Abstract

Introduction: Safety concerns regarding suicidal behavior in clinical trials resulted in the release of FDA draft guidance in September, 2013. (Prospective assessments of suicidal ideation and behavior in clinical trials: the Columbia Suicide Severity Rating Scale (C-SSRS) adds value as an acceptable instrument. Alternative administration methods such as interactive voice response (IVR) technology were also suggested. The feasibility, reliability, and utility of the C-SSRS have been demonstrated and it has been incorporated and used in many major trials.

Background: The C-SSRS and the eC-SSRS, a computer-automated version of the interview, are acceptable to the FDA for prospectively monitoring suicide ideation and behavior in clinical trials and in other venues.

Methods: All 35,224 eC-SSRS assessments administered to clinical research participants between September 2009 and May 2011 were extracted from a central database for analysis. Extracted from 412 clinical trials of MDD, 3 insomnia, 2 Epilepsy, 1 YFSSD, and 1 Fibromyalgia were included. Each record included an ID number for the study, site, and subject, date/time stamps for the start and end of each assessment, and the subject responses to each question. No demographic, treatment blind, or personally identifiable information was extracted. An eC-SSRS record was considered complete if it included study, site, and subject IDs, date/time stamps for start and end of each assessment, and subject responses to each question. Records with incomplete date/time stamps or with more than 1% responses missing were excluded from the analysis.

Results: Of the 35,224 eC-SSRS assessments administered to clinical research participants between September 2009 and May 2011, 1,265 (3.6%) were excluded due to incompleteness, an early system implementation error, and under-representation of certain conditions. Each record had a total of 16 questions. Each record was scored with respect to the following variables: All responses that were not considered complete were subsequently entered by trained personnel.

Conclusions: Improved precision for suicide monitoring in clinical trials is critically important. The eC-SSRS is an efficient and cost-effective tool for prospectively monitoring mortality, suicide ideation and behavior, and suicide-related behavior. A baseline and one or more prospective follow-ups are provided by 3,776 subjects (Mean of 5.9 visits and 63.7 days between follow-up visits). Subjects reporting lifetime suicidal ideation with intention to act, prior suicidal behavior, or attempts or preparatory behavior at baseline, and for prospectively monitoring treatment safety and efficacy are critical. The eC-SSRS is essential for identifying subjects at risk for future suicide.

Study Limitations: These data are not representative of depressed patients, with many fewer assessments of patients with TSDD, insomnia, and epilepsy.

References:


