SIP4.0_TM.SI.04I_Site Onboarding FAQs_Version 1.0

Legal Notice

Table Of Contents

Site Onboarding Frequently Asked Questions R4.0

SECTION 1: Who can Register

1.01 - Who should register in SIP?

- Any Investigator or Site Staff members who participates in Clinical Trials currently
- Any physician or site staff member who is interested in participating in future clinical trials
- Any Organization that supports Investigators and Site Staff in the conduct of clinical trials

1.02 - What kind of Organizations can get access to SIP?

Any corporation, alliance, consortium or network that provides centralized business and/or operational services related to the conduct of clinical trials on behalf of Institutions, Sites or Investigators should also register in SIP. The relationship between the Organization and the Site may be exclusive (for all studies) or study-based (based on a contract for selected studies only). Setting up the Organization in SIP allows the organization staff who registers to become a delegate and conduct study-related activities on behalf of the Site. To request that your Organization be set up in SIP, contact the SIP Help Desk (SIPHelp@cognizant.com). Once your Organization is set up and one member of the Organization is registered, you can invite all of the other members of your staff.

Examples of organizations include but are not limited to:
- Site Management Organizations (SMO)
- Trial Management Organizations (TMO)
- Investigator Site Networks (ISN)
- Independent Practice Associations (IPA)
- Site Alliances or Consortiums

1.03 - Can a Study Broker register in SIP?

Study Brokers are defined as individuals or organizations that locate Sites or Principal Investigators to participate in a Study, but do not support the execution of the Study. Study Brokers while playing a critical role in the Site Selection process, do not have a role in the study beyond this initial process. Therefore, there is no role for Study Brokers in SIP. The Terms and Conditions for SIP do not cover the Study Broker role.

The recommended Site Selection process in SIP should be as follows:

- Sponsor Users identify and add investigators to their Potential Investigator List
- Sponsor Users may or may not send a Feasibility survey to these Potential Investigators
- Principal Investigators accept or decline a study directly in SIP

If a Study Broker is being used to identify investigators, it is up to the sponsor to determine when to add these investigators to their Potential Investigator list. The process for Sponsors and Brokers to work together to identify sites does not need to change. However, it is our policy that only organizations that support study execution and have a contractual relationship with Sites should be granted access to SIP.

1.04 - What role would an Organization play in SIP?

Organization can provide any of the following services on behalf of the sites they represent:

- Organizations provide User Profile delegation, Feasibility Survey and Study Site Maintenance Services in SIP
- Organizations can be assigned as a Delegate in SIP for the Investigators and based on the confirmed affiliations with Facilities/Departments, delegates for feasibility survey and studies they support.
- External Organizations must request affiliation with an existing SIP Facility/Department, and that request must be approved by the Facility Profile Manager (FPM) or Department Profile Manager (DPM) before the Organization will be able to provide support. If an Institution has a central office and has created an Organization which support multiple facilities the individuals who are FPMs and DPMs will be able to approve their own affiliation requests to enable the organization.

1.05 - How can a member of a Sponsor Organization or CRO participating in a study get access to SIP?

Sponsors Study Team members and CRO personnel (including CRAs) do NOT register in SIP the same way as Sites and Organizations. Sponsor and CRO Users must contact the Sponsor SIP Administrator to receive access to SIP. The Cognizant SIP Help Desk cannot provide access to Sponsor or CRO Users.

SECTION 2: Receiving a SIP Invitation

2.01 - How can a Site Staff or Investigator get access to SIP?

Before an Investigator or Site/Institution can access SIP, they must receive an Invitation and Register. There are three ways to receive a SIP Invitation:
1) You can be invited by one of our SIP Sponsors.
2) Someone can invite you from your own Site or Institution. We call these individuals Profile Managers. SIP Profile Managers set up your Site in SIP and can invite others from the institution.
3) You can request a SIP invitation through our SIP Help Desk by sending an email to: SIPHelp@cognizant.com. For more details on the information that needs to be provided, go to www.sharedinvestigator.com and click the Join SIP button.

2.02 - Which members of the Site Staff should register first?

Anyone from the Site can complete registration steps at any time, however before adding a Facility to your User Profile, it is important that all of your clinical locations are set up correctly. If you receive a SIP invitation, and you believe that you are the first from your Site/Institution to be invited, we recommend that you connect the requesting Sponsor with an appropriate Research Director or similar role at your site. If you do not work with any of our existing sponsors please contact SIPOnboarding@Cognizant.com for assistance.

