	Primary Business Address Details Other Contact Details		
	 Additional Contact Numbers—Enter your main/daytime, evening, and 24-hour phone numbers, fax number, and pager number. 		
	Information		
	 National Provider ID (NPI) – A unique 10-digit number is provided to every licensed practitioner in the US. 		
	Adding your Facility and/or Department to your User Profile is critical for all users.	Required	Required
	 Potential Investigators must be added to a Facility before they can accept a Sponsor's Study invitation. Clinical Research Users must be added to Facilities and/or Departments in order to be added to a Study. Facilities must be added for receiving the site feasibility surveys. 		
Facilities	To add a Facility or Department:		
- uonitios	 Click Add Facility. Search for your Facility/Department by entering the relevant details such as Country name and/or other details such as Facility Name or SIP Facility ID. SIP will return all Facilities, along with Departments under the Facilities. If your Facility/Department exists, select and add it to your User Profile. If your Facility/Department does not exist, you can create it. Refer to the Facility Profile Job Aid for details. 		
	Enter your academic degrees and professional certifications. If there are no records, select the Not Applicable check box.	Required	Optional
Education	If the Specialty does not display the specialty, you wish to add, you may update the value under the Degree field in parenthesis. For example, MD (General Practitioner).		
	 Provide your relevant positions including academic appointments. If there are no records, select the Not Applicable check box. Job Title —Enter the job title. Institution/Department—Type the name of the institution or department where you worked or were trained. 	Required	Optional
Professional Experience	 Year Started—Type the year in which the specialization or training was started. 		
	 Current Position—Select the check box if you are still at this position. The Year Completed field will not be available if you select this option. 		
	Year Completed—Type the year in which the specialization or training was completed.		
If you do not worth	Research Experience	Not Applicable -	hackbox
n you do not want	to record your clinical study Research Experience details, select the Study Type - Select the relevant Study types. If you select Other , in the box displayed, type the details of the Study.	Required	Required
	Clinical Study Phases - Select the Clinical Study phases for the trials you have conducted. You can select multiple Clinical Study phases.	Required	Required
	Therapeutic Area(s) of Expertise - Add the Therapeutic areas in which you have Research Expertise.	Required	Required

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 he Therapeutic Areas for the trials y Therapeutic Area—Identify and in which you have expertise. Sub Therapeutic Area—Sele which you have expertise. Number of Completed Studies studies that you have complete and sub-therapeutic area(s). Number of Ongoing Studies clinical studies for the selected area. On-going clinical studies 	ou have conducted: nd select the Therapeutic Area(s) ct the sub-therapeutic areas in es —Type the number of clinical ed for the selected therapeutic —Type the number of ongoing d therapeutic and sub-therapeutic	Required	Required
 Nowever, this section is not required completed GCP training for Sponsor Click Yes for Have you comp click Submit Training Credit and submit training request, readid. GCP training that is on the TransCele Mutually Recognized GCP Training (courses on the following website: http://www.transceleratebiopharmain To submit a GCP training credit required Search for Completed Course USE BY TYPE/PROVIDER: Course Types GCP, EDC and IATA 1 Training (MRT) and reviewed by one sponsor on behalf of a website or a list of MRT courses. If the Provider on your conselect "Other" 	for all roles. To submit your review: leted GCP Training? And then Request . For details to request effer to the <u>Manage Training Job</u> erate GCP list is referred to as (MRT). You can view the list of ac.com/gcp-training-attestation/ test: may be eligible for credit as Mutually Recognized all participating sponsors. Refer to the TransCelerate multiple in the menu, please	Required	Optional
EDC or IATA training By Type And Provider Training Type(Required) GCP ~ Training Provider(Required) 20901 Sponsor MRT MN	By Study Sponsor/CRO Select Sponsor/CRO V Study ID Select Study ID V		
 Training Type as GCP and th for your course. Click Search. From the search results, select closely matches your GCP cout the correct Training Provider for the course again. Selecting the Course Not List Non MRT. It should be used or 	ten select the Training Provider to the Course Title that most urse name. If you did not select to, click the plus (+) icon to search ted button will mark the training as nly for courses or providers that		
	 Arrea of research expertise that you with the search expertise that you with the search experience of the therapeutic Areas. Fotal Clinical Research Experience the Therapeutic Areas for the trials you and the trials of the trial sudies of the trial trial trial of the trial trial trial trial trials of the trial trials of the tria	 Cotal Clinical Research Experience Complete one line for each of the Therapeutic Areas for the trials you have conducted: Therapeutic Area—Identify and select the Therapeutic Area(s) in which you have expertise. Sub Therapeutic Area—Select the sub-therapeutic areas in which you have expertise. Number of Completed Studies—Type the number of clinical studies that you have completed for the selected therapeutic area (s). Number of Ongoing Studies—Type the number of ongoing clinical studies for the selected therapeutic area (s). Number of Ongoing Studies—Type the number of ongoing clinical studies are defined clinical studies that you are currently working on. All Site Users can enter their Good Clinical Practice (GCP) training towever, this section is not required for all roles. To submit your sompleted GCP training for Sponsor review: Click Yes for Have you completed GCP Training? And then click Submit Training request, refer to the Manage Training Job Aid. CP training that is on the TransCelerate GCP list is referred to as Mutually Recognized GCP Training (MRT). You can view the list of sources on the following website: http://www.transceleratetedCP training credit request. Search for Completed Course Use BY TYPE/PROVIDER. Course Types GCP, EDC and MA may be eligible for credit as Mutually Recognized GCP Training course is not listed in the menu, please select of the review of all participating sponsor. Refer to the TrainCelerate webside for all of the solution of the selected the solution of the solution of the selected to a solution of the participation sponsor. Refer to the Training the solution of the participation sponsor. Refer to the Training the solution of the select of the training the solution of th	rere of research expertise that you want to add. You can select inultiple Sub Therapeutic areas. For Cald Clinical Research Experience Complete one line for each of the Therapeutic Areas for the trials you have conducted: • Therapeutic Area—Identify and select the Therapeutic Area(s) in which you have expertise. • Sub Therapeutic Area—Identify and select the Therapeutic areas in which you have expertise. • Number of Ompleted Studies—Type the number of clinical studies that you have completed for the selected therapeutic area (s). • Number of Ongoing Studies—Type the number of ongoing clinical studies for the selected therapeutic area (s). • Number of Ongoing Studies—Type the number of ongoing clinical studies for the selected therapeutic area. • Number of Ongoing Studies—Type the number of ongoing clinical studies for the selected therapeutic area. • Number of Ongoing Studies—Type the number of ongoing clinical studies is not required for all roles. To submit your ownerwer, this section is not required for all roles. To submit your completed GCP training request, refer to the Manage Training Joh Aid. • Click Yes for Have you completed GCP Training-Joh Aid. • Click Yes for Have you completed GCP Training-Joh Aid. • Click Yes for Have you completed GCP Training-Joh Aid. • Click Yes for Have you completed GCP Training-training Joh Aid. • Click Yes for Have you completed GCP Training-training Joh Aid. • Click Yes for Have you completed GCP Training-training Joh Aid. • Click Yes for Have you completed GCP Training-training Joh Aid. • Click Yes for Have you completed GCP Training the list of sources on the following website: • Thy Provoder Following website: • Thy Provide: Submit A GCP training (MRT). You can view the list of sources on the following website: • Thy Provide: Submit A GCP training or below and alphapeedical store that and thereapeedical store that and thereapeedical st

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	If you are updating a User Profile that has been delegated to you by another Site User:		
	 You can submit a GCP Training Credit Request on behalf of the User Profile Owner; however, you cannot access the training details of this user. Also, you can only submit a credit request for a GCP course completed by the User Profile Owner. You cannot select a different course type. To view the User Profile Owner's Training Certificates, click the PDF icon for each certificate. 		
	 If you are raising a GCP Training Credit Request through the User Profile menu, you can cancel the request for training credit at any step of submission. To cancel the training credit request, click Cancel. 		
	You will be navigated to the GCP Training page.		
	If you do not want to record your research experience details, select the Not Applicable check box.	Required	Optional
	This section is used to capture any medical licenses that demonstrate your qualifications for your role on the Study. To add a license or certificate, click Add License . Enter the following for each License:		
	 Type of License License Issuer Issue Date Country State/Province/Region 		
License Details	The following fields are Optional and users can select them as Not Applicable, if necessary, while adding the License details:		
	 Professional License Number Expiration Date Supporting Document 		
	You can upload new versions of the Medical License document when updating the existing license details. Only the last updated document version is displayed here.		
	You can continue to upload an expired license by clicking Upload License in the Expired License pop-up that is displayed.		
	You can also remove expired licenses by clicking the Remove icon, next to the relevant license.		
	Click Upload New Document to attach documents supporting Site and Staff research qualifications.	Optional	Optional
	Select the type of document in Document Type .		
Profile Attachments	The following options are available for document types: certifications, degree certificates, License to Handle Controlled Substances, Radio-Label Handling License, and Joint Rater License. Users can select the document type as Other when they are not sure about the document category type.		
	The previously uploaded document types are displayed here.		
Publications & Presentations	Record relevant publications and presentations associated with your research. Journal and abstracts should be updated in the Publications table and Presentations in the Presentations table.	Optional	Optional

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6.2 Update User Profile Option 2: Upload SIP User Profile Form

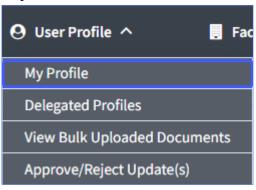
If you prefer to complete a form offline and then upload data into SIP, you can utilize the SIP User Profile Form and upload the completed form on the My Profile page.

Limitations of SIP User Profile Form

- The form does not allow the user to add multiple records for certain sections.
- No attachments are possible via form.
- After SIP imports the details to the User Profile from the SIP User Profile Form, you need to verify and update the details on the My Profile page, as required.
- Automated CV upload feature is available in SIP. Site User can send the CV in any format and request the SIP Helpdesk to automate the CV upload in SIP User Profile format.
- When the User navigates to My Profile, the CV Automation Request pop-up is displayed.
- Download the SIP User Profile Form by using the Click Here to download the Form.
- If all records in the File are correct, click Accept.
- Alternatively, users can update the details in the form and share it with SIP Helpdesk.

To upload the completed SIP User Profile Form

1. On the User Profile menu, click My Profile.



- 2. Click SIP User Profile Form.
- 3. On the SIP User Profile Form dialog box, click Download SIP User Profile Template.

