SHARED INVESTIGATOR PLATFORM

SIP Privacy and Security FAQ for Sites and Investigators

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PRIVACY

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COMPLIANCE, GENERALLY

SIP Privacy and Security FAQ for Sites and Investigators

I. Privacy

1. Where can I find the privacy policy for the SIP?
   The privacy policy is available on SIP landing page (https://www.sharedinvestigator.com/home). Potential users may read the policy prior to registration if they wish, or at the time of registration. Once a user has registered, a link to the privacy policy is at the bottom of every page in the system.
   Please note: the single sign-on service provided by Exostar has a separate privacy policy, which is also accessible on the registration page, or on Exostar's website.

2. Where can I find the terms of use for the SIP?
   The terms of use are available on SIP landing page (https://www.sharedinvestigator.com/home). Potential users may read the terms of use prior to registration if they wish, or at the time of registration.

3. What do I have to consent to when I register as a SIP user?
   Before signing up with SIP, you must first obtain a single sign on from Exostar if you do not already have one. As part of that process, you will need to consent to the Exostar privacy policy and terms of use.

   On the SIP registration screen, you will be asked to accept the SIP privacy policy and terms of use. You will also be asked to consent to allowing your information to be hosted in the Shared Investigator Platform and the Investigator Registry, where it will made available to all participating Sponsors to facilitate the recruitment of investigators for clinical trials.

4. What if I don't want to consent to all of those things?
   Investigators cannot register in SIP without checking all the consent boxes. However, you have the right to withdraw your consent at any time and stop using the system.

5. What is the Investigator Registry?
   The Investigator Registry is a shared repository of consenting investigator, site, and study details created by DrugDev and TransCelerate Biopharma, Inc. and its member companies. The database is designed to facilitate faster identification and recruitment of qualified

investigators based on previous experience and will prevent duplication of site qualification activities. By participating in the SIP, you consent to have your information shared within the Investigator Registry.

6. After I consent, what information will be collected from me?

SIP captures the following information about Investigators in the SIP User Profile.

Data Category	Section Header	Data Element	Required for CV Generation
Basic Details	Name & Critical Contact Details	Title	
		First Name	Yes
		Middle Name	
		Last Name	Yes
		Suffix	
		Initials	
		Mobile/Cell Phone	Yes
		Email Address(es)	
	Job Title & Role	Job Title/Profession	Yes
		Role	Yes
	Primary Business Address	Company/Institution Name	
		Street Name and Number	Yes
		Building/Floor/Room/Suite	Yes
		Additional Address Info	
		Country	Yes
		State/Province/Region	Yes
		City	Yes
		Zip/Postal Code	
	Other Contact Details	Main/Day Time Phone	
		Evening Phone	
		24 Hour Phone	
		Fax Number	
		Pager Number	
Facilities	N/A	Facility	At least one facility is required
		Department	
		State/Province/Region	
		Country	
Education	N/A	Degree/Certificate	At least one record is added or the section is marked 'Not Applicable'
		Institution	
		Specialty	
		Year Completed	
Professional Experience	N/A	Job Title	At least one record is added or the section is marked 'Not Applicable'
		Institution/Department	
		Year Started	
		Current Position	

		Year Completed	
Research Experience	Study Type	Multi-select options	At least one option is selected for 'Study Type' and 'Clinical Study Phases' and one record is added for 'Therapeutic Area(s) of Expertise' and 'Total Clinical Research Experience' or the section is marked 'Not Applicable'
	Clinical Study Phases	Multi-select options	
	Therapeutic Area(s) of Expertise	Therapeutic Area of Expertise	
		Sub Therapeutic Area	
	Total Clinical Research Experience	Therapeutic Area	
		Sub Therapeutic Area	
		Number of Completed Studies	
		Number of Ongoing Studies	
GCP Training	N/A	Course Provider	At least one record is added or the section is answered as 'No'
		Date Completed	
		Expiration Date	
		Status	
		Training Certificate	
License Details	N/A	Type of License	At least one record is added or the section is marked 'Not Applicable'
		License Issuer	
		Professional License Number	
		State/Province/Region	
		Country	
		Issue Date	
		Expiration Date	
		Supporting Document	
Profile Attachments	N/A	Document Name	Not required
		Document Description	Not required
Publications and Presentations	Publications	Journal/Abstract Citation	Not required
		Date Published	Not required
	Presentations	Presentation Title	Not required
		Location	Not required
		Date	Not required

7. Who will be the Data Controller of my data, since all companies will have access to each site/user profile?

The controllers of the investigator data (the **only** processed personal data in SIP) are the participating sponsor companies. Neither Cognizant, nor Exostar, nor DrugDev is the data controller of any investigator data collected in SIP.

