Prospective Suicidal Ideation and Behavior Assessment: An Internet Survey of Pharmaceutical Sponsor Practices


INTRODUCTION

In August 2010 the FDA issued a draft guidance requiring the prospective assessment of suicidal ideation and behavior (SIB) in clinical trials of psychiatric, neurologic, and select other indications [1]. The intent of the guidance was that subjects experiencing SIB would be identified and appropriately managed and that SIB adverse events are collected in a more timely and standardized format.

The ISCTM Suicidality Assessment Workgroup (ISCTM) was formed in 2010 to understand the effects of the FDA guidance on clinical trial practices and to identify challenges in its implementation.

To complement a previous survey of study site experiences and attitudes toward prospective assessment of SIB in clinical trials [2], the ISCTM conducted an online survey of pharmaceutical companies to obtain information on current practices and challenges for sponsors in the implementation of SIB assessments.

RESULTS

A total of 132 responses from 50 different companies were collected for a response rate of 9.1%. Respondents not involved with the implementation of SIB assessments in clinical trials were excluded from further analysis, leaving a total of 89 evaluable responses representing 39 companies.

Table 1 lists factors taken into account by sponsors in deciding whether to include prospective SIB assessments in clinical trials.

Common CNS indications for which SIB monitoring was included are presented in Table 2. The most common non-CNS indications were fibromyalgia (14%) and insomnia or other sleep disorders (31%).

Table 3 shows the look-back periods used at screening and baseline.

Table 4 details SIB assessment instruments used.

LIMITATIONS

The results of this survey of pharmaceutical companies confirm that prospective assessment of SIB has been incorporated into industry sponsored clinical trials across a wide range of CNS and non-CNS indications.

Some line with the FDA’s objective that subjects with SIB receive appropriate treatment, nearly all respondents reported that subjects who develop SIB during clinical trials are referred to a mental health professional for follow-up.

The most common SIB assessment instrument used is the C-SSRS, although other instruments such as the S-STS and the BSS are also used.

Supplemental identification of suicide-related information by study sponsors remains common, and challenges remain regarding standardization of retrospective assessment timesframes and differing approaches to summarizing and analyzing SIB-related study data.

REFERENCES


CONCLUSIONS

The limitations of the study included relatively low survey response rates and the possibility that there were multiple respondents from the same sponsor. Also, due to the wording of some questions, it was not possible to tell if responses referred to past or current practices.

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