Using Registries for TPLC Evidence Appraisal of Medical Devices: An Industry Perspective

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CDRH Workshop:
Leveraging Registries with Medical Device Data for Postmarket Surveillance and Evidence Appraisal throughout the TPLC

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Linear versus Integrated Approach

Design → Preclinical Studies → Pivotal Clinical Study → FDA Approval

Post-approval Studies → MDRs → 522 Studies

FDA Discretionary Studies

Other Surveillance Activities

Registries
Linear versus Integrated Approach

Design → Preclinical Studies → Pivotal Clinical Study → FDA Approval → Post-approval Studies

- MDRs
- 522 Studies
- FDA Discretionary Studies
- Other Surveillance Activities

Registries
A World of Possibilities

- Registry data can be used to:
  - Form the infrastructure to conduct PAS
  - Support expanded indications of marketed devices
  - Support premarket clearance or approval of modified devices
  - Support reclassification petitions
  - Design more clinically relevant preapproval clinical trials
That said...

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Things to Consider

• Balance real-world registry data and subsequent preapproval efficiencies with regulatory compliance
  • Off-label use
  • PAS protocol deviations
  • PAS study reporting requirements
  • MDR
Things to Consider (Continued)

• Registry scope
  • Relationship to company-sponsored PAS
  • How current and future PAS will be integrated into device registries
  • Links to other registries – domestic and/or international
  • Device scope, e.g., one model or combine models into one registry

• Development and implementation
  • Best strategies to incentivize physicians and patients to participate
  • Depth of data collection for a newly created registries, e.g., phased approach or immediately comprehensive
Things to Consider (Continued)

• Sustainable business model
  • Funding
  • Data access
  • Data analysis and reporting
  • Sponsor-specific requirements
    • Data analyses
    • Maintaining regulatory compliance, e.g., sponsor AE or MDR reporting
  • Ensure patient privacy
  • Ensure physician confidentiality
  • Ensure confidentiality of manufacturer-specific data
Summary

• Many possibilities to more fully exploit the potential of registries
• Registries can play a larger role in TPLC, leading to a more efficient preapproval process
• Collaboration with FDA and other stakeholders is key
• Strategize wisely and skillfully plan implementation
• Think big, dream big, do big!
Thank you!