The pharmaceutical industry is continually faced with unique opportunities to improve clinical trial design, often in response to regulatory authorities. Heightened scrutiny surrounding the cardiac safety of all new drug therapies and increasing needs for uniform standards around the digital data that support New Drug Applications (NDA) are driving many innovations in drug development. Two recent initiatives highlight pending changes that should drive the industry to consider the value of outsourcing the digital capture, analysis, and storage of electrocardiograms (ECGs). They are the proposed FDA guidance for Electronic Interchange Standard for Digital ECG and Similar Data and the “Preliminary Concept Paper” establishing guidelines for “The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs,” published jointly with Health Canada.

Since every drug has the potential to cause cardiac problems, it is important for the industry to generate highly precise and accurate cardiac safety data that will allow them to comply with any future FDA or other regulatory initiatives. This level of scientific expertise often requires outsourcing electrocardiograms (ECGs) to a Contract Research Organization (CRO), such as Covance, that offers comprehensive ECG-related services for clinical trials using innovative technology solutions that will meet these challenges.

Covance has processed ECGs in a digital environment for nearly three decades. Now, Covance has raised the bar with the launch of Digitography™, the world’s first interactive ECG analysis and digital annotation system for clinical trials that allows on-screen digital ECG waveform measurement. Electronic magnification to 1 millisecond resolution, without distorting the waveform, provides unmatched precision and accuracy for ECG measurement. The process is totally digital, from initial acquisition using the proprietary MTX-2, 12-lead system, to board-certified cardiologist verifying the quality of the signal in real-time. Cardiologists also interpret and make interval measurements on each ECG waveform measurement. Electronic magnification to 1 millisecond resolution, without distorting the waveform, provides unmatched precision and accuracy for ECG measurement. The process is totally digital, from initial acquisition using the proprietary MTX-2, 12-lead system, to board-certified cardiologist verifying the quality of the signal in real-time. Cardiologists also interpret and make interval measurements on each ECG through an on-screen-reading station. With Digitography, clients receive higher quality data to assist in answering questions around cardiac safety and allowing for more powerful statistical conclusions about new drug therapies. Along with technological leadership, Covance has expanded its global cardiovascular scientific team for centralized ECG services. Comprised of Dr. Jay Mason, a world-renowned cardiologist, Dr. Daniel Goodman, a regulatory expert, and Dr. Boaz Mendzelevski, who has authored more than 120 expert cardiology/QT reports for regulatory submission, this team works to establish methods and criteria for electrocardiographic analysis that help continue a tradition of scientific excellence and innovation. Each member provides full-time safety cardiology consulting to clients in clinical trials from Phase I – IV. The teams’ breadth of experience with the FDA also enables them to provide assistance navigating changes in FDA guidance.

Covance believes that the key to producing accurate and relevant ECG data for clinical trials is by validated science behind the methodology of detection. This rigorous scientific approach to electrocardiography sets Covance ECG services apart from others. The process of waveform measurement is further enhanced by fundamental research on the ECG repolarization, which helps Covance learn better ways to measure, understand, and detect drug problems. Using this scientific approach and state-of-the-art, fully digital technological systems to perform ECG waveform measurement, a client can be confident that ECG data will be managed with rigor from beginning to end. The processes employed by Covance meet or exceed GCP, ICH, ISO 9001, and electronic records standards resulting in maximized data sets and powerfully relevant results.

As a world leader in the drug development services industry, Covance strives to continually develop new and innovative methods for clinical trial management that help reduce the time and cost of drug development, including processes and tools that ensure that their cardiac safety data will meet current and future regulatory requirements for digital submission.