

## **PRIVACY POLICY**

*The Shared Investigator Platform and Investigator Registry*

[www.sharedinvestigator.com](http://www.sharedinvestigator.com)

The pharmaceutical and biotechnology companies (the “**Sponsors**”, “**we**” or “**us**”) who have elected to participate in the Shared Investigator Platform (the “**Platform**”) and the Investigator Registry (the “**Registry**”) are committed to respecting and protecting your privacy. The Sponsors have prepared this Privacy Policy to describe how information is collected on the Platform and Registry, what is done with that information, and how it is protected. A list of current Sponsors for the Platform (which may include Sponsors who joined after your registration) is available at [here](#). A list of current Sponsors for the Registry is available at [here](#).

### 1. About Us

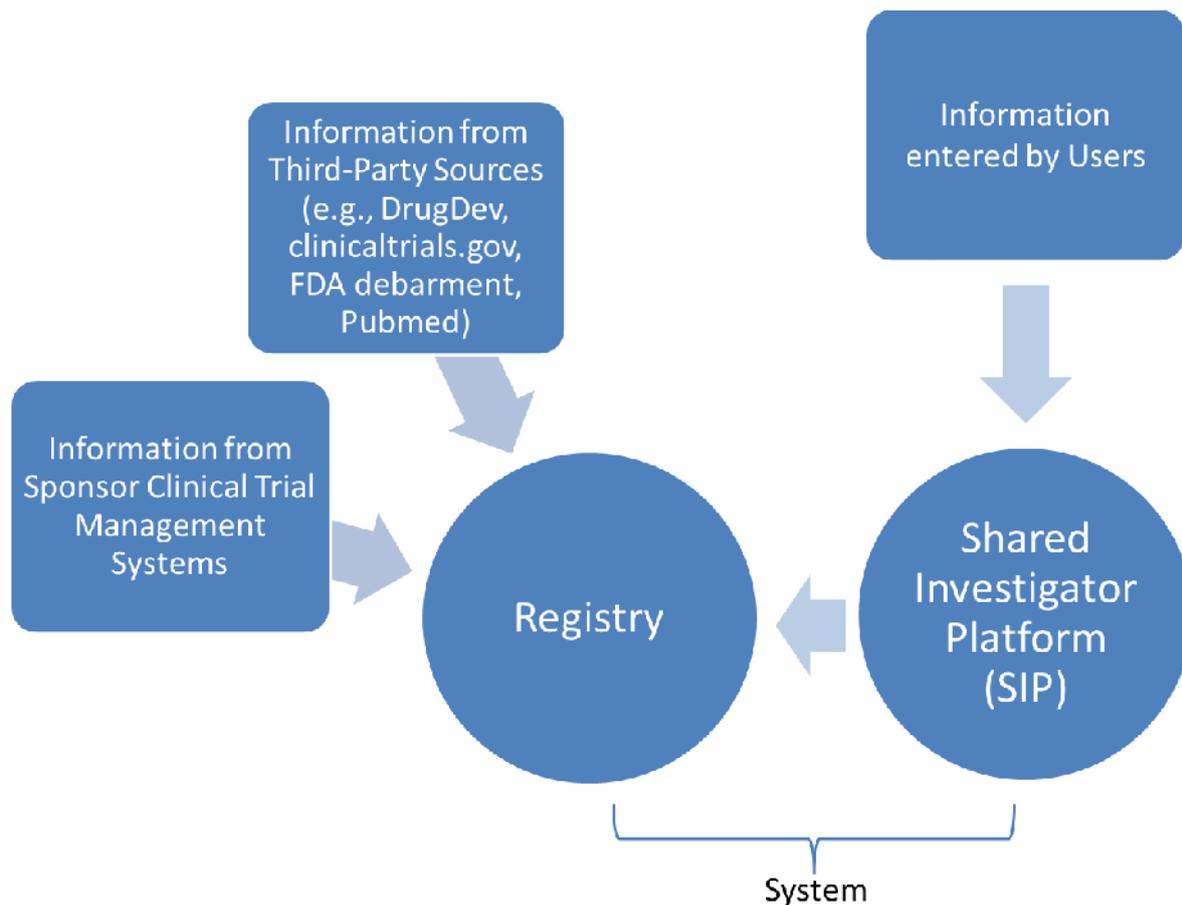
TransCelerate Biopharma Inc. (“**TransCelerate**”) is an association of more than twenty leading global clinical trial sponsors. It is a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world. For more information, please visit <http://www.transceleratebiopharmainc.com>.

