Real-World Evidence: A CDRH Perspective

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Patients are at the Heart of What We Do

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.
We face a critical public health challenge

The U.S. regulatory standard for market approval protects patients by setting a high public health bar but imposes costs that make the U.S. marketplace less attractive for innovators thereby delaying patient access to important technologies.

The solution is to reduce the time and cost of the total product life cycle...

device development, assessment, review, manufacturing, monitoring, and reimbursement – without compromising the reasonable assurance of safety and effectiveness standard.
Learning Medical Device Ecosystem

Total Product Life Cycle (TPLC) Framework

INFORMATION FLOW

Premarket Review

Premarket Decision

Postmarket Surveillance

TIME TO MARKET
Learning Medical Device Ecosystem

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Expedited Access Pathway

Premarket Review

Benefit - Risk

Premarket Decision

Postmarket Surveillance

TIME TO MARKET
Leverage RWE to support regulatory decisions

Active Surveillance – better protects pts

Shared system to inform the entire ecosystem – pts, clinicians, providers, payers, FDA, industry

Embedded in Health Care System – data collected during routine care
What are the Opportunities - Clinical Evidence Along the TPLC

**Flexibility**
- “Can’t always get what you want....”
- But if we are flexible, we can “get what we need”

**Innovation**
- Real World Evidence – significant human experience with a marketed device
- Clinical research incorporated into clinical practice and workflow

**Collaborations**
- NEST
- Industry groups
- Patient and clinician groups
Innovation – Evidence Gathering

**RWD Sources**
- EHR’s, Claims, Registries, Administrative Data, Patients, Mobile Devices

**Trial Data**
- Control Group
- Device Group

**Post Approval Study Data**
- PAS Device

**Real World Experience Data**
- Device Group

Image courtesy of Dr. Laschinger.
Good Decisions Require High Quality RWE

‘Fit for Purpose’

Factors that improve data quality - completeness, consistency, accurate, and contain all critical data elements needed to evaluate a medical device and its claims

Relevant & Reliable

Benefit

Risk
Collaborations – CDRH Priorities to Support RWE NEST

- Award grant to MDIC to support NEST development and implementation (3 M in 2016)
- MDUFA IV User Fee Agreement—Pilot projects funded to determine the usability of RWE for Expanded IFU, New clearances/approvals, improved device malfunction reporting
- Issue Draft Guidance to clarify how RWE may be used to support regulatory decisions (issued 7/27/16)
- Increase access to and use of RWE to support regulatory decisions
- Work with the Medical Device Ecosystem, e.g.; federal partners, health care system, manufacturers, payers and patients to build NEST
The Value Proposition for NEST

**Patients/Clinicians**
- More timely access to safer, more effective devices
- Better information about the use of a given device in practice

**Hospitals, Health Systems**
- Improved quality
- Reliable assurances of safety
- Possibly, reduced reporting requirements

**Payers**
- Access to high-quality evidence on device performance in clinical practice

**Medical Device Industry**
- High-quality evidence at lower cost, in less time, to support premarket approval/clearance, payer coverage
- Meet or reduce the need for postmarket study and adverse event reporting requirements
- Potential for premarket-postmarket shift owing to strong assurances that postmarket RWE would be generated
- May obviate the need for FDA premarket review of some device modifications because more timely and informative routine data collection
Some Regulatory Uses for RWE

- Control arm for pivotal clinical study
- New indications for approved devices
- Studying new improvements to devices
- Replacing “formal” post approval study – Links other RWD sources
- Adverse event reporting – automated fashion
- Shifts to pre-postmarket balance
Some Non-Regulatory Uses for RWE

- Informing the community on optimal care
- Identifying needs and gaps
- Market analysis
- Assessing quality of care
Registry Assessment of Peripheral Interventional Devices
Infrainguinal Arterial Occlusive Disease

Treatment Heterogeneity

Patient Conditions

Specialty, Training, Experience

Disease Location

Disease Severity

Treatment Options

Device Heterogeneity

Angioplasty Balloons

Stents

Other Devices Used for PAD

Total Occlusion Crossing Devices

Atherect. Devices

Other Devices Used for PAD
Transcatheter Heart Valves
Use of Registry Data for Post Market Surveillance and Label Expansion
“It is probably true that one of the commonest features of new ideas – certainly of practical new ideas – is their imperfection”

A.J. Youngson
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A.J. Youngson
Potential Benefits of a National Evaluation System for Medical Devices

- Better Leverage Real World Data
- More Efficient & Timely Postmarket Data Collection
- Help Strike the Right Premarket – Postmarket Balance
- Contribute to Premarket Indication Expansion
- Reduce Other Regulatory Burdens
- Meet Other Stakeholder Needs
Quality Systems Approach to RWE

Support NEST - Process

- Engage in broad collaboration and discussion
- MDUFA IV

Work with Stakeholders - People

- CDRH RWE “tactical team”
- Consider new and flexible approaches

Develop and clarify Policies

- RWE guidance – draft to final
- Outreach pre-submission meetings with FDA