Obtaining a More Comprehensive Understanding of Site and Subject Preferences for Clinical Assessment Technologies: Key Implications for the Industry

Lytle, D, Cohen, EA, Rock, CR, Komorowsky, AE, Friedmann, B, and Murphy, MF

Worldwide Clinical Trials, King of Prussia, PA

Scientific Poster Abstract
Poster Submission to the 2016 ISCTM Annual Scientific Meeting, Washington, DC

The Methodological Question Being Addressed: How do sites and subjects view the use of clinical assessment technologies compared to traditional paper measures; how could the industry move forward in order to effectively implement these assessment solutions?

Introduction: As technology continues to grow, so does its use within the clinical trial industry. In particular, tablet- and computer-based eSource/e-Clinical Outcome Assessments (eCOA) and electronic Patient Reported Outcomes (ePRO) solutions are increasingly being used. In previously reported survey data related to international sites’ preferences using eCOA solutions (Lytle et al., 2015), results indicated that sites have strong preferences for paper based assessments (paper assessments had a +62 basis-point preference ratio). Additional data were collected in the Lytle et al. global survey and is presented here to provide a more comprehensive perspective on site (and perceived subject’s) preferences for electronic outcome solutions.

Methods: Site coordinators and raters were anonymously surveyed from US and ROW sites. The sites designated to receive the survey had previously participated in numerous psychiatric and neurocognition studies. Sites were queried in regards to the burden of eCOA solutions and paper-based assessments; we also obtained sites’ preferences regarding the modalities of how the raters receive feedback from rater reliability groups. Finally, responses were obtained from sites regarding patient and caregiver feedback they received about the ePRO and paper based assessments. Results: Data indicate that sites’ preferences for paper based outcome measures over eCOA can partially be explained by the burden of preparing the latter for each patient (60% of respondents indicated that the preparation of the eCOA solution was cumbersome). Surveyed sites also reported that the eCOA device also presented a “barrier” or distraction during the patient interview. When sites do not use eCOA solutions for a particular study, they reported that the transmission of the traditional paper-based assessments was actually more of a burden than the preparation of eCOA solutions (68% of respondents indicated that this was cumbersome, with 75% of coordinators indicating that this was cumbersome); nevertheless, the sites continued to prefer paper assessments overall as compared to eCOA solutions. Sites also revealed interesting preferences for how they receive clinical feedback from a rater reliability group, with e-mail being the most favored mechanism (+81 basis-point preference ratio). Finally, the sites reported that patients and caregivers also strongly preferred paper based PROs (+70 basis-point preference ratio). Conclusions: Understanding site preferences - and adapting to sites’ issues in relation to paper based and electronic outcome assessments - will further the implementation of electronic solutions and ultimately enhance the overall quality of rater assessments. The poster provides suggestions of how the industry should be mindful of the findings in this study when developing and providing sites with eCOA solutions.
Disclosures: All authors are employees of Worldwide Clinical Trials and have no conflicts of interest.