

# Impact of public-private partnerships in cardiology

What do I know about “cardiology”? How about...

# **IMPACT OF PPPs ON FDA/CDER/DIVISION OF CARDIOVASCULAR & RENAL PRODUCTS**

# Community interactions 1991-2002

- Sporadic interactions with DIA, AHA, ACC, ...
- Annual several-day meetings organized by Borer/Somberg

# Drug development think-tank series

- Borer/Somberg meetings
- DCRI think-tanks → white papers
  - Medical product development, public health
- CSRC think-tanks → white papers
- CVCT annual meetings → some publications
  - Trial design, medical product development

# Catalyst: Drug-induced TdP

- ICH (\*)
  - S7B Non-clinical work-up (Koerner)
  - E14 Clinical work-up (Temple, Throckmorton)
- ECG Warehouse (CRADA)
  - Data standards (\*)
- MOU with Duke University → CSRC (\*)
- ILSI-HESI Cardiovascular group (\*)

# ILSI-HESI Cardiac Safety Committee

- White papers/projects in the non-clinical space
- ~90 member institutions
- Subgroups
  - Proarrhythmia
  - Contractility
  - Predictive strategies
  - Cardiomyocytes
  - Biomarkers

# CSRC evolution

- From TQT to cardiac safety remit
- Bridges to HESI and cardio-oncology
- From think-tanks/white papers to projects
- Public health mission

# Beyond cardiac

- Kidney Health Initiative (ASN)
- CTTI
- CDISC
- Critical Path Institute/Predictive Safety Testing Consortium



# Impacts

- Individually
  - Rich opportunities for input and expertise not otherwise readily available
  - Improved transparency regarding regulatory concerns
- Collectively
  - Infrastructure that has enabled CiPA

# Comprehensive In vitro Proarrhythmia Assay

- Seeks to improve specificity of proarrhythmia assessment
- Probably largest non-clinical development project of all time
- Has no articles of incorporation, no budget, no officers, no contract, and no rules of order—but does have a series of PPPs dedicated to performing various aspects of the program
- Working! Expects to deliver complete specifications and validation data by end of 2017.
- Inconceivable in 2002.



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