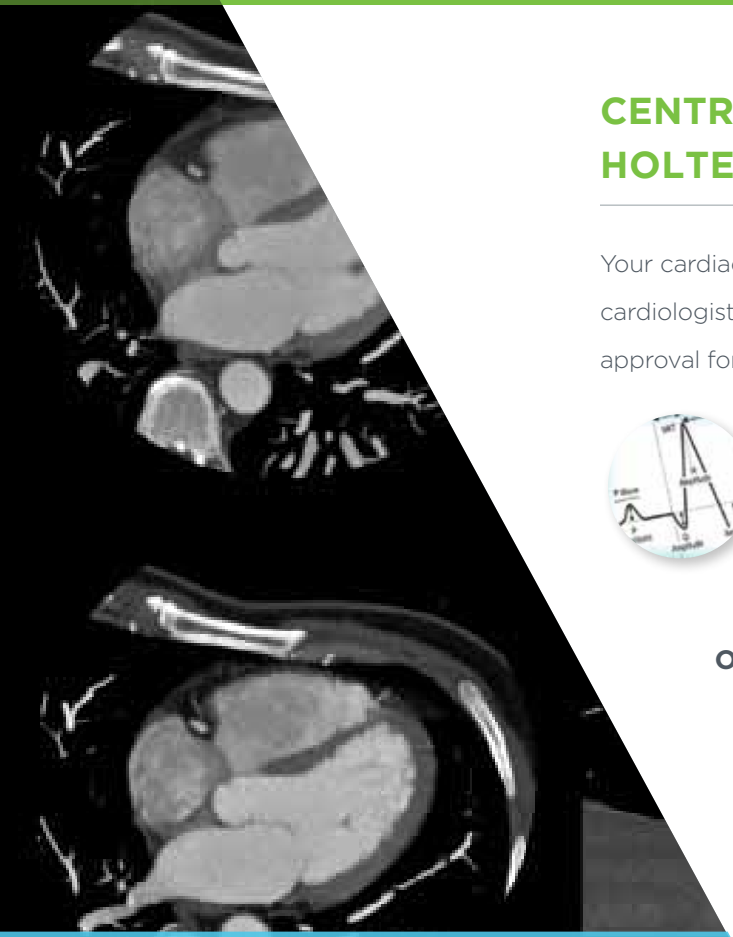
COMPREHENSIVE CARDIAC SAFETY SOLUTIONS

Global Clinical Trial Services Advancing Safer and More Effective Treatments

Past high-profile drug withdrawals and non-approvals have prompted Cardiac Safety to become a regulatory guideline requiring dedicated safety assessments as a condition for approval for most drugs. In Bioclinica you will find the global scientific leadership, recognized regulatory expertise and exceptional project delivery to support your routine clinical trials and dedicated cardiac safety studies with high-quality centralized cardiac safety services.

BIOCLINICA®
CARDIAC SAFETY



CENTRALIZED ECG SERVICES, HOLTER MONITORING, AND TQT STUDIES

Your cardiac safety study relies on the accurate collection and evaluation of ECG data. Our team of board-certified cardiologists and certified cardiographic 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 and rhythm monitoring.
- Consulting services: extensive expertise in designing and implementing Thorough QT (TQT) studies and Intensive QT (IQT).

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.

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.

IN TODAY'S CLINICAL TRIALS, IMAGES OF THE HEART AND VASCULATURE PROVIDE KEY ENDPOINTS FOR DETERMINING THE EFFICACY AND SAFETY OF NEW TREATMENTS.

BLOOD PRESSURE MONITORING

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

- Centralized management and standardized BP technology including:
  - a) Ambulatory blood pressure monitoring (ABPM)
  - b) Tele-monitored self-monitored home BP (T-SMBP)
  - c) Centralized automated office BP (C-AOBP)
- Advanced hemodynamic monitoring and analysis capabilities (Pulse Wave Analysis and Central Aortic Systolic Pressure).

CARDIOVASCULAR IMAGING

We offer independent expert review of cardiovascular anatomic and functional images and provide high quality quantitative data in support of novel therapeutics and medical devices. Our cardiac imaging experts have experience with advanced cardiovascular imaging modalities, meeting sponsors' needs for quantitative endpoints.

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

INNOVATIVE TECHNOLOGIES

Bioclinica's Cardiac Safety Services are built on proven medical expertise supported by innovative technology called WebHeart®, a proprietary, 21 CFR part 11 compliant web-enabled platform for the acquisition, management, analysis and reporting of cardiac 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 data from clinical trial sites, making it easy and cost effective for sponsors to manage the collection and archival of all images from a study.

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

BIOCLINICA®
SEE MORE CLEARLY

Clinical trials are complex and monolithic approaches are the norm. But the most successful trials require the ability to see key details and uncover hidden insights. Bioclinica is specifically structured to create clarity in the clinical trial process—so you can make better decisions.

About Bioclinica

Bioclinica is a specialty services provider that utilizes expertise and technology to create clarity in the clinical trial process. Bioclinica is organized by three business segments to deliver focused service supporting multifaceted technologies. The Medical Imaging and Biomarkers segment provides medical imaging and cardiac safety services and includes a molecular marker laboratory. The eHealth Solutions segment comprises an eClinical technology platform and professional services along with financial lifecycle, safety and regulatory solutions. Under the Global Clinical Research segment, Bioclinica offers a network of research sites, patient recruitment-retention solutions, and a post-approval research division. **Bioclinica.com**

For more information about our medical imaging, cardiac safety and molecular markers services, please contact Bioclinica at **sales@Bioclinica.com**.

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