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A public-private consortium advances cardiac safety evaluation: achievements of the HESI Cardiac Safety Technical Committee.

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Abstract

INTRODUCTION: The evaluation of cardiovascular side-effects is a critical element in the development of all new drugs and chemicals. Cardiac safety issues are a major cause of attrition and withdrawal due to adverse drug reactions (ADRs) in pharmaceutical drug development.

METHODS: The evolution of the HESI Technical Committee on Cardiac Safety from 2000-2013 is presented as an example of an effective international consortium of academic, government, and industry scientists working to improve cardiac safety.

RESULTS AND DISCUSSION: The HESI Technical Committee Working Groups facilitated the development of a variety of platforms for resource sharing and communication among experts that led to innovative strategies for improved drug safety. The positive impacts arising from these Working Groups are described in this article.

KEYWORDS: ADRs, Animal models, CDER, CV, Cardiac biomarkers, Cardiac repolarization, Cardiac safety, Center for Drug Evaluation and Research, ECG, EMA, EWG, European Medicines Agency, Expert Working Group, FDA, HESI, Health and Environmental Sciences Institute, ICH, IKr, ILSI, ILSI/HESI, IND, Integrated risk assessment, International Conference on Harmonization, International Life Sciences Institute, JPMA, Japanese Pharmaceutical Manufacturer Association, NDA, PRODACT, PSTC, Predictive Safety Testing Consortium, QTc, SC-CM, Stem cells, TQT, TdP, US FDA, United States Food and Drug Administration, adverse drug reactions, cTn, cardiac troponin, cardiovascular, corrected QT interval, delayed rectifier potassium current, electrocardiogram, hERG, human ether-á-go-go related gene, investigational new drug, new drug application, project for database construction, stem-cell derived cardiac myocytes, thorough QT study, torsades de pointes

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