Current CSRC ECG Data Warehouse

Under FDA’s Critical Path Initiative:

Cardiac Safety Research Consortium (CSRC) MOU Duke – FDA (2006))

ECG Warehouse FDA–Mortara (2004)

Non-Drug and Moxifloxacin ECGs Released by Sponsor

20 TQT Studies Released to Date

>500 Congenital Long QT ECGs

Available for Research Projects Approved by SOC
CSRC ALGORITHM DATASET PROCESS

ECG Algorithm Datasets
(Waveforms, Baseline Data)

Algorithm Development Datasets
For exploratory testing of partially established or development of new algorithms
(Unblinded)

Algorithm Testing Datasets
For definitive testing of established algorithms and ECG test criteria
(Blinded)

(Provisional Performance) (Publication Performance)
CSRC Governance Structure

- Scientific Oversight Committee (SOC) evaluates proposals for CSRC ECG data use
  - Foster collaboration and fair access to data
  - Should be a trivial process for algorithm researchers
  - [http://www.cardiac-safety.org](http://www.cardiac-safety.org)

- ECG Data Warehouse Committee
  - Ensure that efforts are practical and can be implemented in a reasonable timeframe
  - Available to answer any questions
  - Transfer necessary data
Publications


Key Projects this Year

- **Comparison of Automated Interval Measurements in Widely Used Algorithms in Digital ECGs**
  - Follow-up project comparing 7 algorithms
  - 800 ECGs
    - Normal, Moxifloxacin, LQT1 and LQT2
  - Two new project proposals

- **Sudden Cardiac Death in the Young**
  - National Cardiac Screening Warehouse Pilot Study
Members

- Fabio Badilini, PhD (AMPS) – Co-Chair
- Cindy Green, PhD (Duke) – Co-Chair
- Mike Li, PhD (FDA)
- Paul Kligfield, MD (Cornell)
- Boaz Mendzelevski, MD (Cardiac Safety Consultants)
- Johan DeBie, PhD (Mortara)
- Catherine Ortemann-Renon, PhD, PharmD (Sanofi)
- Valarie Morrow, MD (Duke)
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