Exostar has controllership of the login and registration data that a User submits in order to set up an Exostar account to sign onto the SIP. This is the user name and the user's email.

Exostar must have controllership over this data because the SSO system is a standalone system with other clients outside SIP.

8. What legal basis is being used for the processing of data?
   Consent is the legal basis for processing data added by the user into the SIP.

9. How do I know which sponsors will have access to my information?
   A list of sponsors currently participating in SIP is available through a hyperlink on the registration page and Section 8 of the privacy policy. As new sponsors join the system, you will be sent notices announcing that they have joined the system. Those new sponsors will also have access to your investigator information, but not any data from specific clinical trials. As always, you have the right to withdraw your consent and stop using the system at any time.
   A list of sponsors currently participating in the Investigator Registry is available in Section 8 of the Privacy Policy.

10. Is there are way to limit access to my information to selected Sponsors?
    All participating SIP Sponsors will have read-only access to the user profile information of all registered site users. Any other information you provide through the Platform, for example, communications with a Sponsor, will not be shared with other Sponsors.

11. Is my information shared with any third parties? Which ones?

    The Sponsors share your information with service providers who provide services that are necessary to operate the Platform or Registry, including Cognizant and DrugDev, and as otherwise disclosed in this Privacy Policy. The Sponsors may also share your information with third party partners it retains to assist in the conduct of clinical trials, for example, clinical research organizations. The System also uses other trusted third parties to provide additional services, such as Exostar LLC who provide identity access management services. Your information will therefore be available to, and used by, these third party partners, where it is necessary in order for them to provide their services to the Sponsors.

12. How can I withdraw my consent to have my information shared within the SIP?
    You can contact the SIP Help Desk at SIPHelp@cognizant.com. Please note that withdrawing your consent to have your information shared within the SIP only covers SIP, and not the registry.

    Please note, however, that we will not delete information relating to ongoing clinical trials or information which the Sponsors need to retain to meet their regulatory requirements. As a consequence:

    - If you are currently participating in an ongoing clinical trial, your request will not be actioned, and you will need to resubmit your request when the trial is complete.

- If you have previously participated in a clinical trial utilizing the Platform, although your profile will no longer be visible in the Platform, please note the relevant Sponsor(s) will retain your information as necessary for their own record-keeping obligations.

13. How can I withdraw my consent to have my information shared within the Registry?

You can contact the SIP Help Desk at SIPHelp@cognizant.com, and they will coordinate with the Registry.

14. How long is my account/information kept active within the SIP?

Provided you have not deleted your account, if you do not login to the Platform for three years, your account will be automatically closed, and your information may be deleted thereafter (except for information which it is necessary to retain for record-keeping purposes). You will receive an email notification prior to closing your account, so you have time to login to your account and prevent this.

15. How can I delete my account?

If you would like to close your account so you are no longer visible in the Platform, please contact the SIP Help Desk at SIPHelp@cognizant.com. Please note, however, that we will not delete information relating to ongoing clinical trials or information which the Sponsors need to retain to meet their regulatory requirements. As a consequence:

- If you are currently participating in an ongoing clinical trial, your request will not be actioned, and you will need to resubmit your request when the trial is complete.
- If you have previously participated in a clinical trial utilizing the Platform, although your profile will no longer be visible in the Platform, please note the relevant Sponsor(s) will retain your information as necessary for their own record-keeping obligations.

16. Is there a separate consent to set up a Facility Profile or Department?

Site users consent to all terms during initial registration. A Site user is not required to accept any additional consent during the creation of Facility or Department.
For additional information, please refer to Section 8 – EEA Data Controllers in the Privacy Policy.

17. What information is captured about each of our Site Staff?

SIP captures the following information about Site Staff in the SIP User Profile. The information captured for site staff users is the same as for investigators. The only differences are the fields that are mandatory for CV generation.

