



Registry Use in Regulatory Decision Making for Obesity Devices

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Why registries?

- Sentinel Initiative (2008)- FDAAA
- National Evaluation System for Health Technology (NEST) – CDRH Strategic Priority
- USHHS 2015 Health Information Technology Certification

Physicians/Societies

- ASMBBS and ACS – MBSAQIP
- Accreditation
- Quality Improvement programs
- Support education on obesity care
- Creation of evidence-based practice guidelines

Regulatory Decision Making

- Reasonable assurance of safety and effectiveness (RASE)
- Randomized Control Trials
 - Challenges with RCT – Excessive Complexity, Cost, Time, Inadequate representation
 - Limited long-term data
 - Limited number of subjects

Lauer, Michael S., and Ralph B. D'Agostino Sr. "The randomized registry trial--the next disruptive technology in clinical research?." The New England journal of medicine 369.17 (2013): 1579.

Steps To Registry Success

- Uniform Case Report Forms (CRFs)
- Standardize and Adjudicate outcomes
- Ensure High quality data – addressing missing data fields
- Addressing informed consent issues
- Develop incentives for sustainability

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Benefits of Registry Data

- Utilization of global case report forms (CRFs)
 - Core data elements
 - Benefits pre- and post-market assessment
 - Lowers reviewer regulatory burden
- Standardized controls with Objective performance goals
- Improved comparison of effectiveness

Benefits of a Registry

- Long-term data capture
- Using registry infrastructure to nest IDE studies
- Broadly contribute to education/learning about obesity and obesity devices

Benefits to Industry

- Reduction in time and cost of premarket approval
- Reduction in PAS enrollment
- Improvement in new or iterative device development
- Expansion of device indications
- Labeling updates
- Coverage and reimbursement decisions

Conclusion

- Registries are here to stay
- Building blocks are being assembled
- Precedents have been set
- Multi-stakeholder collaboration – essential



THANK YOU

Challenges to Decision Making

- No Consensus on effectiveness
 - Clinically meaningful weight loss
 - Durability/Maintenance
- Assessment of safety
- No standardized control
- Delayed, incomplete, or cancelled PAS
 - Lack of data --- incomplete B-R analysis