Advancements in assessing cardiovascular safety and a changing regulatory landscape pose challenges for clinical trial sponsors seeking drug approvals. You rely on a cardiovascular service provider with the experience to support a wide range of centralized assessments and the expertise to implement successful safety and efficacy programs.
Know the risks: over the last 2 decades, up to 45% of drug withdrawals and non-approvals in the United States are caused by cardiac side effects.

Your cardiac safety study relies on the accurate collection and evaluation of ECG data. Our team of board-certified cardiologists and certified cardiological technicians ensure the delivery of high quality data in support of regulatory approval for your compound or medical device.

- A full range of centralized ECG technology and evaluation methodologies.
- The latest in digital Holter recording technology.
- Extensive expertise in designing and implementing Thorough QT (TQT) studies.

Our TQT expertise is highlighted by the development of novel study designs and the successful completion of the first regulatory mandated TQT studies in Japan and China.

ABPM data are increasingly being evaluated for determining the efficacy and safety of therapeutics and medical devices during regulatory review. You want a partner with the knowledge and experience to develop and implement blood pressure endpoints in your clinical study.

- Centralized collection and management of automated office and home BP.
- Standardization of equipment and protocols across clinical sites, ensuring high quality data.
- Remote telemonitoring for electronic capture and transfer of study data.
- Advanced hemodynamic monitoring and analysis capabilities (Pulse Wave Analysis and Central Aortic Systolic Pressure).

With advances in imaging modalities, clinicians and sponsors now have access to sensitive and quantitative cardiac measurements, enabling more accurate assessments of drug safety and efficacy. Our cardiac imaging experts have experience with advanced cardiovascular imaging modalities, meeting sponsors' needs for quantitative endpoints.

- Echocardiography (ECHO)
- Cardiac Magnetic Resonance Imaging (MRI)
- Cardiac Computed Tomography (CT)
- Nuclear Medicine (PET, SPECT, MUGA)

We offer expert independent review of cardiovascular images and provide high quality quantitative data in support of novel therapeutics and medical devices.

BioClinica's Cardiovascular Services are built on an innovative technology called WebHeart®, a proprietary, 21 CFR part 11 compliant platform for the acquisition, management, analysis and reporting of cardiovascular safety and efficacy data.

- Rapid and real-time management of centralized ECG data via secure internet access.
- Configurable for sponsor-specific protocols.
- Regulatory submission-ready ECG data (Mortara® certified and annotated XML files).

BioClinica's technology enables streamlined electronic transfer of medical images from clinical trial sites, making it easy and cost effective for sponsors to manage the collection and archival of all images from a study.

- Images are de-identified and securely submitted with real time quality checks and rapid query resolution.
- Sponsors can access images via a secure web portal.
- Elimination of courier services saving sponsors time and money.

BioClinica operates the world’s largest and most experienced imaging core lab together with world-class cardiovascular safety services providing you the scientific and regulatory expertise and technology you need to run high quality, cost effective and successful cardiovascular safety programs.

Cardiovascular Solutions

-know the risks: the association of many oncology drugs with cardiotoxic side effects necessitates independent cardiac safety studies. BioClinica's Cardio-Oncology expertise can help you tailor a program to assess potential risks early in your clinical pipeline.