



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