Joseph Kitzmiller et al., J Clin Exp Cardiolog 2014, 5:3
http://dx.doi.org/10.4172/2155-9880.S1.020

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Clinical & Experimental Cardiology
April 14-16, 2014 Hilton San Antonio Airport, TX, USA

A developing registry of cardiac clinical findings (ECG and Holter-monitor parameters) in early-phase pharmaceutical trials

Joseph Kitzmiller, Marjorie Neidecker, Eduard Mikulik and Glen Apseloff
The Ohio State University Medical Center, USA

Cardiotoxicty remains a paramount concern in drug development. The FDA mandates significant preclinical analyses of emerging pharmaceuticals, and findings from *in vitro* and animal models provide guidance regarding the necessary level of cardiotoxity monitoring during the early clinical phases of drug development. Assessments of cardiotoxicity can include serial electrocardiograms (ECGs), Holter-monitoring, telemetry, plasma or serum biomarker tests, or even advanced structural and functional imaging modalities. Thorough QTc studies may also be undertaken to examine the risk for arrhythmias. However, for presumed low-risk compounds, cardiac monitoring may be minimal.

Our recently established registry (n~1,000) of study participants in early-phase clinical trials includes demographic information and ECG data (heart rate, intervals, segments, and overall interpretation) for all registrants and the Holter-report findings (numbers of pauses, accelerations, and decelerations in a 24-hour period and an overall interpretation) for nearly half of the registrants. Participants are considered normal healthy after evaluation of clinical laboratory tests, physical examination, and medical and medication histories. Standard statistical analyses of the ECG and Holter-reports of the individuals in our registry of normal healthy participants have been computed. These will be compared historically established normal ECG parameters. ECG parameters and findings will also be compared between individuals with normal and abnormal Holter-reports.

Biography

Joseph Kitzmiller, M.D., Ph.D., F.C.P. is a Translational Scholar with the National Institutes of Health and a faculty member in the Colleges of Medicine and Engineering at the Ohio State University (OSU). He is an Associate Director of the OSU's Center for Pharmacogenomics and Director of their Clinical Pharmacology Fellowship training program. He is a Clinical Supervisor and Consultant for Ohio Clinical Trials and a physician with the Ohio Association of Free Clinics. His completed his Ph.D. in Biomedical Engineering and received postdoctoral training in both Internal Medicine and Clinical Pharmacology. A Board-Certified Clinical Pharmacologist with the American Board of Clinical Pharmacology and a Certified Physician Investigator with the Association of Pharmaceutical Physician Investigators (APPI), he has focused his primary research efforts on investigating genetic influences on cardiovascular disease and pharmacotherapies. He also supervises implements early- and mid-phase drug-development research, with a special interest in cardiotoxicity.

joseph.kitzmiller@osumc.edu