



Excellence in Cardiac Safety

Transforming images into information.
Turning information into knowledge.
Mapping Life Pixel by Pixel.™

ICON Medical Imaging provides clients with fully integrated Cardiac Safety services. We offer focused expertise in Cardiology, industry leading on-line technology and network of Clinical experts. Our technology allows real-time access to clinical data and progress of the project.

Cardiac Safety Overview:

The Role of Imaging, ECG, Endpoint Adjudication, and Data Safety Monitoring Boards

The evaluation of the risk of a particular drug compared to its perceived benefit is fundamental to the approval of new drugs. The clinical evaluation of drug safety is well established as part of the regulatory process evaluated by the FDA. Traditional components of this evaluation have included assessment of adverse events, vital signs, and laboratory findings. Many medications, whether for cardiac or noncardiac indications, have potential cardiac effects. These can occur as effects on the heart muscle itself. Such effects can involve pump function, the blood vessels leading to the lung, causing increased pressure in the heart and the lung arteries, the valves, or affect the filling pressure in the heart. These effects can be directly visualized with a widely available portable tool based on principles of Ultrasound: Echocardiography. Pump function (expressed as left ventricular ejection fraction), can also be measured by Nuclear Techniques such as gated MUGA and magnetic resonance imaging (MRI).

Similarly, drugs may affect electrical conduction within heart cells or may affect oxygen usage in the heart muscle. The changes can be detected using Electrocardiography to assess ECG waveforms, an indirect measure of ischemia, or conduction intervals of which the most critical is the QT interval. ECG can be performed as a single snapshot in time, at multiple intervals or continuously, depending on the safety concern.

Both Echocardiography and ECG are highly quantitative with well defined ranges of normal values. The core laboratory environment is ideally suited to the clinical trial process when performed with appropriate trial design and criteria for clinically significant abnormalities. Both Echo and ECG can be acquired digitally, subjected to sophisticated and reproducible methods of analysis by trained technologists, and then over-read by experienced senior Cardiologists.

ICON Medical Imaging provides a process where the core laboratory function has expanded to incorporate clinical and regulatory aspects of cardiac safety monitoring, a unique integration of ECG and Echo into a single database, and methods of interaction with the sponsor to identify clinically significant evidence of cardiac toxicity. ICON Medical Imaging conducts ongoing intra-reader variability assessment of left ventricular volumes and function at the level of the technologist and the Over-reader, to ensure consistency in data analysis

Additional evaluation of cardiac safety may include determination of composite clinical cardiac endpoints (such as death, revascularization, myocardial infarction) and integrated evaluation of all safety information. The latter can be performed as part of a Data Safety Monitoring Board (DSMB). These Endpoint and DSMB services have previously been performed in the Academic sector using a paper based system, leaving an unmet need for an electronic system for data viewing and case report form recording.

What are the benefits of choosing ICON Medical Imaging for support of Cardiac Safety in a clinical trial?

- An in-house, Board certified Cardiologist Chief Medical Officer with significant biotechnology and regulatory experience in the area of Cardiac Imaging and Cardiac Safety. This experience is unique in the Commercial Core Laboratory sector.
- Significant experience in Cardiac Safety trial design.
- Experienced in the quantitative measures of cardiac function by Echocardiography, MUGA, and MRI. A team of Imaging Specialists trained to perform quantitative measurements in each imaging modality.
- Able to participate in trial and charter design to establish appropriate toxicity threshold.
- Able to design blinded reads, train sites and train Physician image Over-readers.
- Ongoing program of intra-reader variability testing for LV function assessment.
- Able to offer quantitative digital ECG, and specialized advice in the design and conduct of ECG aspects of Cardiac Safety studies in partnership with eResearch Technology (eRT).
- Provides Clinical Endpoint Adjudication and DSMB services based upon the electronic on-line MIRA™ platform and logic driven eCRF, using our network of expert Physician Adjudicators.
- The MIRA™ technology platform is a unique project management, data display system, which allows the ability to track the progress of data, and also to support integrated blinded read and eCRF.

To learn how ICON Medical Imaging can support your unique trial needs, contact us today.

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