cardiac safety solutions
trusted expertise in a complex regulatory landscape
cardiac safety solutions: your proactive ally

In *The New Health*, where cardiac safety concerns have become the leading cause of market withdrawals and discontinuation in drug development, biopharmaceutical companies must understand and demonstrate a compound’s cardiac safety profile earlier in the process, when options remain and before more resources are invested. As your ally, Quintiles can guide you through a complex and shifting regulatory environment. Our scientists can help you identify risk early in the process, so that you can proactively adjust course, saving you both time and money.

But world-class expertise alone isn’t enough. To be successful, you also need strong execution. Quintiles delivers a powerful combination of high performance ECG monitoring and drug development expertise. The result? You get the team you need to help you make better decisions, earlier — and meet regulatory expectations at each step of development.

Expert Knowledge, Executed Brilliantly.

We believe in getting the science right. Exactly right. That’s why Quintiles has assembled a worldwide group of cardiovascular safety experts who provide insight and guidance across the drug development lifecycle.

**Expertise in Cardiac Safety Methodology, Analysis and Regulatory Reporting**

**Interdisciplinary Cardiac Safety Services Team**

From protocol review through final data submission, our group of interdisciplinary experts can help you take the right steps to meet your objectives. Our consultative expertise mirrors the Interdisciplinary Review Team of the FDA, applying the same level of scrutiny to your program that you’ll face with regulators.

**Cardiac Safety Research Team**

When you’re dealing with cardiac safety assessment, you want to work with experts at the top of their field. Quintiles’ dedicated team of researchers is actively shaping the science and regulatory landscape, with more than 30 published papers, as well as industry standard textbooks to their credit. No other ECG core lab has this many dedicated researchers working to advance the science and methodology of cardiac safety every day.

**Complementary Lifecycle Cardiovascular Safety Expertise**

**Non-clinical Cardiotoxicity and Cardioprotection Team**

Whether your compound is in early development or you’re working in the later phases, Quintiles can provide rapid insight into potential drug cardiotoxicity — and cardio-protective effects — at the cellular level. Through our CardioCheck team, we can apply our proprietary screening process to help you identify and potentially ameliorate negative influences the drug may have on cardiac myocytes.

**Cardiovascular Outcomes Study Teams**

Quintiles has the capabilities necessary to conduct large cardiovascular outcomes studies, required in anti-diabetic drugs for Type 2 and, increasingly for drugs in other indications. Tapping cardiologists, endocrinologists, and nephrologists from across the company, as well as seasoned project staff, we offer proven expertise in study design and operations — including the identification of the Major Adverse Cardiovascular Events (MACE) clinical endpoints.
Quintiles Methodology is *Engineered for Reliability*

Quintiles is dedicated to discovering new ways to give you the most accurate picture of your product’s cardiac safety profile by using best-in-class technology.

**Digital ECG devices** Quintiles’ sophisticated, validated equipment is not only easy for sites to use; its preview feature also helps ensure data of the highest quality.

**Physician and cardiologist review** Quintiles ECG reviewers and board certified cardiologists follow a consistent and effective methodology, ensuring medical review and QC of each ECG. ECG analysis is completed in accordance to the ICH E14 guidelines for digital analysis.

**Real-time data** Study data, including individual ECGs and reports, are provided almost immediately in an easy-to-navigate format through our proprietary Web portal. Features include drill down menus for protocol, site, subject, and visit-specific information; dashboards with graphical overview of study information; access to ECG tracings with annotations and ECG reports with subject identifiers; online query resolution and DCF management, and enhanced site support.

**Biometric signatures** Electronic fingerprints are used every time data are entered or changed in our secure system. This produces a solid audit trail to help ensure data compliance.

**Automated platforms** Quintiles’ Cardiac Safety Research Team has evaluated the leading automatic analysis algorithms and has integrated the use of these new tools into our proprietary processing platform. These systems offer increased savings over standard analysis techniques and significantly shorten analysis timelines for early phase trials in normal, healthy patient populations.

**Rapid and seamless transfer of data** For high-volume TQT studies, Quintiles offers wholly owned Phase I clinics in the U.S., Europe and Asia directly connected to our ECG core laboratory. Using ECG acquisition platforms such as Mortara Surveyor System and a private WAN at our clinic, we streamline the collection of mass volumes of cardiac safety data — eliminating extra steps through an efficient Quintiles-integrated process.

With more than 20 dedicated cardiologists, over 300 MDs, and around 400 PhDs at Quintiles, we have the multi-faceted expertise and insights you need to understand your product’s risk-benefit profile.

Wherever you are in the world, Quintiles is there. Our extensive and well-trained network of professionals is spread across multiple time zones. This means your lead contact is always available — on your time — to help ensure that your study runs smoothly.

Global regulatory knowledge and best practices keep your study in compliance with relevant country regulations.

A single point of contact makes communication easy. With experienced Cardiac Safety Project Managers located across the U.S., Europe, India and Japan, you’ll always have a contact nearby. Your dedicated Project Manager is supported by his or her customer team, ensuring that the deliverables, expectations, customer satisfaction and study goals are achieved efficiently and within target.

Global offices located in more than 60 countries, allow us to deploy equipment and set up studies efficiently and effectively within the targeted timelines.

Our help desk is always available for investigators from anywhere in the world. We offer coverage 24 hours a day, 365 days a year — and service in 22 different languages.

Experience you can rely on: Quintiles has operated our own ECG core lab since 1998, has conducted more than 1,000 ECG-specific trials, and has acquired data in 82 countries.

Integrated data, better insights: When you partner with Quintiles for your clinical trial and ECG analysis, our advanced, proprietary data system provides an integrated view of your data, helping you make more informed decisions.

ECG Core Lab Services

> 12-lead digital ECG analysis and interpretation
> Multiple analysis options: automated, semi-automated and fully manual methods
> Thorough QT analysis per E14 guidelines
> 12- and 3-lead Holter analysis and interpretation
> Snapshot ECG extraction and analysis from Holter data set
> Paper scan and digitization
> Provision of ECG/Holter equipment, training and support to sites
> Statistical and ECG expert report writing
> Protocol review and consultation
> Secure Web portal providing access to standard reports, graphs and charts, data displays and ECG tracings
> Annotated XML submission in HL7 format to FDA
> Ambulatory blood pressure monitoring
> Full QT study capabilities: TQT, intensive QT, SAD, MAD and C-QT modeling and simulation

Consistent. Experienced. Sophisticated.

Quintiles is uniquely qualified to help you understand the cardiac safety of your drug through our leading scientific expertise, innovative technology, and global presence. Talk to the experts at Quintiles about cardiac safety for your clinical program.

Join us for success in the New Health

We’re here for you.

Toll Free: 1 866 267 4479
Direct: 1 973 850 7571
Email: clinical@quintiles.com
Website: www.quintiles.com/cardiacsafety