



CSRC ECG WAREHOUSE DATABASE USE STATEMENT OF PRINCIPLES

Background of the CSRC ECG Warehouse:

The CSRC is a public-private partnership, and ECG data in the ECG warehouse are owned by the entities (generally pharmaceutical company sponsors) that submit ECGs in the course of drug development or post-market surveillance. Release of the ECG data to CSRC for additional analysis represents a collaborative effort of scientific good will on the part of the data owners. Within the CSRC, a Scientific Oversight Committee (SOC) has been formed to evaluate proposals for use of the released ECG data and to foster collaboration within the research community. Individual research protocols cleared by the SOC are approved by the Executive Committee.

Purpose:

This document addresses the principles underlying the use of databases from the ECG warehouse of the CSRC public-private partnership for the evaluation and testing of ECG algorithms relating to cardiac safety. These principles are designed to preserve the fairness and public interest of access to these data commensurate with the mission of the CSRC.

ECG Algorithm Objectives:

The construct of the CSRC ECG warehouse data supports algorithm development using:

1. Placebo waveforms
2. Moxifloxacin waveforms

ECG Warehouse algorithm testing:

Toward the ends specified above, development and testing of algorithms are expected to include one or both of the following components:

1. ECG waveform characterization & measurement features
2. Patient descriptor interaction features

ECG data sets:

The datasets will include complete baseline, placebo, and moxifloxacin arms of representative thorough QT studies and pooled datasets.

ECG Warehouse partitioning:

CSRC will maintain a partition between publicly released waveform and descriptor data ("unblinded" data) and waveforms released without descriptor data ("blinded" data). Unblinded data may be used for sponsors to train/develop algorithms, or to use for other preliminary testing steps and strategies. All reporting of outputs using unblinded data will be clearly identified as unblinded "training" results. Algorithm performance will only be reported from assessments of unique, independent blinded data cohorts scored by the CSRC.



ECG Warehouse access:

ECG waveforms from the warehouse will be made available for sponsors of SOC approved projects. Waveform release has been designed so that algorithm developers can execute their own algorithms without needing to release proprietary measurement strategies. For blinded dataset performance evaluation (scoring) of endpoints, such as moxifloxacin signal detection, sponsor's measurements from blinded data ECG waveforms will be submitted to the CSRC statistics group where they will be matched to descriptors including treatment assignments (placebo vs. moxifloxacin), and scores will be returned to sponsors. The statistical analyses plan will be submitted to the CSRC before release of the blinded data sets. **The CSRC expects to charge a fee for use of the blinded data set to cover the CSRC costs associated with the maintenance of the ECG dataset and the algorithm scoring of the blinded data set.**

Publication/dissemination of algorithm performance:

Publication or dissemination of algorithm performance will be expected from those sponsors using the blinded data set(s). Commitments to public domain information release at the time of SOC approval will be expected to be delivered by sponsors in the form of such reports in the public domain.

Sponsors will agree that any publication/dissemination of results from unblinded study cohorts will clearly indicate that performance results represent only unblinded training data.

For any questions, please contact cardiacsafety@mc.duke.edu