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Cerner collaborates with the International SAE Consortium to Study Drug-related Serious Adverse Events

The International Serious Adverse Events Consortium (SAEC) announced it is working with Cerner, Inc. to identify genetic markers that may help predict which individuals are at risk for a range of drug-related serious adverse events (SAEs). The collaboration will diversify the SAEC methods for developing SAE research cohorts, essential to its research. The research collaboration will focus on three SAEs: hepatotoxicity, serious skin rashes and cardiac dysfunctions such as prolonged QT.

The SAEC will compare the genetic and clinical data from these cases to a healthy control group, with the goal to identify genetic mutations that are associated with the SAE. Through this initial research, the Consortium hopes to provide a foundation for the next generation of studies that will validate the role of these genetic variations in instances of drug-related SAEs. The SAEC has established its information technology (IT) infrastructure, at its data analysis and coordinating center at Columbia University, to provide the research community with free and unencumbered access to study data. Results generated from these initial genetic association studies will be available to all qualified researchers for future study and validation.

The International Serious Adverse Event Consortium (SAEC) is a 501(c)3 organization* dedicated to identifying and validating DNA-variants useful in predicting the risk of drug-related serious adverse events. The Consortium brings together the pharmaceutical industry, regulatory authorities and academic centers to address clinical and scientific issues associated with drug-related serious adverse events. SAEC members include representatives from the pharmaceutical and diagnostics industries, scientific community, and government.

- Pharmaceutical industry partners have been closely involved in all aspects of the Consortium launch, providing ongoing consultation on the development and structure of the Consortium's scientific model, contributing cohort data and underwriting costs of SAEC studies. SAEC members include: Abbott, Daiichi Sankyo, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi-Aventis, Takeda and Wyeth.
- Clinical/Research partners are helping to collect and analyze data from the SAEC studies. Partners include Newcastle University/DILIGEN, EUDRAGENE (a European academic Consortium conducting research on drug-related liver toxicity) Malaga University, Dundee University and Expression Analysis, Inc. Columbia University is hosting the Consortium's data analysis and coordinating center.
- Medical research charities are providing their guidance and expertise on the scientific process along with financial support. The latest to join is The Wellcome Trust.
- The FDA is providing consultation on the direction of the SAEC, and the design and conduct of SAEC studies. The SAEC will also consult the EMEA (the European Agency for the Evaluation of Medicinal Products) and other international regulatory bodies for guidance on its efforts.

For additional information please contact:

Arthur Holden

Chairman and CEO, SAE Consortium, Ltd.
8770 W. Bryn Mawr Avenue, Suite 1300
Chicago, Illinois
Phone: 1-773-867-8595
Email: aholden@earthlink.net