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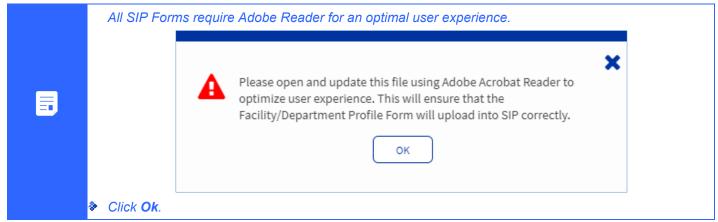


Version 1.1.0.22 [01 Aug, 2022]

Last Updated Release R 8.0

```
My Profile
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y r ronte		Last Modified Date 02-May-2022
Boston 1234 Siteu	r Sane Massachusetts 567890 Isersip450+13@gmail.com	2 Click to view the SIP User Profile Form
USER PROFILE	CV HISTORY	× SIP User Profile Form
Sasic Details	Basic Details	A This form is available for one time upload. Any data you have entered will be overwritten.
 Facilities Education Professional Experience 	Please use the lega regulatory docume For Principal Inves for patients to inqu	To complete your SIP User Profile offline, download the SIP User Profile Form and uplead it here. Download SIP User Profile Template Click to download the SIP User Profile Template
 Research Experience 	Your User Profile D	If you are uploading the Form on behalf of someone else, please ensure that you are uploading the form into the correct SIP User Profile.
SCP Training		Choose File Choose File to select the updated SIP User Profile Template
✔ License Details		A Please wait while your form is uploaded. This may take a few minutes. You will receive a confirmation message when the upload is complete.
Profile Attachments Publications & Presentations		Upload Click Upload to upload the selected SIP User Profile Template
Preview SIP Abbreviated CV		Phone 1234567890
Generate & eSign SIP Abbreviated CV		Email Address siteusersip450+13@gmail.com



- 4. Type/Select the required details in the SIP User Profile Form.
- 5. Click Save after modifying the form details.
- 6. Click Choose File to upload the SIP User Profile Form, on the SIP User Profile Form dialog box.

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Open					
→ ↑ ↓ > Th	is PC → Downloads →		5 V	⊘ Search Downloa	ads
ganize 🔻 🛛 New folde	er			===	· 🔳 (
Quick access	Name	Date modified	Туре	Size	
Desktop	∨ Today (1)				
OneDrive - Cogniza	SIP_User_Profile_Form	02-05-2022 21:10	Adobe Acrobat Docu	и 4,616 KB	
🤱 Sundaresan, Yadhu	> Last week (5)				
This PC	> Last month (3)				
青 Libraries					
💣 Network					
API Documentation					
form					
proof					
7.0 - March 20 - Ou					
File n	ame: SIP_User_Profile_Form		~	All Files	
				Open	Cancel

7. Click Upload Document to upload the SIP User Profile Form.

6.3 Update User Profile Option 3: Delegation

The **Delegate** feature allows you to delegate the completion of your User Profile to another Site User or an Organization.

A Delegate is a Site User or an Organization to whom another Site User (Delegator) assigns the task of updating the User Profile.

Your User Profile Delegate can perform the following updates to your User Profile:

- Delegates can modify all the information in the Basic Details section except your email address information
- Delegates can update the Basic Details section in the User Profile Form
- Delegates can mark a facility as the primary facility on your behalf
- Delegates can select the facilities on your behalf that are to be displayed in the CV.

Delegates can complete all the sections in the **My Profile** page for a delegated user profile and send the changes back to the User Profile Owner for approval.

This depends on the User Profile Approval flag setting chosen by the user profile owner. Refer to <u>Step 3: Configuring</u> <u>User Profile Approval Settings (User Profile Owner)</u> section for more information.



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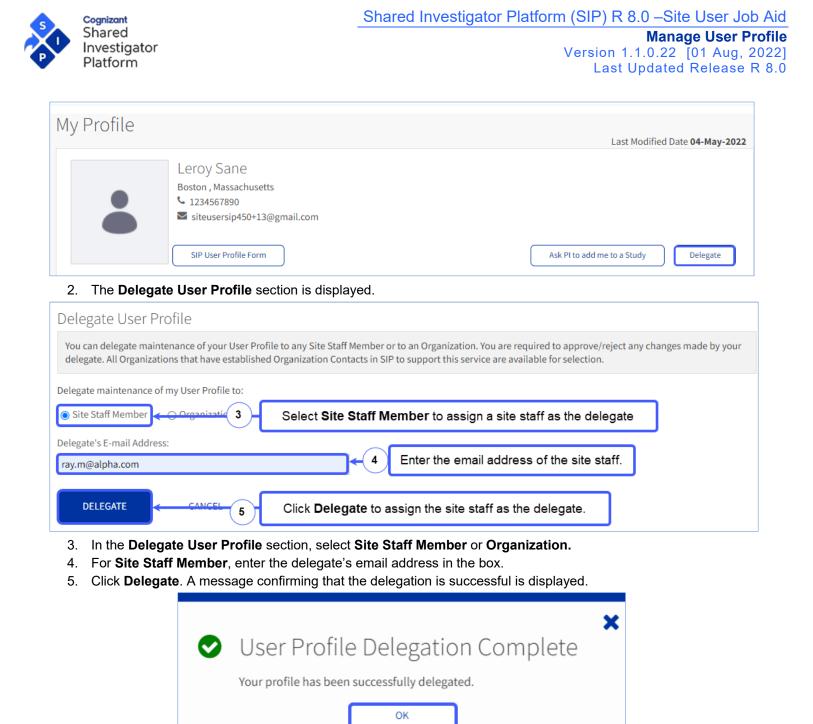
If you select an Organization as the Delegate, then the Organization will assign an Organization Contact who will update your User Profile.

6.3.1 Step 1: Assign a Delegate

1. On the **My Profile** page, click **Delegate**.

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The name of the delegate will be displayed on the My Profile page.

OR

For Organization, follow the steps provided below before completing Step 3.

- 6. In the Search Organization section, select the Organization Name and/or Country as the search criteria.
- 7. Click **Search**. The list of Organizations affiliated with your Facility/Department who have at least one User Profile contact and are providing the user profile updating service are displayed.

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Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Delegate User Profile					
	· · · · · · · · · · · · · · · · · · ·	per or to an Organization. You are required to approve/reject any changes n SIP to support this service are available for selection.	made by your		
Delegate maintenance of my User Pro	3 Select Or	ganization to delegate the user profile to an organization	on contact		
Search Organization 6 Select the State/Province/Region details to search for the organization					
Not finding the Organization you we	ere looking for? Contact Helpdesk to r	equest addition of the Organization			
Organization Name	Country	State/Province/Region			
Apollo SMO	Select or Type	Select State/Province/Region 🔻			
SEARCH CLEAR SE	7 Click Search after	selecting the search parameters to search for the organ	nization		

In the Search Results section, select the Organization that you want to assign as a delegate to update your 8. user profile.

	Search Results		
	Select Organization Name *	Address	
	Apollo SMO	51 Main Street, Chicago, Illinois, United S	tates of America, 60021
	8 Select the necessary organ results.	nization from the search	Show 10 v entries Showing 1 to 1 of 1 entries
	Not finding the Organization you were looking for? Contact Helpdesk to	o request addition of the Organization.	-
	DELEGATE 9 Click Delegate to	delegate the user profile to the s	selected organization from the search
9.	Click Delegate . A message confirming that th	e delegation is successful i	s displayed.

	User Profile Delegation Complete
	Your profile has been successfully delegated to the selected Organization. The delegate's name will display on your User Profile once assigned by the Organization. You will be required to approve/reject any changes made by the delegate OK
۶	<i>If the Delegate is not registered in SIP, the Not a Registered SIP User dialog box is displayed. To send an email containing a registration invite to the delegate, click Send Registration Invite.</i>
۵	If you need to change the Delegate, in the Delegate dialog box, click ^{See} next to the Delegate To field.

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

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To revoke the delegation authority of a Delegate for your User Profile, on the My Profile page, click Undelegate. On the Undelegate Profile dialog box click Yes. Click OK. You can click Delegate to delegate the User Profile to another Site User again. If you delegate your profile after undelegating, any changes that you have not approved will appear in your User Profile.

6.3.2 Step 2: Configuring User Profile Approval Settings (User Profile Owner)

The User Profile Owner can select the following options to configure approval or rejection of the profile updates by a Delegate to their User Profile page.

To Configure User Profile Approval Settings

- (MS
- 1. Click the *icon* on the top right corner of the application. A menu appears.
- 2. Select Settings. The Settings page appears.
- 3. Navigate to the Set User Profile Approval Flag section.

ility 🗸 👹	Sponsor/CRO 🗡	📄 Documents 🌱	🛡 Safety 🗡	🔟 Survey 🗸	묘 Training ^	
ottings				1	Click the user profile icon on the top right corner of the application. A menu appears	MS
ettings				\sim		Md Farhan Siddiq
Add Alternative E-mail Ad	ldress User Pr	rofile Approval Flag		2	Select Settings to configure the approval settings.	sunnyjis49@yopmail. User Id : siddiquem_2
Set e-mail Preferences	approva	will determine if the changes don before the changes are saved to y n change the preferences anytime	our profile. By default, the fla	ig will be marked as "Approval F	Required".	Settings
Change Password	pending	approval.			, ,	€ Logout
Update Challenge Questi		al Required 🔿 Approval Not Requ	iired 4		o set the approval requirement ser profile.	

The Profile Owner can select the following options to approve or reject the profile updates by a Delegate:

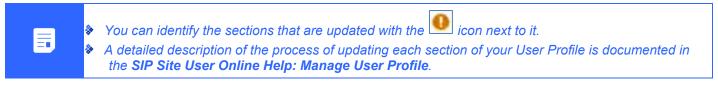
- **Approval Required** User Profile Owner reviews the updates made by the Delegate before approval.
 - Approval Not Required All changes made by Delegate to the User Profile are automatically approved.

Refer to User Profile Delegation section in the <u>Central Delegation Job Aid</u> for detailed information on configuring, approving or rejecting delegate changes for a user profile.

6.3.3 Step 3: Approve or Reject User Profile Updates (User Profile Owner)

To approve or reject Delegate updates to a User Profile:

1. On the User Profile menu, click Approve/Reject Update(s).



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

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- Navigate through the sections of the User Profile that were updated by the Delegate and review the updates. For each section with an update by the Delegate, you can click **Approve This Change** or **Reject This Change** to approve or reject the change respectively.
- 3. To approve the updates, in the User Profile navigation pane, click Approve All Changes, and then click OK.

