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

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Presenter Disclosure Information

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The following relationships exist related to this presentation:

None
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.
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
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 CDRRH and industry

- **Poor-quality submissions** that do not include or coherently describe relevant information
Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies

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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
Stakeholders

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

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