### cognizant shared investigator platform

## R10.1- Site User Job Aid Site User Registration Version 1.24 [17 Nov 2023] Last Updated R9.1

#### **Table of Contents**

1	I hin	gs to Do Before You Register	4
	1.1	Check Your Browser Version and Installed Plugins	4
	1.2	What is Exostar?	4
	1.3	How we use Exostar's SAM solution with SIP?	4
	1.4	Allow Emails from SIP and Exostar Email Addresses	4
2	Regi	ster in SIP	5
	2.1	Check Your Email Account for the Invitation Email	5
	2.2	Click the registration URL in the Invitation Email	5
	2.3	Accept the SIP Terms and Conditions	6
	2.4	Consent for Data Sharing to SIP Sponsors	7
	2.5	Consent for Data Storage in IR	8
	2.6	Consent for Sharing the Contact and Profile Information with Investigator Registry	8
	2.7	Confirm Your Email Address and SIP Role	9
	2.8	Scenarios and Navigations	9
	2.9	Primary Business Address Update	10
	2.10	Complete the Personal Information page	10
	2.11	Set your Password and Security/Challenge Questions and Activate your Exostar Account	12
	2.12	Existing User with an Active Account	16
3	Appe	endix	19
	3.1	Appendix 1	20

cognizant shared investigator platform

R10.1- Site User Job Aid
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### **Revision History**

Version	Date	Author	Changes
1.1.0.19	24 June 2022	Cognizant Technology Solutions	Release 7.1 Single Column Layout R 7.1 Enhancements Exostar Account Activation
1.1.0.20	04 July 2022	Cognizant Technology Solutions	Release R 7.1.1. enhancements
1.1.0.21	04 Aug 2022	Cognizant Technology Solutions	Release R8.0 enhancements
1.1.0.22	04 Nov 2022	Cognizant Technology Solutions	Release 8.2 enhancements
1.1.0.23	16 June 2023	Cognizant Technology Solutions	Release 9.0 enhancements
1.1.0.24	17 Nov 2023	Cognizant Technology Solutions	Release 9.1 enhancements

#### 1 Things to Do Before You Register

Before you register in SIP, you need to ensure that your system meets the minimum requirements for using SIP:

#### 1.1 Check Your Browser Version and Installed Plugins

SIP is best viewed on Microsoft® Internet Explorer (IE) 11, Mozilla® Firefox 50 and above, Google® Chrome 53 and above, or Safari 9 and above, Microsoft® Edge 11. To confirm your browser and installed plugin versions, ask your local IT Administrator for assistance or contact the SIP Help Desk.

Check Your System Requirements (Display Resolution)



In addition, you need to disable pop-up blockers in your browser. To do this, ask your local IT administrator for assistance or contact the SIP Help Desk.

SIP is best viewed with a minimum screen resolution of 1024x768 pixels and a color depth of 16-bit.

To confirm the display resolution of your screen, ask your local IT Administrator for assistance or contact the SIP Help Desk.

#### 1.2 What is Exostar?

Exostar is a company that provides identity, credentialing, and access solutions. We utilize Exostar's Secure Access Manager (SAM) to manage Single Sign-On (SSO) credentials and to provide secure access to applications you may utilize while participating in clinical trials.

#### 1.3 How we use Exostar's SAM solution with SIP?

Your SIP username and password are managed and provided through SAM. When you access SIP, SAM authenticates your credentials. Through SAM, you can also reset your SIP/SSO registered email address, login password, and security questions.

Exostar also provides the following capabilities in SIP:

- Allows site users to securely e-sign documents in SIP
- Allows seamless access to other sponsor applications using SSO capabilities. Since your Exostar credentials
  are SSO enabled, you'll have the ability to access other SSO enabled systems without entering user names
  and passwords by clicking on a link to these systems in SIP.
- Allows site users to reset the SIP/SSO registered email address, login password, and security questions.

Note: SSO applications and SSO user access must be enabled by sponsors.

#### 1.4 Allow Emails from SIP and Exostar Email Addresses



To avoid important emails from SIP and Exostar from going to your email Junk or Spam folder, add the following email addresses to the Trusted Source Settings in your mailbox:

- SIPSupport@exostar.com
- do-not-reply@sharedinvestigator.com
- support@sharedinvestigator.com

To do this, ask your local IT Administrator for assistance or contact the SIP Help Desk.

