

FAQ- TransCelerate CV Template



Question	Answer
Is the CV template mandatory?	<p><i>No, the CV template is not mandatory. The purpose of the form 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. The CV Template was created to capture research staff member's qualifications. The template can be used for any individual that is required to provide a CV to a sponsor (e.g. Primary investigator/ sub-investigator/ study coordinator/study nurse).</i></p>
Will the CV be shared across the TransCelerate member companies?	<p><i>No. The site should keep a copy of the completed form on file. The form will be in an electronic format, with drop down or check boxes to keep the form simple and easy to use. There will be free text input boxes for providing any necessary explanations. Upon additional requests from another member company the site should open the template – review content and update if needed – send with a current date to the requesting member company.</i></p> <p><i>TransCelerate does have an initiative to create a site portal in the future please visit the TransCeleratebiopharmainc.com website www.transCeleratebiopharmainc.com to read more about this initiative.</i></p>
Does the TransCelerate CV template have an expiration term?	<p><i>The form will be requested by each sponsor each time it is needed for a study, each sponsor will follow their own policy regarding the expiry of the CV template. Once the CV template is completed for an individual at the site, the site or the individual should maintain a copy of the form on file and update it for each new request.</i></p>
Is a wet signature required?	<p><i>Some member sponsors do require the template to have a signature and this will be communicated by the sponsor at the time the CV is requested.</i></p>
Are all of the TransCelerate member companies implementing the CV template?	<p><i>Many TransCelerate members have begun using the CV Template, starting in Q4 of 2013 and adoption is expected to continue into Q2 2014 and as new members join TransCelerate. 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 grow and sponsors amend existing SOPs.</i></p>
The CV template does not expand to allow for additional information – education- training – clinical trials – publications?	<p><i>The form is intended to be a <u>summary</u> of the person's education- training and clinical trial experience. The person completing the form should consider the most relevant, recent history that pertains to conducting clinical research.</i></p>
Will the forms always be electronic?	<p><i>Yes that is the intent – this allows the sites to easily update the form and for easy exchange of required forms</i></p>
Do you need to be a TransCelerate member to access the CV template?	<p><i>No membership is required – the forms are accessible to all on transceleratebiopharmainc.com .</i></p>
Is the CV template a global tool?	<p><i>Yes - The CV template is a global tool – it is currently only available in English. Some country regulatory authorities may require a CV to be in a local language so those countries may not be able to utilize CV template for regulatory submission – however we would still encourage the use of the template for sponsor companies.</i></p>