International Serious Adverse Event Consortium (iSAEC)

Research Areas

- Biomarker Research
  Safety, Genomic Biomarker
- Basic Research

At a Glance

- Status: Active Consortium
- Year Launched: 2007
- Initiating Organization: iSAEC
- Initiator Type: Third-party organization
- Location: International

Abstract

The international Serious Adverse Event Consortium (iSAEC) is a nonprofit, biomedical research organization founded in 2007. It consists of leading pharmaceutical companies, the Wellcome Trust, and academic institutions and receives scientific and strategic input from the U.S. Food and Drug Administration (FDA) and other international regulatory bodies. Its mission is to identify deoxyribonucleic (DNA)-variants useful in understanding the risk of drug-related serious adverse events (SAEs).

Mission

In iSAEC’s second phase (2010-2015) the consortium is developing novel, international, clinical networks to deepen the understanding of the genetics of the following SAEs (across a diverse range of ethnic populations):

Consortium History
June 2007: Consortium established
September 2007 to October 2009: Phase 1 research plan
December 2009 to December 2015: Phase 2 research plan

Structure & Governance

iSAEC is governed by a Board of Directors (BOD), which has management control over the corporation’s property, activities, and funds. The BOD consists of one director from each sponsoring member and the chief executive officer, ex officio. The BOD structure also allows for involvement of other nonprofit research and governmental organizations via associate membership. The BOD functions and makes its decisions using a “majority rules” model. All key research collaborations are formed via a rigorous Request for Proposals process, with final selection determined by the Scientific Management Committee. All sponsored research collaborations are governed by milestone-based agreements, whereby the iSAEC preserves its right to restructure or exit any collaboration in which underperformance is a recurring issue. iSAEC retains independent financial management and has the right to audited financial statements. iSAEC also retains dedicated legal counsel.

The BOD has appointed two major committees to advise on research and policy matters: Scientific Management Committee (SMC) and the Public Relations/Communications Advisory Committee.

Financing

iSAEC is a 501(c)(3) nonprofit membership corporation (under the Internal Revenue Service (IRS) Code) formed to engender the required organization, processes, and resources required to identify and validate DNA variants useful in predicting the risk of drug-induced SAEs. As such, it functions with the explicit purpose of enhancing the “public good.” Its members are organizations engaged principally in the business of discovering, developing, and marketing pharmaceutical products, or charitable, governmental, or other nonprofit organizations with an interest in the field of medical science.

iSAEC’s dues-paying members include the following organizations who have supported its research endeavors in Phase 1 and/or Phase 2: Abbott Laboratories, Amgen, Diiachi-Sankyo, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, Sanofi, Takeda, and Wellcome Trust.
Membership in iSAEC is open to all dues-paying parties with a strong interest in the consortium’s scientific agenda. Membership is open to pharmaceutical, biotech, and clinical research organizations, and other health care–related companies interested in improving the safe use of pharmaceutical products through the application of state-of-the art molecular biology. iSAEC has a uniform, fixed membership dues structure defined by its Phase 1 research plan. Inquiries for the current iSAEC dues policies should be directed to Arthur Holden, iSAEC chairman. Membership dues are deemed to be fully tax-deductible under the IRS code.

**Intellectual Property**

To promote the public welfare and to enable the broadest beneficial use of the results of its research programs, iSAEC will make research data available to qualified biomedical researchers, at no charge, in a uniform manner. To limit the risks to privacy of the data subjects and to comply with any other limitations on the use of such data (e.g., limitations contained in consents obtained from data subjects), only those research data that are made anonymous and approved by the SMC shall be released to qualified researchers.

**Data Sharing**

All iSAEC research results are made available publicly within 12 months of the completion of the study group’s genotyping and data quality control efforts. iSAEC’s data portal provides the research community with access to these study data. Data can be accessed in bulk or through a customizable query builder.

iSAEC is a nonprofit corporation formed to carry out scientific research in the public good. As such, it is committed to make the results and raw data supporting its work publicly available, in a responsible manner, to maximize the public benefit. Upon publication, these data are available on a nondiscriminatory basis to all qualified biomedical researchers that agree to iSAEC’s terms of use:

To qualify for data access researchers must agree to the following restrictions:

**Impact/Accomplishment**
iSAEC’s initial studies have successfully identified genetic variants associated with drug-related liver toxicity (DILI) and serious skin rashes (SSR). The majority of iSAEC’s genetic findings have been specific to a given drug versus across multiple drugs. However, a number of cross-drug genetic alleles are starting to emerge that may provide important insights into the underlying biology/mechanism of drug-induced SAEs (e.g., HLA*5701 or UGT1A1*28). The findings clearly demonstrate an important role for the MHC genomic region (Chromosome 6) in the pathology of immunologically mediated SAEs such as DILI and SSR. They also emphasize the importance of immune regulation genes, in addition to a number of well-characterized drug metabolism (ADME) genes.

Links/Social Media Feed

Homepage http://www.saeconsortium.org/

Points of Contact

Arthur L. Holden (CEO and Chairman)
SAEC Consortium, Ltd.
8770 W. Bryn Mawr Avenue, Suite 1300
Chicago, IL 60631
phone: 773-867-8595 (office)
phone: 708-826-6390 (cell)
fax: 773-867-8596
email: aholden@earthlink.net

Matthew R. Nelson, Ph.D. (Co-Chair, Scientific Management Committee)
Manager, Capability Development, Genetic Epidemiology & Analysis
GlaxoSmithKline
Five Moore Drive, MAI.A1227
Research Triangle Park, NC 27709-3398
phone: 919-483-8367

Sally John, Ph.D. (Co-Chair, Scientific Management Committee)
Director Molecular Medicine
Pfizer Inc.
50 Pequot Ave
New London, CT 06320
phone: 860-732-2313

Aris Floratos, Ph.D. (Director, Data Analysis and Coordination Center)
Executive Research Director
Center for Computational Biology and Bioinformatics
Columbia University
1130 St. Nicholas Avenue
New York, NY 10032
phone: 212-851-5102

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