

# What are the potential uses for RWD in supplementation of clinical trials

- Yes
  - Patient Identification
  - Patient Recruitment
  - Patient Consent
  - Post Marketing Safety Assessment (MI, CVA, Procedures?)
    - HR is dependent on data sources used
- No
  - Non-inferiority safety studies
- Maybe
  - Everything Else

# What are the required characteristics for use of RWD?

- Exposure (people, duration)
  - What RWE is best
  - What are the source of bias
  - How is sensitivity of conclusions communicated
- Type of Events
  - Hard vs. soft
  - Regional differences
  - Payment differences
- Confounders
  - Known
  - Emergent
  - Unknown
- All
  - Selection,
  - information bias
  - Access to care
  - Payment policies
  - misclassification

# Remaining issues

- What are criteria for suggesting databases?
- Do they have to reproduce findings of RCT?
- How are empirical sources of bias evaluated?
  - How often does this have to be repeated?
  - How do you do quantitative bias testing?
  - What are the characteristics we should use?
- How do we define CV outcomes by database?

# Next Steps

- Using multiple data approaches together can add significant value
- There are many issues and likely how to best do this requires an iterative approach
- Create a working group to develop a multi-approach study strategy
  - Identify challenges and “solutions”