# DOCUMENTING QUALIFICATION:

## A Quick-Reference Guide for Investigators and their Delegates

The CTTI recommendations[1] on "Identifying Qualified Investigators and Their Delegates to Conduct Sponsored Clinical Trials," call for sponsors, contract research organizations (CROs), and site teams to assume greater control of qualification. This approach depends upon:

- Investigators and their delegates being empowered to own and maintain their qualification activities, underscoring their position as partners in ensuring the quality conduct of clinical trials, and
- Sponsors and CROs being willing to accept documentation of relevant education and experience as evidence of whether investigators and their delegates are qualified.

CTTI has created a documentation template[2] to help investigators and their delegates **maintain a record of qualification activities in a single document** that is comprehensive enough to apply to multiple trials. Use this template to document learning activities as well as the successful application of knowledge and skills pertinent to your role in conducting clinical research. Share this documentation of your qualification with sponsors and/or CROs during feasibility assessments to demonstrate your preparedness. This documentation will also be valuable if you are assigned training you have already satisfied, either through completion of the training itself, or through an equivalent combination of education and experience.

This approach to qualification supports the transfer of experience between trials. This will allow sponsors, CROs, and site teams to focus on addressing protocol-specific gaps in preparedness, improve study execution, and eliminate redundant training.

| INVESTIGATORS AND THEIR DELEGATES ARE ENCOURAGED TO: | SPONSORS AND CROS ARE ENCOURAGED TO: |
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| Identify and document the completion of previous relevant training and/or certification. | Accept documentation of 1) the completion of previous relevant training, and/or 2) the continued application of knowledge and skills during the conduct of clinical trials as evidence that investigators and their delegates are qualified. |
| Maintain and update this template as new and relevant qualification activities occur. | Consider the previous application of required skills (whenever demonstrated and documented) when tailoring protocol-specific programming to meet individual learning needs. |
| Assess any gaps in knowledge and skills where you could benefit from further learning. | Recognize that different members of the site team may benefit from different types of education and experience in pursuit of the same learning goal. |
| Consider your performance on past protocols to develop policies, procedures, or educational programming to improve the conduct of future studies. | |

[1] CTTI recommendations are developed with input from a multi-stakeholder team of experts.
[2] Other options for documentation include TransCelerate's Investigator Registry, LifeSphere's Investigator Portal, or relevant certification.