MAYO CLINIC

Evaluation & Utilization of Novel Transcatheter Valve Technologies in the U.S. and Abroad

David R. Holmes, Jr., M.D.

Mayo Clinic, Rochester

ACC Evolving Valve Management Strategies Roundtable
Washington, DC
December 2015

Presenter Disclosure Information

David R. Holmes, Jr., M.D.

"Evaluation & Utilization of Novel Transcatheter Valve Technologies in the U.S. and Abroad"

The following relationships exist related to this presentation:

None

MAYO CLINIC

Background

- 2004
  - 87% of clinical studies for medical technology products listed in clinicaltrials.gov were conducted in U.S.
- 2009
  - 45% of clinical studies for medical technology products listed in clinicaltrials.gov were conducted in U.S.

MAYO CLINIC

TAVR

- TAVR
  - 2002 – 1st human case
  - 2007 – CE MARK approval
  - 2011 – U.S. approval
- Mitra-Clip
  - 2003 – 1st human case
  - 2007 – CE MARK approval
  - 2013 – U.S. approval

MAYO CLINIC

Barriers to Innovating in the U.S.

- **Insufficient predictability** of what information is needed to allow for the initiation of clinical studies
  - Data requirements can be difficult to identify
    - Increasingly complex devices
    - No established guidance or standards for innovative devices
    - No generally accepted method for justifying data requirements
- **Ineffective communication** between CDRH and industry
- **Poor-quality submissions** that do not include or coherently describe relevant information

MAYO CLINIC

MAYO CLINIC

Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies

Andrew Farb, MD and Dorothy Abel, BSBME

Andrew Farb, MD and Dorothy Abel, BSBME
Office of Device Evaluation
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Goals

- Improved access to beneficial devices is a shared interest of all participants in the clinical studies ecosystem

MAYO CLINIC

Stakeholders

- Patients
- Investigators
- Sponsors
- FDA
- IRB
- Sites
- Payers
- Funders

MAYO CLINIC

IRB Protocols

- Agreement to treat EFS differently and efficiently
- Rapid turnaround ? 30 days
- Development of a common template for consent
- ?consideration of central IRB

MAYO CLINIC

Site Consideration

- Culture of clinical study quality and commitment
- Well developed infrastructure
- Track record – research subject monitoring, quality, excellence
- Commitment from IRB to develop protocols in a timely efficient manner
  - ? central IRB
- Commitment to constrain costs
- Access to study participants

MAYO CLINIC


MAYO
CLINIC