

# FAQ- TransCelerate Facility Profile Form (FPF)

| QUESTION  | ANSWER  |
|---|---|
| <b>Why was this form created?</b>   | <p>Currently most sponsor companies collect site capability information prior to an actual study visit. The purpose of the form is to reduce the number of separate forms from each sponsor creating a “One size fits all” approach to documents reducing redundancy and creating efficiencies for sites.</p> <p>(NOTE: The Facility Profile Form replaces the retired Site Profile Form (SPF) as an option to complete the facility profile offline with the capability to upload to the Shared Investigator Platform (SIP) when creating a facility.)</p>   |
| <b>Will the Facility Profile Form (FPF) be shared across the TransCelerate Member Companies?</b>    | <p><u><i>For Non-Shared Investigator Platform Users</i></u><br/>This form v1 August 7 2017 is in an electronic format, with drop down or check boxes to keep the form simple and easy to use. The site maintains the form and provides the form upon request to a sponsor. The e-form is not shared across TransCelerate Member Companies.</p> <p><u><i>For Shared Investigator Platform Users</i></u><br/>Users will create a facility profile directly in SIP. Once a facility profile has been created in SIP, it is available to all SIP sponsors.</p> <p>(NOTE: If you have completed a version of the Site Profile Form template V3.2 Feb 19, 2014 or earlier, it is recommended you complete the current version of the Facility Profile Form v1 August 7, 2017, which is compatible for future integration with SIP.)</p> |
| <b>Does the Facility Profile Form (FPF) have an expiration term?</b>                                | <p><u><i>For Non-Shared Investigator Platform Users</i></u><br/>The form will be requested by each participating sponsor each time it is needed for a study. The benefit is that the site does not have to fill out a separate form for each sponsor. Once completed by a site, the site will save an electronic copy on file and update it for each request.</p> <p><u><i>For Shared Investigator Platform Users</i></u><br/>Users will maintain their facility profile directly in SIP. SIP Sponsors will ask you to review and confirm the accuracy of your SIP facility profile during feasibility or site selection activities.</p>  |
| <b>Do you need to be a TransCelerate member to access Facility Profile Form (FPF)?</b>              | <p>No membership is required – all forms are publically accessible on <a href="http://transceleratebiopharmainc.com">transceleratebiopharmainc.com</a>. Sites invited to register in the Shared Investigator Platform by SIP sponsors can complete the facility profile directly in SIP or upload a completed version of the Facility Profile Form v1 August 7, 2017.</p> <p>(NOTE: For more information on the Shared Investigator Platform <a href="#">click here</a>.)</p>   |
| <b>Are all of the TransCelerate Member Companies implementing the Facility Profile Form (FPF) ?</b> | <p>Many TransCelerate Members Companies have begun using the FPF (or the retired SPF). While each member makes its own decision about whether to implement, the expectation is that the significant efficiencies available to both sponsors and sites will lead to widespread adoption, especially as TransCelerate membership grows.</p> <p>(NOTE: TransCelerate Member Companies who adopt the SIP will be inviting sites, as needed. Adoption is currently limited so participation is by invitation only at this time.)</p>   |
| <b>Is the Facility Profile Form (FPF) a global tool?</b>  | <p>Yes - The FPF is a global tool, but is available in English only.</p>  |
| <b>Does the Facility Profile Form (FPF) require a signature?</b>                                    | <p>The e-form does not require a signature. In SIP the facility profile will be maintained by a designated facility profile manager(s).</p>   |