	<u>چ</u>	To reject the updates, in the User Profile navigation pane, click Reject All Changes . You will be unable to remove the current delegation of your User Profile unless you Approve or Reject the updates.
--	----------	---

7 Facility Details

My Profile - Facilities section allows you to add a Facility and/or Department to your User Profile. Adding a Facility/Department is mandatory for the following:

- Accepting Study selection invitations from Sponsor Users.
- Allowing Principal Investigator(s) at Facilities and/or Departments to add you as Study Site Staff for Studies conducted at those Facilities/Departments.

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.

Add a Facility to your User Profile

1. On the My Profile—Facilities section, click Add Facility.

	Centinela Hospital Medical Center 555 East Hardy Street, Inglewood, California, United States of America, 90301 FC122020181116221389	Department of Medicines 555 East Hardy Street, 3rd Floor, Beside ITI Saraswat Bank, Inglewood, California, United States of America, 90301 FC122820180644391395	00
lity/Departn Add Facility	nent provides Delegation Manager services. View Facility Association Requests	Show Rows 10 V Page 1 of 2	> >

- 2. In the Search Facility page, enter any or all of the search criteria.
- 3. Click Search.

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

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ognizant hared hvestigator latform			8.0 –Site User C Manage User 1.0.22 [01 Aug Jpdated Releas	Profile , 2022]
Search Facility				
To search for a facility: • Choose the country in order to co	2 / C	Select the parameters: Facility country, state, city, name, Fac Drganization details to search for a facility.	cility ID, or <mark>—</mark>	
When searching for Country andDo not use abbreviations.	State/Province/Region you	a may enter all or part of a word.		
Organization site users can use 'C)rganizations' filter to sear	rch only those facilities which are affiliated to their Organization.		
Facility Country (Required)	Facility State/	/Province/Region Facility City		

Facility Country (Required)	Facility State/Province/Region	Facility City
United States of America	Select or Type	
Facility Name	SIP Facility ID	Organizations
Blessings Hospital		Select or Type
Search only for SIP registered faciliti	es. This search result shall include facilities with accente	d characters (e.g. ü).

Select	Facility Name [▲]	Address	City≑	State/Province/Regi on≑	SIP Facility ID	Contact FPM	FPM Approval Required?	Delegation Manager Available?	Organization Name
0	!@#	Testa Place, Fairfield County	Norwalk	Connecticut	FC0816201813222 11017		No	No	View
0	"FAcility R"	"10 Main Street"	"Main City"	American Samoa	FC0924201919550 92180		Yes	No	View
0	123	1220, U.S. 22, Somerset County	Bridgewater	New Jersey	FC0905201819481 61074		No	No	View
0	123	123, Meadow Lane, Montgomery County	Coffeyville	Kansas	FC0913201807483 91082		No	No	View
0	15825 Laguna Canyon Road	1 Main Road	Click the ra profile.	idio button to sel	ect the facility to FC0430201819165 40703	add to yo	ur user	No	View
0	21st Century Oncology	7340 East Thomas Road	Scottsdale	Arizona	FC0508201814103 50728		No	No	View
0	21st Century Oncology	8946 77th Terrace East	Lakewood Ranch	Florida	FC0629201819355 50799		No	No	View
0	21st Century Oncology	7341 Gladiolus Drive	Fort Myers	Florida	FC0516201816454 00738		No	No	View
0	21st Century Oncology	350 North West 84th Avenue	Plantation	Florida	FC0514201820215 00735		No	No	View
0	\ /:*?" USA Eye Center\ /:*?" Facility\ /:*?"	1900 Street, Southeastern,, NA	Salem	Virginia	FC1209202007343 53466		No	No	View
				Showing 1 to 10 c	of 2,017 entries Sho	w 10 🗙 entr	ies	Page 1 o	202 > >

5. 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.

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6. In Add Department(s) page, select one or more departments and click Add Departments to your User Profile.

Add	Department(s	;)					
 Se Cl Cl Ol 	Department(s) elect and click "Add Departm lick "Create New Departmen lick "No Department" if you nly FPMs/DPMs and Affiliated you have used 'Organization	t" if you want to create a ne want association with Facil d OPMs (Profile Managers)	ew Department for the F lity only. You will be nav will be able to Create De	Facility you just added to yo igated to the Facilities secti epartment.	on in User Profile.	all appear in	this screen.
	Department Name Click to add t	Address he selected departm	City≑ ent to your user pi	State/Province/Region \$	SIP Department ID	Contact DPM	DPM Approval Required?
	Test Department 1002	Street 1002, Building- 1002	Bridgewater	New Jersey	FC072820181333280 894		No
					Showing 1 to 1 o	of 1 entries	Show 10 🗸 entries
A	NDD DEPARTMENTS TO YOUR	USER PROFILE	CREATE NEW DEPAR	TMENT	NO DEPARTMENT		

- 7. You can click Create New Department or click No Department if the Facility does not have a department.
- 8. The Facilities section is updated with the details of the added facility.

How to add any Facilities and affiliated Departments that will be displayed in SIP Curriculum?

1. In the **My Facilities** page, in the **Display as CV?** column, select the check box to select Facilities and affiliated Departments.

Primary Facility	Facility Name and Address 🚔	Department Name and Address 🗢	Actions
*	15825 Laguna Canyon Road 1 Main Road, Irvine, California, United States of America, 92618 FC043020181916540703		00
☆	21st Century Oncology 8946 77th Terrace East, Lakewood Ranch, Florida, United States of America, 34202 FC062920181935550799		O ₀

- Click on the Star ★ icon to choose one Facility as primary. Only one of the Facilities can be selected as Primary Facility. Department cannot be selected as the Primary facility. If you are not sure which Facility to use, then skip this step.
 - User's Primary Facility (where the Star icon is selected) will be listed first on the User's CV, if the same facility is selected as 'Display on CV?' (checkbox). The Primary Facility will always be listed first in the CV.
- 3. Click Generate CV.

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





If you have not selected any facility to be displayed on your SIP CV, a warning message is diplayed. To continue to generate the CV, click Generate CV.

What if no Facility is returned in the search results?

If a Facility Profile or Department Profile matching your search criteria is not found in SIP a message informing you to refine your search or contact the **SIP Helpdesk** to add a Facility, is displayed.

How do I select a Facility without a Department name?

- 1. Select or Add a Facility. To add a Facility, refer to Add a Facility to your User Profile.
- 2. If the Facility is an existing Facility, in the **Select Facility** section, select the Facility.

Select	Facility Name 🕈	Address	City\$	State/Province/Regi on€	SIP Facility ID	Contact FPM	FPM Approval Required?	Delegation Manager Available?	Organizatio Name
0	!@#	Testa Place, Fairfield County	Norwalk	Connecticut	FC0816201813222 11017		No	No	View
0	"FAcility R"	"10 Main Street"	"Main City"	American Samoa	FC0924201919550 92180		Yes	No	View
0	123	1220, U.S. 22, Somerset County	Bridgewater	New Jersey	FC0905201819481 61074		No	No	View
0	123	123, Meadow Lane, Montgomery County	Coffeyville	Kansas	FC0913201807483 91082		No	No	View
0	15825 Laguna Canyon Road	1 Main Boad	Click the ra profile.	idio button to sel	ect the facility to FC0430201819165 40703	add to yo	ur user	No	View
0	21st Century Oncology	7340 East Thomas Road	Scottsdale	Arizona	FC0508201814103 50728		No	No	View
0	21st Century Oncology	8946 77th Terrace East	Lakewood Ranch	Florida	FC0629201819355 50799		No	No	View
0	21st Century Oncology	7341 Gladiolus Drive	Fort Myers	Florida	FC0516201816454 00738		No	No	View
0	21st Century Oncology	350 North West 84th Avenue	Plantation	Florida	FC0514201820215 00735		No	No	View
0	\ /:*?" USA Eye Center\ /:*?" Facility\ /:*?"	1900 Street, Southeastern,, NA	Salem	Virginia	FC1209202007343 53466		No	No	View
				Showing 1 to 10 c	of 2,017 entries Sho	w 10 🗸 entr	ries	Page 1 of	202 > >

- 3. Click Add Facility to your User Profile.
- 4. In the Add Department(s) page, click No Department.

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

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Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Add Department(s)

	/				
Add Department(s)					
 Select and click "Add Departm Click "Create New Departmen Click "No Department" if you v Only FPMs/DPMs and Affiliated If you have used 'Organization 	t" if you want to create a ne want association with Facil d OPMs (Profile Managers)	ew Department for the lity only. You will be nav will be able to Create D	Facility you just added to rigated to the Facilities see epartment.		
Department Name *	Address	City≑		E SIP Department ID Centact DRM Approva	l
Test Department 1002	Street 1002, Building- 1002	Bridgewater	New Jersey	FC072820181333280 🖂 No	
4				Showing 1 to 1 of 1 entries Show 10 🗸 e	• ntries
ADD DEPARTMENTS TO YOUR	USER PROFILE	CREATE NEW DEPAR	TMENT	NO DEPARTMENT	
he newly added Facility i	s displayed in the l	Facilities section	of the My Profile	page.	
				O ²	

*	To remove a Facility, My Profile > Facilities section, in the corresponding row, click and then click Remove Facility. You cannot remove a facility for which you are the FPM/DPM/Site Staff or if you are added to a Department within that Facility. In addition, you cannot remove facilities which are being onboarded to SIP as part of migration to the SIP platform.
*	You can also add department or export a facility profile or send a message to the FPM by clicking and again clicking Add Department or Export Facility Profile, or Send Message to FPM, respectively.

You can select a facility as your primary facility by clicking the star icon for that facility in the **Primary Facility** column of the **Facilities** section. A detailed description of the process of creating a Facility Profile or a Department Profile is documented in the <u>SIP Site User Online Help</u>.

7.1 Add Facility Contacts

After you add a Facility to your User Profile, you need to add the Facility Roles. Facility Roles include Primary Facility Profile Manager (FPM), Department Profile Manager (DPM), Facility Clinical Trial Contact (FCTC), Head of Facility (HoF), Head of Facility Delegate (HoFD), Budget/Financial Contact, Regulatory Contact (Facility/Department), Clinical Trial Manager, Contract Manager, Delegation Manager and Clinical Research Manager.

For more information on roles, refer to Facility Contacts in SIP Site User Online Help.

If no FPM or DPM is assigned to a facility or department, you can click the **assign FPM/DPM** icon in the **Actions** column of the **Facilities** section of the **My Profile** page. FPM or DPM can edit the Facility or Department Profile. FPM or DPM can also assign Delegation Managers for their Facility or Department.

