Comprehensive Cardiovascular Safety and ECG Core Laboratory Services

As the world's largest early phase clinical pharmacology CRO with an integrated ECG core laboratory, Celerion can support your cardiovascular safety studies whether you are planning to conduct a standalone thorough QT (TQT) study, ascending dose study or seeking a TQT substitution.

We pioneered the hybrid ECG core laboratory by leveraging the precision, speed and cost of computers coupled with the accuracy of highly skilled US board-certified cardiologist readers. Using Bluetooth Holter technology in concert with sophisticated and validated automated software algorithms, we operationalize real-time safety and high-quality cardiodynamic ECG extractions from continuous 12-lead digital ECG recordings with a single device. This translates into improved efficiency by shortening deliverable timelines and reducing costs.

Advantages of partnering with Celerion include:

- ✓ A team of US board-certified cardiologists rather than simply "skilled readers"
- ✓ Single blinded reader *per study* rather than per subject thereby optimized uniformity and consistency
- ✓ Embedded ECG core laboratory in our clinical units offers the advantages of a *single* contract, *single* study and project manager, and a *single* database
- ✓ A dedicated team of highly experienced ECG core laboratory associates with direct visibility of study conduct thereby ensuring data integrity and quality
- ✓ The highest QT quality data with FDA ECG warehouse QT metrics > 99%^{ile}

Our integrated ECG core laboratory within our clinical facilities allows one dedicated team to focus and actively participate in acquisition of cardiovascular data. This 'hands-on' approach permits immediate troubleshooting and resolution of any equipment related issues thereby mitigating against data loss while delivering high-quality data.

Celerion Differentiators:

Experience:

- ECG core laboratory and clinical pharmacology senior staff have more than 100 years of combined experience working with regulatory authorities and assisting with study design, data analysis, and expert report writing
- Clinical conduct associates are trained and certified on use of the Holter device and standard collection protocols thereby requiring no additional training or learning curve of new equipment, processes and procedures
- Extensive experience with complex and adaptive study designs including a range of investigational products

Expertise:

- US board-certified cardiologists with over 40 years of industry experience reading Holter and ECG data for the pharmaceutical industry with intra- and inter-reader variability results that meet and exceed industry standards
- 24/7 cardiologist consultative availability to PI and medical monitor for issues at screening, during dose escalation or evaluating adverse events

Efficiencies:

- Capacity to include more than 200 study subjects and dose over 60 participants on the same day reducing time and conduct costs
- Harmonized PGs and SOPs which enable sponsors to run their studies at any of our clinical sites with oversight of ECG acquisition during clinical conduct
- All equipment and supplies are maintained on site for immediate accessibility, rapid start up, troubleshooting and intervention

Our full service solutions for early clinical studies include protocol development, bioanalysis, statistical analysis and report writing, which facilitates ease and efficiency of partnering with one vendor, with tailored services to meet each sponsor's needs.

Accurate evaluation of the QT interval is critical in evaluating proarrhythmic potential of a compound. However, there are multiple off-target effects of compounds which may require a more comprehensive assessment of cardiovascular safety. Our ECG core laboratory team can provide a full suite of cardiovascular services to profile a compound's off target cardiac and vascular effects. These include stress testing, Holter and ambulatory blood pressure monitoring, platelet aggregation, cardiac biomarker evaluation and noninvasive cardiac imaging.

Comprehensive Services for Cardiovascular Safety Assessment

Cardiovascular Safety Services	Details
TQT and continuous Holter ECG monitoring	Comprehensive services for planning, implementation, conduct, analysis and reporting of concentration QT (cQT) and TQT studies using our highly automated hybrid core laboratory
Noninvasive cardiac imaging	Multiple imaging modalities to evaluate cardiac structure, function and myocardial blood flow including nuclear perfusion studies, cardiac computed tomography (CT), cardiac magnetic resonance imaging (CMRI), cardiac positron emission tomography (PET) and 2D and 3D Doppler color flow echocardiography
Physiologic stress testing	Treadmill, bicycle or hand crank ergometry used to assess a compound's effect on cardiovascular function and performance
Platelet aggregation	CLIA and CAP-certified laboratories located in the clinic allow for fast processing and analysis of samples to assess for early pro-aggregant and anti-aggregant signals
Ambulatory blood pressure monitoring	24 hour monitoring to assess off target blood pressure response by central tendency analysis with potential correlation to PK/PD data
Real-time telemetry monitoring	ACLS certified nurses are utilized for real time arrhythmia detection and review
Cardiac serum biomarkers	Biomarkers including cardiac troponin and brain naturetic peptides are used to evaluate direct myocyte injury and presence of heart failure
Central overread of ECGs	Our core lab team is available for centralized review of ECGs acquired at non-Celerion sites

View our extensive list of peer-reviewed publications and other resources contributing to the field early phase proarrhythmia risk assessment