

RAPID

**National Evaluation System for
health Technology (NEST)**

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Patients are at the Heart of What We Do

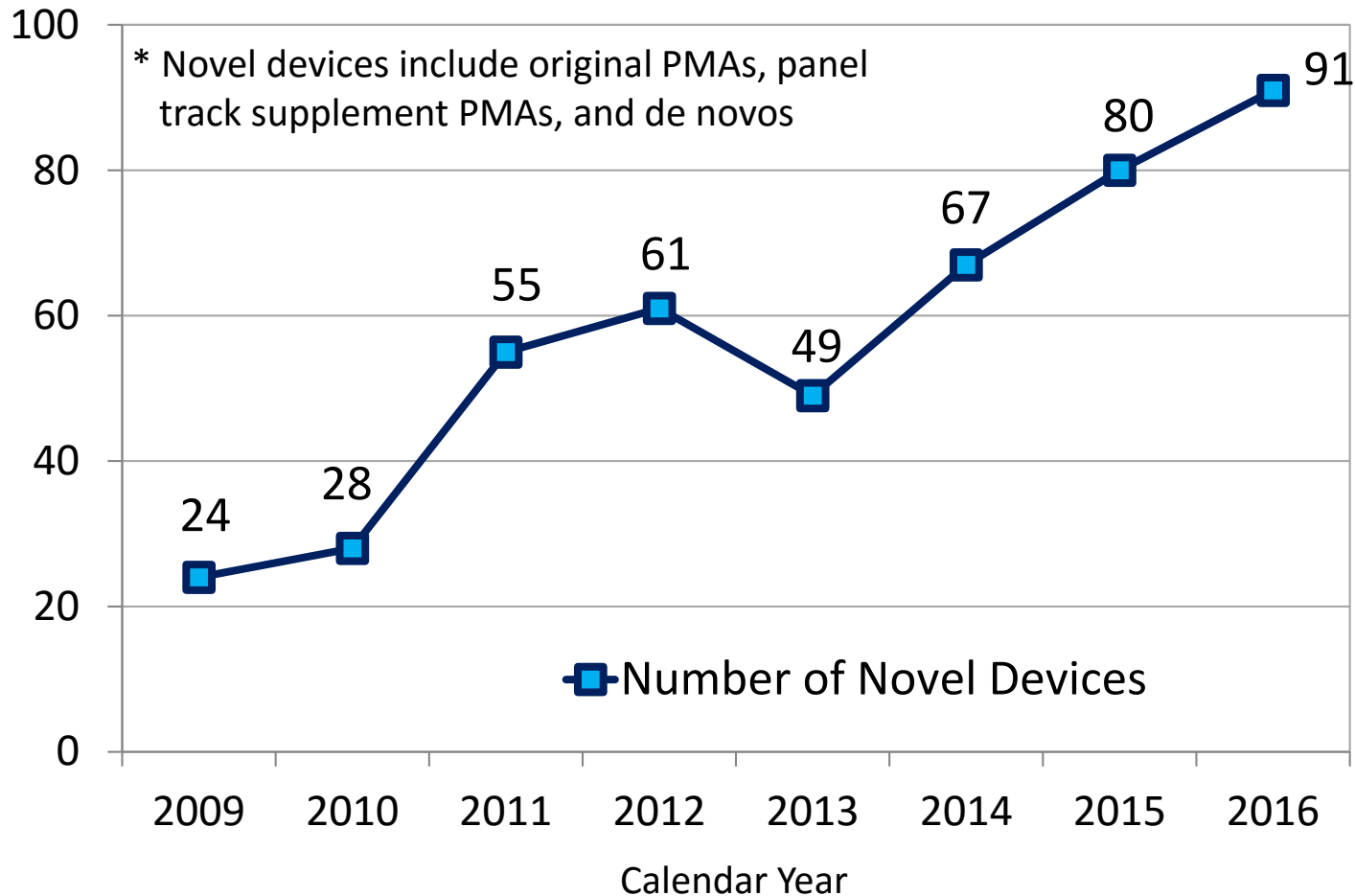


CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Novel Device Approvals



>3-fold Increase in # of Novel Device Approvals



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

The FDA logo is a blue square with the white letters "FDA" inside. It is positioned in the top right corner of the slide.

