ERT Industry Poll and Sponsor Endorsement Confirms eC-SSRS is an Effective Method of Suicidality Monitoring in Clinical Trials

RealWire

PHILADELPHIA, PA 30 June 2010 ERT, a leading provider of centralized services to global pharmaceutical, biotechnology and medical device companies, announces that a recent survey of over 250 respondents reported that all clinicians polled found the Columbia Suicide Severity Rating Scale (C-SSRS) to be an effective method for prospectively monitoring suicidality. Furthermore, 99% of respondents thought the self-rated eC-SSRS would be an effective approach to meeting this new regulatory requirement. The eC-SSRS is a pioneering self-rated version of the C-SSRS that coordinates the patient reported input with the investigators' review. These findings are supported by users of the eC-SSRS, including Carl Gommoll, Director, Clinical Development, Forest Research Institute, who states, "We are very pleased that the self-rated eC-SSRS suicidality monitoring approach has been readily accepted by our investigators."

The poll was conducted during a recent webinar entitled, "Suicidality Monitoring in Clinical Trials," with presentations provided by collaborators in the development of the eC-SSRS, including Dr. Kelly Posner, Director of the Center for Suicide Risk Assessment (CSRA) at Columbia University, Dr. John Greist, CEO of Healthcare Technology Systems, and Michael Federico of ERT. Dr. Posner outlined the need for improved and more standardized suicidality monitoring and the advantages of the C-SSRS verses only documenting spontaneous adverse events. The C-SSRS has been identified by the FDA as an acceptable assessment instrument for prospectively monitoring suicidal behaviors in clinical trials. The webinar also highlighted that a more consistent and systematic assessment, such as eC-SSRS combined with clinician review, would more clearly delineate the relationship between suicidal adverse events and medication treatment with more meaningful data within a study, as well as across studies, improving pooled analyses.

ERT's eC-SSRS solution provides customers with a scientifically sound, cost-effective and convenient method of prospectively monitoring for suicidality and has been designed in line with FDA requirements. Dr. Greist presented data from the successful eC-SSRS validation study sponsored by a major pharmaceutical company with results demonstrating high levels of feasibility, reliability and validity for assessing suicidality and protecting patient safety. Many large and mid-size pharmaceutical companies are choosing to implement the eC-SSRS solution.

Using this approach can also lessen site burden and reduce sponsor costs by as much as 45%. The results of the webinar poll indicated that 97% of study managers thought that using the coordinated self-rated eC-SSRS verses a clinician-only administered approach could reduce their cost.

“We are delighted that the results of the recent webinar have indicated that clinicians and study managers accept the need for an effective suicidality monitoring approach and are embracing the eC-SSRS as a cost effective solution,” comments Michael Federico, Vice President, ePRO Solutions, ERT. “It is essential that pharmaceutical companies identify an effective monitoring method early on to relieve the burden on investigator sites and make the transition as seamless as possible.”

For further information on ERT and its technology and services, please email info@ert.com [1], call +1 215 972 0420 or visit www.ert.com [2].

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About ERT
Based in Philadelphia, PA, eResearchTechnology, Inc. (www.ert.com [2]) is a global provider of technology and services to the pharmaceutical, biotechnology and medical device industries. The Company is a market leader in providing centralized core-diagnostic electrocardiographic (ECG) technology and services to evaluate cardiac safety in clinical development. It is also a leading provider of centralized respiratory technology and services to evaluate pulmonary function efficacy and safety in clinical development. Sponsors can further use the Company’s solutions to streamline the clinical trials process by automating the collection, analysis, and distribution of ePRO clinical data using multi-mode technology in all phases of clinical development as well as selected medical devices for the clinical trials and healthcare industries.

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