2.03 - What E-Mail Address should I use to register in SIP?

You should use your Primary Business E-Mail Address to register in SIP. You can only have one email address. If you have any question about which email address to use, we recommend confirming the preferred option with your Institution Leadership.

2.04 - I received a SIP Invitation at the wrong E-Mail Address. How can I change it?

You can either register under the existing email address and then update the email address after registration is completed by accessing Exostar (https://secureaccess.exostar.com), or you should notify the individual who sent the invitation to resend it to the correct email address.

2.05 - I am an investigator and I received a SIP Invitation. Can I have one of my staff members register on my behalf?

No. SIP Invitations are unique to each user and cannot be forwarded to another individual. Have your Delegate contact the individual who sent you the invitation, provide their email address, and request their own invitation. Your Delegate should register as a "Clinical Research User". Once your delegate has registered, they can assist you in registering and you can Delegate SIP maintenance to them.

2.06 - How do I register in SIP?

Registering in SIP is easy, for details on how to register, see the 3 minute video - How to Register and Delegate and Set Up Delegates in SIP or the User Registration Job Aid. Both are available on www.sharedinvestigator.com on the Resources page.

2.07 - How long does it take to register?

Once you receive an invitation, it takes approximately 10-15 minutes to register. If you are an Investigator, we recommend that your delegate register first, so you can register and immediately set up your delegates.

2.08 - I didn't receive the SIP invitation email or the activation email. What should I do?

During the registration process you will receive two emails, the SIP Invitation email from support@sharedinvestigator.com and the SIP Activation email from SIPSupport@exostar.com .

Depending on your email settings, it is possible that the email was sent to your Junk or Spam folder in your email. To address this issue, we recommend you add the following email addresses to the list of Trusted Sources in your email.

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

This will ensure that all SIP emails and/or notifications are received. If you are not able to locate the invitation email sent by a Sponsor, contact the individual who sent it to have the invitation resent.

2.09 - SIP requires that I provide a phone number. What if I don't want to provide my personal phone number?

While the phone number field is required, you can provide whatever phone number you would like. If you prefer not to provide your personal phone number, you may provide your department phone number.

SECTION 3: IT - Technical Challenges

3.01 - I am having issues viewing SIP. Is there something I can do?

The User Registration Job Aid provides a list of items that might address any of the issues you are experiencing:

- **Check your Browser version** – A list of the latest browsers supported by SIP. If you are having issues viewing any of the information in SIP, we recommend updating your browser.
- **Check your Display Resolution** - SIP is best viewed with a minimum screen resolution of 1024x768 pixels and a color depth of 16-bit.

- **Firewalls** – Some institutions has firewalls that will block the receipt of SIP emails.

For additional assistance, we recommend contacting your local IT Administrator or SIPHelp at SIPHelp@cognizant.com .

3.02 - Our site does not currently utilize online training. We tried to use electronic training in the past but were not able to get our physicians to complete this training in a timely fashion. What options does SIP provide?

SIP does utilize online training. If a site/institution prefers to conduct training in a group setting, SIP does allow Site Monitors to upload an attendance sheet as proof of training. Contact your Study Sponsor for details, as each Sponsor may have their own training procedures.

SECTION 4: Security and Password Management

4.01 - Who is Exostar and how do they support SIP?

Exostar is the SIP Credentialing provider who manages Single Sign-On (SSO) access to sponsor-provided applications through SIP. The Exostar Service Agreement describes the terms under which each Site User is permitted to use Exostar. Many of our SIP Sponsors and CROs already work with Exostar, and there is a chance that you may already be registered with Exostar. If you have an existing account with Exostar and are using different emails addresses/different IDs, you will want to consolidate your accounts into one single account with one email address, which will provide you with the maximum single sign on benefits. See "What should I do if I have an existing Exostar account?" for details.

4.02 - What should I do if I have any existing Exostar account?

If you already have an account with Exostar, there is a chance that you may already be registered with Exostar. To determine whether you have an existing Exostar account go to the link below and enter any potential email address(es) under which you might have registered along with your zip code.

https://portal.exostar.com/idprov/accesslogin/ForgetUserId.faces.