Data Category	Section Header	Data Element	Site Staff- Require for CV Generation
Basic Details	Name & Critical Contact Details	Title	
		First Name	Yes
		Middle Name	
		Last Name	Yes
		Suffix	
		Initials	
		Mobile/Cell Phone	Yes
		Email Address	Yes
	Job Title & Role	Job Title/Profession	
		Role	Yes
	Primary Business Address	Company/Institution Name	
		Street Name and Number	Yes
		Building/Floor/Room/Suite	Yes
		Additional Address Info	
		Country	Yes
		State/Province/Region	Yes
		City	Yes
		Zip/Postal Code	
	Other Contact Details	Main/Day Time Phone	
		Evening Phone	
		24 Hour Phone	
		Fax Number	
		Pager Number	
Facilities	N/A	Facility	At least one facility is required
		Department	
		State/Province/Region	
		Country	
Education	N/A	Degree/Certificate	At least one record is added or the section is marked 'Not Applicable'
		Institution	
		Specialty	
		Year Completed	
Professional Experience	N/A	Job Title	At least one record is added or the section is marked 'Not Applicable'
		Institution/Department	
		Year Started	
		Current Position	
		Year Completed	
Research Experience	Study Type	Multi-select options	At least one option is selected for 'Study Type' and 'Clinical Study Phases' and one record is added for
	Clinical Study Phases	Multi-select options	
	Therapeutic Area(s) of Expertise	Therapeutic Area of Expertise	
		Sub Therapeutic Area	

	Total Clinical Research Experience	Therapeutic Area	'Therapeutic Area(s) of Expertise' and 'Total Clinical Research Experience' or the section is marked 'Not Applicable'
		Sub Therapeutic Area	
		Number of Completed Studies	
		Number of Ongoing Studies	
GCP Training	N/A	Course Provider	At least one record is added or the section is answered as 'No'
		Date Completed	
		Expiration Date	
		Status	
		Training Certificate	
License Details	N/A	Type of License	At least one record is added or the section is marked 'Not Applicable'
		License Issuer	
		Professional License Number	
		State/Province/Region	
		Country	
		Issue Date	
		Expiration Date	
		Supporting Document	
Profile Attachments	N/A	Document Name	Not Required
		Document Description	Not Required
Publications and Presentations	Publications	Journal/Abstract Citation	Not Required
		Date Published	Not Required
	Presentations	Presentation Title	Not Required
		Location	Not Required
		Date	Not Required

18. If my staff registers in SIP who will have access to their information?

All participating Sponsor Users in SIP have access to the SIP Site User Profiles for all registered SIP Site Users. Site Users cannot see the User Profiles of other site users with the following exceptions:

- Facility Profile Managers – Individuals with the Facility Profile Manager, Head of Facility, and Head of Facility Delegate roles can view the User Profiles of the Investigators and Site Staff who have added the Facility to their User Profile.
- Department Profile Managers – Individuals with the Department Profile Manager, Head of Facility, and Head of Facility Delegate roles can view the User Profiles of the Investigators and Site Staff who have added the Department within the Facility to their User Profile.
- User Profile Delegates – Individuals who are chosen as User Profile Delegate by an Investigator or Site Staff member can view and update the User Profile.
- Organization Staff – Organizations that have a confirmed relationship with a Facility can view the User Profiles of the staff that are affiliated with those Facilities. The

ability to view the Profiles depends on the nature of the relationship between the Organization and the Facility. This is new as a Release R3.1. Details on this relationship are available in the Organization Profile.

Please refer to the definitions of Facility, department and Organization here.

19. Is there are way to limit access to my Institution or staff information to selected Sponsors?
    No. All participating SIP Sponsors will have read-only access to the user profile information of all registered site users. Sponsors will also have read only access to the profiles of all the facilities/departments and organizations in SIP.

20. Will the institution be notified when their information is shared with other parties?
    As part of the registration process, each user consents to their information being used in the Shared Investigator Platform and the Investigator Registry where it will be made available to all participating Sponsors to facilitate the recruitment of investigators for clinical trials. The institution will not be notified each time their information is viewed.

21. Does the system use cookies?
    Yes. Below please find a table of the types of cookies, their uses, and if it is possible to opt out and how to do so.

