# Use of Cardiovascular End Point Document in Cardiovascular and Non-Cardiovascular Trials: *Regulatory Perspective*

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# No disclosures

# The opinions expressed here are my own

# Cardiovascular Data Standards

# Summary

- The CV End Point Document can be used in both CV and Non-CV Trials
  - There are basic criteria that need to be satisfied to define particular end point events for both types of trials
  - These basic criteria will facilitate the conduct of meta-analyses for safety and effectiveness (within and across development programs)
  - Level of detail collected between CV and Non-CV Trials will be different (e.g., MI types)
- Source Documents remain a key part of the FDA Review process

# Thank you