If you have an existing Exostar accounts using different email addresses, contact Exostar and request that your existing accounts be consolidated under your preferred email address. When this is completed, you will be able to register in SIP under your preferred email and utilize your existing Exostar password to register.

4.03 - What are the criteria to set up a valid password?

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

4.04 - What should I do if I forget my SIP ID?

Your SIP User ID or your registered email address can be used to login. If you have forgotten both of these, you can call the SIP Help Desk for assistance.

4.05 - What should I do if I have forgotten my password?

To reset your password, refer to Site_User_Job_Aid_Password_Management.

4.06 - What should I do if I have forgotten the security questions and answers?

If you have forgotten the security questions and answers, please contact the SIP Help Desk.

4.07 - Why do I have to answer Security questions when I log in?

Exostar, our authentication provider for SIP, has implemented a two-step authentication security procedure to ensure the highest level of security for your clinical trial data. Most Site Users will only be asked to provide their user name and password. There are a number of different reasons why you may be asked to answer your security questions including:

- If you do not login for more than thirty days
- If you log in from a new device
- If login from a device that was last used by another site user
- If you login from one location and within a short period of time login from a new location

4.08 - What is the purpose of registering your device in Exostar?

You can register your device (cell/mobile number) for additional security and to simplify the password reset process. Registering your device would allow you to reset your password using a One Time Password (OTP) received on your registered device (cell/mobile number. For more information, refer to Manage OTP Password Job Aid.

4.09 - What is the process of registering a new device in Exostar?

After you log on to Exostar, navigate to **My Account > OTP > Manage OTP – One time Password** section, click **Register**. You need to register your phone number and enter the verification code. Your verification code expires in two minutes. You can regenerate the code by clicking **Resend Code**. In the **Manage Phone** section, set the required phone number as the default phone number.

4.10 - How do I remove my device from Exostar OTP?

Yes, you can revoke the OTP feature. After you revoke the OTP feature, you cannot use the phone to reset your password and will need to register again for availing this service. For more information, refer to Manage OTP Password Job Aid.

SECTION 5: Access to Site/Institution Data

5.01 - Who has access to the Investigator, Staff, Facility and Study data stored in SIP?

Refer to the Privacy FAQ document available on www.sharedinvestigator.com under the Resources button, legal documents section for a complete description of the type of Investigator, Staff, Facility and Study data that is captured in SIP, and which roles have access to this data and how these permissions are granted.

5.02 - Is there an option for the Site User to determine which Sponsor has the ability to see his/her Site User Information?

We do not currently have this option to specify the information that one Sponsor will see versus another in the SIP environment. However, Sites are under no obligation to respond to Sponsors they are not interested in working with.

5.03 - Can a Sponsor User become a Delegate for a Site User?

No. In accordance GCP and other regulatory requirements, Site and Sponsor roles should remain separate. Sites may delegate their SIP responsibilities to an Organization with whom they currently work or to a third party.

SECTION 6: Site Data Integration with SIP/Single Sign On (SSO)

6.01 - Which Site/Institution systems can be integrated with SIP?

If a site is interested in simplifying and streamlining their data flow, SIP can integrate with many of your Site Systems. SIP currently has APIs to support integration with the following Site/Institution systems:

- Clinical Trial Management Systems (CTMS)
- eRegulatory Binders/eInvestigator Site File (Document Systems) – Coming in late-2020.

6.02 - Our Site/Institution/Organization is interested in integrating our CTMS with SIP. What should we do?

If your site is interested in integrating your existing CTMS with SIP you should:

1. **Sign a Non-Disclosure Agreement with Cognizant.**

    To request the NDA contact us at SIPOnboarding@cognizant.com

2. **Complete SIP Site Data Assessment**

    With the NDA in place, we will share our SIP Site Data Assessment worksheet that provides a list of all the fields in our User Profile and Facility/Department Profiles. This document provides detailed information about each field, the field type, whether the field is required or not, the source (how it is populated), and any associated business rules. This is all of the data that SIP required from our Sites. We will also share our API Specification, which describes the information we could share with your CTMS.

