AAMI Risk Management Summit
Post-market Benefit-Risk Assessments

Terminology Matters

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Medical Devices Are Critical to Our Nation’s Health...

- Total Knee Replacement: 676,000
- Total Hip Replacement: 327,000
- Insertion of Coronary Artery Stents: 528,000
- Cardiac Catheterizations: 1.1 million
- Arteriography & Angiocardiography: 1.9 million
- Diagnostic Ultrasound: 902,000
- CAT Scans: 497,000

Total Domestic Inpatient Procedures: 48.0 million

CDRH Vision

• Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

• The U.S. is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

• U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.

• Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

• Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.
CDRH 2014-2015 Strategic Priorities

Strengthen the Clinical Trial Enterprise in the US

Strike the Right Balance Between Premarket and Postmarket Data Collection

Provide Excellent Customer Service
Strengthen the Clinical Trial Enterprise

CDRH FY 2015 Target:
Reduce overall median time to full appropriate IDE approval to 30 days
To Achieve These Goals

• The ability to accurately assess Risks and weigh Benefits/Risks in Pre-Market and Post-Market regulatory situations will be key.

• Broad input from stakeholders will be helpful in optimizing benefit/risk assessments.

• Communication of FDA approaches will help harmonize expectations of CDRH and industry and minimize risk to the public when safety concerns arise.
Risk and Benefit/Risk
Pre-Market Initiatives

• Clinical Trials
• Innovation for Novel Devices
• Expedited Access Program (EAP)
• Benefit / Risk Decision Making
  - PMA
  - De Novo
  - IDE
  - 510(k)
• Balancing Pre-Post Market Data Collection
Risk and Benefit/Risk
Post-Market Initiatives

• National System for Medical Device
  Postmarket Surveillance
• Medical Device Registry Task Force
• Signal Management Process
Why Does Terminology Matter?

• Enhances our chance of reaching similar conclusion

• Fosters development of a Common Framework
Premarket Benefit Risk

- Discussed in 2012 Premarket Benefit Risk guidance*
- CDRH goal is to leverage premarket BR
- Bring that to the post-market space

Pre-market to Post-market

- Harmonize terminology
- Employ TPLC approach
- Improve likelihood of reaching similar conclusions
- When different, help focus conversations to resolve those differences
Issues for Consideration

• Benefit
  – “a helpful or good effect, or something intended to help”

• Risk

• Goal of Post-market BR assessments
  – “to minimize problems in the market”
What Can We do?

- Develop a Common Framework
- Leverage Pre-market BR as appropriate
- Develop Post-market BR factors
Examples
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