Dynamic Repolarization Analysis: A New Era in Cardiovascular Safety

SPEAKER: Daniel B. Goodman, MD
Vice President and Medical Director, BioTelemetry Research

Dr. Goodman directs all aspects of protocol planning and development for Sponsors, and for analysis of cardiac safety results. He is materially involved in innovations in medical technology and novel analyses, as well as in implementing the latest regulatory initiatives. He has direct interactions with key sponsor personnel and with academic experts to provide expert consulting solutions. Dr. Goodman received his training at Yale University and Cornell University Medical School. In the early 1990s, he founded Cardiology for Clinical Trials, one of the world’s first cardiac core labs. Dr. Goodman went on to direct medical affairs for Covance Cardiac Safety Services from 1994 until 2007. After this post, Dr. Goodman worked closely with the medical team as a senior scientific consultant for several years, while practicing medicine intermittently. Dr. Goodman is an international thought leader in cardiac safety testing, developing protocols, producing scientific reports, conferring with regulators and publishing extensively.

Abstract: An innovative path for determination of cardiac repolarization safety is the use of enhanced analysis of continuous 12-lead Holter recordings in early human-phase testing.

BioTelemetry Research introduces a service called Dynamic Repolarization Analysis Data collection is during typical SAD and/or MAD studies. In addition to exposure-response regression analysis using measures of QT intervals not requiring correction for heart rate, and analysis of T wave sub-intervals and morphology, it includes dynamic QT/RR beat-to-beat restitution analysis, to examine the ability of the heart to recover from one beat to the next during changes in heart rate. Together, these novel measures will allow differentiation of benign from arrhythmogenic QT prolongation.

As a division of BioTelemetry (Nasdaq: BEAT), BioTelemetry Research is part of the world’s largest cardiac data network—processing 200,000 million heartbeats, monitoring 50,000 patients, supporting 30,000 devices and provisioning 20,000 sites every month.

As compliments to this industry-leading cardiovascular service offering, our expanded clinical trial services include advanced imaging and respiratory testing.

Every day, BioTelemetry Research supports Phase I-IV trials for the world’s largest pharmaceutical organizations, specialty pharmaceutical firms, emerging biotechnology companies, and medical device manufacturers.