# FDA Postmarket Endeavors

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# CDRH Postmarket Tools

- Reporting of Adverse Events & Product Problems
  - Medical Device Reporting
  - Medical Product Surveillance Network
- Post-Approval Studies
- Postmarket Surveillance
  - Section 522 of the Federal F, D & C Act
- CDRH Epidemiologic Research Program
- FDA Sentinel Initiative

# FDA - Mandated Postmarket Device Studies

- 162 ongoing device PAS studies
- 4 ongoing device PS studies
- Potential role of national registries and large administrative databases as infrastructure to fulfill postmarket commitments

# CDRH Epidemiologic Research

- Robust, FDA – funded, epidemiologic research program
  - Task-order contract with ACC
  - Task-order Contract with STS
  - Contract with Kaiser Permanente
  - IAA with AHRQ

# CDRH Registry Efforts

- National registry data for surveillance
  - INTERMACS Registry
  - ICD lead safety: ACC National Cardiovascular Data Registry (NCDR)
- Linking registry data with claims data
  - STS National Adult Cardiac Surgery Database (TMR )
  - ACC NCDR /AHRQ (DES, heart valves)
- Evolving efforts to use registries to fulfill postmarket commitments

# Interagency Registry for Mechanically-Assisted Circulatory Support (INTERMACS)*

- Joint effort of the NHLBI, CMS, FDA, clinicians, scientists and industry in conjunction with the UAB and UNOS.
- Devices used for destination therapy, bridge to transplant, bridge to recovery
- National registry of clinical & laboratory data from 2K patients annually over 5 years
- Among goals are refine patient selection, improve clinical management, guide improvements in technology
- Provides FDA with “all” reports of adverse events & provides national infrastructure for post-approval studies

**www.intermacs.org*

# ACC National Cardiovascular Data Registries (NCDR)*

- Collaborated with FDA to address safety issue: hemostasis device bleeding complications
- At FDA's request, enhanced national ICD registry to begin collecting data on lead safety
- Collaborating in development of other registries
  - Ablation for atrial fibrillation

*****www.ncdr.com*

# Society of Thoracic Surgeons (STS)* National Database

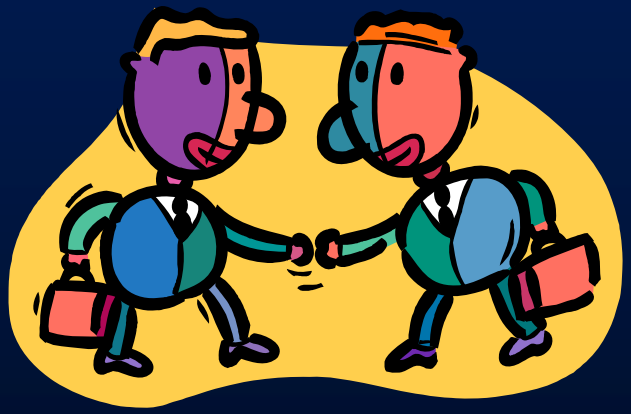
- Ongoing task-order contract with FDA
- Study mortality and morbidity associated with the two approved TMR systems (2000-2007 STS data)
- Linking to CMS data for long-term follow-up
- Univariate and multivariate analysis controlling for co-morbidities

* *www.STS.org*

# Lessons Learned

- Leveraging and establishing partnerships with registries augments both regulatory science and surveillance efforts
- It is never too early to start thinking about collaboration
- Cultivate partnerships

# Thank you!



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