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The Signal

Mixing eCOA Modes: How to Respond Post-COVID Mitigation

Over the early months of the pandemic, we worked with clients to implement mitigations for studies that continued but were affected by social distancing and movement restrictions. This meant rethinking the data collection process for eCOA assessments that were supposed to be conducted at sites. These included conducting clinician ratings via telemedicine as well as collecting ePRO data using web back up, telephone interviews, or paper that would otherwise be gathered on a tablet during a site visit.

One of the key principals in these mitigations was to ensure that the mode of administration is identifiable in the final dataset so that its impact could be explored later, if needed.

Of course, mixing administration modes may not be the only potential source of variability leading researchers to further explore the robustness of study findings during the pandemic. Differences may have been generated in the characteristics of enrolled patients before and during the pandemic in addition to changes in patients behavior or mental health – both of which could impact certain COA measures.

In my recent session at this year's DIA Annual Meeting, I explored this topic with Andrew Potter, Mathematical Statistician at Center for Drug Evaluation and Research (CDER), FDA and Alan Kott, Practice Leader in Data Analytics at Signant Health.

Analytics for Data Consistency

Summary statistics and exploratory analytics approaches are valuable to assess the consistency of data between administration modes. For example, the mean square successive difference is a useful measure of variability that considers gradual shifts in mean, as we might see for COA data collected over time. Exploring the consistency of the distribution of this statistic by mode of administration provides one view of data consistency between modes.

Statistical Analyses of Data Variances

The ICH E9 (R1) addendum on estimands and sensitivity analysis states that "Inferences based on a particular estimand should be robust to limitations in the data and deviations from the assumptions used in the statistical model for the main estimator. This robustness is evaluated through a sensitivity analysis." Evaluating the impact of administration mode by

including it as a covariate in the analysis of variance may be one approach to evaluating the robustness of study findings to the mixing of modes.

Check out our Considerations for Mixing Modes of Patient-Reported Outcomes Data Collection white paper to learn more.

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