Cookie type	Why used?	How to opt out?
Analytics cookies	The Platform serves cookies to collect analytical information, used for internal business reporting reasons, and to help us improve and develop the Platform.	You can remove these cookies by changing your browser settings, as described below.
Authentication cookies (3rd party cookies, for example, those served by Exostar, LLC)	Used to verify login credentials provided by Authorized Users who wish to access the Platform. The third parties serve cookies to the devices of verified Authorized Users to enable them to access secure areas of the Platform.	These cookies are strictly necessary to provide secure access to the Platform. However, you can remove these cookies by changing your browser settings, as described below.
Personalization cookies (3rd party cookies for example, those served by	These cookies allow you to access a personalized version of the Platform, for example, setting the type of browser used to access the Platform, the regional configuration from which the Platform is accessed, etc.	You can remove these cookies by changing your browser settings, as described below.

Essential/Technical cookies	These are the cookies which allow an Authorized User to browse the Platform and to use the different options or services, for example so that the Platform remembers who you are when you within pages of the Platform.	These cookies are strictly necessary to use to the Platform. However, you can remove these cookies by changing your browser settings, as described below.

If you wish to do so, you can disable cookies on your device by indicating this in the preferences or options menus in your browser. However, some parts of the Platform will not operate correctly if you disable certain cookies. You should consult with your browser's provider/manufacturer if you have any questions regarding disabling cookies.

You can configure your cookies settings or deactivate your cookies on the main available browsers at the following links:

- **Google Chrome** https://support.google.com/accounts/answer/61416?hl=en
- **Mozilla Firefox** https://support.mozilla.org/en-US/kb/enable-and-disable-cookies-website-preferences
- **Internet Explorer** http://windows.microsoft.com/en-gb/internet-explorer/delete-manage-cookies#ie=ie-10-win-7
- **Safari** https://support.apple.com/kb/PH17191?viewlocale=enUS&locale=enUS
- **Safari for IOS (iPhone and iPad)** https://support.apple.com/en-gb/HT201265
- **Chrome for Android** https://support.google.com/chrome/answer/2392971?hl=en-GB

II. Security

1. How are Site User access and permissions to data determined?

SIP controls the User access to information based on roles assigned to each user. When Site User is registered in SIP as an Investigator or a Clinical Research User prior to participating in a study, they have access to only the below data in SIP:

a. Own and delegated User profile (Refer CV field details from #7 Question),
b. Own Assigned and Completed trainings, GCP and Informational Program Courses in SIP.
c. Name and Address of available facilities in the SIP. Access to the following facility details is granted only if the user is associated with the facility.
    - Facility Contacts
    - Therapeutic Areas & Patient Population
    - IRB/ERB/Ethics Committee
    - Local, Central, Review Only IRB/ERB/Ethics Committee
    - Other Review Boards
    - Local Lab
    - Consent & Training
    - Facility & Equipment
    - Investigational Product (IP) & Controlled Substances
    - Source Documentation
    - Additional Information & Attachments
d. Assigned Surveys for which site user is recipient
e. Common documents like own CV, Medical license, User profile attachments, Training Certificates, associated facility documents like Local, Central IRB/ERB/Ethics Committee attachments, Investigational Product & Controlled Substances documentation.
f. Site User Registration and Facility/Department Contact details report

Once the site user is associated with a Study then permissions are further granted to access the Study Workspace data and the Study Site data for which user acts as site staff. Based upon the site staff role assigned, the permissions are extended to view Study Reports in the system. If a Site User is removed from a site staff role permission to view the Study workspace is revoked, terminating access to the study data.

These permissions for each role assigned to a Site User in SIP are defined in a comprehensive "Role based" matrix that defines the access for each Sponsor and Site User role at module/business function level.

The SIP Role Matrix is updated with each SIP release, and the system is tested to ensure that users are being granted access to the right information based on their role. Key changes in role-based access are communicated to users as needed.

Any changes in data access which affects user privacy would be communicated to users prior to the release of this information.

2. The terms of use states that SIP cannot be guaranteed to be 100% free of malware. Why?
The vendor is unable to provide a 100% guarantee because, unfortunately, bad actors continue on the web and it is impossible to guarantee complete immunity from these attacks. However, security measures are in place to protect the SIP. For more information on those measures, please see below.

3. What can I do to help make sure my data is secure?
All SIP Users are responsible for maintaining the secrecy of their own passwords and for not sharing their login credentials with others in their staff. Each Site User should have their own account and delegation of work should be formally delegated in the system rather than allowing multiple individuals on the staff to use a single account. This is critical from a security perspective.

If an individual believes that their account has been compromised and is no longer secure, contact the SIP Help Desk at SIPHelp@cognizant.com immediately.

