THE ELECTRONIC AGE: INTEGRATING ePRO / eCOA TO REDUCE PATIENT, SITE, AND STUDY TEAM BURDEN

Authors: Elisa Holzbaur (BS), Jennifer Ross (MS, M.Phil.Ed.) & Tracey Rothrock (BS)

Objectives

- Although some have fully embraced and incorporated electronic Patient Reported Outcomes (ePRO) / electronic Clinical Outcomes Assessments (eCOA) in clinical designs, many continue to pair Paper PRO / COA.
- It is estimated that less than half of clinical trials with PRO use electronic Patient Reported Outcomes.
- This conceptual paper reviews the reasons for Paper PRO / COA continued use. According to FDA guidance, it is expected that electronic PRO / COA are the standard for clinical trials within the next five years.
- Although there are some barriers to fully adopting the study teams, sites, and patient and may influence their willingness to actively participate in the trial, there are often benefits that may impact the overall project results and ability to use the data to its fullest potential. These benefits are identified within this paper.

Results

The Top 5 benefits of ePRO adoption are reviewed in Table 1. These benefits are reviewed in Table 2. Each barrier has associated risks or concerns that can be addressed through mitigation strategies and methods to facilitate the transition from paper PRO / COA to ePRO / eCOA.

Conclusions

- There are effective mitigation strategies that can be implemented to minimize the risks associated with moving from Paper PRO / COA to ePRO / eCOA. These strategies are reviewed in Table 3.
- In the age of technological advancements, including integration into clinical trials is important to mitigate potential risks and minimize the burden to clinical trial staff and participants. It is important to leverage the full benefits of electronic PRO / COA.

References


Table 1: Benefits of ePRO Adoption

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<th>Benefit</th>
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<td>1.</td>
<td>Reduced Burden to Study Teams, Sites, and Patients.</td>
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