CHICKEN SOUP FOR THE BUSY COORDINATOR

DEC 2024

Use of Electronic Patient Reported Outcomes (ePRO) in Clinical Trials

Scenario

The following observations were noted from the first Site Monitoring Visit conducted for a clinical trial in relation to the use of electronic Patient Reported Outcomes (ePRO). Samantha, a Clinical Research Coordinator (CRC), was tasked to share her learning points with her team.

Observations identified during Monitoring	Learning Points

Participant did not complete the ePRO at the required frequency due to device malfunction.	**ePROs may be used to capture important, time-sensitive data on treatment effects and participant experiences. Adherence to the protocol-specified completion schedule is crucial for data validity and in some cases, participant safety monitoring. Back-up options are necessary to prevent data loss and maintain data integrity.**
	• CRC should review the ePRO to ensure that the participants have completed the ePRO at the required frequency, and escalate any non-compliances to the PI.
	• CRC should check with the PI / sponsor on the availability of any back-up options (e.g., web-based PRO or paper PRO).
	• In the event paper PROs were used as a back-up option,
	  ○ The CRC should refer to the ePRO completion guidelines for completion of paper PROs.
	  ○ CRC should check with the sponsor on the requirements to transcribe the PRO data from the paper PRO to ePRO.
	  ○ Adequate quality control should be implemented to ensure the quality of the transcribed data (e.g., trial monitoring).

Participant could not complete the ePRO personally, as he/she was unable to read English.	**Most ePROs are designed for direct participant input. Third party completion, use of non-validated translations or ad-hoc interpretation may introduce errors or bias, potentially compromising the trial data.** • CRC should request the sponsor to provide validated translations of the ePROs for participants who are unable to read English. • In the event of a lack of a validated translation, CRC should check with the sponsor if an alternative process has been established for completion of ePROs.
The CRC had transcribed the ePRO data from the paper PRO to the ePRO and raised data request changes for ePRO responses, despite not being delegated by the PI to do so.	**Data errors and unauthorised changes made to data could impact the reliability of trial results. Therefore, robust processes are needed to safeguard the integrity of trial data.** • The CRC should be delegated by the PI prior to any data change request made for the ePRO responses, as data change request for ePRO responses is a significant trial-related activity. • The CRC should seek approval from the PI prior to making any data change requests to the ePRO responses collected from participants. • The CRC should ensure that the data changes are justified and supported by source records around the time of original entry.
PI did not have access to ePRO data.	**Investigators should have adequate oversight of ePRO data in order to ensure protocol compliance, participant safety and data credibility.** • CRC should notify the sponsor immediately and ensure that the PI is granted access to ePRO data, in order to ensure adequate investigator oversight.

Reference: ICH E6 (R2) GCP Guideline

Article Contributed By: Ms. Valerie Lai, Regulatory Specialist, Health Sciences Authority
Edited By: NHG Group Research & Innovation, OHRPP

Proudly brought to you by: Clinical Research Coordinator Society (CRCS)
(researchcoord@nhg.com.sg)