Delegation Managers can set up and manage delegates on behalf of site users affiliated to the facility or department. In the **Facility Contacts** page, perform any one of the following:

1. To delegate the task of completing the Facility Profile to another FPM/DPM user, click Add Facility Contact.

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Version 1.1.0.22 [01 Aug, 2022]

Last Updated Release R 8.0

elect rimary PM	Name	E-mail Address	Roles	Actions
*	John, Alex	champ.user.sip+26@gmail.com	Facility Profile Manager Clinical Research Manager Delegation Manager	3
☆	Asparzad, Jia	frk.azor.ahai+50@gmail.com	Budget/Financial Contact	1
☆	Braxton, Tracy	frk.azor.ahai+25@gmail.com	Regulatory Contact (Facility/Department)	۵ ک
☆	John, Paul	ralph.sip.john+2@gmail.com	Contingency Contact - Business Delegation Manager	3

- 2. To search for Site Users within the Facility, in the Facility/Department section, type/select the search criteria.
- 3. To search for Site Users who do not belong to your Facility, in the **By Email Address** section, type/select the search criteria.

Search For Facility/Department Cor	itact 😑
Search for individuals within your Facilities by Facility search enough to return less than 100 records.	/Department name or by E-mail Address. You must limit your Select the parameters to search for the user
By Facility/Department	By E-mail Address
Search for individuals within your Facility. If the user you are s does not show up in the search results, he or she may not hav Facility between you and him/her. If this occurs, search by em	e a common whom you are searching.
Facility Name Last Name	Email Address
Americana Orthopaedics 🔹	
Department Name First Name	
Select or Type 🔻	
Click to sear	rch CANCEL

- 4. Click Search.
- 5. Select the required Site Users in the Site User Search Results section.

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

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Site User Search Results

Select the individual to whom you want	to assign a Facility role. If the individual you are seeking, does not appear go back
and search by e-mail address	

 Adams, Rachel racheladams326@gmail.com Investigator Asparzad, Jia frk.azor.ahai+50@gmail.com Dr. Bell, Ryan sip.reg01+1311@gmail.com Braxton, Tracy frk.azor.ahai+25@gmail.com Senior Doctor Cook1, Tim anuragshukla3001@gmail.com Geller, Ross champ.user.sip+30@gmail.com Gibbs, Adam ralph.sip.john+89@gmail.com John, Alex champ.user.sip+26@gmail.com John, Paul ralph.sip.john+2@gmail.com 	elect	Name	E-mail Address	Job Title/Profession
OBell, Ryansip.reg01+1311@gmail.comOBraxton, Tracyfrk.azor.ahai+25@gmail.comSenior DoctorOCook1, Timanuragshukla3001@gmail.com-OGeller, Rosschamp.user.sip+30@gmail.com-OGibbs, Adamralph.sip.john+89@gmail.com-OJohn, Alexchamp.user.sip+26@gmail.comDoctorOJohn, Paulralph.sip.john+2@gmail.com-	0	Adams, Rachel	racheladams326@gmail.com	Investigator
OBraxton, Tracyfrk.azor.ahai+25@gmail.comSenior DoctorOCook1, Timanuragshukla3001@gmail.com-OGeller, Rosschamp.user.sip+30@gmail.com-OGibbs, Adamralph.sip.john+89@gmail.com-OJohn, Alexchamp.user.sip+26@gmail.comDoctorOJohn, Paulralph.sip.john+2@gmail.com-	0	Asparzad, Jia	frk.azor.ahai+50@gmail.com	Dr.
OCook1, Timanuragshukla3001@gmail.comOGeller, Rosschamp.user.sip+30@gmail.comOGibbs, Adamralph.sip.john+89@gmail.comOJohn, Alexchamp.user.sip+26@gmail.comOJohn, Paulralph.sip.john+2@gmail.com	0	Bell, Ryan	sip.reg01+1311@gmail.com	
O Geller, Ross champ.user.sip+30@gmail.com O Gibbs, Adam ralph.sip.john+89@gmail.com O John, Alex champ.user.sip+26@gmail.com O John, Paul ralph.sip.john+2@gmail.com	0	Braxton, Tracy	frk.azor.ahai+25@gmail.com	Senior Doctor
Gibbs, Adam ralph.sip.john+89@gmail.com John, Alex champ.user.sip+26@gmail.com John, Paul ralph.sip.john+2@gmail.com	0	Cook1, Tim	anuragshukla3001@gmail.com	
O John, Alex champ.user.sip+26@gmail.com Doctor O John, Paul ralph.sip.john+2@gmail.com Doctor	0	Geller, Ross	champ.user.sip+30@gmail.com	
John, Paul ralph.sip.john+2@gmail.com	\circ	Gibbs, Adam	ralph.sip.john+89@gmail.com	
	0	John, Alex	champ.user.sip+26@gmail.com	Doctor
o John Palph ralph sin john@gmail.com	\circ	John, Paul	ralph.sip.john+2@gmail.com	
	\odot	John, Ralph	ralph.sip.john@gmail.com	
	SE	LECT FACILITY CONTACT	Click to add the s	elected user as the facility

6. Click Select Facility Contact.

7.2 Add Department to your User Profile

You can add a Department to the Facility to associate yourself to the Department in the Facility.

- 1. On the Facility menu, click My Facilities.
- 2. To view departments for a specific Facility, in the corresponding row, click View Departments icon.
- 3. In the Departments in <Facility Name> section, the list of departments associated with the Facility is displayed.



Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Add Department(s)

Add Department(s	»)					
Add Department(s)						
 Select and click "Add Departm Click "Create New Departmen Click "No Department" if you Only FPMs/DPMs and Affiliate If you have used 'Organization 	nt" if you want to create a ne want association with Facili d OPMs (Profile Managers) v	w Department for the F ity only. You will be navi will be able to Create De	facility you just added to yo igated to the Facilities section opartment.	ion in User Profile.	all appear in	this screen.
Department Name*	Address	City≑	State/Province/Region 🗢	SIP Department ID	Contact DPM	DPM Approval Required?
Test Department 1002	Street 1002, Building- 1002	Bridgewater	New Jersey	FC072820181333280 894		No
•						•
				Showing 1 to 1 o	of 1 entries	Show 10 🗙 entries
ADD DEPARTMENTS TO YOUR	USER PROFILE	CREATE NEW DEPART	TMENT	NO DEPARTMENT		

4. To add an existing department, select the existing department and click **Add Departments to your User Profile**.

	 To upload SIP Department Profile Form, click Upload SIP Department Profile Form. Click Download SIP Department Profile Template. All SIP Forms require Adobe Reader for an optimal user experience.
.	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.
	 Click OK. To create a new department, in the Department (s) page, click Create New Department. Otherwise, to continue associating the selected Facility Profile without selecting a Department, click No Department.
7.3 Remov	ve Your Facility

You can remove a Facility and/or Department Profile from your User Profile, if you are no longer associated with the corresponding Research Facility and/or Department.

1. On the **User Profile—Facilities** page, under Action, click the icon in the row corresponding to the Facility and/or Department.

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

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	✓	24	ABC Medical Center 8 Medical Parkway, Dallas, Texas, United States of America, 75234	ABC Departme 8 Medical Park States of Amer	Add Department	0
		☆	FC073020180747080899 Americana Orthopaedics * 1673 West Shore, Boise, California, United	FC1012202005	Export Department Profile Remove Department)¢
2.			States of America, 83702 FC062120210623114151		Send Message to DPM	
			Remove Department Are you sure you want to remove this Dep Remove Cancel	artment?	×	
	♦ /	f you ar Manage f you ar	r, you cannot remove a Facility and/or Depa e the Primary Facility Profile Manager of a I er, before you can remove your User Profile e the Principal Investigator or Study Site Sta not remove the Facility/Department from yo	Facility, you must a from the Facility. aff working on an a	assign another Primary Facility	

Contact the Sponsor User to request a Principal Investigator change for that Study.

8 Preview SIP SIP CV

The **Preview SIP SIP CV** feature allows you to generate and view a print preview of your SIP CV from your current User Profile details.

9 Generate & E-sign SIP CV

The Generate & e-Sign SIP CV feature allows you to generate your CV from your current User Profile details.

9.1 Logic for Records Displayed in SIP CV

The SIP CV is designed as an SIP CV and displays only the important information from your user profile. When you generate an SIP CV, the number of records displayed in the different sections of the CV and the logic for the displayed details are as follows:

9.1.1 Basic Details

The SIP CV will display the latest details from your user profile.

9.1.2 Facilities

If you are associated with multiple facilities, the **Facilities** section shall display only 10 facilities as per the logic given below:

3. The selected primary facility shall be displayed first.

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

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- 4. The list of facilities that have departments associated will be displayed in the ascending alphabetical order of facility name and department name.
- 5. The rest of the facilities with no departments will be displayed in the ascending alphabetical order of facility name.

9.1.3 Education

If you have multiple educational qualifications, the **Education** section shall display only 5 records on the generated CV as per the following logic:

The education details where Specialty is available shall be displayed on the CV, else the records shall be displayed in the descending order of the Year Completed.

9.1.4 **Professional Experience**

The Professional Experience section shall display only 5 records in the descending order of the Year Started.

9.1.5 Research Experience

If you have many years of research experience entered in your user profile, the details in **Research Experience** section of the SIP CV shall be displayed as follows:

- 1. The Study Types and Clinical Study Phases are displayed in the same order as they appear in the user profile.
- 2. The 'Therapeutic Area of Expertise' details are displayed separated by a semi-colon.
- 3. Only 15 records from the **Total Clinical Research Experience** section in the user profile shall be displayed in the descending order of the Number of completed studies followed by the descending order of ongoing studies.

9.1.6 GCP Training

The GCP Training section shall display only 1 record as per the logic given below:

- 1. Trainings in Certificate Valid or Completed status with latest Expiration Date shall be displayed first on the CV.
- 2. If there are no trainings available in certificate valid or completed status, then the Trainings in 'Submitted' or 'Sent for Review' status with the latest Expiration Date shall be displayed on the CV.
- 3. If the latest Expiration Date is the same for two records then the record shall be displayed in the ascending order of the course provider name.

9.1.7 License Details

The License Details section shall display only 5 records in the following order of License type:

- 1. Medical Doctor
- 2. License to practice
- 3. Physician Assistant
- 4. Other
- 5. Licenses whose Expiration Date has passed shall not be displayed on the CV.

After you generate the CV, it becomes available to all the participating SIP Sponsors to whom the Site User has provided consent.



