BIOCLINICA®
CARDIAC SAFETY

CENTRALIZED ECG SERVICES

Cardiac Services Advancing Safer Treatments

CHOOSE BIOCLINICA FOR YOUR CARDIOVASCULAR SAFETY STUDY:

- More than 30 years of experience
- Board-certified cardiologists and certified cardiographic technicians (CCT)
- Global operational support
- Active participation with the ICH, CRSC and FDA

INNOVATIVE TECHNOLOGY

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

Features and benefits:

- Rapid and real-time management of ECG data via secure internet access
- Configurable for sponsor-specific protocols
- Compatibility with all ECG and ABPM technologies and operating systems
- Centralized storage of cardiovascular data
- Regulatory submission-ready ECG data (Mortara® certified and annotated XML files)
- Role-based, 'rights-restricted' security model
- No special software, plug-ins, or add-ons required

Bioclinica has the scientific expertise, experience and regulatory insight to support your cardiovascular safety study across all clinical trial phases, from protocol design to regulatory submission.

ECG services

- Standardized digital 12-lead ECG and equipment
- Flexible turnaround times on ECG overreads based on global cardiac safety team
- On-screen manual, semi-automated and automated ECG
- Industry recognized expertise of the AMPS platform (BRAVO)
- Direct ECG upload and transfer from Phase I units
- 12-lead ECG hardcopy digitization and overread

Digital Holter

- Continuous Holter recording technology (24+ hours and 12-lead)
- Analysis of Holter data for Arrhythmia and Heart Rate Variability (HRV)
- Advanced, clinic-based heart rate monitoring
- Web upload of Holter data from clinical sites

Thorough and Intensive QT studies

- Innovative study design with full protocol and SAP development
- Advanced ECG data capture and analysis by board-certified cardiologists
- Expertise and guidance for regulatory submissions (FDA, EMA, PMDA, and CFDA)
- Expertise with TQT reports and reader variability reports
- Successful completion of first regulatory-mandated TQT studies in Japan and China
- Simplified logistics through novel ECG timepoint extractions from Holter recordings

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