The quality of Electronic Patient Reported Outcome (ePRO) data far exceeds that of data collected on paper, as various forms of missing data can be prevented. However, even with automated reminders, patients may still be non-compliant with ePRO assessments, leading to missing data.
UNDERSTANDING THE REASONS FOR NON-COMPLIANCE CAN HELP TO BETTER PLAN AND INCORPORATE PROACTIVE MITIGATION STRATEGIES IN ePRO SYSTEMS

Additionally, it may be used for exploratory purposes, allowing sponsors to gather preliminary information to guide the planning of future trials. Examples of types of ePRO data collected include study medication usage for drug reconciliation reasons, symptom presence or severity to determine protocol eligibility, and responses over time to indicate improvement or worsening of symptoms / diseases. Given the type of information collected, the impacts of missing data can be substantial.

In clinical trials that use ePRO responses to support primary / secondary endpoints, the overall risk is low when compliance rates are high (e.g., 90-100%). When compliance rates drop below 80%, the bias introduced in the results increases, data quality decreases, and the possibility of not being able to analyse the data is more likely. Depending on the level of missing data, the impact could require recruiting additional patients or could even require re-running the entire trial.

To prevent missing data, it is important to identify the reasons why patients are non-compliant. As reported by patients in a recent survey (more than one response allowed), the major causes of non-compliance were they forgot (51.4%), too busy (41.1%), diary access (27.6%), other (2.7%), and too sick (1.0%) (1). Understanding the reasons for non-compliance can help to better plan and incorporate proactive mitigation strategies in ePRO systems and ensure that they are included in clinical trial protocols.

References

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