4. What security measures are in place to avoid potential "misuse" of the data in SIP?
SIP has the following security measures in place to ensure the security of your information:
- Infrastructure - SIP is hosted in secured Data Centers within a De-Militarized Zone (DMZ). This is basically achieved using Firewalls and other tools which provide the monitoring and scanning abilities. Any events triggered by the tools are sent to the support desk who handle them based on well-defined SOPs.
  - Firewall - The firewalls and associated Intrusion Prevention System (IPS) module provide network security by preventing unwanted or malicious network traffic and in directing legitimate network traffic correctly according to its source and destination. There are IPS modules associated with every firewall instance which are configured to scan the DMZ traffic. Firewalls also provide the SSL VPN functionality for remote management of the infrastructure. SSL VPN solution is integrated with RSA 2-Factor authentication to provide more security. RSA uses a combination of 2 factors (PIN +Token code) in order to validate the user authentication.
  - Anti-Virus – Anti Virus Tool used here combines anti-virus, anti-spyware, firewall, and intrusion prevention technologies to stop and remove malicious software. It also extends coverage to new security risks and reduces the cost of responding to outbreaks with the industry's lowest impact on system performance.
  - Security Information and Event Management(SIEM) – SIP uses an SIEM software that collects and aggregates log data generated throughout the infrastructure, from host systems and applications to network and security devices such as firewalls and antivirus filters.

- *Encryption* - The Platform uses industry-standard 128 bit "Secure Socket Layer" encryption to protect your personal information when you access secure areas of the Platform.
  - The Advanced Encryption Standard (AES) algorithm used for column level encryption and decryption of PII data
  - Oracle standard package DBMS_CRYPTO with AES128 algorithm is used for storing the Personally Identifiably Information (PII data) in encrypted format

Please note that no transmission over the Internet or any public network can ever be guaranteed 100% secure, and we cannot accept liability for any security compromise to transmissions over such networks.

- *Access Control* – SIP application maintains the access control information of individual user to manage important data sets like Study, Site, Roles etc.
  - Authorization Checks - The SIP application verifies if the logged in user is authorized to access the resource or data set the user has requested. For example, when users click on a specific Study or Study Site, the application performs an authorization check to ensure that the user has valid access to that Study and/or Study Site before providing access to the information in the database.
  - Database Queries – The system is designed using Database Queries which ensure that only accessible data is returned for a given user and organization.
  - Single Sign-On - The Sponsor (also referred to sometimes as Member Company) users logged in using SSO by which the application receives the organization information to which user is associated.
  - Exostar – Exostar maintains the Site User credentials and performs Site User authentication. For additional details on the security of our SSO provider please contact Exostar at customersupport@exostar.com.
- *Sponsor Level Security* - The Sponsors and their service providers are also responsible for taking appropriate technical, administrative and organizational measures to ensure that personally-identifiable information (PII) is protected against accidental or unlawful destruction and against accidental loss, alteration, unauthorized disclosure or access, as well as against all other unlawful forms of processing. For additional information on Sponsor security of information, please contact each sponsor directly. Sponsor Contacts are available through the SIP Help Desk.
- *Anti-Virus Engine on the platform*: SIP uses an Anti-Virus Engine, which kicks off whenever any file upload request reaches the Portal Server. If the file being uploaded happens to be a virus infected file, then the scanner throws an exception which is caught to display the custom message on the SIP screen.
- **Periodic Vulnerability Assessments** – SIP development and support teams are involved in periodic assessments of the application code as well as the infrastructure. The team performs regular assessment of code.

- Static Application Security Testing (SAST) is used to review the code base for vulnerabilities as defined by OWASP TOP 9 (Open Web Application Security Project)
- Dynamic Application Security Testing (DAST) is used to detect conditions indicative of a security vulnerability in an application in its running state
- Infrastructure Vulnerability Assessment is performed to detect vulnerabilities with the underlying software and hardware on which the application is hosted
- Penetration Testing is performed to detect any of the known vulnerabilities like system configuration flaws or weak passwords and try to break in to the network.

III. Compliance, Generally

1. Is SIP compliant with the General Data Protection Regulation ("GDPR")?
   Yes.

2. Is SIP compliant with Good Clinical Practice (GCP) requirements?
   Yes, GCP requirements are included in our User Requirements, and the system is tested to ensure that these requirements are met during each release.