Safety Assessments in Medical Device Studies

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Safety Data Sources

- IDE clinical studies
- Other clinical studies
  - Registries
  - OUS studies
- Post-market monitoring
- Non-clinical data
  - Computational modeling
  - Animal and bench testing

Device trials are unique

- Trials tend to be smaller than drug trials
- Some novel, many “me-too”
- Many not blinded or randomized
- Many are not controlled
- Adaptive designs increasingly common
- Endpoints highly diverse
- Typically, single pivotal trial follows feasibility stage(s)
- Designed to support a “reasonable assurance of safety and effectiveness” for the marketing application

Striking the Right Balance Between Pre- and Postmarket Evaluation

- Use appropriate amount of pre-market data to make primary decisions about approvability of new devices (safety, effectiveness)
- Use postmarket data to
  - Improve precision around low-rate safety events
  - Identify device malfunctions and take corrective action as necessary
  - Modify pre-market expectations for next generation devices.

Other tools for gathering safety data

- Continued access studies during review of the marketing application
- Registry data to compliment trials
- OUS study data
  - Particularly if well planned and executed
  - FDA does not regulate but is willing to discuss prior to initiation