

# **Cardiac Toxicity Breakout Group**

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# Cardiac Toxicity Biomarker Issues

- u Not Just QT!
- u Standardization
- u Mechanisms' relationship to biomarkers
- u Who will be responsible?
- u Liberate the FDA data
- u Access to compounds
- u Defining/expanding role of NIH

# Standardization—Critical Issue

- u Data collection
- u Drug names—identification
- u Patient data—identification
- u Data submission
- u Should be standardized across  
NIH/Industry/FDA/Academia
- u Adequate annotation of data
- u Adequate curation of data

# Mechanisms

- u Important to relate biomarkers
  - l To mechanisms
    - w To “design out” toxicity
    - w To develop better biomarkers
  - l To long term clinical outcomes
  - l To define those that correlate
  - l To define those that do not correlate

# Responsibility

- u Who should be responsible for bringing groups together?
- u Who will pay?
- u What is mechanism?
- u What are incentives vs. requirements?
  - l Carrot and/or stick issue

# Liberating the FDA Data

- u Would allow access to data
- u Would allow non competitive access
- u Would allow access to “old drug” data
- u Will require legislation
  - l Could be a quick win!

# Access to Compounds

- u With preclinical toxicity data
- u Look for correlations lack of correlation
- u Allow comparison across studies

# Refining NIH Role in Biomarker Development

- u Convene a standing group including NHLBI, FDA, industry and academia to identify and prioritize high impact (in terms of public health) opportunities to recommend specific targets for research funding
  - | Technology and animal model development aimed at translation into human studies
  - | Development of biomarkers in detailed human studies of genomics, proteomics and metabolomics
  - | Develop human studies to validate biomarkers in adequately sized longitudinal cohorts
  - | Define role of Standard Development

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