

## TransCelerate BioPharma Facility Profile Form-Guidance Document

### Background

The Facility Profile Form is intended to capture site capabilities during the site qualification process that is conducted prior to the start of a study. It does not replace protocol/study specific activities. The intent of this form is to reduce the administrative burden on Investigative Sites by collecting information in a consistent way across multiple sponsor companies – reducing the duplicative completion of similar forms.

With the launch of the [Shared Investigator Platform](#) (SIP), TransCelerate sought ways to further streamline efficiencies for Investigative Sites. As sites are invited by sponsors to join SIP, they will take part in onboarding activities to complete their profiles which includes providing facility details. This off-line version of the SIP Facility Profile Form will streamline sites’ SIP onboarding experience as it is upload-able to SIP.

If you previously completed the TransCelerate Site Profile Form, it is recommended that you begin using the Facility Profile Form. The Site Profile Form v3.2 was retired in October 2017 and replaced with the Facility Profile Form.

### Use

Use will vary depending on if the Investigative Site is currently using the Shared Investigator Platform (SIP).

Site <b>NOT</b> using SIP	Site <b>USING</b> SIP
<ul style="list-style-type: none"> <li>You may begin using the Facility Profile Form located on the TransCelerate <a href="#">Site Qualifications and Training Initiative Asset Page</a>.</li> <li>You should keep a copy of your facility profile and upon request, review and update the content, date and send to the sponsor.</li> <li>If you are invited to join SIP by your sponsor, this form is upload-able to SIP however you’ll be provided specific onboarding instructions by your sponsor which you should follow carefully.</li> <li><b>Note for Sites not using SIP:</b> There are 2 additional forms (User Profile and Department Profile) that correlate with the Facility Profile Form when onboarding to SIP. While these additional forms are not required when using the off-line Facility Profile Form, they may be pertinent for future SIP integration.</li> </ul>	<ul style="list-style-type: none"> <li>The Facility Profile Form has been integrated into SIP so you <u>do not</u> need to complete this off-line version of the form unless you are being directed to by your sponsor as part of your SIP onboarding process.</li> <li>Once your facility information is in SIP, a completed Facility Profile Form can be exported from SIP, so it can be shared easily with sponsor companies not currently utilizing SIP.</li> <li>The Facility Profile Form export from SIP will look the same as the off-line version of form but contain all your specific information.</li> <li>Your facility profile information should be maintained directly in the platform.</li> </ul>

### Contents

- This Facility Profile Form is a compilation of the information commonly collected by Sponsor companies regarding site capabilities, organizational structure and current contact information.
- TransCelerate Members Companies may accept and implement the Facility Profile Form either through the Shared Investigator Platform (SIP) or via the off-line version of form.
- The Facility Profile Form is not intended to replace an onsite study visit or capture any protocol/study specific information.

### General Considerations

- A sponsor should inquire if the site has previously completed the TransCelerate Facility Profile Form or if it is a user of SIP. If it is a user of SIP, the site can export its Facility Profile Form directly from the system. If it is not a SIP user, then please follow the sponsor's instructions for completion of the form.
- Once completed, the form should be issued by the site to the requesting sponsor.
- The site should be instructed to keep a copy of this form and upon new requests, review the contents, update if necessary, date the form and send to the new requestor. If you are a SIP user, your facility profile should be maintained directly in the platform.

#### **If you experience software compatibility issues completing TransCelerate forms:**

Please check your Adobe software version. The minimum system requirement is Adobe Reader. We advise you to download the newest version of Adobe Reader, which can be found for free on the Adobe website. Please click on the link below and follow steps 1-3.

<http://get.adobe.com/reader/>

If for any reason the newest version did not download correctly, please uninstall the current version on your computer and reinstall the newest version. If you have issues accessing or completing the form, please contact the individual/member sponsor who requested the form.