



# **CARDIAC SAFETY**

## RESEARCH CONSORTIUM

**Cindy L Green, PhD**

Co-Chair

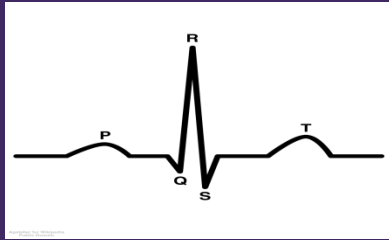
ECG Data Warehouse Committee

# 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)



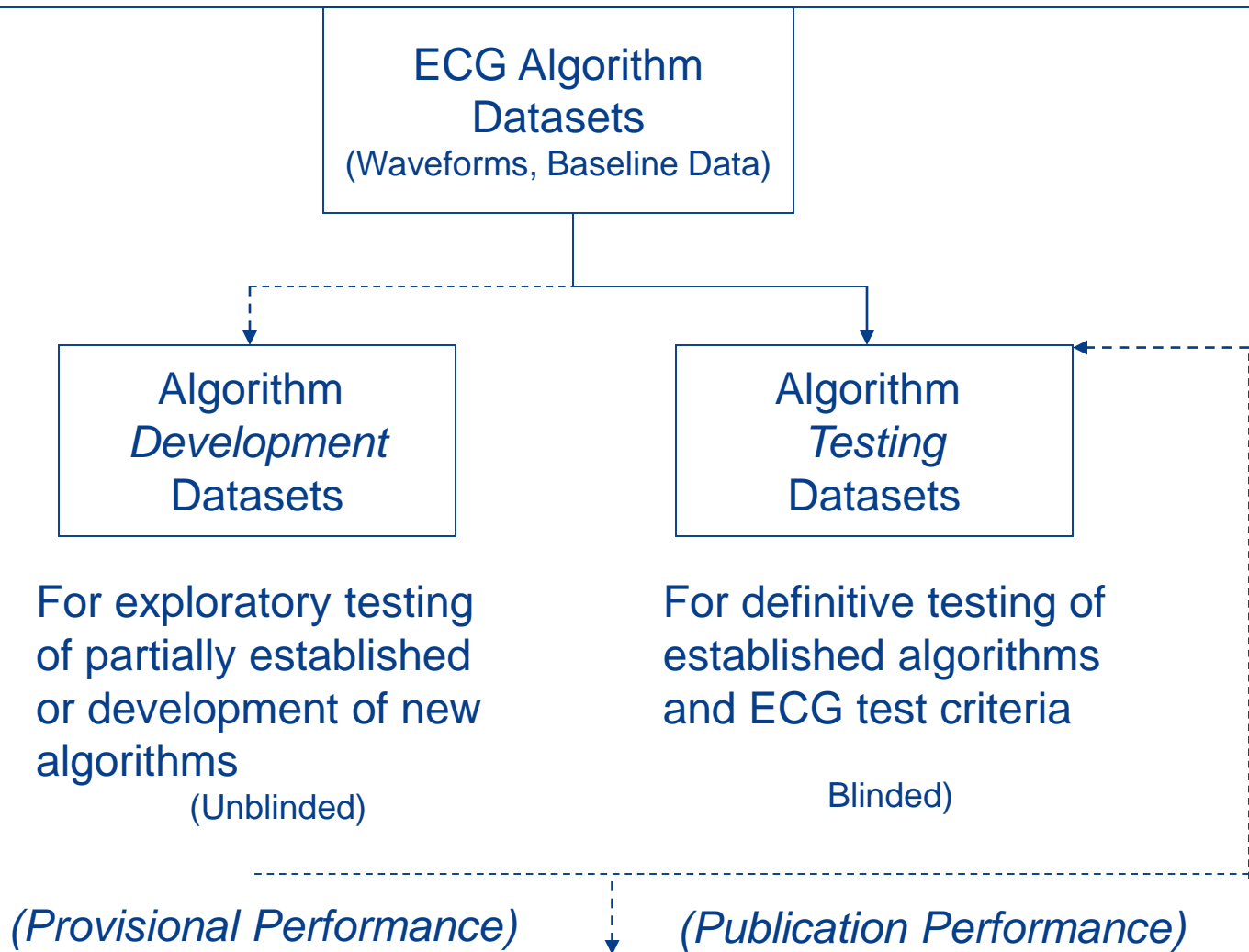
Non-Drug and  
Moxifloxacin ECGs  
Released by  
Sponsor

20 TQT Studies  
Released to Date

>500 Congenital  
Long QT ECGs

Available for  
Research Projects  
Approved by SOC

# CSRC ALGORITHM DATASET PROCESS



# CSRC Governance Structure

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- 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>
- 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

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- Kligfield P, Green C, et. al. The Cardiac Safety Research Consortium electrocardiogram warehouse: thorough QT database specifications and principles of use for algorithm development and testing. *Am Heart J* 2010 Dec;160(6):1023-28.
- Green CL, Kligfield P, et. al. Detection of QT prolongation using a novel electrocardiographic analysis algorithm applying intelligent automation: Prospective blinded evaluation using the Cardiac Safety Research Consortium electrocardiographic database. *Am Heart J* 2012 Mar;163(3):365-71.
- Kligfield P, Badilini F, et. al. Comparison of automated measurements of electrocardiographic intervals and durations by computer-based algorithms of digital electrocardiographs. *Am Heart J* 2014;167(2):150-59.

# Key Projects this Year

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- 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

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- 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)
- Mitchell Krucoff, MD (Duke)



# For more information:

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[www.Cardiac-Safety.org](http://www.Cardiac-Safety.org)  
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