ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

ISCTM Suicidal Ideation & Behavior Assessment Work Group

ISCTM Meeting

September 30, 2013

Current Co-chairs: Adam Butler

Phil Chappell

Co-Chair-Elect: Atul Mahableshwarkar

ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

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?

ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

Survey Development & Methodology

- 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

ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

Interim Results

- 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

ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

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)

ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

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.