Clario Cardiac Safety: Consulting services

Industry-leading expertise to maximize the potential of your drug candidate

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Increase confidence with our science and expertise

Cardiac safety continues to be the #1 safety-related cause of drug development failure. Relying on local site ECG interpretation and onboard device algorithms is convenient, but differences across devices and sites introduce significant data variability and accuracy concerns, potentially compromising the future of an otherwise promising drug candidate. Leverage Clario's industry-leading ECG core lab and team of world-class cardiac safety experts to provide guidance on the clinical strategies most likely to yield success, the regulatory pitfalls to anticipate or avoid and the cost-saving measures that won't cost you your whole development program.

More QT experience than any ECG lab in the world

9 of every 10 drug candidates fail – leverage our experts to give your drug the best chance of success.

Our experience drives a better experience for you

Collaborate with our global team of industry-recognized cardiac leaders, regulatory specialists and statistical experts with credibility derived from more than 15,400 cardiac safety studies across all phases and diverse indications. Have confidence in your study results by leveraging our unparalleled scientific, technology and operational expertise to guide you from protocol through final report, from small studies to the largest, most complex global trials.

- **Protocol and study design:** Avoid safety and regulatory issues long before they become critical with strategic protocol and study design advice for early- and late-phase studies.
- **Strategy optimization:** Select the best strategy for analyzing cardiac safety by considering protocols and sites and determining the best device and integrated solution.
- **Two-way integration with external systems:** Experience rapid configuration and analysis, quality-driven visibility and additional endpoint integration into Clario's EXPERT®, our proprietary technology platform.
- **Global footprint:** Realize better site training, fewer queries and no missing data with our Center of Excellence, ensuring 24/7/365 customer care and 98% overall satisfaction.
- **High-quality, integrated data:** Evaluate your compound's cardiac safety profile, including effects on ECG, blood pressure, arrhythmias, myocardial ischemia and direct myocardial toxicity by collecting and analyzing high-quality, integrated data.
- **Easy visibility:** Understand your study's progress and potential issues early with real-time analytics and clinical and operational study data all in one place.
- **Flexible workflow:** Experience an easy and hassle-free, on-time and on-budget study that can be adapted to your needs.
- **Statistical analysis:** Benefit from expertise in analyzing QT data from both early-phase studies and dedicated thorough QT studies, including statistical analysis plan development and authoring expert reports for regulatory submission.

Our Cardiac Safety consulting experts

Our in-house, world-renowned cardiac safety consultants have worked with regulatory authorities for decades and have a thorough understanding of the methodologies and processes that should be employed to ensure quality outcomes.

Empower your studies with unrivaled expertise

Todd Rudo, M.D.

EVP & Chief Medical Officer

Dr. Todd Rudo is EVP and Chief Medical Officer at Clario, providing medical and scientific leadership across the organization. He has nearly 20 years of clinical cardiology and pharmaceutical research experience, with a career predominantly focused on drug safety. Dr. Rudo has board certifications in cardiology, cardiac electrophysiology, nuclear cardiology, adult echocardiography and internal medicine. His team provides expert consulting to clients on scientific and regulatory strategy and ensures Clario's product portfolio is scientifically robust, generating high-quality clinical trial endpoint data.

Borje Darpo, M.D., Ph.D.

Chief Scientific Officer, Cardiac Safety

Dr. Borje Darpo has held key roles on projects in all phases of clinical development. He has authored internal QT guidance documents for the design and conduct of clinical QT assessment. In collaboration with industry-leading cardiac safety experts and the U.S. Food and Drug Administration, Dr. Darpo led the IQ-CSRC study, which validated the concept of applying exposure response analysis on data from early-stage clinical trials to replace the TQT study. In addition to his role at Clario, he is an associate professor of cardiology at the Karolinska Institute in Sweden.

Vickas Patel, M.D., Ph.D.

Vice President and Chief Medical Officer, Cardiology

Dr. Vic Patel is board certified in cardiology with a PhD in Biophysics and has done extensive research on arrhythmia mechanisms. For 11 years, he served as a faculty member at U. Penn. School of Medicine, where he directed the Molecular Arrhythmia Research program and practiced clinical electrophysiology. Dr. Patel spent the next 8 years in drug development and cardiac safety as a clinical development leader and therapy area head across all phases. At Clario, Dr. Patel oversees cardiology consulting and ECG/Holter core lab services while leading the biostatistics and medical writing groups.

Robert Kleiman, M.D.

Chief Science and Regulatory Advisory, Cardiology

As Chief Science and Regulatory Advisor, Cardiology, Dr. Kleiman primarily serves in a consultative capacity, advising sponsors on the optimal cardiac safety strategy for their development programs. He is a board-certified cardiologist and cardiac electrophysiologist who has performed research in basic cellular electrophysiology, clinical electrophysiology and cardiac safety during drug development. Dr. Kleiman practiced clinical cardiac electrophysiology for 12 years before joining Clario in 2003.

Monitor every heartbeat with precision and ensure safety. To learn more, go to clario.com or email sales@clario.com.

About Clario

Clario is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move forward with confidence. With nearly 50 years of clinical and therapeutic experience, Clario balances knowledge of what works with a vision for what's next.

Powered by the EXPERT® technology platform, Clario's solutions enhance trial transparency, optimize site performance, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from Clario-supported studies. Pharma companies, biotechs and CROs have relied on Clario solutions in 27,000+ studies spanning more than eight million patients to date.

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