ISCTM Suicidal Ideation & Behavior Assessment Work Group

ISCTM Meeting
September 30, 2013

Current Co-chairs: Adam Butler
Phil Chappell

Co-Chair-Elect: Atul Mahableshwarkar
Workshop Objectives

• Review development and implementation of a survey of sponsor experiences in implementing SIB assessments in clinical trials
  – Process followed
  – Survey questions/items and response options
  – Development of mailing list
  – Survey conduct via Survey Monkey

• Present interim results

• Discuss next steps
  – Collection & analysis of completed survey data
  – Presentation of final results at FEB 2014 ISCTM Meeting
  – Publications
    • Data based paper
    • Open question: Should the ISCTM develop a position paper in connection with the survey?
• Systematic information on sponsor practices & experiences in implementation of SIB assessments in clinical trials is lacking
• The ISCTM SIB working group created a 30 question survey to assess sponsor practices
  • Preliminary version developed, beta tested by SIB group members and final version tested by non WG members from Pharma and Biotech
• Developed a list of industry representatives from 178 companies (large and small pharma, US and ex-US) to survey
• Administered the survey globally (AUG 15 through SEP 12) utilizing online tool, “Survey Monkey”
  • Survey was sent to 1447 people at Pharma and Biotech companies
  • Not sent to staff from CROs, vendors or academia
• Survey completed by 129 staff from 50 companies, 86 of whom were involved in implementation of SIB assessment
• Preliminary analysis of results from the 86 respondents were presented and discussed at workshop
• Respondent characteristics
  – Majority were from large (51.6%) or mid-sized (34.7%) pharma
  – Had extensive experience in industry (>11 years)
  – Were directly involved in clinical trials (ie in clinical development, medical affairs, study management, project manage)
  – By training, respondents had very diverse backgrounds, including basic scientists, psychiatrists, psychologists, other physician specialties, neurologists, nurses, pharmacologists, pharmacists, and other disciplines
Interim Results

- The results showed SIB assessments are included in studies of a broad array of CNS and non-CNS indications.
- Despite existing regulatory guidance, there is large variation in sponsor practices with regard to:
  - Period of past time over which SIB is assessed at screening and baseline.
  - The look-back assessment periods used in different indications.
  - The way study level SIB data is summarized.
  - How patients who report SIB during clinical trials are managed.
- A substantial proportion (41.3%) of respondents indicated their company continued to conduct retrospective analyses while also including prospective assessments in clinical trials.
- The major challenges identified by sponsors included cross-cultural differences in acceptance of SIB assessments and site difficulty in obtaining a baseline SIB history (also a top challenge identified in our previous survey of study sites).
Workshop Discussion

• Group agreed that the survey respondents were a representative sample and that additional respondents should not be sought

• Despite the limitations of the study, the group felt the survey succeeded in identifying the major ongoing issues faced by industry sponsors in implementation of SIB assessments in clinical trials.

• Some additional analyses were suggested to address the large variations in how SIB assessments are being conducted by industry sponsors.