Global Medical Technology Alliance
Innovating for a Healthier World

Registry Principles

GMTA

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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/publication of data

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.) AHRP 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 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 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

- Safety signals identified
  - Reported to company for further investigation and validation

- Regulatory bodies seek input from company before taking regulatory action based on registry data