Coordinated Registry Networks -*based Clinical Trial Options*

An Industry Perspective

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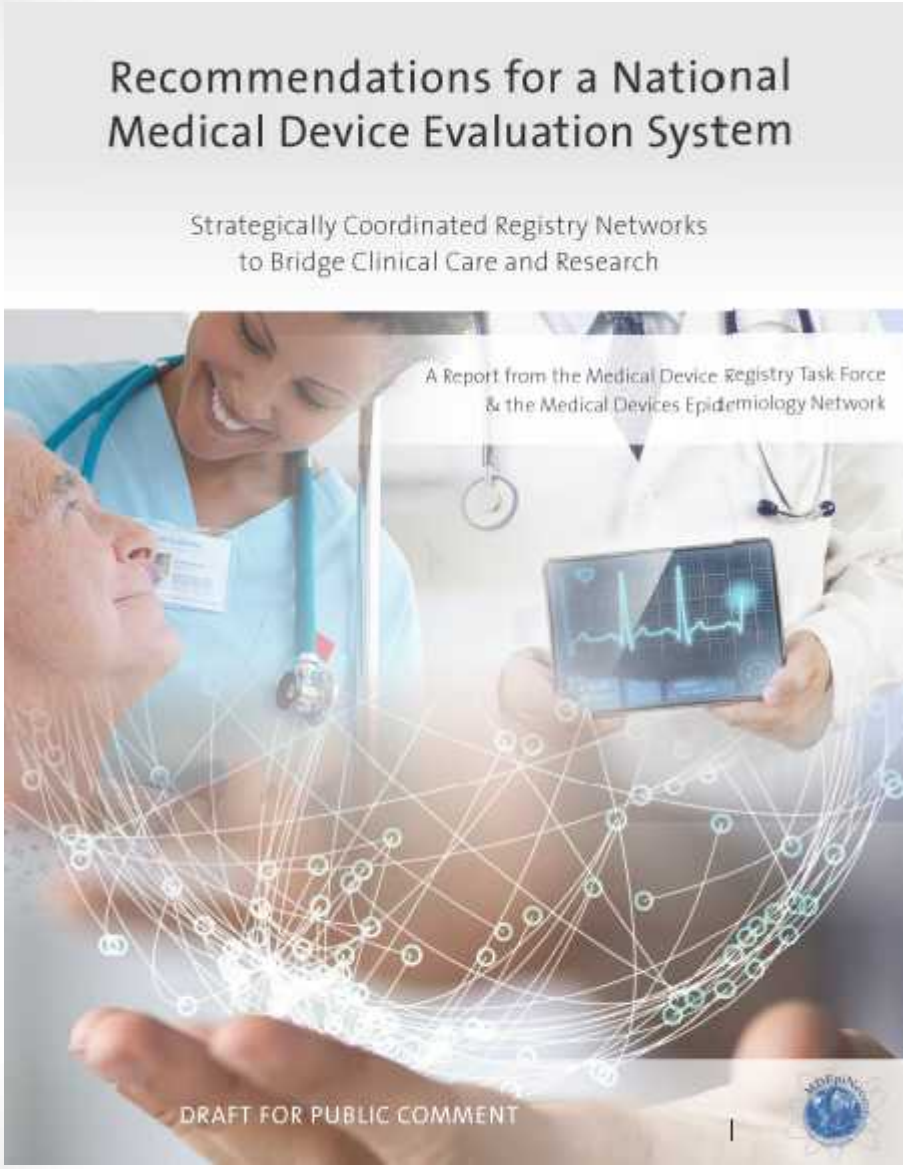


A National System Built on Flexible, Strategically Coordinated Registry Networks (CRNs)

- Connecting "complementary" existing registries and electronic non-registry data sources (e.g. EHR, administrative data) each correcting the deficiencies of the other (device identifiers, operator proficiency, outcomes ascertainment, duration of follow up)
- Broad range of interoperability solutions for systems flexibility customized to device specific CRN objectives (e.g. benefit/risk, safety surveillance) and available existing resource, if any (eg. existing registries, EHR data fields, standardized definitions)
- Evolution of a National System based on systems flexibility able to continuously adapt to both rapid changes in electronic modalities of health care data collection and the rapid pace of medical device innovation (eg. a learning National System)

Coordinated Registry Networks

Industry Desired Objectives

- Alignment from key stakeholders in clinical data collection
  - *Societies Regulators, CMS, Industry*
- Multi-physician /specialty involvement
- Structured system that standardizes data elements
  - *Safety, Efficacy, Cost Effectiveness*
- Provides interoperable data
- Provides data elements by device identification
- Provides a more efficient evaluation system
  - *Rapid data evaluation*
  - *Cost efficient*
- System and process adaptability for emerging technologies

