Clinical Trial Site Experiences & Attitudes Towards Prospective Assessments of Suicidal Ideation and Behavior (SIB): Results of a Global Internet-based Survey

ISCTM Suicidal Ideation and Behavior Assessment Working Group
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ABSTRACT

INTRODUCTION

In September 2010 the FDA released a draft guidance recommending the prospective assessment of suicidal ideation and behavior (SIB) in clinical trials. The guidance requires SIB monitoring in drug and biological studies in psychiatric and certain other clinical trials to ensure (1) that patients experiencing these events are identified and properly treated, and (2) more complete and complete data are collected for these events. Since its release, there has been a widespread implementation of SIB assessments in clinical trials conducted at sites worldwide.

The International Society for CNS Clinical Trials and Methodology (ISCTM) SIB Assessment Working Group (WG) was formed to understand the effects of the guidance on clinical and research practice, and to identify challenges to its implementation.

The WG held two face-to-face meetings regarding the prospective assessment of SIB involving an array of stakeholders from CNS clinical trials: investigators, raters, and other clinical trial site staff; pharmaceutical sponsors; and vendors who support these studies. Based on these discussions, the WG developed an anecdotal picture of the implementation challenges and benefits.

To build a better evidence base on what impact the inclusion of SIB assessments has had on clinical research sites, the WG designed a brief internet-based survey regarding site experiences and attitudes regarding these assessments.

METHODS

• Summaries of the face-to-face meetings were used to generate 20 items, including 5 demographic questions.
• A list of 6058 study sites that had participated in at least one CNS clinical trial in the prior two years was obtained from an independent vendor’s contact database.
• An email invitation to participate from the ISCTM Secretariat with a link to the online survey was distributed to a list of 6058 sites that had participated in at least one CNS clinical trial in the prior two years.
• Instructions encouraged respondents to speak with others at their site about their experiences implementing the assessment of SIB and to provide one response from the site that reflected the broader experience.
• Responses were collected over a 3-week period using SurveyMonkey™ and summarized descriptively.

RESULTS

• 1044 responses were collected (16.9% response rate); 25 sites that had not conducted SIB assessments were excluded for a total of 979 evaluable responses.
• Respondents reflected a wide coverage of geographic regions with surveys returned from 61 countries. (Figure 2)
• Respondents held a variety of roles at the sites and had a wide variety of training backgrounds (Table 1)
• The majority (80.1%) had personally conducted prospective SIB assessments.
• In general sites had extensive experience with SIB assessments, predominantly in CNS indications, though non-CNS indications were also represented. (Table 2)
• The majority of sites indicated (agreed/strongly agreed) that SIB assessment has been “worth the additional burden” (73%) and that it was “easy to incorporate” (73%) and has “improved subject safety” (74%). (Figure 1)
• Identifying subjects at risk of suicide was endorsed by 84.1% of sites as the most important benefit; the greatest challenge was getting accurate baseline lifetime history (51.1%). (Tables 3 & 4)
• Open-ended responses revealed positive comments along with specific challenges to the use of these assessments, such as in cognitively impaired populations. (Table 5)
• Respondents from outside the US agreed more strongly with most opinion items, including that rates in general do not feel comfortable asking about SIB but were less likely to identify the accuracy of baseline SIB history assessments as an issue
• US sites expressed less concern over the accuracy of baseline SIB history assessments than other roles at the site.

CONCLUSIONS

• This study, the first to look at this topic, found that the inclusion of prospective SIB assessment is generally viewed positively.
• Nevertheless, approximately a quarter of respondents reported important implementation challenges.
• Study limitations include internet-based survey methodology (self-report with no independent verification), recruitment of sites based on CNS trial experience, and no comparison to previous standard practice.
• These findings may help guide stakeholders’ use of SIB assessments in clinical trials.

**Table 1:** Respondent Characteristics

**Table 2:** Therapeutic Experience by Respondents

**Table 3:** Benefits Endorsed by Respondents

**Table 4:** Challenges Endorsed by Respondents

**Table 5:** Responses to Open-Ended Question