- 1. From Control Panel, click Internet Options, and
- 2. Select the Security tab.
- 3. Click Trusted Sites.
- 4. Select Sites.
- 5. In the Add this website to the zone, type the following:

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

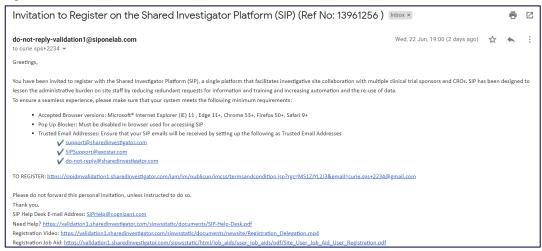
- \*.sharedinvestigator.com;
  - 6. Click Add.
  - 7. Click Close.
  - 8. Click Ok.

#### 2 Register in SIP

The registration process below is for Site User Registration.

#### 2.1 Check Your Email Account for the Invitation Email

To register in SIP, you must first receive an invitation from a Sponsor User or a Site User. Site Users already in SIP can also request a registration email for a non-SIP user.



The invitation email includes the URL and instructions required to register. If the user clicks on a wrong invitation link, links that were forwarded from other users, the following pop-up message is displayed:





The verification code in the email received expires in 30 minutes.

#### 2.2 Click the registration URL in the Invitation Email

This step initiates the registration process and displays the Consent for Sharing Data with the SIP and Investigator Registry page in your browser.

If the invitation code is already used for SIP registration, the following pop-up message is displayed:

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

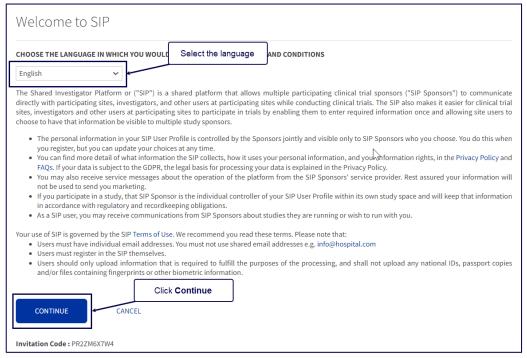


If the invitation code is invalid, the following pop-up message is displayed:



#### 2.3 Accept the SIP Terms and Conditions

1. In the Language drop-down-list, English is displayed as the default language.



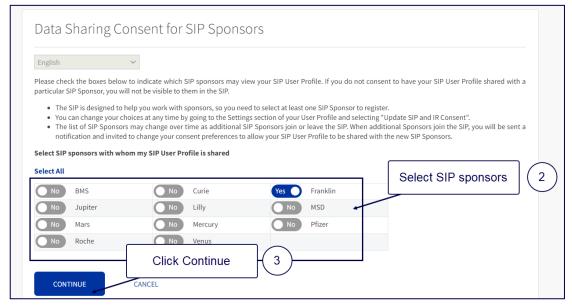
- Select the language to view the SIP Terms and Conditions in the respective language. The list of languages include:
  - Arabic
  - Chinese (Mandarin)

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

- Chinese (Traditional)
- English
- French (Canadian)
- French (European)
- German
- Italian
- Japanese
- Korean
- Portuguese (Brazilian)
- Portuguese (Portuguese)
- Russian
- Spanish (European)
- Spanish (Latin American)
- 3. Review all SIP Terms and Conditions.
- 4. Select all the check boxes.
- 5. Click **Continue**. Consent is required for SIP registration.

#### 2.4 Consent for Data Sharing to SIP Sponsors

- 1. In the Data Sharing Consent for SIP Sponsors, select the language to view the displayed content.
- Select SIP sponsors with whom my SIP User Profile is shared to indicate which SIP sponsors may view your SIP User Profile.





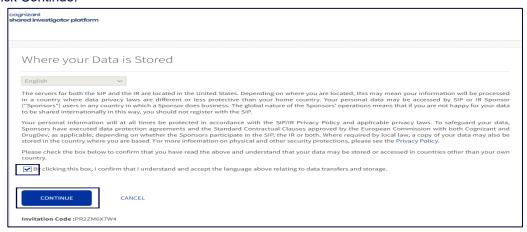
Ensure you select atleast one SIP Sponsor to register. You can change your choices at any time by navgating to the Settings section of User Profile and selecting "Update SIP and IR Consent".

