



Celerion Solution

Over 40 years of experience

Over 40 years conducting, First-in-Human, clinical Proof-of-Concept and patient dose response studies, cardiovascular safety and clinical pharmacology research supporting product labeling

Global presence

with more than 600 beds at three global Celerion facilities, in addition to a network of audited specialty sites in North America, Europe, South Korea and Singapore. Celerion scans the globe to find solutions to clients' early clinical research needs

Extensive expertise

on modeling and simulation, study design, medical writing (protocols and reports), clinical data sciences, biostatistics, and PK/PD analysis

Highly qualified scientists

assist in designing robust, efficient clinical studies as well as analyzing and interpreting data both during and post clinical conduct

Bioanalytical services

at two global locations for method development and validation for small and large molecule assays for the analysis of drugs, metabolites, and biomarkers in a broad range of biological fluids

Drug development services team

provides regulatory, drug development and program management support to complement Celerion's service offering

www.celerion.com



Cardiovascular Safety Services

Translating Science to Medicine in Cardiovascular Safety Services

Translating science into medicine, Celerion is a premier provider of early clinical research and translational clinical pharmacology sciences. Key to advancing new drug candidates rapidly in early clinical research is determining how knowledge gained from discovery research translates to drug action and effects in humans. Celerion leverages its experience, expertise and specially equipped facilities to offer a wide range of cardiovascular safety studies.

Experience and Expertise

Celerion is a leading provider of cardiovascular safety services in early clinical research, with over 40 years of clinical research experience, including 100s of studies to evaluate cardiovascular liability, and more than 60 Thorough QT (TQT) studies completed.

- _ Broad range of TQT studies performed involving 50 to 250 participants, demonstrating Celerion's ability to efficiently conduct studies of varying size while maintaining strict data quality and patient safety standards.
- _ US Board certified cardiologists with over 25 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.
- _ ECG Core lab senior staff has more than 15 years of experience working with regulatory authorities and assisting with study design, data analysis, and expert report writing.
- _ Industry leading highly automated ECG Core Lab reduces both time and cost for analyzing ECG data while ensuring the highest level of accuracy and precision.

Seamless Integration of ECG Core Lab Services

- _ Celerion's ECG Core lab is located at our clinical facility, allowing one team to focus on providing high quality cardiovascular safety data. This enables accelerated study completion timelines and thereby significantly reduces cost. Co-locating the ECG Core lab and the clinical site allows direct visibility and oversight of clinical conduct by the ECG Core lab staff. This enables technical and scientific expertise to be available to the clinical site for faster decision making and ensures data integrity.
- _ Celerion provides all support services for early clinical studies including protocol development, bioanalysis, statistical analysis and report writing, with the ease and economy of working with one vendor for all study needs.

Comprehensive Services for Cardiovascular Safety Assessment

Precise evaluation of the QT interval is important in evaluating arrhythmia potential of a compound. However there are multiple off target effects of compounds which may require a more comprehensive assessment of cardiovascular safety. Celerion offers the following services:

Cardiovascular Safety Services	Comments
TQT and Intensive ECG Monitoring	Comprehensive services for planning, implementation, conduct, analysis and reporting of intensive ECG and TQT studies using our highly automated core laboratory
Noninvasive cardiac imaging	Multiple imaging modalities to evaluate cardiac structure, function and myocardial perfusion 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
Flow mediated dilation with noninvasive doppler ultrasound	Assessment of vascular reactivity and endothelial function as a marker for cardiovascular risk
Platelet aggregation	CLIA and CAP certified lab located in the clinic allows 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 Pharmacokinetic/Pharmacodynamic data
Real-time Telemetry Monitoring	ACLS certified nurses are utilized for real time arrhythmia detection and review
Cardiac Serum Biomarkers	Biomarkers are used to evaluate direct myocyte toxicity and heart failure, including cardiac troponin and natriuretic peptides
Central over-read of ECGs	Our core lab team is available for centralized review of ECGs acquired at non Celerion sites