The Sponsors and TransCelerate collaborated to develop both the Platform and the Registry. However, TransCelerate has no access to any of the information you or the Sponsors provide to the Platform and Registry and is neither a data controller nor a data processor for any of the information in Platform or Registry. The data controllers for the various types of information collected by the Platform and Registry are outlined below in Section 8. In this Privacy Policy you will also see references to Cognizant Technology Solutions (“**Cognizant**”) and DrugDev Inc. (“**DrugDev**”), who are service providers commissioned by the Sponsors and TransCelerate to develop and maintain the Platform and the Registry, respectively.

The Platform and Registry (collectively the “**System**”) are provided for the benefit of Sponsors, clinical trial investigators, nurses, clinical research personnel, facility managers, and other personnel identified by the Sponsors (“**Authorized Users**”). If you are not an Authorized User, you are not permitted to use the Platform or Registry. Please refer to our [Terms of Use](#) for further details.

### 2. How Does the System Work?

The System is composed of the Platform and the Registry. Information from the Registry is made available to you, other Authorized Users and Sponsors through the Platform. Below is a visual representation of how the Registry and the Platform integrate.



### 3. What Information Does the System Collect?

We explain below the types of information that are collected when you use the System and the purposes for which this information is used.

(a) Information entered directly by Users:

When you use the System, you may supply the following information:

- username, password and other information you provide to access the Platform;
- information about your professional and research facility profile as an Authorized User of the Platform, for example your CV, contact details, licensing details, information about your research facility and your association with institutions;
- operational information relating to the conduct of clinical trials that you wish to exchange with Sponsors or other Authorized Users, for example: information about clinical trial milestone dates, the nature of the trial, the conducting investigators and other site staff, financial disclosures, and previous clinical study experience;
- documents relating to the conduct of clinical trials that you choose to upload to the Platform and share with Sponsors or other Authorized Users;
- information relating to confirmations of recognition by Sponsors of completed training courses and certifications required for participation within clinical trials;

- information relating to any online training courses you have taken to learn how to use the Platform; and
- information about requests for support you have submitted using Platform helpdesk services.

This information is processed on the basis of your consent, which you give when you register for the Platform, complete your profile and otherwise provide information in the System. You can withdraw your consent to this processing and request that we delete your profile from the Platform.

However, if you have participated in, or are participating in, a clinical trial with a Sponsor, that Sponsor will continue to process your personal information as necessary to comply with its legal and regulatory obligations to maintain records in respect of that clinical trial and/or to perform a contract with you.

(b) Information from third party sources:

When you use the System information may be obtained from third party sources to augment your user or site profile information. Information about you and your facility may be sourced from DrugDev and other third party databases such as [clinicaltrials.gov](http://clinicaltrials.gov), FDA debarment, and Pubmed, and could include, for example, information about your participation in clinical trials or debarment status. DrugDev references these data sources to verify accurate and up-to-date details about your professional profile, and produce a record which is used by Sponsors.

This information is processed on the basis that it is necessary for the Sponsors' legitimate interests in conducting clinical research, to be able to verify, update and augment the information which each Sponsor holds about investigators and facilities.

(c) Information from Sponsor Clinical Trial Management Systems

When you use the System, the following information may be obtained from Sponsors' clinical trial management systems ("CTMS"):

- information concerning any training you have undertaken with Sponsors for the purpose of conducting clinical trials, which is pulled from the Sponsors' learning management systems; and
- information related to you and your site's clinical research activities, including:
  - Institutional details;
  - Investigator's name, business mailing address, telephone details and e-mail address;
  - Good Clinical Practice training details for investigators (GCP training; date(s) and related Sponsor of GCP training);
  - Clinical trial details for those trials for which enrolment has been completed (e.g., protocol title, phase, protocol number, therapeutic area, indication, number of patients consented, enrolled, and completed per protocol); and
  - the following dates relevant for the individual site: site opened, first patient consented, last patient consented, first patient enrolled, last patient enrolled, and last patient last visit.