    Before considering an integration we would receive data from your systems, we need to understand what data you have, how the data is maintained, how often is it updated, and for any Personally Identifiable Data (PII) how the data is collected and approved. This assessment helps us determine whether the data we would need is in your systems or not and if proper consent has been secured in order to share the data with SIP. Please complete this assessment and return it to us

3. **SIP Technical Assessment**

    Based on the information you provide we will assign a Data Architect who will schedule a call with your team to discuss integration options. The architect will send you a questionnaire in advance of the call so your team prepare. The Technical Assessment questionnaire includes questions about system security, system access, and data format among others.

4. **SIP Data Exchange Recommendation**

    The data and technical assessments help our team recommend the best approach for leveraging your existing data in SIP. There are three common approaches that make sense:
    - Manual Entry of Site Data into SIP and send to Site Systems
    - Load Data to SIP and send to Site Systems
    - Bi-Directional Data Exchange between Site Systems and SIP

Once we mutually agree on the best strategy, we will provide you with a time and cost estimate to complete this work.

6.03 - Our Site/Institution/Organization is interested in integrating our existing eRegulatory Binder/eISF with SIP. What should we do?

SIP is in the process of creating APIs, which can allow SIP to exchange data and documents with many of the leading cloud-based eRegulatory systems. If your site has implemented an eISF and wishes to explore integration with SIP, please contact the representative at your eRegulatory Binder Company and ask about SIP integration. Vendor integration projects will start in 2020.

Key benefits of eISF integration include:

- Time Savings
- Site/Sponsor Documents in Sync
- Sites Leverage Technology Investment
- Improve Compliance/Inspection Readiness

6.04 - Will all systems be Single Sign-On?

All of the SIP modules will be Single Sign-On and will leverage your SIP registered email address as your user ID and your SIP password. Other systems that you login to for each sponsor and on each study will depend on whether the Sponsor has set the system up for SSO or not.

6.05 - Who should I contact if my site/institution wishes to explore Single Sign On for Site applications?

Exostar is the authentication provider for SIP. If you have questions about these topics, the Site can contact Tom Johnson (Tom.Johnson@exostar.com) directly. If the Site is interested in connecting with any of their existing IT applications to the industry-wide Single Sign-On (SSO), Exostar can assist. The Exostar Terms of Access and the Privacy Policy documents are available in the SIP Terms and Conditions document via web links or from www.sharedinvestigator.com go to the Resources page/Legal section.

SECTION 7: SIP Onboarding Welcome Package and Training Materials

7.01 - What documents are available to assist in onboarding an Institution?

The following documents are included in the Institution onboarding welcome packet:

- SIP for Research Directors Job Aid – Describes how to get registered in SIP and how to onboard your institution.
- SIP Welcome Letters – Sample template letters which describe the value of SIP and how to register.
- SIP Bulk Invitations Job Aid – Describes how an individual with a Profile Manager role can send invitations to the remaining site staff and track site registrations.

If you have questions about how to get your site or institution onboarded into SIP, please contact the SIP Sponsors you work with for more information or if you don't have a SIP Sponsor contact, contact us at SIPOnboarding@cognizant.com so we can connect you with the right individuals at your SIP Sponsor.

7.02 - How can I confirm that my Site/Institution is set up correctly in SIP?

Go to User Profile and conduct a Facility search. See the Site User Facility Profile Job Aid available in the SIP Help section for details.   If you see duplicate Facilities, incorrect facilities, or need an Organization set up contact the SIP Helpdesk for assistance. Only the SIP Help Desk can add new facilities, change the Facility Name or Address, or add a new organization. Any Site User can add a Department under the Facility.

SECTION 8: Mutually-Recognized Training

8.01 - What courses are available for Mutually-Recognized Training (MRT) recognition by all SIP Sponsors?

Currently SIP provides MRT for GCP, EDC and IATA courses. The Training courses and the criteria for approving them are under the purview of the SQT Team which is part of TransCelerate. A full list of approved courses is available in SIP and online at the following links.

- GCP Training – For questions about GCP Training go to: https://transceleratebiopharmainc.com/gcp-training-attestation/
- EDC Training - For questions about GCP Training go to: https://transceleratebiopharmainc.com/edc-training-attestation/

To request that a new course be added, contact the SQT Team at SQT@transceleratebiopharmainc.com.

8.02 - My certificate for mutually-recognized training was not approved. What can I do?

Only courses approved by the SQT team will be granted MRT credit. SIP Sponsors reserve the right to require additional training if it is required. For questions regarding MRT approval, follow up with your Sponsor representative, who can guide you as to their specific training requirements. You may also contact the SQT team at SQT@transceleratebiopharmainc.com.