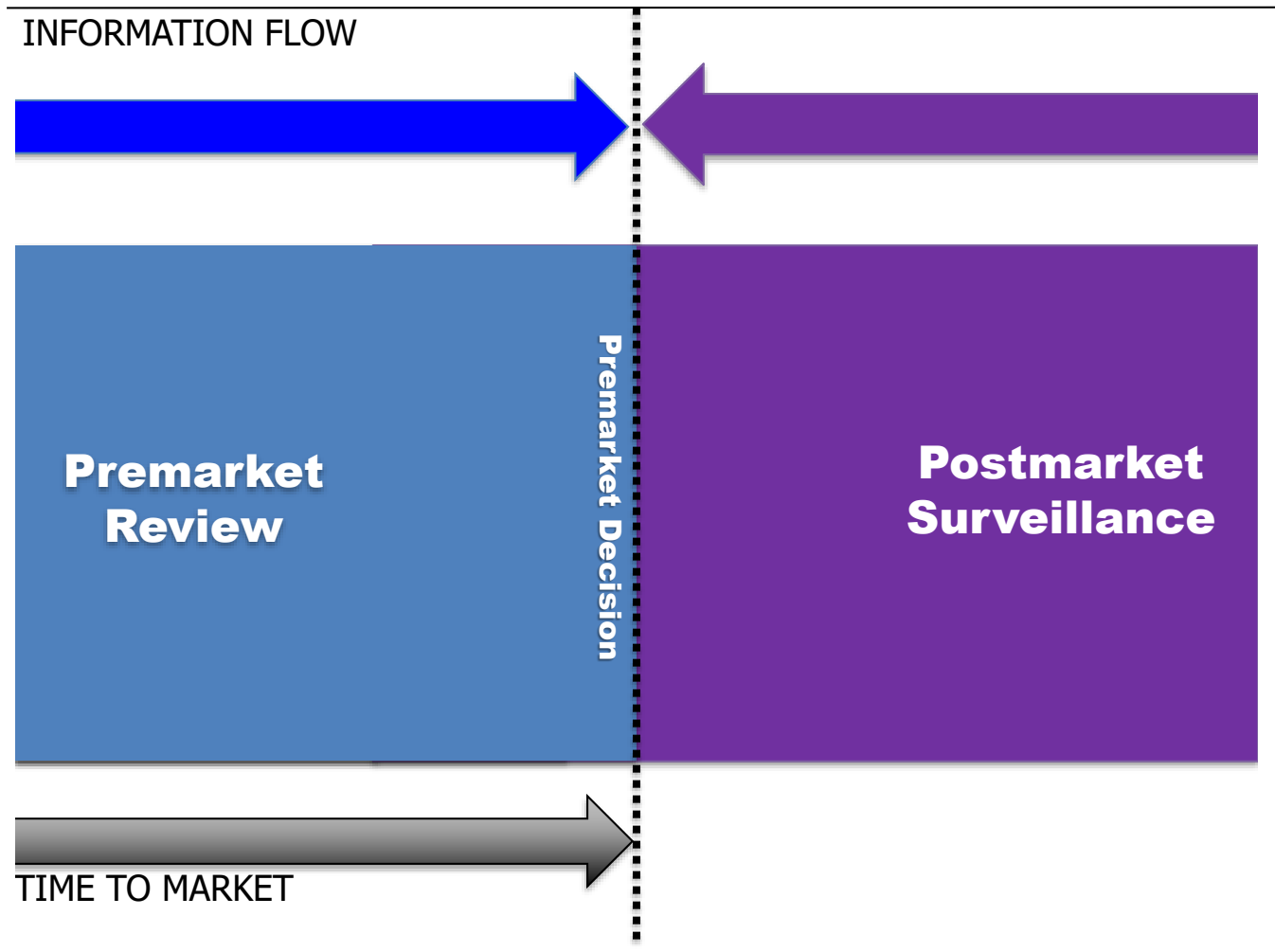
Vision

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

Learning Medical Device Ecosystem