This information is processed on the basis that it is necessary for the Sponsors' legitimate interests in conducting clinical research, to be able to quickly and efficiently access the information in their CTMS, and augment it with the information provided by Authorized Users. Where you give your specific consent, this information, as it relates to you, will be shared between all Sponsors.

If you have participated in, or are participating in, a clinical trial with a Sponsor, this information may also be processed by that Sponsor in order to comply with its legal and regulatory obligations to maintain records in respect of that clinical trial and/or to perform a contract with you.

(d) Information which is collected automatically

We also collect certain information automatically from your device when you use the Platform. This may include information about your device (such as your IP address, browser type, operating system, language preferences and region), your use of the Platform (such as the date and time of your visit, the pages you access, and the time spent on the Platform), and cookie data. Please see Section 5 below for more information about the System's use of cookies.

We also maintain a record of additions or changes to data you have provided for audit purposes, including username, date and time stamp, and information around the changes made.

This information is processed on the basis that it is necessary for the Sponsors' legitimate interests to provide the Platform functionality to Authorized Users and to understand how it is used and any problems. This enables improvements to be made to the System. Some of the information retained for audit purposes in order to satisfy the Sponsor's legal and regulatory obligations.

## 4. How Do We Use this Information?

We use this information to provide and maintain the System for the benefit of the Sponsors and other Authorized Users, in order to facilitate better collaboration and information-sharing across the biopharmaceutical research and development community. For example, the Sponsors may use the information to:

- verify your access to the Platform;
- contact you or your designees for the purposes of conducting feasibility surveys, site identification, assessment, and qualification for trial opportunities, and other operational purposes related to trial conduct such as training and document exchange;
- conduct operational monitoring of the conduct of clinical trials by you and other Authorized Users (for example delegates) affiliated with you or your site;
- review your completion of required sponsor or study-related training, or any Platform training;
- fulfill requests made by you for technical support, and provide you with helpdesk services in connection with your use of the Platform; and
- maintain, improve and develop the Platform.

Please note that other Authorized Users with whom you choose to share your profile, such as your delegate, will be able to view your user profile information and clinical trial operation information. You can elect to share your profile by changing your User Settings.

Aside from the sharing with Authorized Users with whom you choose to share your profile, by joining the Platform, and clicking “consent,” you consent to the sharing of your User Profile and Site Profile Information with **all** participating Sponsors in the Platform and the Registry. If a new Sponsor joins either the Registry or the Platform after you have joined the Platform, you will be notified. Any other information you provide through the Platform, for example, communications with a Sponsor, will not be shared with other Sponsors.

## 5. The Platform's Use of Cookies

Similar to nearly all websites, the Platform serves cookies to its users. Cookies are small pieces of data that are served by the Platform to your web browser and which are stored on your device. They help to collect certain analytical information and to recognize you as a returning visitor to the Platform. They also enable you to access secure areas of the Platform.

### Types of cookies according to the length of time that they remain active

Please be aware that some cookies only last during your browsing session (Session cookies) and other cookies remain on your device for longer periods of time, which could be minutes or several years (Persistent cookies).

### Types of cookies according to their purpose and management

Specifically, the cookies served through the Platform include:

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.

<p>Personalization cookies (3rd party cookies for example, those served by Exostar, LLC)</p>	<p>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.</p>	<p>You can remove these cookies by changing your browser settings, as described below.</p>
<p>Essential/Technical cookies</p>	<p>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.</p>	<p>These cookies are strictly necessary to use to the Platform.  However, you can remove these cookies by changing your browser settings, as described below.</p>

## Cookie Management

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:

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

## 6. Disclosure to Third Parties

The Sponsors will not sell, trade, rent or otherwise pass on your personal information to others, except as described in this Privacy Policy or otherwise with your prior consent. 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.

Where your personal information on the Platform is controlled by a party other than the Sponsors, Cognizant, or DrugDev that party is responsible for telling you how it uses your information through a separate privacy notice or policy. For example, personal information you enter to obtain an Exostar login is governed by the Exostar privacy policy. You can refer to any privacy policies published by our third party partners to find out more about their practices. These policies should be available on the System or through the partners' individual websites.

