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**PGxHEALTH, DIVISION OF CLINICAL DATA, INC., CONTRIBUTES ITS CLOZAPINE PATIENT SAMPLES TO THE INTERNATIONAL SERIOUS ADVERSE EVENT CONSORTIUM**  
*PGxHealth to contribute important research assets to further the work of innovative international genomics research consortium*

**Chicago (November XX, 2009)** – The International Serious Adverse Events Consortium ([SAEC](http://www.pgxhealth.com/)) announced today that PGxHealth (<http://www.pgxhealth.com/>), a division of Clinical Data, Inc., has contributed a collection of clozapine-induced agranulocytosis (CIA) cases and related data, to the SAEC's research efforts to identify genetic variants predictive of drug induced serious adverse events. The SAEC is a novel, non-profit international research consortium formed by the global pharmaceutical industry to better understand the role of genetics in drug safety. Clinical Data is a biotechnology company focused on utilizing its drug development and biomarker expertise to develop therapeutic and diagnostic products with enhanced efficacy and tolerability. Clinical Data will become an associate member of the consortium, as part of the collaboration.

Clozapine is an atypical antipsychotic agent used extensively in the treatment of schizophrenia patients. The main factor limiting its use is the risk of potentially fatal agranulocytosis, estimated in less than 2 percent of treated patients. Agranulocytosis is the failure of the bone marrow to produce enough white blood cells (neutrophils) results in significantly reduced immune response. As a result it is available through a special FDA sanctioned special surveillance system the Clozapine Patient Management System (CPMS). Under this program, patients must have a weekly white-cell count to receive their supply of the drug.

The SAEC will receive materials and data relating to candidate gene and genome-wide association studies of CIA already completed by PGxHealth. These data corroborate the already published evidence for genetic associations in HLA region (Chromosome 6) consistent with a proposed immunological mechanism as an important causal factor associated with CIA. The SAEC plans to expand on these data by conducted more extensive genetic studies using cutting-edge genotyping and whole genome sequencing techniques.

“Our genetic research to date on both drug-induced liver injury and serious skin rashes point to a strong role of the immune systems in contributing to these adverse responses.” said Arthur L. Holden, Chairman of the SAEC. “By adding the special collection to our research into the genetics of drug induced serious adverse events, we hope to further our understanding into the genetics of immunologically mediated adverse responses to a number of important therapies. We also plan to use these resources to pilot our efforts to use whole genome sequencing technology to better understand the role of rare genetic variation in adverse drug responses.”

“We are extremely pleased to be supporting the effort of international collaborators and scientists working on behalf of the SAEC, to uncover the genetics driving drug hypersensitivity reactions,” said Marcia Lewis, Ph.D., Vice President, Biomarker Development at PGxHealth. “Our goal in contributing our clozapine patient samples is to facilitate, and possibly accelerate, the important research of the Consortium.”

Founded in the fall of 2007, the SAEC is a private, global partnership of leading pharmaceutical companies, the U.S. Food and Drug Administration and academic institutions from around the world to identify and confirm genetic markers that may help predict which patients are at risk for drug-related serious adverse events. Through identifying and ultimately validating genetic markers associated with SAEs, the Consortium hopes to reduce the patient and economic costs caused by drug-related SAEs. The SAEC also hopes to improve the flow of safe and effective medical therapies by better addressing idiosyncratic safety risks of new drugs before they reach the market.

The SAEC has established its information technology (IT) infrastructure at its data analysis and coordinating center at Columbia University. It will 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.

### **About the International SAEC**

The International Serious Adverse Event Consortium ([SAEC](#), [www.saeconsortium.org](http://www.saeconsortium.org)) 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 industries, the scientific community, and the Wellcome Trust.

- 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.
- The FDA is providing consultation on the direction of the SAEC and the design and conduct of SAEC studies.

### **About the Clinical Data, Inc.**

Clinical Data develops first-in-class and best-in-category therapeutics. The Company is advancing its late-stage drug candidates for [central nervous system disorders](#) and [cardiovascular diseases](#), to be followed by promising drug candidates in other major therapeutic areas. Clinical Data is utilizing its drug development and biomarker expertise to develop products with enhanced efficacy and tolerability to improve patient health and reduce costs. To learn more, please visit the Company's website at [www.clda.com](http://www.clda.com).