CENTRE FOR HEALTHCARE INNOVATION

CHI Learning & Development System (CHILD)
Content Submission Form

Title

Proper Research Planning & Conduct – Tips, Tricks & Techniques

Site Initiation Visit (SIV)

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From the Monitor's Desk

Site Initiation Visit (SIV): What is it, and what is it for?

"Huh? What is a SIV? Sorry, but I am not familiar with this term."

"We really can't squeeze out any time to arrange for a SIV. PI has made it clear that we need to start recruitment immediately."

"All our study team members are already familiar with the study protocol and know what they need to do. Why do we need to have a separate meeting to discuss about it again? SIV or no SIV, it feels like it does not make any difference!"

These are some of the common sentiments expressed by the study team - do any of them resonate with you? This article aims to shed some light on the definition and purpose of a SIV.

Let us consider each of the above statements:

"Huh? What is a SIV? Sorry, but I am not familiar with this term."

The Site Initiation Visit, or SIV, as it is abbreviated, is a meeting held by the PI, for his/her study team members, including Co-Investigators, Clinical Research Assistants or Research Assistants. Depending on the nature of the study, there could also be study sponsor representatives, external collaborators, study vendors, or study monitor/CRA in attendance.

The main objective of the SIV is to ensure that the study team has an adequate understanding of the details of the research protocol, and are aware of their specific tasks, as delegated by the PI.

"We really can't squeeze out time to arrange for a SIV. PI has made it clear that we need to start recruitment immediately."

While conducting the SIV is not mandatory, it is vital in maintaining study quality and proper research conduct. Not having one would also mean forgoing an opportunity for key discussions to take place.

The following are some areas that should be discussed clearly: Management and reporting of safety events; accountability of biological specimens; Investigational Product/Device inventory; access to study supplies, documents, electronic database and study facilities. As these areas are prone to deviations, it is important to place emphasis on the critical processes involved.

"All our study team members are already familiar with the study protocol and know what they need to do. Why do we need to have a separate meeting to discuss about it again? SIV or no SIV, it feels like it does not make any difference!"

In addition to the points outlined earlier, having the SIV helps establish a channel of communication for the study team, which is especially important if they are comprised of multi-disciplinary members. Having a combined discussion helps clarify work processes and prevents duplicative efforts. It presents an opportunity to discuss and align recruitment strategies. As studies vary in complexity, having this discussion provides much-needed clarity, thereby ensuring a smooth execution while reducing any potential protocol deviations.

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Apart from performing study monitoring, study monitors play a supportive role to the overall conduct of the research study. Of those that have engaged the services of a study monitor, training on Good Clinical Practice (GCP) and proper research conduct is routinely provided to the study team during the SIV.

If your study is not currently supported by a study monitor, and you have questions or clarifications related to the SIV, I would be more than happy to take your queries at ai_ling_LOKE@ttsh.com.sg.

References (Intranet/ H-VPN access required):

501-B03 PCR SOP: Study Initiation

509-016 Study Initiation Meeting Attendance Log

505-001 Training Record Form Template

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