The CV will include the most important information from the User Profile and not all of the information will be available in the CV.

Each time you generate your CV or a Sponsor User downloads your CV, the CV history is updated on the CV History tab. For more information, refer to <u>SIP CV History</u>.

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

SIP Help Desk Email: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>



9.2 To Generate the Abbreviated CV

- 1. On the User Profile menu, click My Profile.
- 2. Click Generate & eSign Abbreviated SIP CV. The Review CV Prior To Signing screen appears.

A	Review CV Prior To Signing
	Review your Abbreviated CV prior to signing to ensure that the critical information is included. By signing the CV, you are confirming that the data provided is complete and correct.
	Generate and Sign CV Cancel

- 3. Click Generate and Sign CV.
- 4. On the E-Sign page, in the User ID box, enter your User ID.
- 5. In the **Password** box, enter your password.
- 6. Click E-Sign.

S Ir P	Bign Bign Bign
Please enter your User ID/Email I	ID, Password and click E-Sign
0-7	
E-S	IGN
Unauthorized access to this syste offense.	em may constitute a criminal
Help	Customer Service

7. Click OK.



Site users will get a notification in SIP if the user has not regenerated the CV in the past 2 years. Notification is triggered if the Site user has neither regenerated the CV or uploaded Non-SIP CV in the past 2 years.

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

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10 CV History

The **CV History** tab displays the details of all previous versions of your CV. If required, you can view and track significant changes made to the CV. This feature also allows you to download and view the different versions of your CV that were downloaded by Sponsor Users. The **CV History** tab is also available to the Delegate.

- 1. On the User Profile menu, click **My Profile**.
- 2. On the **My Profile** page, click the **CV History** tab to view your CV history.

USER PROFILE	CV HISTORY	EXPORTED USER PROFILE			
SIP ABBREVIATED CV	HISTORY				
SIP ABBREVIATED CV VERSION This section provides access to a		ur SIP Abbreviated CV.			
CV Document Name				Status	View CV
CV_Rohit-Shetty_16-Apr-2021_				Active	w 🔎
View More >>					
DOWNLOADED SIP CURRICULU This section provides you with t CV Document Name		aded by Sponsors/CRO Date Downloaded		Energy	CPO Logo View CV
	00.00.47.CNT		Sponsor/CRO Name		CRO Logo View CV
CV_Rohit-Shetty_16-Apr-2021_	08-09-47_GMT	27-Oct-2021	Franklin	FRANKLI	n W LA
View More >>					
NON-SIP CV HISTORY	(
NON-SIP CV VERSION HISTORY This section provides access to a		ur Non-SIP CV.			
Non-SIP CV Document Name				Status	View CV
Non-SIP CV_Rohit-Shetty_23-D	ec-2021_06-44-06_GMT			Active	ß
View More >>					
DOWNLOADED NON-SIP CURRI This section provides you with t		valoaded by Sponsors/CRO			
Non-SIP CV Document Name	ne list of Non-Sir CV S do	Date Downloaded	Sponsor/CRO Name	Spopsor/	CRO Logo View CV
Non-SIP CV_Rohit-Shetty_27-0	ct-2021_07-09-12_GMT	27-Oct-2021	Franklin		
ton on ev_noncety_21-0	CC FOFT_01-00-15_0M1	21-000-2021	- Controlling	FRANKLI	N 🗠
View More >>					

SIP Abbreviated CV History

0

- **SIP Abbreviated CV Version History** section displays the details of the latest active version of your CV.
 - Word format: Download and view your CV in Microsoft® Word format.
 - PDF format: Download and view your CV in PDF format.
 - View More >>: View all your CV generation records till date.
- Downloaded SIP Curriculum Vitae section -Displays the download records of the latest active version of your CV by Sponsor Users to date.
 - Word format: Download and view your CV in Microsoft[®] Word format.
 - PDF format: Download and view your CV in PDF format.
 - View More >>: View the download records of all versions of your CV by Sponsor Users till date.

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

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Non-SIP CV History

Non-SIP CV Version History section - displays the details of the latest active version of your Non-SIP CV.

Uploaded Non-SIP CV			1
Non-SIP CV Document Name	Status	View CV	
Non-SIP CV_Rohit-Shetty_23-Dec-2021_06-44-06_GMT	Active		
Non-SIP CV_Rohit-Shetty_23-Dec-2021_06-00-11_GMT	Inactive		
Non-SIP CV_Rohit-Shetty_23-Dec-2021_05-59-41_GMT	Inactive		
Non-SIP CV_Rohit-Shetty_23-Dec-2021_05-56-20_GMT	Inactive		
Non-SIP CV_Rohit-Shetty_23-Dec-2021_05-54-59_GMT	Inactive		
Non-SIP CV_Rohit-Shetty_27-Oct-2021_07-09-12_GMT	Inactive		
Non-SIP CV_Rohit-Shetty_27-Oct-2021_07-01-36_GMT	Inactive	Ŵ	
Non-SIP CV_Rohit-Shetty_22-Oct-2021_06-39-07_GMT	Inactive	W	

- Word format: Download and view your Non-SIP CV in Word format.
- PDF format: Download and view your Non-SIP CV in PDF format.
- View More >>: View all your Non-SIP CV generation records till date.
- Downloaded Non-SIP Curriculum Vitae section Displays the download records of the latest active version of your CV by Sponsor Users to date.

Ion-SIP CV Document Name	Date Downloaded	Sponsor/CRO Name	Sponsor/CRO	View CV
			Logo	
Non-SIP CV_Rohit-Shetty_27-Oct-2021_07-09-12_GMT	27-Oct-2021	Franklin	FRANKLIN	

Only the Sponsors to whom the site user has consented will be able to pull the site user's CV or access their User Profile page.

- Word format: Download and view your Non-SIP CV in Word format.
- PDF format: Download and view your Non-SIP CV in PDF format.
- View More >>: View the download records of all versions of your Non-SIP CV by Sponsor Users till date.

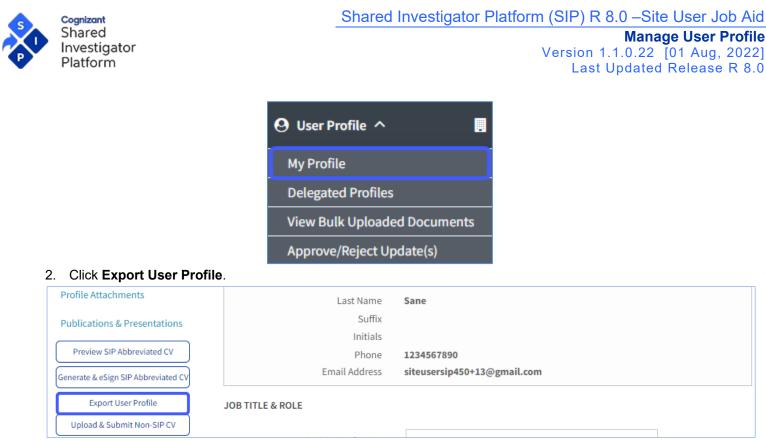
11 Export User Profile

The Profile Export varies from CV generation since more data related to sections like personal information, facility details, and education, professional experience, research experience, license details, can be exported. The Export User Profile option does not include any attachments. The Export feature provides a detailed view of the User Profile and may be utilized at any time.

1. On the User Profile menu, click My Profile.

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

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3. In the Export User Profile dialog box, click Export User Profile.

	×
The Exported User Profile:	
 May take up to 15 minutes to download and will be available on the Exported User Pro The Export will not include User Profile attachments. 	file Tab
It will take around 15 minutes to export your User Profile.	

 On the Exported User Profile page, you will see the Export in Progress status. Click the refresh icon to view the exported User Profile. To download the User Profile in Word or PDF format, click the Word Format or PDF Format buttons respectively.

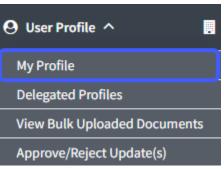
12 Exported User Profile

The **Exported User Profile** tab displays your exported SIP User Profile. This section provides access to your exported SIP User Profile.

1. On the User Profile menu, click My Profile.

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2. On the My Profile page, click the Exported User Profile tab to view the user profile that you exported.

13 Upload & Submit Non-SIP CV

The **Upload & Submit Non-SIP CV** feature allows you to upload a CV generated outside SIP in the PDF or Word format.

1. On the **My Profile** page, click **Upload & Submit Non-SIP CV**.

License Details		First Name	Leroy
		Middle Name	
Profile Attachments		Last Name	Sane
Publications & Presentations		Suffix	
		Initials	
Preview SIP Abbreviated CV		Phone	1234567890
Generate & eSign SIP Abbreviated CV		Email Address	siteusersip450+13@gmail.com
Export User Profile	JOB TITLE & ROLE		
Upload & Submit Non-SIP CV			

2. The following pop-up screen appears.

	×
Upload your Non-SIP CV	
You can upload your Non-SIP CV in pdf or word format. Please ensure that you upload the correct CV. System will not validate the uploaded document.	
Upload Non-SIP CV Choose File NON-SIP CV.pdf	
UPLOAD CANCEL	

3. Click **Choose File** to select the Non-SIP CV document to be uploaded. The Non-SIP CV document can be uploaded in the PDF or Word document.

The Non-SIP CV document can be downloaded only in the same format as it was uploaded to SIP.

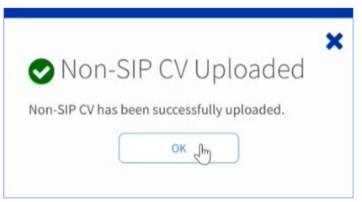
8. Click Upload.

The following message is displayed when the Non-SIP CV is successfully uploaded to SIP.

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

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The uploaded Non-SIP CV document is now displayed in the **Non-SIP CV Version History** section of the **CV History** tab.

The Uploaded Non-SIP CV document is flown to **Study Documents** Library for all the studies associated with the site user depending on the document management system used by the study.

Refer to the <u>Non-SIP CV Version History</u> section of the **CV History** tab for more information on how to view SIP and Non-SIP Generated CV information.

14 Historical Study Information

Investigators can view the study history and associated metrics from SIP.

- 1. On the User Profile menu, click My Profile.
- 2. On the My Profile page, click PI Study History. The following pop-up screen appears.

	×
PI Study History	
You will be redirected to an external partner website. Click OK to continue.	
