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”