3. Click Continue.

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

#### 2.5 Consent for Data Storage in IR

- 1. Select the language to view the displayed content.
- 2. In the Where Your Data is Stored page, read through the content to understand that your data may be stored or accessed in countries other than your own country.
- Select the check box to accept the consent related to data transfers and storage.
- 4. Click Continue.



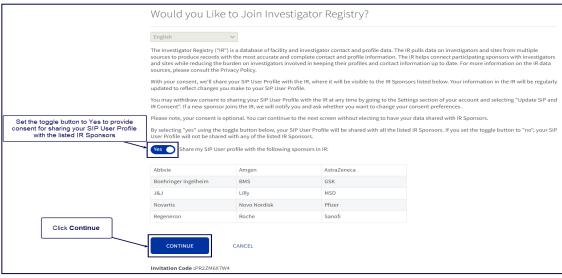
#### 2.6 Consent for Sharing the Contact and Profile Information with Investigator Registry

To Provide Consent for sharing your SIP User Profile that has the contact and profile information with the Sponsors listed in IR, where it will be visible to the IR Sponsors selected to have your data shared with IR Sponsors.

Select Yes to provide your consent for sharing your SIP User Profile with Sponsors listed in IR.



Consent for sharing the SIP User Profile with IR is optional. Storing the profile information in IR helps maintain the up to date user profile information of Investigators which is made vissible to participating IR Sponsors. You can continue to the next screen without selecting to have your data shared with IR Sponsors listed in the page. There is an option to withdraw the consent for sharing with IR by navigating to the Settings section and selecting Update SIP and IR Consent.



#### Click Continue.

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

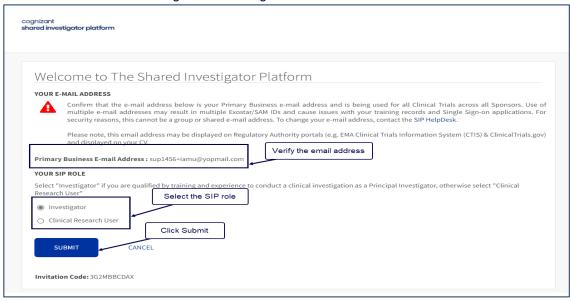
#### 2.7 Confirm Your Email Address and SIP Role

1. Verify your email address displayed below.



To modify the registered email address, contact the SIP Helpdesk.

2. Select your role as an Investigator or a Clinical Research User. Confirm your email address and follow the onscreen instructions to continue to login with existing Exostar credentials.



3. Click Submit to confirm. On clicking Submit, one of the following scenarios occur.

#### 2.8 Scenarios and Navigations

#### Option A

If the Exostar User has an existing account with active status and already provided the address details and if all
mandatory details are filled and if the State/Province/Region is correctly set in Exostar, navigate to section 2.12.

#### Option B

• If the Exostar user has an existing account with active status and if any one of the mandatory fields is NULL or if the State/Province/Region is not provided, navigate to section 2.9 and section 2.12.

#### Option C

• If the Exostar user has an existing account with inactive status or not completed the first time login and if all mandatory fields are filled with correct State/Province/Region details set in Exostar, navigate to <a href="section 2.11">section 2.11</a>.

#### Option D

• If the Exostar user has an existing account and inactive status or not completed the first time login and if all mandatory fields are filled and if any one of the mandatory fields is NULL or if the State/Province/Region details is incorrectly set in Exostar, navigate to <a href="section 2.9">section 2.9</a> and <a href="section 2.11">section 2.11</a>.

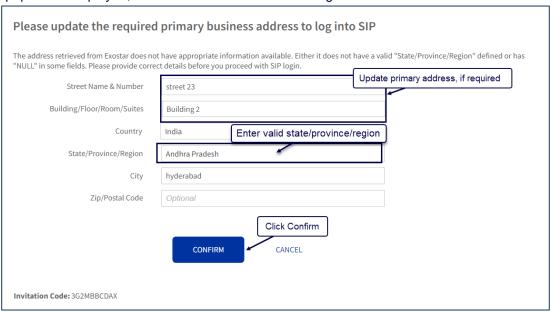
#### Option E

If you are not an Exostar user, navigate to <u>section 2.10</u> and <u>section 2.11</u>.

