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.”*

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