

# ARRHYTHMIAS RELATED TO QT INTERVAL CHANGES: TRANSLATIONAL VIEW

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## Disclosure

- ◆ Dr. Kowey has or is currently consulting with several pharmaceutical companies on an ad hoc basis.
- ◆ He holds no equity interest in any pharmaceutical firm.

# What's Broken

1. QT measurement is a poor surrogate
2. TQT studies have hit a wall
3. TQT has become an industry
4. Regulators increasingly scrutinizing imperfect studies

# What's Needed Now

1. Validate pre-clinical models
2. Integrate pre-clinical and clinical assessments
3. Streamline TQT
  - Automate
  - Omit positive comparator
  - Accept innovative designs (like PK/PD)

## What's Needed Long-Term

1. Carefully planned and executed post-marketing studies predicated on solid pre-clinical and clinical data.
2. Better surveillance for events of interest by an educated physician public.
3. Acknowledgment by leaders that “stuff happens” and that post-marketing discovery of a cardiac safety issue is a victory and not a failure.