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

#### 2.9 Primary Business Address Update

In the Popup that is displayed, enter the valid Sate/Province/Region.



- 2. Update the required primary business address, if the retrieved address from Exostar does not have the correct state/province/region details.
- 3. Click Confirm.

#### 2.10 Complete the Personal Information page

On the **SIP User Registration** page, please complete the Personal Information, Contact Information, and Time Zone sections. Optional fields are indicated on the screen.

#### **Personal Information:**

- Please use your legal/full name when registering to SIP. Your name as entered here will be used on regulatory documents such as your Curriculum Vitae, FDA Form 1572, and Financial Disclosure Form.
- Please do not enter more than 50 characters for the first, middle, or last name fields.
- If you have multiple family names, it is recommended that you enter only one name as your last name.
- Please refer to the table in the <u>Appendix 1</u> which provides the special characters and languages supported in Exostar.

#### **Contact Information:**

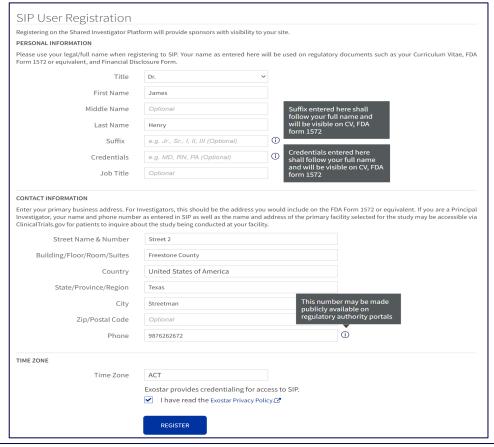
- Enter your primary business address. For Investigators, this should be the address you would include on the FDA Form 1572 or equivalent.
- If you are a Principal Investigator, your name and phone number as entered in SIP as well as the name and address of the primary facility selected for the study may be accessible via ClinicalTrials.gov for patients to inquire about the study being conducted at your facility.

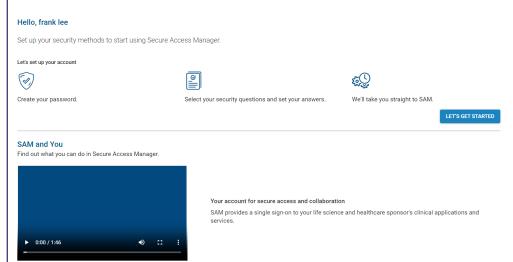
#### **Accept Exostar Terms and Conditions and submit the details**

 Review the Exostar Privacy Policy and select the I agree to Exostar LLC's Terms and have read the Exostar Privacy Policy check box.

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

Site User Registration Version 1.24 [17 Nov 2023] Last Updated R9.1







In case the Site User closes the browser by mistake, during the setting up of a Password, the user need to follow the steps available in the <u>Appendix</u> section to complete the registration process.

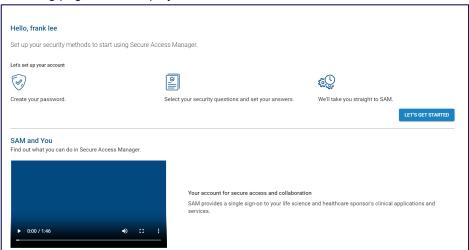
The personal information and contact information shall be pre-filled with the information that is provided while sending the registration invitation.

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

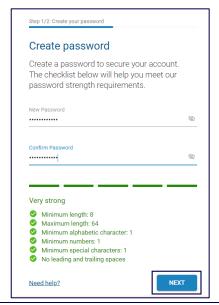
#### 2.11 Set your Password and Security/Challenge Questions and Activate your Exostar Account

To set up your password and Security/Challenge Questions

In the following page that is displayed, click Create Password.



