

# Cardiac Safety Research Consortium

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# The right ingredients

- Critical Path Initiative
- Need to evaluate pro-arrhythmic potential for new drugs (ICH E-14)
- Data standards and warehouse for digital ECGs

# Evolution

- 2005: Digital ECG Warehouse on-line
- October 2005: FDA-DCRI sponsor meeting to discuss research priorities
- September 2006: FDA-DCRI Memorandum of Agreement
- November 2006: Second research priorities meeting
- January 2007: CSRC Governance structure

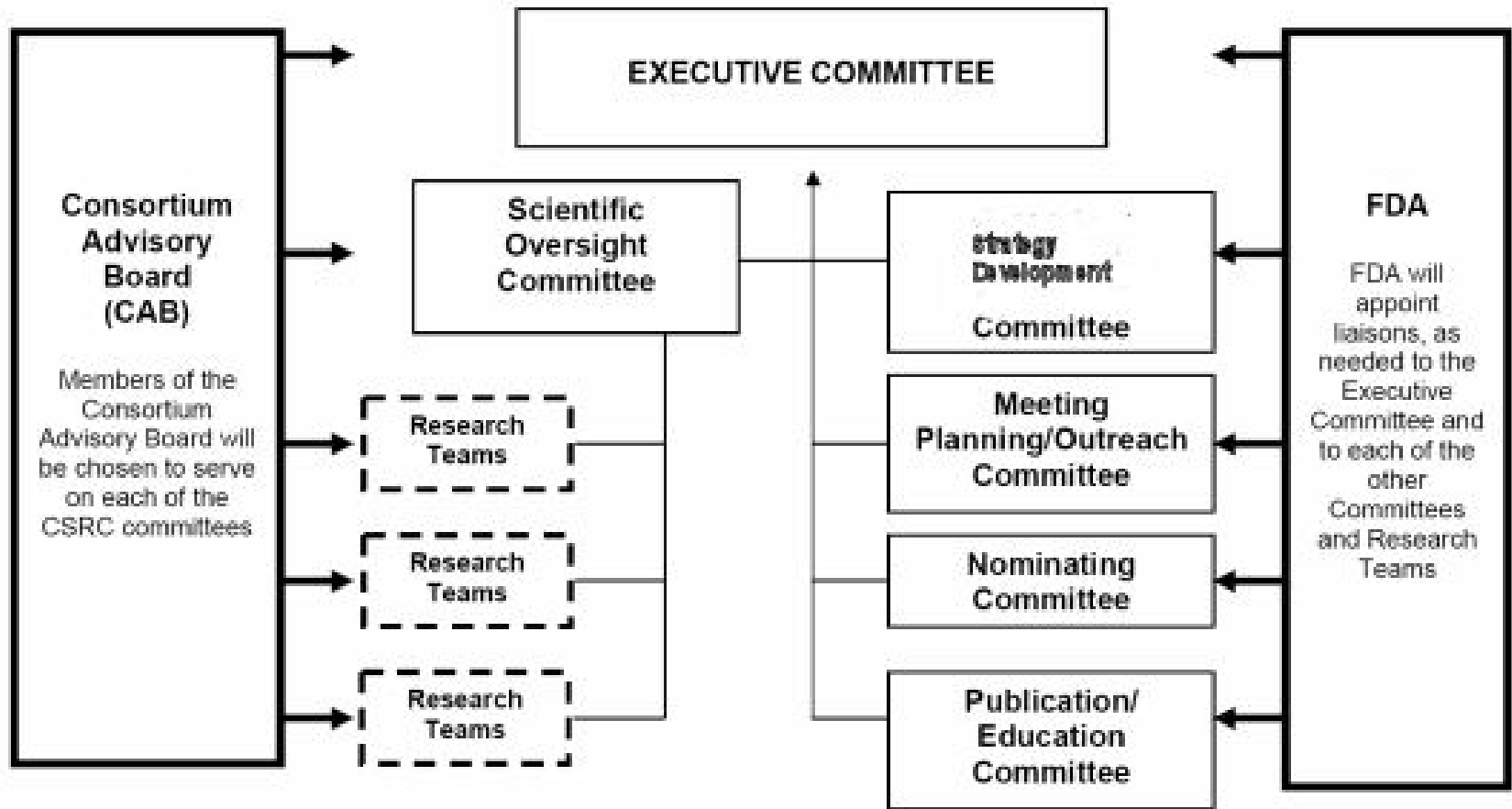
# CSRC Mission

“To advance scientific knowledge on cardiac safety for new and existing medical products by building a collaborative environment based upon the principles of the FDA’s Critical Path Initiative as well as other public health priorities.”

# Operating principles

- Transparency
- Inclusion of stakeholders
  - FDA, Pharma, CRO, tech companies, academics
- Leverage existing resources
  - ECG data
  - Other cardiovascular clinical datasets
  - Data collection when necessary

# Organization



# Executive Committee

- Marilyn Agin (Pfizer)
- Daniel Bloomfield (Merck)
- Benjamin Eloff (FDA/CDRH)
- John Finkle (GSK)
- Paul Kligfield (Cornell)
- Mitch Krucoff (Duke)
- Justin Mortara (Mortara Instruments)
- Phillip Sager (AstraZeneca)
- Wendy Sanhai (FDA/OC)
- Norman Stockbridge (FDA/CDER)

# Development strategy

- QT assessment of oncologic drugs
- Assessment of arrhythmias in early phase clinical trials

# Some research projects

- ECG morphology to detect moxifloxacin or other ventricular repolarization effects
- Normal values for ECG parameters
- Incidence of arrhythmias in normals
- Establishment of a warehouse for Holter data
- Optimal duration of antiplatelet therapy with drug-eluting coronary artery stents

# Open issues

- Research priorities
- Access to data
- Developed intellectual property
- Funding for projects requiring data collection

# Get involved!

- [www.cardiac-safety.org](http://www.cardiac-safety.org)