Registries and Opportunities for the Total Product Life Cycle

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AHWP Annual Meeting 2015, Bangkok

Acknowledgements and Disclaimer

- Acknowledgements:
  - Janet Trunzo, Senior Vice President, Technology and Regulatory, AdvaMed
  - IMDRF Registries Working Group (Report to Management Committee, September 2015)

- Disclaimer
  - Errors are attributable to the author
  - All opinions are those of the author

Todays agenda

- Global interest in registries
- AdvaMed principles of registries

IMDRF Registries Working Group Scope

- Evaluate, compare & contrast current approaches to international data models in different device areas: – Orthopedics – Cardiac – Vascular •
- Generate essential principles document(s) for international collaboration & data sharing
- Complete proposal in two stages:
  - Essential principles of data linkage for regulatory convergence
  - Essential principles of analytic methodologies for device evaluation

IMDRF Registries Working Group

- Report posted:
  - Integrating Device Registries and Innovative Tools for Enhanced Medical Device Evaluation and Tracking : An Update to the IMDRF Management Committee September 2015
- Mirror organizations
  - EU Regulators
  - MDEpiNet

Recommendations for a National Medical Device Evaluation System

Strategically Coordinated Registry Networks to Bridge Clinical Care and Research

Report

- Recommendations for a National Medical Device Evaluation System
  - Strategically Coordinated Registry Networks to Bridge Clinical Care and Research
    - A Report from the Medical Device Registry Task Force & the Medical Devices Epidemiological Network

Key Elements of Registry Principles

- Definition
- Objectives for a registry
- Threshold questions
- Data Governance Committee
- Well-balanced registry design
- Registry data use
- Policies for use and publication of data by stakeholders

Definition of a Registry

"..an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more pre-determined scientific, clinical, or policy purposes."*

* Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHSA290200500351 TO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.

Objectives for a Registry

- Improve patient care and outcomes
- Improve patient access to new therapies
- Evaluate "real-world" safety and/or effectiveness of products
- Meet regulatory requirements for post-market surveillance

Threshold Questions

- Is registry the least-burdensome means to collect the necessary data to achieve the scientific objectives?
- Do objectives warrant the level of investment required to develop and maintain a registry?
- Are there reliable data collection instruments available to collect the data?
- Will the registry have a stable and diverse source of funding to promote long-term sustainability?

Data Governance Committee

- Representation by all stakeholders
- Rules governing review and access to data should be established:
  - Review and acceptance process for data requests and data analysis plans.
  - Controlled process for data access/data release
  - Guidelines for data transparency.
  - Process for device safety data reporting, including how information is shared with the manufacturer.

Well-balanced Registry Design

- Research purpose—hypothesis-based designs
- Collection of information—definitions for success and failure
- Appropriate quality plan for monitoring, auditing, validation
- Collection of sufficient data to allow risk adjustments
- Defined process for considering changes after initiation of registry

Registry Data Use

- Data shared upon request by qualified scientific/medical researchers for purposes benefiting public health or patient care.
- System to manage process for reviewing requests
- Policies for use and publication of registry data
- Policies to protect against unauthorized use of data

Policies for use and publication

- Industry financial support
  - Company access to its own data and aggregate data
- Safety signals identified
  - Reported to company for further investigation
- Regulatory bodies seek input from company before taking regulatory action based on registry data

AdvaMed Registry Principles

- Developed by several AdvaMed working groups
- AdvaMed Board approved in December 2013
- Presented to FDA on January 2014
- Publicly announced in early February 2014
- Presented at IMDRF in March 2014
- Use with other interested stakeholders as needed

Conclusion

- There is a growing interest in registries worldwide
- Registries can serve an important role in providing information about medical devices
- Certain principles should be considered as registries are established