Please note that the Sponsors reserve the right to disclose your personal information to third parties where they believe this is necessary in order to exercise, establish or defend their legal rights; to comply with any legal obligation to which they are subject (such as an order of a court of competent jurisdiction); to protect

the vital interests of any person; and/or to a potential purchaser in connection with any planned sale of their business or assets.

## 7. International Data Transfers

We may transfer the personal information we store about you to countries other than the country in which the information originally was collected. Those countries may not have same data protection laws as the country in which you initially provided the information. The information that is collected through the Platform will be hosted on servers based in the United States of America and the European Union, and may be accessed in any country where an Authorized User is located. The Registry is hosted by DrugDev in the United States of America.

By choosing to store data in the Registry or Platform you acknowledge and agree to the transfer of your personal information to the U.S. and elsewhere in the world. Even though these countries may not have data protection laws that are equivalent to the laws of the country in which you are resident, your personal information will at all times be protected in accordance with this Privacy Policy and subject to applicable law. The Sponsors have also implemented adequate safeguards, including for example the EU Standard Contractual Clauses, so that personal information transferred out of the European Economic Area will be protected wherever it is processed. Please contact the Sponsor that invited you to join the System for more details about these safeguards.

## 8. EEA Data Controllers

If you are a visitor from the European Economic Area, the data controllers of your personal information are as follows:

(a) the Sponsors (as individual, not joint controllers) for their representatives' passwords, clinical trial information, clinical trial documents clinical trial training information which you or they supply to the Platform, and personal information displayed in your professional profile that has been sourced from Sponsor CTMS systems or information in your user profile entered by you into SIP. More details on this data are available in Section 3 of this Policy. A list of current Sponsors for the Platform (which may include Sponsors who joined after your registration) is available at [here](#). A list of current Sponsors for the Registry is available at [here](#);

(b) Cognizant Technology Solutions US Corporation, the world headquarters of which is at 500 Frank W. Burr Boulevard, Teaneck, NJ 07666, United States of America, for the following categories of information;

- Helpdesk Information is information you may submit via email or telephone in relation to any requests for support and helpdesk services supported by Cognizant. This information is used to provide you with support and helpdesk services in connection with your use of the Platform.
- SIP Training Information is information you may submit relating to any online training courses taken by you on the Platform to learn more about and how to best use the Platform functionality. Cognizant uses this information to provide, support and monitor any Platform training courses you may sign-up for or attend.

- Analytical Information is information that your browser automatically sends to Cognizant when the you use the Platform (including IP address, browser type, operating system, language preferences and geographic region), as well as information Cognizant captures automatically in web server logs about your use of the Platform. This information is collected for the purpose of improving the Platform.

(c) DrugDev, Inc., the world headquarters of which is at 1170 Devon Park Drive, Suite 300, Wayne, PA 19087, United States of America, for personal information processed within the DrugDev Investigator Network. More details on this data are available in Section 3 of this Policy;

Cognizant and DrugDev will not share your personal information with anyone outside the Platform other than the Sponsors and those involved in the delivery of the Platform or Registry as described in this Privacy Policy, except with third party partners who provide services that are necessary to operate the Platform and as otherwise disclosed in this Privacy Policy. In order to provide Platform or Registry services, Cognizant or DrugDev may transfer your data outside of the European Economic Area, and in doing so, Cognizant or DrugDev will ensure adequate protection in accordance with European data protection rules. Any queries regarding Cognizant controlled information should be directed to Cognizant per Section 8(b) of this Privacy Policy. Any queries regarding DrugDev controlled information should be directed to DrugDev per Section 8(c) of this Privacy Policy.

(d) Exostar, LLC, the world headquarters of which is at 13241 Woodland Park Road, Suite 400, Herndon, VA 20171, United States of America, for personal information collected about health care professional login details using the Exopass sign-on service (processed for identity access management purposes) and any cookies served by Exostar. Exostar has a separate privacy policy, which you can refer to at [here](#).

## 9. How to Access, Correct and Delete your Personal Information

You can request to access, correct or delete the personal information you entered into the Platform at any time. Depending on where you are located, you may under local also have a right to 'data portability'. The simplest way to exercise these rights is to log in to your account on the Platform and use the controls provided there to access and update your account profile.

Alternatively, you can contact the Sponsor or Sponsors with whom you work. They will respond to the request in accordance with their own policies and procedures. Please note that if you request access to a copy of your personal information, this may be subject to a fee, where permitted by applicable law.

