

# Impact of CiPA on Drug Development

## FDA Perspective

Norman Stockbridge

Division of Cardiovascular and Renal  
Products, FDA/CDER



# Outline

Unregulated

Local

Soon



Future

Universal

Regulated

# CIPA impact

The logo for CIPA impact features the word "CIPA" in a large, red, serif font. To its right, the word "impact" is written in a smaller, black, sans-serif font. A decorative graphic of thin, yellow-green lines curves over the top of "CIPA" and under "impact", resembling a stylized wave or a signal waveform.

- Regulatory
  - Define the principal, authoritative basis for proarrhythmia assessment, trumping anything short of TdP.
  - Revised labeling for drugs with warnings based on non-concentration-dependent effects on QT.
- Pre-regulatory
  - Shared and scientifically and technically sound basis for making business decisions on compound selection.
  - Fewer false positive results to sideline otherwise potentially good molecular candidates.

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- Local

- Leverages deep understanding of mechanism of TdP.
- Uses human ion channels and nearly human cardiac myocytes.
- Uses high-throughput techniques to narrow estimates of free parameters.
- Prediction based on assumption-free reconstruction.

- Universal

- These same principles...
  - Mechanism-based
  - Human machinery
  - High-throughput assays
- ...ought to be applicable to other forms of
  - Cardiotoxicity
  - Other organ toxicities

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- Soon

- Fruit of a collaboration among academics, industry, and regulators.
- Shared resource for
  - data analysis,
  - interpretation, and
  - learning.
- Benefit to drug developers and public health

- Not soon

- Lower potential energy barrier to future collaborations.
- Data sharing in other problem areas related to drug development.
- Redefining the proprietary/public boundary