OK Cancel	

3. Click **OK**. A new window is displayed with the historical study information.

STUDY DATA	DrugDev Sparkt
Golden Number DD45733 Dr. Stephen Adshead	
NCT Number	Title
If you have not completed a study as a PI with one of the Investigator Registry member companies, no study data will display. If you have a question, please contact us or email us directly at tdse_datasupport@iqvia.com.	

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

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15 Delegated User Profile - Update a User Profile Delegated to You

You can view the user profiles delegated to you under the **Profile Status** section in **Delegated User Profile sub**section of the SIP Landing page.

	Cognizant Shared Investigator Platform					¢	0	premanjan1950+0203@gma	t0121 Kk Ll ail.com 🕝 tl est02t_4043
🖷 Home	😫 User Profile 🗡	🔋 Facility 🌱	誉 Sponsor/CRO 🗸	🗋 Documents 🌱	Ū Safety ∽	Lini. Survey 🗸	묘 Training Ƴ	陷 Reports	💄 Admin 🌱
٢	News (Franklin)		News (Curie)	we forward w	News (Mercury) 04-Jan-20 Additiona	021 I Slots Available I	News (Mars)	04-Jan-2021 OnlyMarsNews	>
TASK	S (12) STUDY SPEC	IFIC TASKS (8)				<u>My Tasks</u>	PROFILE ST	ATUS	
	ALL		NEW				O My Profile		Completed
	0 12 Urgent Overd	0 Due Today	0 Due Later		Filte	er by: Type Sponsor/CRO	Delegated	User Profiles	2 🌶
							RECENT ST	UDIES	
	12 Overdue	Document Exchange Tasks (1)	itudy Information Tasks (8) User Profile Managen	nent Tasks (3)			Study 4 for Florer		
							study3 for Floren		
							study2 for Floren	ce cune	

Or,

You can also be view the delegated user profiles from the **Delegated Profiles** page on the **User Profile** menu.

To view the delegated user profiles:

 On the SIP Site User Landing page, in the Profile Status section, click the arrow or the number displayed on the Delegated User Profile. The number indicates the total number of User Profiles delegated to you. Or,

On the User Profile menu, click Delegated Profiles. The Delegated Profiles page is displayed.

Jelegala	ed Profiles				
Profile Status 🕯	🗧 SIP User ID 🗢	First Name 🗖	Last Name ≑	Delegate Effective From ≑	Delegator's Approval Preference ≑
0	mahurek	kanishka	m	31-Aug-2021	Approval Required
⊘	nicky	nicky	n	31-Aug-2021	Approval Required

The following details are displayed on the **Delegated Profiles** page:

- Delegator's User Profile Completion Status,
- Delegator's SIP User ID,
- Delegator's First Name and Last Name,
- Date the profile was delegated,
- Delegator's Approval Preferences.
- 2. Click the SIP User ID of the Site User whose User Profile you want to update.

As a Delegate, you can modify all the Basic Details except the email address of the actual Profile Owner.

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

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Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

My Profile Last Modified Date 10-Feb-2022 Mary Poe Fishers, Indiana **%** 7406447993 mrsmarypoe@gmail.com On behalf of Mary Poe SIP User Profile Form **CV HISTORY** EXPORTED USER PROFILE **USER PROFILE** Basic Details Modify the details of the delegated user profile Dasic Details Facilities Please use the legal/full name when updating user profile in SIP. The name as entered here will be used on regulatory documents such as Curriculum Vitae, FDA Form 1572 or equivalent, and Financial Disclosure Form. Education For Principal Investigators, the name and phone number as entered in SIP may be accessible via ClinicalTrials.gov for patients to inquire about the study being conducted at the facility. Professional Experience As a delegate, you will be able to edit the Basic Details section of the delegated profile except for the e-mail address. Research Experience NAME & CRITICAL CONTACT DETAILS GCP Training Title Edit Miss License Details First Name Mary **Profile Attachments** Middle Name Last Name Poe Publications & Presentations Suffix Send All Changes Initials For Approval Phone 7406447993 Email Address Export User Profile mrsmarypoe@gmail.com Preview SIP Abbreviated CV **JOB TITLE & ROLE** Generate SIP Abbreviated CV Job Title/Profession Upload & Submit Non-SIP CV Role Investigator O Clinical Research User 3. The My Profile page of the Delegator will be displayed.

Update the User Profile details. 4.

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



ADDITIONAL INFORMATION		
staff. By completing this section, spons	ncrease the representation of women and m ors will have a better understanding of the di . Not completing the diversity questions will	versity profile at your site.
Gender (US Only)	(Optional/Applicable in US Only)	
Ethnicity & Race (US Only)	(Optional/Applicable in US Only)	
National Provider ID	(Optional/Applicable in US Only)	
	SAVE	Facilities >

- 5. Click **Save** and then click **OK**.
- 6. In the User Profile navigation pane, click **Send All Changes for Approval**. This depends on the User Profile Approval Flag settings configured by the Delegator. Refer to <u>Step 3: Configuring User Profile Approval Settings</u> (<u>User Profile Owner</u>) section for more information.
- 7. All your changes in the User Profile are sent to the User Profile Owner for approval and a confirmation message is displayed.
- 8. Click OK.

Send All Changes For Approval button performs an implicit save and sends the data for approval, even if the **Save** button had not been clicked for the particular section.

16 Delegates - Bulk Upload

The **Bulk Upload** option allows delegates to upload multiple documents for multiple investigators at once. Delegates can bulk upload the following types of documents on behalf of the profile owners:

- License Details
- Profile Attachments
- Non-SIP CV
- GCP Training Credit Request

16.1 Points to Remember for Bulk Upload by Delegates

- 2. The **GCP Training credit Request** and **Non-SIP CV** documents uploaded by a delegate are auto-approved even when the User Profile Setting is set as **Approval Required**.
- 3. When bulk-uploading documents for Profile Attachments and License Details for delegated user profiles,
- If there are changes pending Delegator's approval for the user profile section, then delegate won't be able to bulk upload documents for that user profile section. Hence before bulk uploading, ensure that there are no changes pending approval from Delegator for the section.
- If there are no changes pending, the documents uploaded through bulk upload will be auto-approved even when the User Profile Setting is Approval Required.

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

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- 4. For MRT GCP credit requests submitted by the delegate for courses listed in SIP, system will create one request ID per course title/user across all adopting sponsors.
- 5. For GCP credit requests submitted by the delegate for courses not listed in SIP, system will create one request ID per course title/user/associated sponsor. i.e. system will treat it as an NMRT.
- 6. Delegates can view the details of their past bulk uploads in the **View Bulk Uploaded Documents** screen even after being removed from the delegate role.

16.2 Bulk Upload License Details

Delegates can bulk upload License Details for multiple Investigators using the License Details Template.

To Bulk Upload License Details

1. On the menu bar, click **User Profile**, and then select **Delegated Profiles**. The **Delegated Profiles** page is displayed.

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e 🗢

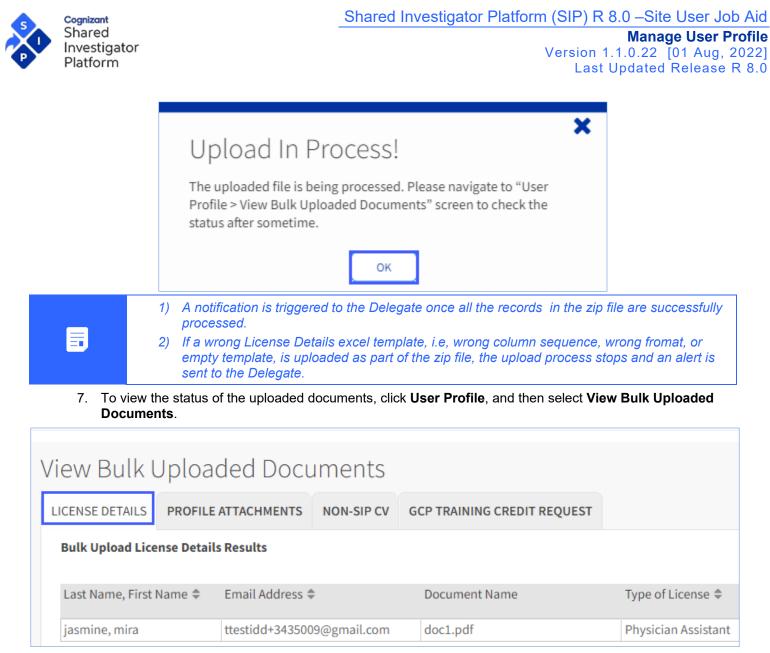
2. Click Bulk Upload. The Bulk Upload page appears, and the License Details tab is displayed by default.



Bulk Upload To Bulk Upload License Details for multiple delegated users, click or Download License Details Template To Bulk Upload Profile Attachments for multiple delegated users, click on Download Profile Attachments Template To Bulk Upload Non-SIP CV for multiple delegated users, click on Download Non-SIP CV Template LICENSE DETAILS **PROFILE ATTACHMENTS NON-SIP CV** GCP TRAINING CREDIT REQUEST Provide details on any Medical Licenses that the selected users currently hold. To upload License Details for multiple delegated profiles, upload your zip file by clicking on below Upload button. This zip file should have a License Details Template and corresponding License Document for each Investigator. En . Upload License Details* Choose File License details.zip UPLOAD CANCEL 3. Click Download License Details Template to download the excel template for bulk uploading license details. 1) Refer to the **Read Me** sheet in excel template for information on the mandatory fields and specific instructions on template upload. 2) The First Name, Last Name and Email Address details of all the profiles delegated to the site user are pre-populated in the License Details excel template. Do not modify the pre-populated information otherwise it will give an error. 3) The file name of the supporting license document (with extension) should be entered in **Document** Name column of excel template. This is case-sensitive so ensure that it is an exact match otherwise an error will be displayed. 4) Multiple entries for the same site user are allowed. 4. Once all details are filled in the template, zip the file containing License Details Template and corresponding License Documents for each Investigator. License Details Template and license documents should be in the same folder otherwise an error will be displayed. 5. Click **Choose File** to select the zip file that contains the excel template and the supporting license documents. 1) If any other file other than a ZIP format is selected for upload, error pop-up box appears. 2) The maximum file size allowed is 50 MB. If the file size limit is exceeded, error pop-up box appears. 6. Click **Upload** after selecting the zip file. The following pop-up message 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: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>



- 8. The following are the statuses available for the records being uploaded:
 - o Processing the documents are currently being processed for upload.
 - **Error** an error has occurred when uploading the documents. Failed records are marked as error with a hyperlink in the **Uploaded Status** column of the **View Uploaded Documents** screen.
