Pooled ECG Data Could Enhance Cardiac Research

BY JEFF EVANS
Senior Writer

The Food and Drug Administration has begun a new initiative aimed at improving the ability to identify and predict cardiac side effects of drugs and devices under development.

In partnership with the Duke Clinical Research Institute (DCRI), Durham, N.C., the FDA first will use an electronic database of 200,000-300,000 digital electrocardiogram recordings to understand the effects that some drugs and devices may have on heart function. The recordings have been submitted from about 30 clinical trials that were conducted as a part of new drug applications during the last 2 years, Dr. Norman Stockbridge, director of the division of cardiovascular and renal products at the Center for Drug Evaluation and Research, said in a teleconference.

The database standardizes recordings that have been pooled from different ECG waveforms into a single, digitized format for analysis.

For decades "we've received generally low-quality copies of ECGs on paper," said Dr. Janet Woodcock, deputy commissioner for operations at the FDA. "We've been really limited in our ability to use this information to understand why some treatments affected a patient's heart or even to be able to predict whether treatment would affect someone's heart."

The FDA and DCRI are developing a consortium to leverage the resources and expertise of members from academia, industry, patient advocacy groups, other government agencies, and nonprofit organizations to discover where ECG data can fill gaps where new cardiac biomarkers are needed and to prioritize research projects based on the findings.

One immediate application of the ECG database will be to review gender differences in the effects of drugs on ECG recordings, since it is not known if differences in drug responses drive the higher risk of drug-induced arrhythmias in women, compared with men, Dr. Woodcock said.

The electronic ECG database will help to identify new ways of detecting problems such as QT interval prolongation with greater precision and at earlier stages, said Dr. Robert Califf, director of DCRI.

"QT interval prolongation has been the downfall of many drugs, but also it is a side effect of many useful drugs, including all of the atypical antipsychotics," Dr. Califf pointed out.

Other early work with the ECG database is involved in describing placebo groups in studies and differences in the parameters of the QT interval in men, women, and people of different body sizes

and other clinical features, he added.

"For studies that help us refine how we measure ECGs, we can use that to improve the standards" for measuring drug safety, Dr. Woodcock said. "For example, we still don't know the meaning of some of the degrees of QT prolongation."

"FDA might change its guidance [to pharmaceutical companies] based on information we get from this, and this might even change how drugs are developed," she said.

Many other biomarkers outside of ECG data will be considered under the FDA-DCRI partnership, which is a part of the FDA's Critical Path Initiative to modernize the drug development process.

"All of industry that's interested in cardiac biomarkers will be participating in this to the extent that they wish," Dr. Califf said. ■

Index of Advertisers

CLASSIFIEDS

Also Available at www.familypracticenews.com

CONTINUING EDUCATION