W09-03 - SURVEILLANCE IN CLINICAL TRIALS

W.C.Yavorsky[1,2]

[1]ProPhase LLC, New York, NY, [2]CROnos CCS Inc., Hamilton, NJ, USA

The FDA, EMA and MRHA draft guidance of late 2011 recommends the adoption of more risk-based methods by sponsors to monitor clinical investigations. In neuroscience trials, the data verification and site monitoring process is effective in confirming adherence to good clinical practices and adherence to the protocol guidelines; however, does not adequately assess the actual quality of the outcome measure data from a clinical perspective and, too often, does not account for serious protocol deviations in a timely manner. This session discusses data driven risk-based quality control methods currently utilized in neuroscience clinical trials to determine the quality of outcome measure data. In this session, participants will learn how robust data monitoring platforms and sophisticated analytics ensure that emerging risk signals are identified early, addressed in a consistent way, and corrected in a timely manner.

Learning Objectives:

From this workshop, clinicians and statisticians in industry and academia will learn:

1. Identifying discrepancies and inconsistencies in data that reflect possible risk signals;
2. Evaluating the severity of the risk signal and how they influence study outcome;
3. Preventing risk signals from becoming challenges that could impact the results of the study.

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