 - Uploaded the document has been successfully uploaded. Respective updates will be visible in Investigator's User Profile section.
- 9. Clicking on the Error hyperlink displays all the errors associated with the record. The following screen appears.

SIP Help Desk Email: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>



Error Details	×
This Investigator is not delegated to you. First Name is not correct. Last Name is not correct. Document file extension is missing in the Template. Required Field 'Type of License' is not provided. Invalid date format for 'Issue Date'. State Code is not valid. Invalid date format for 'Expiration Date'. Document Name provided in template is not same as the License document filename or the Template and License document are in different folders.	
ОК	

10. Click on **Export** to download all the bulk-uploaded **License Details** records by the delegate in excel format. Users can also print all the records displayed in View Bulk Uploaded Documents screen using the **Print** option.

16.3 Bulk Upload Profile Attachments

Delegates can bulk upload Profile Attachments details for multiple Investigators using the **Profile Attachments Template**.

To Bulk Upload Profile Attachments

1. On the menu bar, click **User Profile**, and then select **Delegated Profiles**. The **Delegated Profiles** page is displayed.



2. Click Bulk Upload. The Bulk Upload page appears. Select the Profile Attachments tab.

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

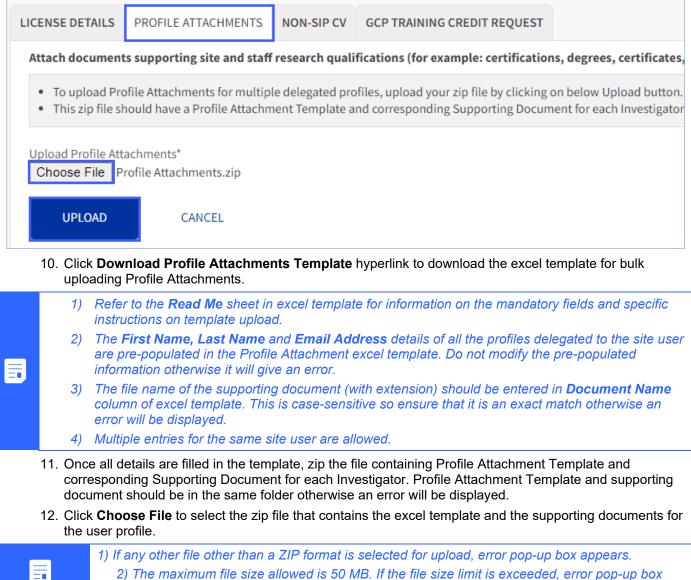
SIP Help Desk Email: SIPHelp@Cognizant.com | Telephone: See Help Desk



Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Bulk Upload

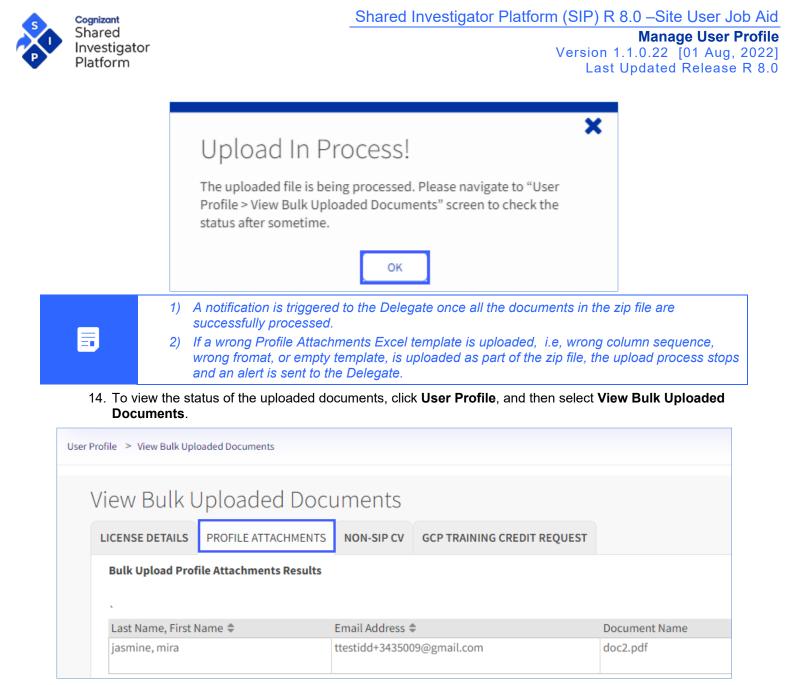
- To Bulk Upload License Details for multiple delegated users, click on Download License Details Template
- To Bulk Upload Profile Attachments for multiple delegated users, click on Download Profile Attachments Template
- To Bulk Upload Non-SIP CV for multiple delegated users, click on Download Non-SIP CV Template



2) The maximum file size allowed is 50 MB. If the file size limit is exceeded, error pop-up box appears.

13. Click **Upload** after selecting the zip file. The following pop-up message appears.

SIP Help Desk Email: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>



- 15. The following are the statuses available for the records being uploaded:
 - **Processing** the documents are currently being processed for upload.
 - **Error** an error has occurred when uploading the documents. Failed records are marked as error with a hyperlink in the **Uploaded Status** column of the **View Uploaded Documents** screen.
 - **Uploaded** the document has been successfully uploaded. Respective updates will be visible in Investigator's User Profile section.
- 16. Clicking on the Error hyperlink displays all the errors associated with the record. The following screen appears.

SIP Help Desk Email: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>



	×
Error Details	
Email is not in the valid format. This site-user is not registered with SIP. Document Name is same for more than one record. Required Field 'Document Type' is not provided	
ок	

10. Click on **Export** to download all the bulk-uploaded **Profile Attachments** records by the delegate in excel format. Users can also print all the records displayed in View Bulk Uploaded Documents screen using the **Print** option.

16.4 Bulk Upload NON-SIP CV

Delegates can bulk upload NON-SIP CV for multiple Investigators using the NON-SIP CV Template.

To Bulk Upload NON-SIP CV

1. On the menu bar, click **User Profile**, and then select **Delegated Profiles**. The **Delegated Profiles** page is displayed.

Delegate	d Profiles				
You can bulk uplo the "Bulk Upload		ense Details, GCP Training Cr	redit Requests, Non-SIP	CV & Profile Attachments for all In	vestigators in below table, by clicking on
Profile Status ≑	SIP User ID 🜲	First Name 🗖	Last Name 🗢	Delegate Effective From 🗢	Delegator's Approval Preference 🗢
0	poem_5460	Mary	Poe	17-Feb-2021	Approval Required
BULK UPLC					Show Rows 10 V Page 1 of 1

2. Click Bulk Upload. The Bulk Upload page appears. Select the NON-SIP CV tab.

SIP Help Desk Email: <u>SIPHelp@Cognizant.com</u> | Telephone: See <u>Help Desk</u>

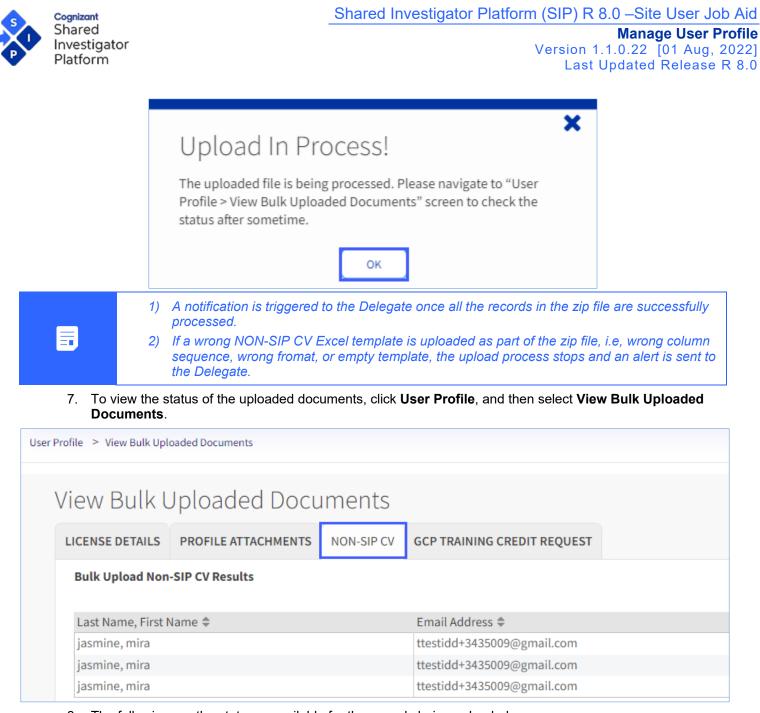
For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

Investi Platfoi		Shared Investigator Platform (SIP) R 8.0 –Site User Manage User Version 1.1.0.22 [01 Aug Last Updated Releas
Bulk	Upload	
 To Bu 	Ik Upload Profile Attachments for	tiple delegated users, click on Download License Details Template r multiple delegated users, <u>click on Download Profile Attachments</u> Template e delegated users, click on <mark>Download Non-SIP CV Template</mark>
LICENSE	E DETAILS PROFILE ATTACHME	ENTS NON-SIP CV GCP TRAINING CREDIT REQUEST
You ca	an upload Non-SIP CV in pdf or w	word format. Please ensure that you upload the correct CV. System will not validate the uploaded document.