2. On the **Create a password** page, enter the new password, confirm by re-entering the password, and then click **NEXT.** 





In case the Site User closes the browser by mistake, during the setting up of a Password, the new user or user with an inactive account need to follow the steps available in the <u>Appendix</u> section to complete the registration process.

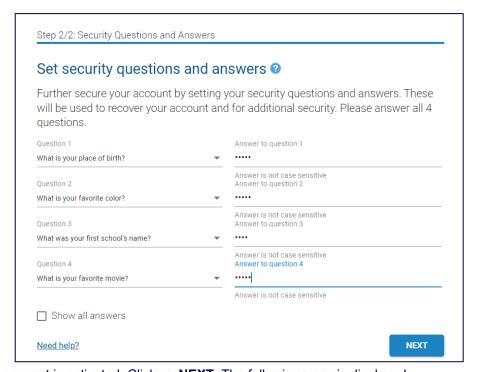
3. On the **Set Security questions** page, select your four security questions and type your response for each of the question, and then click **NEXT.** 



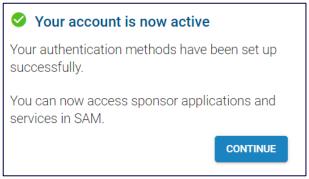
Refer below link for Security Question and Answer policy details:

https://my.exostar.com/display/EFD/Security+Question+and+Answer+Policy

The Exostar system will encounter an error if users fail to provide the security answers within a specified time frame.



4. Your account is activated. Click on **NEXT**. The following page is displayed.



5. On the **Service Agreement** page, select the required check boxes, and then click **Accept**. You must accept the Exostar terms and conditions of the Service Agreement in order to proceed.

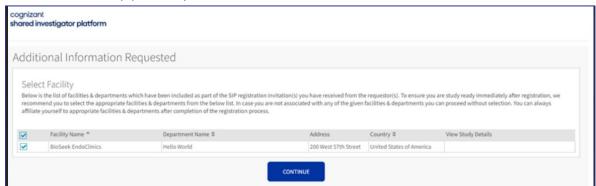


#### To select or deselect the Facility

Site User may receive multiple invitations from Sponsor or from Site Staff.

If Site User receives invitation from Sponsor by one of the following methods in SIP, the following page is displayed:

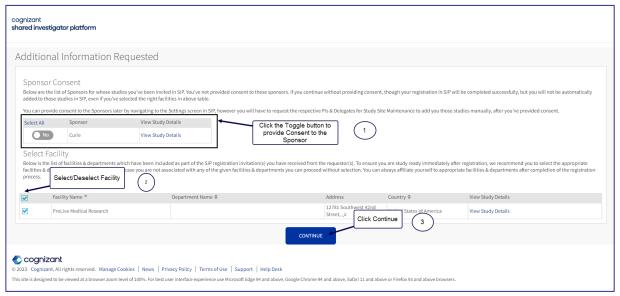
- o (Admin Send Site User Registration Invitation)
  - Invite Site Users (Manual Entry)
  - Invite Site Users (Upload File)



Select or deselect the facility.

Or

If the Site User receives the invitation from the Other Site Staff page, the following screen is displayed.



- Click the Toggle button to provide Consent to the Sponsor.
- 2. Select/Deselect the Facility.
- 3. Click Continue.

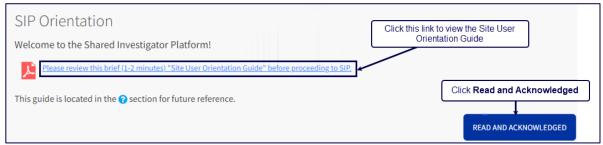


If you do not provide consent to Sponsor, after completing the registration process, you will be added to the selected Facilities as part of the SIP registration invitation but will not be added to the Studies. You have the option to provide consent by navigating to the Settings screen in SIP. You may need to request the Principal Invetigator or Study Site Maintenance Delegate to add you to studies manually.



If the Exostar Admin creates the site user profile, through the bulk upload process, it is mandatory for the Site User to review and accept the SIP Terms and Conditions. The Site User, in this case will need to perform steps 1-5 of the <u>Set your Password and Security/Challenge Questions and Activate your Exostar Account section below, before proceeding to step 6.</u>

4. Complete the Mandatory SIP Orientation (Site User Orientation Guide).



- Click the link to view the Site User Orientation Guide.
- 6. After you have viewed the Site User Orientation Guide, close it, and click Read and Acknowledged. This button will be enabled after you open the Site User Orientation Guide.
- 7. You will be redirected to Shared Investigator Platform Home page.