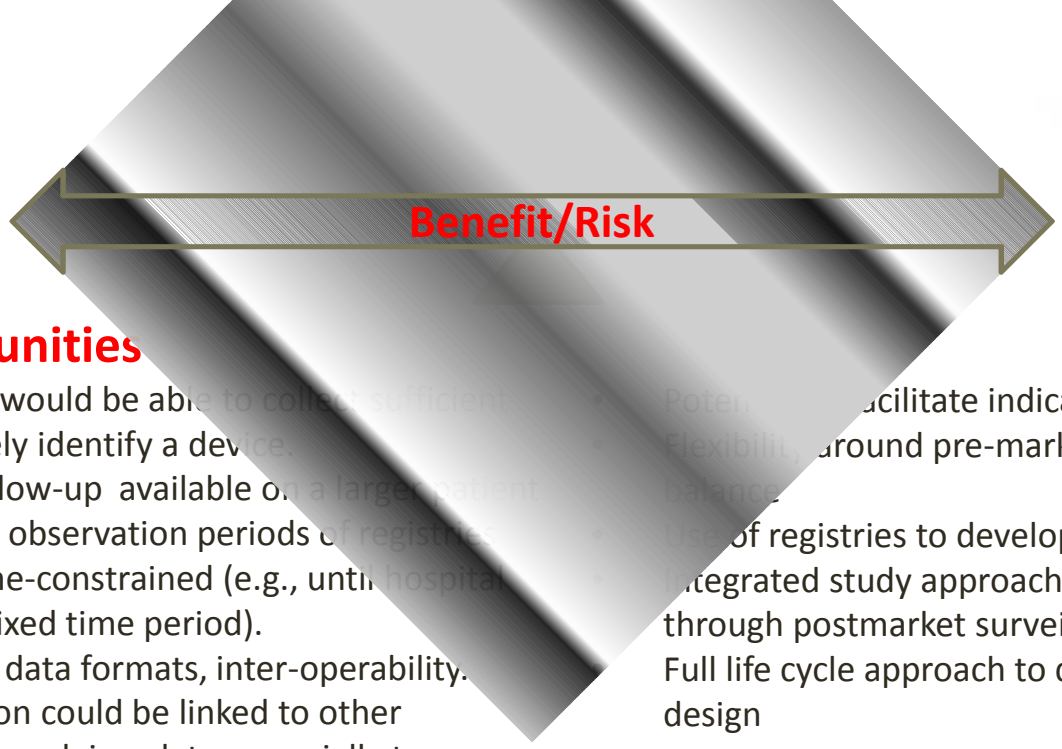
Device Registry Landscape

Societies

- **STS-ACC TVT Registry**
  - The TVT registry captures clinical data on transcatheter aortic valve procedures conducted in non-federal hospitals. The registry was created to comply with Centers for Medicare & Medicaid Services (CMS) coverage and payment criteria for Medicare patients undergoing commercial transcatheter valve procedures
- **ACC National Cardiovascular Data Registry (NCDR)**
  - Cardiac catheterization and percutaneous coronary interventions (CathPCI Registry)
  - Implantable cardioverter-defibrillator procedures (ICD Registry),
  - Congenital heart disease catheterization procedures (IMPACT registry)
  - Carotid artery and peripheral vascular interventions (PVI registry)
  - Acute myocardial infarction (ACTION-GWTG registry)
  - Transcatheter aortic valve replacement implants (STS/ACC TVT Registry)
  - Ambulatory care (PINNACLE).

Government

- **CART Program**
  - VA cardiac catheterization laboratories, the CART system software includes data fields to capture any unexpected problems with medical devices used during the procedure.



CRN Opportunities

- A network that would be able to collect sufficient detail to uniquely identify a device.
- Longer term follow-up available on a larger patient population- the observation periods of registries are typically time-constrained (e.g., until hospital discharge or a fixed time period).
- Heterogeneous data formats, inter-operability. Device evaluation could be linked to other registries, EHRs or claims data, especially to accomplish long-term tracking.
- Increased stakeholder value perception and of a calculable return on investment- compelling incentives to accrue knowledge about the safety, benefit and risk profiles of medical devices .
- Consistent data quality.
- Multiple key stakeholder efficiencies (time and cost)- seamless data capture integrated into the workflow with electronic data interchange into the registry, making data contribution less expensive and less time-consuming
- Increased rigor and data collection on health care economics- real cost-benefit and comparative effectiveness data.
- Poten[illegible]cilitate indication expansion
- Flexibili[illegible]round pre-market vs. post-market balance
- Use of registries to develop OPC
- Integrated study approach from pivotal IDE through postmarket surveillance
- Full life cycle approach to drive iterative device design

CRN Points for Consideration

- Stakeholder alignment and involvement
  - Industry representation from diverse companies
  - Pre-specified data analysis, data access and dissemination
  - Use data to identify safety signals and determine if device iteration mitigated risk – unsure if the registry data will be sufficient to make these determinations. Clearer understanding of stakeholders involvement and industries role in the investigations.
- Staged approach (pilot to full program implementation)

Summary Points

- Multiple key stakeholders are conducting registries and all have deficiencies for medical device evaluation
- Linking data through CRNs can support correction of such deficiencies
- A culture of pre-competitive collaboration, good will and trust is necessary, therefore multiple stakeholders *MUST* be involved in the implementation of a medical device evaluation system
- Alignment and approval must be gained from all key stakeholders on data analysis and utilization (Societies, Clinical Community, Regulators, CMS, Industry)