ALTASCIENCES
CLINICAL SERVICES

Cardiac Safety Assessment

Clinical Testing of QT Prolongation - Early or Late

The FDA allows determination of a drug's clinical QT prolongation effect through concentration/effect modelling, thus it is possible to test for QT prolongation as early as first-in-human studies.

Altasciences is at the forefront of early cardiac safety assessment through collaborations with a number of leading core ECG vendors. We support many sponsors who prefer to run a thorough QT (TQT) prolongation study during, or just before the start of, Phase III studies. To date, we have conducted over 30 studies in intensive ECGs to meet the criteria set in the E14 guidance.

Early QT Assessment Advantages

- Potential elimination of the traditional TQT study for some drugs if the early trial is scientifically rigorous and adequately designed; provides preparatory information for cases where the TQT study will need to be completed
- Improved development package for licensing or further in-house development
- Considerable time and cost savings if TQT waiver is obtained
- Possibility to collect data and analyze later in development cycle

Thorough QT Assessment Advantages

- By waiting to run a TQT study after Phase II, the derisking occurs later in development and the cost is incurred only for compounds clearly showing potential
- By end of Phase II, the understanding of the pharmacokinetics of the parent and potential active metabolites and how they relate to efficacy has been more elucidated

Regardless of your timing and approach, Altasciences can support you. Our clinical sites have **dedicated cardiac safety assessment teams**. At the protocol writing stage, we ensure the order of clinical assessments does not interfere with ECG extraction, and throughout clinical conduct we take all precautions to limit changes in heart rate.

Our **clinical units are specially designed** for conducting intensive ECG studies, and have hospital beds with sufficient space around them for multiple staff to perform procedures in quick succession. Our ECG teams understand that minimizing the variability helps ensure a signal is seen with the positive control.

Seamless Full Service

We recognize the importance of communication. To this end, a dedicated Project Manager is assigned to each program and works closely with all key stakeholders to ensure seamless and timely communication, and successful completion of each project. We also encourage sponsors to reach out to any member of the Altasciences team with questions, such as to our Data Managers or Biostatisticians who are well versed on studies with intensive ECGs.

Protocol Design and Development

We are well-positioned to advise sponsors on design, conduct, interpretation, and regulatory communication on traditional TQT and early phase QT studies.

Multiple Collaborative Relationships

- Cardiac safety assessment protocol development
- Clinical study design
- Advanced cardiac monitoring

Advanced Cardiac Monitoring

Our clinical facilities are ERT-certified and work with ERT and other providers.

Member of the CSRC

As a member of the Cardiac Safety Research Consortium (CSRC), we participate with industry leaders on key issues that impact cardiovascular safety, including alternative approaches to ICH E14 for the assessment of arrhythmia liability in early drug development.

Clinical Operations

We have expertise in supporting both routine and intensive evaluation of ECG effects in a variety of Phase I studies, such as single ascending and multiple ascending dose.

- Specially-designed early QT safety assessment unit to minimize cardiac monitoring interference
- Innovative dual mode ECG and Holter monitoring
- Intranet data centralization
- Full-service capabilities for cardiac safety assessment provide a one-stop solution

Clinical Pharmacology Solutions

- 345,000 participants in database
- Rapid recruitment
- Retention excellence
- Dedicated research physicians
- Specialized pharmacy

Final Analysis

Altasciences' research services team works closely with the clinical team to ensure data collection flows seamlessly into the reporting phase. Data from the safety database, cardiac assessments, and the clinical labs are compiled. The Tables, Listings and Figures, as well as the clinical study report, meet CDISC requirements.

Medical Writing

- Meaningful interpretation of pharmacodynamic results
- Team with over 20 years' experience

Biostatistics

- Programmed using SAS®
- Statistical results and appendices for CSR
- CDISC-compliant, Regulatory submission-ready package

Data Management

- Complete plan
- Electronic Data Capture
- CDISC Certified

Bioanalysis

- High throughput bioassays
- Method feasibility, transfer, development, and validation in multiple matrices
- LC-MS/MS and Ligand Binding

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