To refer to Manage Password details, refer to the Manage Password Job aid.

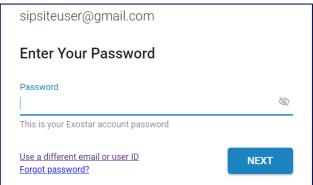
For a detailed description on each activity explained in this Job Aid, refer to the SIP Site User Online Help.

#### 2.12 Existing User with an Active Account

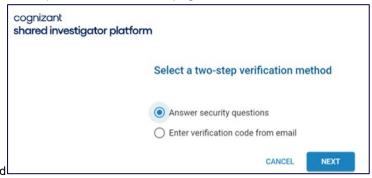
 In the Login page that is displayed with the email address registered with your Exostar Account, click Next.



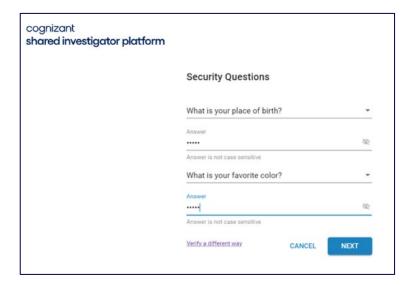
2. In the Enter your Password page, enter your password.



3. In the Select a two-step verification method page, click Next.



4. In the **Security Questions** page, set the security questions and answers.





The Exostar system will encounter an error if users fail to provide the security answers within a specified time frame.

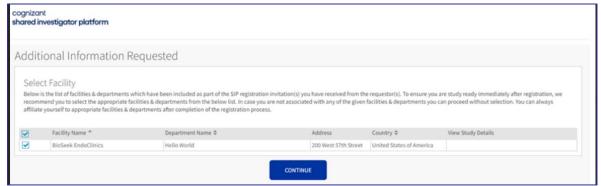
5. Click Next.

#### To Select/Deselect Facility

Site User may receive multiple invitations from Sponsor or from Site Staff.

If Site User receives invitation from Sponsor by one of the following methods in SIP, the following page is displayed:

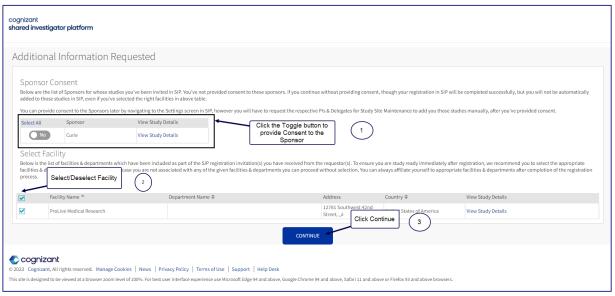
- (Admin Send Site User Registration Invitation)
  - Invite Site Users (Manual Entry)
  - Invite Site Users (Upload File)



Select or deselect the facility.

Or

If the Site User receives the invitation from the Other Site Staff page, the following screen is displayed.



- Click the Toggle button to provide Consent to the Sponsor.
- 2. Select/Deselect the Facility.
- 3. Click Continue.

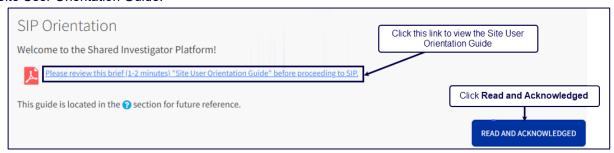


If you do not provide consent to Sponsor, after completing the registration process, you will be added to the selected Facilities as part of the SIP registration invitation but will not be added to the Studies. You have the option to provide consent by navigating to the Settings screen in SIP. You may need to request the Principal Invetigator or Study Site Maintenance Delegate to add you to studies manually.



If the Exostar Admin creates the site user profile, through the bulk upload process, it is mandatory for the Site User to review and accept the SIP Terms and Conditions. The Site User, in this case will need to perform steps 1-5 of the <u>Set your Password and Security/Challenge Questions and Activate your Exostar Account section</u> below, before proceeding to step 6.

