



Contact: Arthur Holden  
Chairman, SAE Consortium, Ltd.

8770 W. Bryn Mawr Ave., Suite 1300  
Chicago, Illinois  
Phone: 1-773-867-8595

**INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (iSAEC)  
ANNOUNCES DATA RELEASE FROM ITS GLOBAL RESEARCH COLLABORATION  
TO IDENTIFY GENETIC MARKERS RELATED TO DRUG INDUCED SERIOUS  
ADVERSE EVENTS**

*Nonprofit consortium unites industry, academia and government in the study of the  
genetics of drug safety*

**Chicago (March 20, 2012)** – The International Serious Adverse Events Consortium (iSAEC) announced today its sixth data release from its research efforts designed to discover genetic markers that may predict individuals at risk for serious drug induced adverse events. To date, the iSAEC has released anonymous clinical and genotyping data on almost 2,000 cases and controls, covering drug induced liver, skin/hypersensitivity, cardiac, and agranulocytosis injury. The iSAEC is a nonprofit research corporation, launched in the fall of 2007, now in its second phase of research, comprised and funded by leading pharmaceutical companies and the Wellcome Trust. The U.S. Food and Drug Administration (FDA) also contributes to the scientific and strategic direction of this novel research effort.

The current data release includes anonymous clinical and genotyping data on 360 Nevirapine exposed cases and controls. Nevirapine is an anti-HIV drug which is known to cause hypersensitivity reactions including DRESS and SJS/TEN in select patients. It is used extensively in Sub-Saharan Africa, which has 68% of the global burden of HIV/AIDS, yet only 10% of the patients are treated with anti-retrovirals. The collection and initial characterization of these Malawian hypersensitivity cases was performed by the Wellcome Trust's Sanger Centre, in conjunction with the University of Liverpool and the iSAEC. Studies results are being replicated and are in the process of being published.

Patients respond differently to medicines, and all medicines can have adverse effects in some people. The SAEAC's work is based on the hypothesis that many of these differences may have a genetic basis. Its research studies are exploring the impact genetics can have on how individuals respond to medicines. There are a large number of drugs that can cause livery injury or skin rashes in a small subset of patients. Although the exact mechanisms behind such rare and unpredictable serious adverse reactions are unknown, research suggests a genetic contribution.

These data can be accessed via the iSAEC's ([www.saeconsortium.org](http://www.saeconsortium.org)) website. Qualified researchers, who enter into a data use agreement, can obtain free access to these data for exclusive use in biomedical research.

**iSAEC Membership and Collaborators**

The iSAEC's participants include representatives from the pharmaceutical industry, the scientific community, and government.

- Pharmaceutical industry members are closely involved in all aspects of the Consortium's research, providing ongoing consultation on the development and structure of the Consortium's scientific models, and contributing cohort data and underwriting costs of SAE research/operations. The iSAEC's 10 Phase 2 funding members include: Abbott, Amgen, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda and the Wellcome Trust.
- iSAEC provides researchers with open access to its data through a controlled-access database. Twelve months after genotyping studies are complete, data is released without any patent or intellectual property constraints, allowing for further use and study by interested researchers.
- The FDA is providing consultation on the conduct of iSAEC studies and data release.

# # #

### **About the iSAEC**

The International Serious Adverse Event Consortium (iSAEC) is a 501(c) 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. iSAEC partners are providing financial support, in-kind donations, and participation in data collection to the Stage II research. The iSAEC is the only privately-funded partnership currently dedicated to studying SAE genomics.