SECTION 9: Legal, Data Privacy and Compliance

9.01 - How will the information I share in SIP be used?

The information you provide in SIP will be shared with all SIP Sponsors for the sole purpose of providing you with study opportunities and running clinical trials. SIP profile information is also provided to the Investigator Registry as described in the SIP Terms and Conditions (For details please see the SIP Terms and Conditions Document).. Each Site or Organization User is presented with these conditions and must agree to these terms in order to register in SIP. For more details, refer to the SIP Terms of Use, SIP Privacy Policy, and SIP Privacy FAQs documents available on the SIP Website (www.sharedinvestigator.com / Resources page. If after reviewing these documents, you have additional questions, please submit your questions in writing to SIPprivacy@cognizant.com.

9.02 - Is SIP GDPR Compliant?

Yes. See the SIP Privacy Policy and Privacy FAQs for details. If after reviewing these documents, you have additional questions, please submit your questions in writing to SIPprivacy@cognizant.com.

9.03 - Can patient information be stored in SIP?

No. Sites and Sponsors should NOT store any patient data in SIP. Patient data repositories should not be stored in SIP so patients are not inadvertently unblinded.   SIP does not currently have these controls in place, and is intended to support the exchange of operational information between Sites and Sponsors only.

9.04 - Can a Site/Institution use SIP as the primary system of record for electronic or digital records, which relate to a clinical trial?

No. The SIP Terms and Conditions explicitly prohibit the use of SIP as a system of record or as a primary means to meet any obligations for creating, maintaining and/or archiving electronic or digital records relating to a GxP requirement. SIP Document Exchange provides bulk upload and bulk download features, which allow a Site/Institution with an electronic system to exchange documents with SIP. In 2020, SIP will also have APIs available for many of the leading Electronic Investigator Site File (eISF) and Electronic Regulatory Binder applications. For more information, see the Site System Integration section.

9.05 - What roles does TransCelerate play in the Shared Investigator Platform?

TransCelerate started the Shared Investigator Platform (SIP) in 2014. SIP is one of many initiatives started by TransCelarate to help improve the way Clinical Trials are conducted. Cognizant was selected to build SIP, and once the platform achieved the milestones set for it, it was to be turned over to Cognizant to own and to run. This transition occurred in 2019. In 2019, Cognizant took over full control of the platform and is now able to market and sell SIP to other clinical trial sponsors and to CROs.

SECTION 10: SIP Help and Training

10.01 - How can I get training on SIP?

SIP Registration related Training Materials are available on www.sharedinvestigator.com/Resources. After registering all available training materials are available in the Help Section located under the ? icon in the top right hand corner of SIP. We also provide free webinars. To see a list of upcoming webinars go to www.sharedinvestigator.com/Events .

10.02 - Does the SIP Help Desk support multiple languages?

Yes, the SIP Help Desk currently supports multiple languages. If you require support in a language other than English, please contact SIPHelp@cognizant.com to be routed to the right contacts.

10.03 - Are any of the SIP Documents and SIP Training Materials available in languages other than English?

The following documents are currently available in multiple languages:

- SIP Legal Documents – Including SIP Terms of Use, Privacy Policy, Privacy FAQs. These documents are currently translated into Japanese only. Go to www.sharedinvestigator.com/ Resources Page. These documents are publicly available, and you do not need a SIP Login to access them.

- SIP Training Materials – Currently there are role-based job aids which focus on registration, delegation, and basic system navigation which have been translated into 14 languages. These documents are available in the SIP Help section.   To access these document, login to SIP and click on the ? icon on the top right side of the SIP home page.
    - ✓ SIP for Research Directors
    - ✓ SIP for Investigators

✓ SIP for Site Staff

✓ SIP for Profile Managers

10.04 - How do I contact the SIP Help Desk?

You can reach the Service Help Desk by using the following options, which are also found in the footer of the SIP Public Landing Page:

- Call Us - For Global Help Desk numbers, click here.

- E-mail Us: SIPHelp@Cognizant.com

- Submit a Ticket - Registered Users can report issues by using the Service Now Ticketing tool. After logging on click on the **Support** link in the application footer. This works well for common issues such as issues logging in or password resets.