4. In the SIP Orientation page that is displayed, complete the first time login training by reading and acknowledging the Site User Orientation Guide.



- 5. Click the link to view the Site User Orientation Guide.
- After you have viewed the Site User Orientation Guide, close it, and click Read and Acknowledged. This button will be enabled after you open the Site User Orientation Guide.
- 7. You will be redirected to Shared Investigator Platform Home page.

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

#### 3 Appendix

#### To complete the Registration process

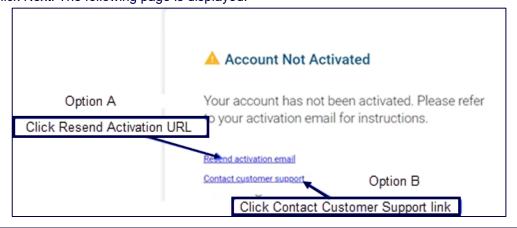
- 1. Log on to SIP by using the link www.sharedinvestigator.com.
- 2. Click Site Login.



3. In the Login page that is displayed, click enter the email or User ID registered with your Exostar account.



4. Click Next. The following page is displayed.





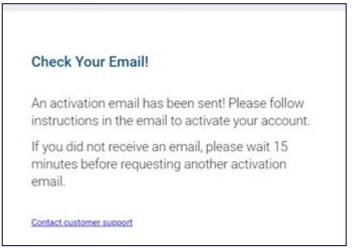
Option A: To activate your account to complete the first time login, click Resend activation email link. The activation email will be sent to your registered e-mail address.

Option B: To contact the Customer Support, click the Contact Customer Support link.

#### To activate your account in Exostar

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

5. Click Resend Activation Email link. The following page is displayed. The email with activation link will be sent to your registered e-mail address.



6. Check your Email. Click on the activation URL available in the email.





The validity of the activation URL link availbale in the email to activate your account is 14 days.

7. In the Create Password page that is displayed, set your password and security challenge questions.

#### 3.1 Appendix 1

The table below provides the list of special characters supported in Exostar.

Special Characters	Description
Ç C	Majuscule C-cedilla
ü u	Letter u with umlaut or diaeresis ; u-umlaut
é e	Letter e with acute accent or e-acute
â a	Letter a with circumflex accent or a-circumflex
ä a	Letter a with umlaut or diaeresis ; a-umlaut
à a	Letter a with grave accent

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

å	aa	Letter a with a ring
ç	С	Minuscule c-cedilla
ê	е	Letter e with circumflex accent or e-circumflex
ë	е	Letter e with umlaut or diaeresis ; e-umlauts
è	е	Letter e with grave accent
ï	i	Letter i with umlaut or diaeresis ; i-umlaut
î	i	Letter i with circumflex accent or i-circumflex
ì	i	Letter i with grave accent
Ä	Α	Letter A with umlaut or diaeresis ; A-umlaut
Å	Aa	Letter A with a ring
É	E	Letter E with acute accent or E-acute
æ	ae	Latin diphthong ae in lowercase
Æ	AE	Latin diphthong AE in uppercase
ô	0	Letter o with circumflex accent or o-circumflex
ö	0	Letter o with umlaut or diaeresis ; o-umlaut
ò	0	Letter o with grave accent
û	u	Letter u with circumflex accent or u-circumflex
ù	u	Letter u with grave accent
ÿ	ij	Lowercase letter y with diaeresis
Ϋ	IJ	Uppercase letter Y with diaeresis
Ö	0	Letter O with umlaut or diaeresis ; O-umlaut
Ü	U	Letter U with umlaut or diaeresis ; U-umlaut
Ø	0	Lowercase slashed zero or empty set
£	_	Pound sign; symbol for the pound sterling
Ø	0	Uppercase slashed zero or empty set
×	_	Multiplication sign
á	а	Lowercase letter a with acute accent or a-acute
Í	į	Lowercase letter i with acute accent or i-acute
ó	0	Lowercase letter o with acute accent or o-acute
ú	u	Lowercase letter u with acute accent or u-acute
ñ	n	Enie; spanish letter enye; lowercase n with tilde
Ñ	N	Spanish letter enye; uppercase N with tilde; enie
a	a	Feminine ordinal indicator
0	0	Masculine ordinal indicator
ن	_	Inverted question marks
®	_	Registered trademark symbol
٦	_	Logical negation symbol
1/2		One half
	1/4	Quarter; one fourth
«		Angle quotes; guillemets; right-pointing quotation mark

