SAFARI and the FUTURE

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Potential Utility for FDA

Pre-market

- Can be used to inform FDA evaluations of pre-market data
  - As registries refine patient selection, improve clinical management, guide improvements in procedures/technology/therapy
- Potentially used to expedite time-to-market
  - Based on reliable post-market data
  - Based on broader range of users/patients
- Potentially useful as historical control data
- Potential development tool for performance goal or eventual OPC

Potential Utility for FDA

Pre-market

- Used as a basis for initiating IDEs (hypothesis generation)
- Use as a potential source population for randomizing to interventions

Potential Utility for FDA

Post-market

- Fills data/knowledge gap in FDA's mission to continue to assure safety and effectiveness of marketed medical devices
  - Short-term (alone and predictive of long-term)
  - Learning curve/training/procedural issues
- Potential linkage to other data sources (e.g., 3rd party payer; VHA, DoD) for longer-term assessments
- Potential for active surveillance of exposures and well-defined outcomes of interest (e.g., MI, stroke)
  - FDA's Sentinel Initiative exploring methodologies

Sentinel Initiative*

- An effort to develop a national, integrated infrastructure of electronic healthcare data systems for medical product safety surveillance
  - Will augment, not replace, existing functionality
- Putting observational data to use, from active surveillance to more formal comparative safety studies
- The proposed model is based on distributed data systems (i.e., the data sources remain at remote locations and are maintained by owners)
  - Convey query results according to strict privacy and security safeguards
  - Device registries, however, offer a common data model within a centralized data system
- A broad national public forum to discuss multitude of issues
- Efforts to be implemented through public-private partnerships

*http://www.fda.gov/oc/initiatives/advance/sentinel

Potential Utility for FDA

Post-market

- Useful as vehicle to fulfill post-approval study requirements in more robust and efficient way (for all parties involved)
  - May contribute to financial sustainability
- Useful as a vehicle for FDA discretionary studies