Prospective Registry Design: CDER Perspective

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Registries: What are they good for?

- Complementary source of data
  - Routine clinical practice
  - Broad patient population
- Large exposure
- Important endpoints
- Can inform about quality of care
How does CDER use Registries?

• Examine associations between drug exposure and adverse outcomes
• Monitor for identified drug risks or safety signals
• Identify potential risk factors
TREAT registry data and drug labeling

• Limitations
  – Non-randomized=potential for bias
    • Unsure this can be mitigated with statistical analysis
  – Non-comprehensive patient enrollment
  – Uncontrolled design limits ability to make inferences antithrombotic therapy and bleeding risk

• Descriptive>>comparative
TREAT registry design

• Be clear on the question
• Prospective plan for analysis
• Consider hybrid designs
• Be realistic about possible label language