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

»	Guillemets; angle quotes; left-pointing quotation marks
Á A	Capital letter A with acute accent or A-acute
ÂA	Capital letter A with circumflex accent or A-circumflex
ÀA	Capital letter A with grave accent
© _	Copyright symbol
¢	Cent symbol
¥ _	Yen and Yuan Sign
	Macron (straight bar placed above a letter)
ã a	Lowercase letter a with tilde or a-tilde
à A	Capital letter A with tilde or A-tilde
<b>"</b>	Generic currency sign
ð th	Lowercase letter eth
Đ Th	Capital letter Eth
Ê E	Letter E with circumflex accent or E-circumflex
ËE	Letter E with umlaut or diaeresis; E-umlaut
ÈE	Capital letter E with grave accent
ĺ	Capital letter I with acute accent or I-acute
î I	Letter I with circumflex accent or I-circumflex
ΪΙΙ	Letter I with umlaut or diaeresis ; I-umlaut
_	Vertical broken bar
ì	Capital letter I with grave accent
Ó O	Capital letter O with acute accent or O-acute
ß s	Letter Eszett ; scharfes S or sharp S
ô O	Letter O with circumflex accent or O-circumflex
Ò O	Capital letter O with grave accent
õ o	Lowercase letter o with tilde or o-tilde
Õ O	Capital letter O with tilde or O-tilde
μ _	Lowercase letter Mu ; micro sign or micron
þ th	Lowercase letter Thorn
Þ Th	Capital letter Thorn
Ú U	Capital letter U with acute accent or U-acute
Û U	Letter U with circumflex accent or U-circumflex
Ù U	Capital letter U with grave accent
ý y	Lowercase letter y with acute accent
Ϋ́Υ	Capital letter Y with acute accent
, _	Acute accent
± _	Plus-minus sign
3/4	Three quarters; three-fourths
1	Paragraph sign or pilcrow ; end paragraph mark

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

 $\textbf{SIP Help Desk} \; \textbf{Email:} \; \underline{\textbf{SIPHelp@Cognizant.com}} \; | \; \textbf{Telephone:} \; \textbf{See} \; \underline{\textbf{Help Desk}}$ 

Thaana Hangul

N'Ko

English Katakana Hiragana Han

### R10.1– Site User Job Aid Site User Registration Version 1.24 [17 Nov 2023]

Last Updated R9.1

÷ _	The division sign; Obelus
<u> _</u>	Cedilla; added under certain letters
°	Degree symbol
. <u>-</u>	Diaresis; placed over a letter
· _	Interpunct or space dot
1 _	Superscript one; exponent 1; first power
3	Superscript three; exponent 3; cube; third power
2	Superscript two; exponent 2; square; second power
i _	Inverted exclamation marks
€ _	The Euro sign
Š S	Capital S with Caron
š s	Lowercase s with Caron
ŽZ	Capital Z with Caron
ž z	Lowercase z with Caron
Œ OE	Latin diphthong AE in uppercase
œ oe	Latin diphthong ae in lowercase
-	Sofy Hyphen
	Non-Breaking Space; space character that prevents automatic line break at its position
The following symbols	: !\""#\$%&'()*+/:;<=>?@[]^_`{ }~"
Language	Unicode
Latin script	(U+0021 - U+007E) (U+00A1 - U+00FF) (U+0180 - U+01BF) (U+1E00 - U+1E9B)
Greek alphabet	(U+0370 - U+03E1) (U+1F00 - U+1FFF)
Cyrillic script	(U+0400 - U+04FF)
Coptic alphabet	(U+03E2 - U+03EF)
Armenian alphabet	(U+0530 - U+058F)
Hebrew	(U+0590 - U+05FF)
Arabic	(U+0600 - U+06FF)
Syriac	(U+0700 - U+074F)

(U+0780 - U+07BF)

(U+1100 - U+11FF)

(U+07C0 - U+07FF)