If you would like to close your account so you are no longer visible in the Platform, please contact [SIPDPO@cognizant.com](mailto:SIPDPO@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.

Your personal information is held in confidence, and you will not receive marketing communications from the Sponsors or any third party provider or partner of a Sponsor as a result of your personal information being submitted to or stored on the Platform or Registry, without your prior consent. However, please note that you may still receive service-related communications relating to the management and use of 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, to the extent required by health authorities or other regulators). You will receive an email notification prior to closing your account, so you have time to login to your account and prevent this.

## 10. Security

The Sponsors and their service providers take appropriate technical, administrative and organizational measures to ensure that your personal information 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. In particular, the Platform uses industry-standard 128 bit "Secure Socket Layer" encryption to protect your personal information when you access secure areas of the Platform.

However, 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.

Users are responsible for maintaining the secrecy of their own passwords. If you have reason to believe that your interaction with us is no longer secure (for example, if you feel that the security of any account you might have with us has been compromised), please immediately notify us by contacting [SIPLHelp@cognizant.com](mailto:SIPLHelp@cognizant.com).

## 11. Children

We do not permit any children to use the Platform or Registry, and consequently do not knowingly collect any personal information from children under the age of 18. If we discover that a child under the age of 18 has provided us with personal information, we will take steps to delete that child's personal information promptly.

## 12. Updates to this Privacy Policy

We may update this Privacy Policy from time to time. Where we make any material changes to this Privacy Policy, we will post the revised policy on the Platform and, if appropriate, take additional measures to bring those changes to your attention (for

example, by e-mailing you). We encourage you to revisit this Privacy Policy on a regular basis to keep informed of our privacy commitments.

Even when the Privacy Policy is updated, your personal information will not be used by the Sponsors for purposes that are incompatible with the reasons for which your personal information was originally collected unless your prior consent has been obtained.

### 13. Do Not Track

"Do Not Track" is a preference that individuals can set in certain browsers which tells websites not to track the individual's activities. When a user turns on Do Not Track, the browser sends a message to websites requesting that they do not track the user. For information about Do Not Track, visit [www.allaboutdnt.org](http://www.allaboutdnt.org).

We treat the data of everyone who comes to our site in accordance with this Privacy Policy, whatever their "Do Not Track" setting. We do not utilize any third party advertising on the System.

### 14. Contact

If you wish to exercise any of your rights described in this Privacy Policy, or have any questions about our collection and use of your personal information, please contact the Sponsor that invited you to join the System. Depending on where you are located, you may also be entitled to contact your local supervisory authority for data protection to access further information about your rights and to lodge a complaint.

Please see below for contact details for each Sponsor's Data Protection Officer.

Abbvie	Andreas Hildebrandt EU Regional Data Protection Officer (DPO) Knollstraße, 67061 Ludwigshafen, Germany
Allergan	<a href="mailto:IR-EUDPO@allergan.com">IR-EUDPO@allergan.com</a>
Amgen	<a href="mailto:privacyoffice@amgen.com">privacyoffice@amgen.com</a>
Astellas	<a href="mailto:AstellasPrivacy@astellas.com">AstellasPrivacy@astellas.com</a>
AstraZeneca	<a href="mailto:privacy@astrazeneca.com">privacy@astrazeneca.com</a> ;
BMS	<a href="mailto:EUDPO@BMS.com">EUDPO@BMS.com</a> .
J&J	<a href="mailto:emeaprivacy@its.jnj.com">emeaprivacy@its.jnj.com</a>
Lilly	<a href="mailto:privacy@lilly.com">privacy@lilly.com</a>
MSD	<a href="mailto:MSD_privacy_office@msd.com">MSD_privacy_office@msd.com</a>
Pfizer	<a href="mailto:privacy.officer@pfizer.com">privacy.officer@pfizer.com</a>
Roche	<a href="mailto:global.privacy@roche.com">global.privacy@roche.com</a>
Sanofi	<a href="mailto:Privacy-Office-Global@sanofi.com">Privacy-Office-Global@sanofi.com</a>
UCB	<a href="mailto:dataprivacy@ucb.com">dataprivacy@ucb.com</a>

## 15. Date of Last Revision

This Privacy Policy was last revised in December 2018.