



# Clario cardiac safety: Consulting services

Monitor every heartbeat with  
precision and ensure safety

CLARIO.

## Minimize risks and bring treatments to market faster

Cardiac safety concerns are among the leading reasons that promising drugs are delayed or abandoned in development and not brought to market. For example, site devices are typically less reliable and can lead to poor inclusion and exclusion criteria and enrollment decisions. These challenges can pose a potential danger to study patients and produce misleading data. Safety issues, coupled with a complex regulatory landscape, mean you need expert guidance to minimize risks and bring clinical treatments to market faster—and with confidence.

## More phase I QT experience than any ECG lab in the world

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## Increase confidence with science and expertise

Optimize the quality and precision of your cardiac safety study data by leveraging tools, strategies and solutions that blend the best of technology and medical expertise. When every millisecond of precision counts, confidently navigate unexpected issues throughout your early-phase trial to close out on-time and on-budget with our Clario Early Precision QT (EPQT) approach. Use your clinical data to make critical decisions in late-phase global studies with our Clario SafePatient ECG solution. Easily address new regulatory demands for blood pressure monitoring with our blood pressure services.

## Our experience drives a better experience for you

Collaborate with our Center of Excellence, a global team of cardiac experts and regulatory specialists that has managed over 10,700 cardiac safety studies, including more than 3,330 early-phase and over 7,370 late-phase studies. 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 and 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
- **Statistical analysis:** 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
- **High-quality, integrated data:** Evaluate your compound's cardiac safety profile, including effects on the 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
- **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



## 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 what methodologies and processes should be employed to ensure quality outcomes.

### **Borje Darpo, M.D., Ph.D.** Chief Scientific Officer

Dr. Borje Darpo has played 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 FDA, 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.

(Access some of Dr. Darpo's abstracts via [PubMed](#) )

### **Robert Kleiman, M.D.** Vice President, Global Cardiology and Chief Medical Officer

As Vice President, Cardiology and Chief Medical Officer at Clario, Dr. Kleiman oversees Clario's cardiology services, consulting with external clients and managing the overall satisfaction of global customers.

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.

(Access some of Dr. Kleiman's abstracts via [PubMed](#))

## Empower your studies with unrivaled expertise

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### **Joel Morganroth, M.D.** Chief Cardiac Consultant

Dr. Morganroth serves as Chief Cardiac Consultant, Cardiac Safety, and was previously Chairman of Board of Directors and Chief Executive Officer for the company.

Dr. Morganroth is a globally-recognized cardiologist and clinical researcher with more than three decades of industry experience. Earlier in his career, he was a Special Government Employee for the U.S. Food and Drug Administration and a consultant to Health Canada.

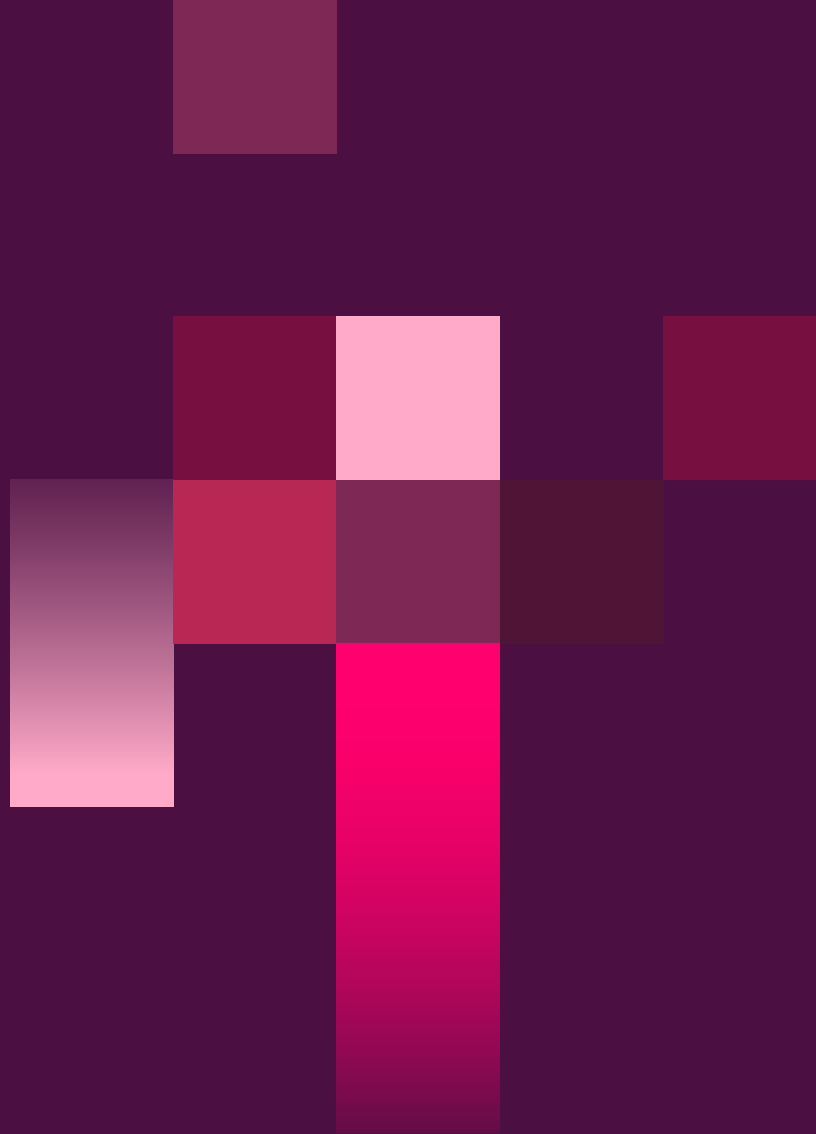
(Access some of Dr. Morganroth's abstracts via [PubMed](#))

### **Todd Rudo, M.D.** Vice President, Global Cardiology and Deputy Chief Medical Officer

Dr. Todd Rudo is the Deputy Chief Medical Officer at Clario, with board certifications in cardiology, cardiac electrophysiology, nuclear cardiology and adult echocardiography. He completed his general medical training at Jefferson Medical College in Philadelphia, PA, and specialty training at Lankenau Medical Center in Wynnewood, PA. In his current role with Clario, he provides cardiac safety consultative support to clients, leads the statistics and medical writing groups, and oversees ECG and Holter/Patch core lab activities.

(Access some of Dr. Rudo's abstracts via [PubMed](#))

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To learn more, go to [clario.com](https://clario.com) or email [sales@clario.com](mailto: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 ahead with confidence. With nearly 50 years of clinical and therapeutic experience, Clario balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, Clario's solutions enhance trial oversight, enable site optimization, 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 10,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, Clario enables customers to bring clinical treatments to patients quickly, and with confidence.



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