• Tł		delegated profiles, upload your zip file by clicking on below Upload button. CV Template and corresponding Non-SIP CV file for each Investigator. Ensure that the template and Non-SIP CV are
Unload		
	d Non-SIP CV* ose File License De…late (1).zip	,
Choo	ose File License De…late (1).zip	
Choo		
Choo 3.	UPLOAD CANCEL Click Download NON-S	SIP CV Template to download the excel template for bulk uploading NON-SIP CV
Choc 3. (UPLOAD CANCEL Click Download NON-S	SIP CV Template to download the excel template for bulk uploading NON-SIP CV e sheet in excel template for information on the mandatory fields and specific
Choc 3. (UPLOAD CANCEL Click Download NON-S 1) Refer to the Read M instructions on template 2) The First Name, Las	SIP CV Template to download the excel template for bulk uploading NON-SIP CV e sheet in excel template for information on the mandatory fields and specific
3. (UPLOAD CANCEL Click Download NON-S 1) Refer to the Read M instructions on template 2) The First Name, Las are pre-populated in the will give an error. 3) The file name of the	SIP CV Template to download the excel template for bulk uploading NON-SIP CV be sheet in excel template for information on the mandatory fields and specific e upload. st Name and Email Address details of all the profiles delegated to the site user
Choc 3. (UPLOAD CANCEL Click Download NON-S Click Download N	SIP CV Template to download the excel template for bulk uploading NON-SIP CV te sheet in excel template for information on the mandatory fields and specific e upload. st Name and Email Address details of all the profiles delegated to the site user e Non-SIP CV template. Do not modify the pre-populated information otherwise it Non-SIP CV (with extension) should be entered in Document Name column of
Choc 3. (4. (UPLOAD CANCEL Click Download NON-S Click Download N	SIP CV Template to download the excel template for bulk uploading NON-SIP CV be sheet in excel template for information on the mandatory fields and specific e upload. St Name and Email Address details of all the profiles delegated to the site user e Non-SIP CV template. Do not modify the pre-populated information otherwise it Non-SIP CV (with extension) should be entered in Document Name column of case-sensitive so ensure that it is an exact match otherwise an error will be
Chool 3. (4. (5. (UPLOAD CANCEL Click Download NON-S CANCEL Click Download NON-S 1) Refer to the Read M instructions on template 2) The First Name, Las are pre-populated in the will give an error. 3) The file name of the excel template. This is of displayed. 4) Multiple entries for the Corresponding Non-SIP should be in the same for	SIP CV Template to download the excel template for bulk uploading NON-SIP CV be sheet in excel template for information on the mandatory fields and specific e upload. St Name and Email Address details of all the profiles delegated to the site user e Non-SIP CV template. Do not modify the pre-populated information otherwise it Non-SIP CV (with extension) should be entered in Document Name column of case-sensitive so ensure that it is an exact match otherwise an error will be the same site user are not allowed. d in the template, zip the file containing NON-SIP CV Template and the CV for each Investigator. Non-SIP CV Template and CVs of the investigators

2) If any other file other than a ZIP file is selected for upload, error pop-up box appears.

6. Click **Upload** after selecting the zip file. The following pop-up message appears.

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- 8. The following are the statuses available for the records being uploaded:
 - **Processing** the documents are currently being processed for upload.
 - **Error** an error has occurred when uploading the documents. Failed records are marked as error with a hyperlink in the **Uploaded Status** column of the **View Bulk Uploaded Documents** screen.
 - **Uploaded** the document has been successfully uploaded. Respective updates will be visible in Delegator's User Profile section.
- 9. Clicking on the Error hyperlink displays all the errors associated with the record. The following screen appears.

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

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Error Details	×
Email is not in the valid format. This site-user is not registered with SIP. Document Name is same for more than one recor	d
Required Field 'Document Type' is not provided	u.
ОК	

10. Click on **Export** to download all the bulk-uploaded NON-SIP CV records by the delegate in excel format. Users can also print all the records displayed in View Bulk Uploaded Documents screen using the **Print** option.

16.5 Bulk Upload Training Credit Request

Delegates can bulk upload Training Credit Request for multiple Investigators using the **Training Credit Request Template**.

To Bulk Upload Training Credit Requests

1. On the menu bar, click **User Profile**, and then select **Delegated Profiles**. The **Delegated Profiles** page is displayed.

d Profiles				
ad documents like Licer ' button.	nse Details, GCP Training Cr	edit Requests, Non-SIP	CV & Profile Attachments for all In	vestigators in below table, by clicking on
SIP User ID ≑	First Name 🗖	Last Name ≑	Delegate Effective From 🗢	Delegator's Approval Preference ≑
poem_5460	Mary	Poe	17-Feb-2021	Approval Required
2	d documents like Lice button. SIP User ID ♦	id documents like License Details, GCP Training Cr button. SIP User ID \$ First Name *	d documents like License Details, GCP Training Credit Requests, Non-SIP button. SIP User ID 🗢 First Name 📤 Last Name 🗢	id documents like License Details, GCP Training Credit Requests, Non-SIP CV & Profile Attachments for all In button. SIP User ID 🗢 First Name 🔷 Last Name 🗢 Delegate Effective From 🗢

2. Click **Bulk Upload**. The **Bulk Upload** page appears. Select the **Training Credit Request** tab. Select the **Training Provider** from the drop-down menu. Click **Search**.

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Manage User Profile

Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Search for Completed Course	
USE BY TYPE/PROVIDER: Course Types GCP, EDC and IATA may be eligible for credit as Mutually the TransCelerate website for a list of MRT courses. If the Provider on your completion certificate USE BY SPONSOR/CRO/STUDY: Use only for CRO/sponsor/study-specific course titles that are no	
By Type And Provider	By Study
Training Type(Required)	Sponsor/CRO
GCP 🗸	Select Sponsor/CRO 🗸
Training Provider(Required)	Study ID
1	Select Study ID 🗸
SEARCH CLEAR SEARCH	

3. The search results are displayed. Click the radio button to select the necessary course to upload the training credit requests.

	course and version you have complet ct a course by mistake and want to ch				t Listed" button.
ect	Course Title ≑	Training Provider ≑	Training Type ≑	Sponsor/CRO ≑	Study ID 🌲
0	25185_Assessment1	Shara1	GCP	-	-
\bigcirc	25193_ILTClass1	Shara1	GCP	-	-
\bigcirc	25193_ILTCourse01	Shara1	GCP	-	-
\bigcirc	Abbvie_GCP_SMRT Updated 2	Provider 1 Updated	GCP	-	-
\bigcirc	Provider MRTTest1	provider 1	GCP	-	-
\bigcirc	Course 1 for UST-1	SIP-1	GCP	-	-
0	Good Clinical Practices Lyon CIC Version August 2016 - Aug-16 - Hospices Civils de Lyon CIC1407	Hospices Civils de Lyon CIC1407	GCP	-	-
0	GCP Training per to Staff Clinico (GCP Trainnig for Clinical Staff) - Version no. 1.0 - Yghea, a Division of Bioikos Ambiente S.r.1	Yghea, a Division of Bioikos Ambiente S.r.1	GCP	-	-
0	GCP Training for Investigators and Study Nurses/Coordinators - Version for Investigators and Study Nurses / Coordinators - Cropha, sprl	1	GCP	-	-
\bigcirc	S pace MRT	Provider 1	GCP	-	-
		Showir	ng 1 to 10 of 45 entries Show	w 10 🗸 entries Pag	ge 1 of 5 > 2

In case the course is not listed in SIP, click on **Course Not Listed** option to manually add your course details. This course will be treated as a Non-MRT course.

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

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Version 1.1.0.22 [01 Aug, 2022] Last Updated Release R 8.0

Enter Course	e Not Lis	sted		×
	-	dit for this course. If this course i and then reviewed by each spo		ently a Mutually Recognized Training course, individually.
TRAINING DETAILS Course Title(Required) Good Clinical Practice		Training Type(Required) GCP	~	Training Provider(Required) London School of Hygiene
		e course details. The Uploa aining Credit Request Ten		reen appears. yperlink to download the template file.
Upload File			<u> </u>	

To upload GCP Training Credit Request for multiple delegated profiles, Download below Training Credit Request Template.

Download Training Credit Request Template

Upload Training Credit Request*
Choose File
License De...late (1).zip

UPLOAD

CANCEL

- 1) Refer to the **Read Me** sheet in excel template for information on the mandatory fields and specific instructions on template upload..
- 2) The **First Name, Last Name** and **Email Address** details of all the profiles delegated to the site user are pre-populated in the **Training Credit Request Template**.
- 3) The course details selected in **Select a Completed Course** screen are also pre-populated in the **Training Credit Request Template**. Do not modify any of the pre-populated information in the template otherwise it will result in error.
- 4) The file name of the GCP certificate (with extension) should be entered in **Document Name** column of excel template. This is case-sensitive so ensure that it is an exact match otherwise an error will be displayed.

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

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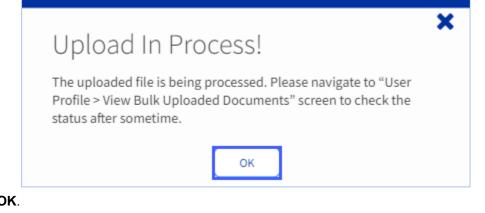
- 6. Once all the details are filled in, zip the file containing the Training Credit Request Template and the corresponding Training certificate for each Investigator. Ensure that the template and certificate are present in the same folder within the ZIP file otherwise an error will be displayed.
- 7. Click Choose File to select the ZIP file containing the Training Creadit Credit Request Template and the supporting GCP completion certificates.



1) The maximum file size allowed is 50 MB. If the file size limit is exceeded, error pop-up box appears.

2) If any other file other than a ZIP file is selected for upload, error pop-up box appears.

8. Click Upload after selecting the zip file. The following pop-up screen appears:



9. Click **OK**.



1) A notification is triggered to the Delegate once all the records in the zip file are successfully processed.

- 2) If a wrong Training Credit Request Excel template i.e, wrong column sequence, wrong fromat, or empty template, is uploaded as part of the zip file, the upload process stops and an alert is sent to the Delegate.
- 10. To view the status of the uploaded documents, click **User Profile**, and then select **View Bulk Uploaded Documents**.

iew Bulk L	Jploa	ded Docu	ments		
LICENSE DETAILS	PROFILE	ATTACHMENTS	NON-SIP CV	GCP TRAINING CREDIT REQUEST	
Bulk Upload Trai	ning Credi	t Request Result	;		
Requested for Las First Name 🖨	st Name,	Email Address 🖨		Document Name	Course Title 🗢
jasmine, mira		ttestidd+343500	9@gmail.com	doc2.pdf	Good Clinical Practice – why and how - 1 BCT Consulting

- 11. The following are the statuses available for the records being uploaded:
 - **Processing** the documents are currently being processed for upload.
 - **Error** an error has occurred when uploading the documents. Failed records are marked as error with a hyperlink in the **Uploaded Status** column of the **View Bulk Uploaded Documents** screen.

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

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- **Uploaded** the document has been successfully uploaded. Respective updates will be visible in Delegator's User Profile section.
- 12. Clicking on the Error hyperlink displays all the errors associated with the record. The following screen appears.

Error Details	:
This Investigator is not delegated to you. Requested for First Name is not correct. Requested for Last Name is not correct. Required Field 'Document Name' is not provided. Training Provider is not the same as chosen in 'Select Completed Course' section. A future date has been selected in 'Training Completion Date'. Course Title is not the same as chosen in 'Select Completed Course' section.	
ОК	

13. Click on **Export** to download all the bulk-uploaded Training Credit Request records by the delegate in excel format. Users can also print all the records displayed in View Bulk Uploaded Documents screen using the **Print** option.