CNS Patients Prefer to Have Training that is Electronic, Interactive and Readily Available When Participating in a Clinical Trial

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The Methodological Question Being Addressed: Are CNS Patients interested in training when participating in a clinical trial?

Introduction: Patient-reported outcomes (PROs) play a critical role in endpoint collection in clinical trials. While regulatory agencies, such as the FDA and EMA recommend patient training, herein the need and interest by patients for training was examined as well as preferences vetted for how patients would choose to be trained.

Methods: We collected responses from 240 participants who have been diagnosed with at least one CNS-related diseases, including addiction, anxiety disorder, bipolar disorder, depression, obsessive compulsive disorder (OCD), attention deficit hyperactivity disorder (ADHD), schizophrenia, Alzheimer's disease, epilepsy/seizure, migraine, multiple sclerosis, amyotrophic lateral sclerosis (ALS), Parkinson's disease and stroke. Participants were asked to report their opinions regarding 1) the necessity of training during clinical trials, 2) preferred training material format and 3) importance of training accessibility. Demographic data (age, gender, education and income) were also collected.

Results: Participants were asked "If you were participating in a clinical trial, do you think it would help to be provided educational materials and training on your role in it, what to expect and the purpose of the clinical trial". 220 participants responded. 94.5% considered educational materials and training "definitely needed" (75%) or "somewhat needed" (19.5%).

Participants were asked "If you were participating in a clinical trial and educational information and training was provided to you on your role and what to expect in a clinical trial, which format would you most prefer to take the training". 221 participants responded, and 98.3% reported that they would be interested in some form of training. Specifically, 68.8% prefer interactive training videos provided on mobile electronic devices or the internet.

Participants were asked "If you were participating in a clinical trial and educational information and training was provided to you about your role and what to expect in a clinical trial, is it important to you to have access to this training at any time during the trial, so you could refresh on it". 87.8% considered it "definitely necessary" (57.0%) or "somewhat necessary" (30.8%) to have access and refresh training at any time during the trial.

Conclusions: Our findings suggest that the vast majority of respondents consider educational materials and training important and requisite for clinical trial participation. Furthermore, most respondents prefer electronic means of training, as well as the ability to readily refresh on training materials. Such a mechanism can be addressed in the form of interactive training videos on the trial device, such as an eCOA handheld or tablet device, where such materials can be accessed offline at any time. Such findings of patient preferences are also in line with regulatory guidance from FDA, EMA & ISPOR regarding PROs

and mechanisms for optimizing the quality of clinical trial data. Our findings suggest that patient and/or caregiver training could be used as an approach to improve data quality and increase signal-to-noise ratio during CNS clinical trial data collection processes.

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