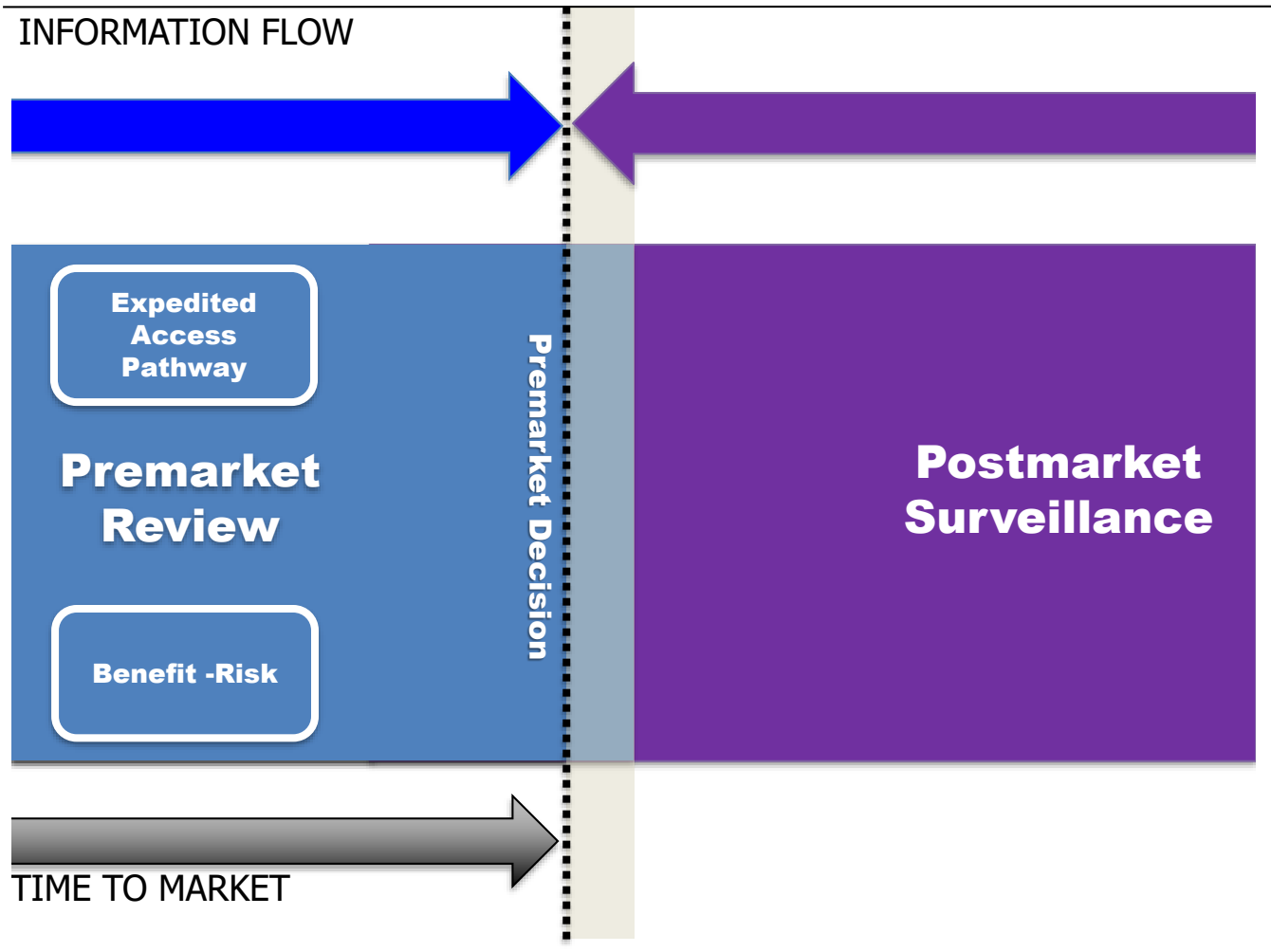


Total Product Life Cycle (TPLC) Framework



Learning Medical Device Ecosystem

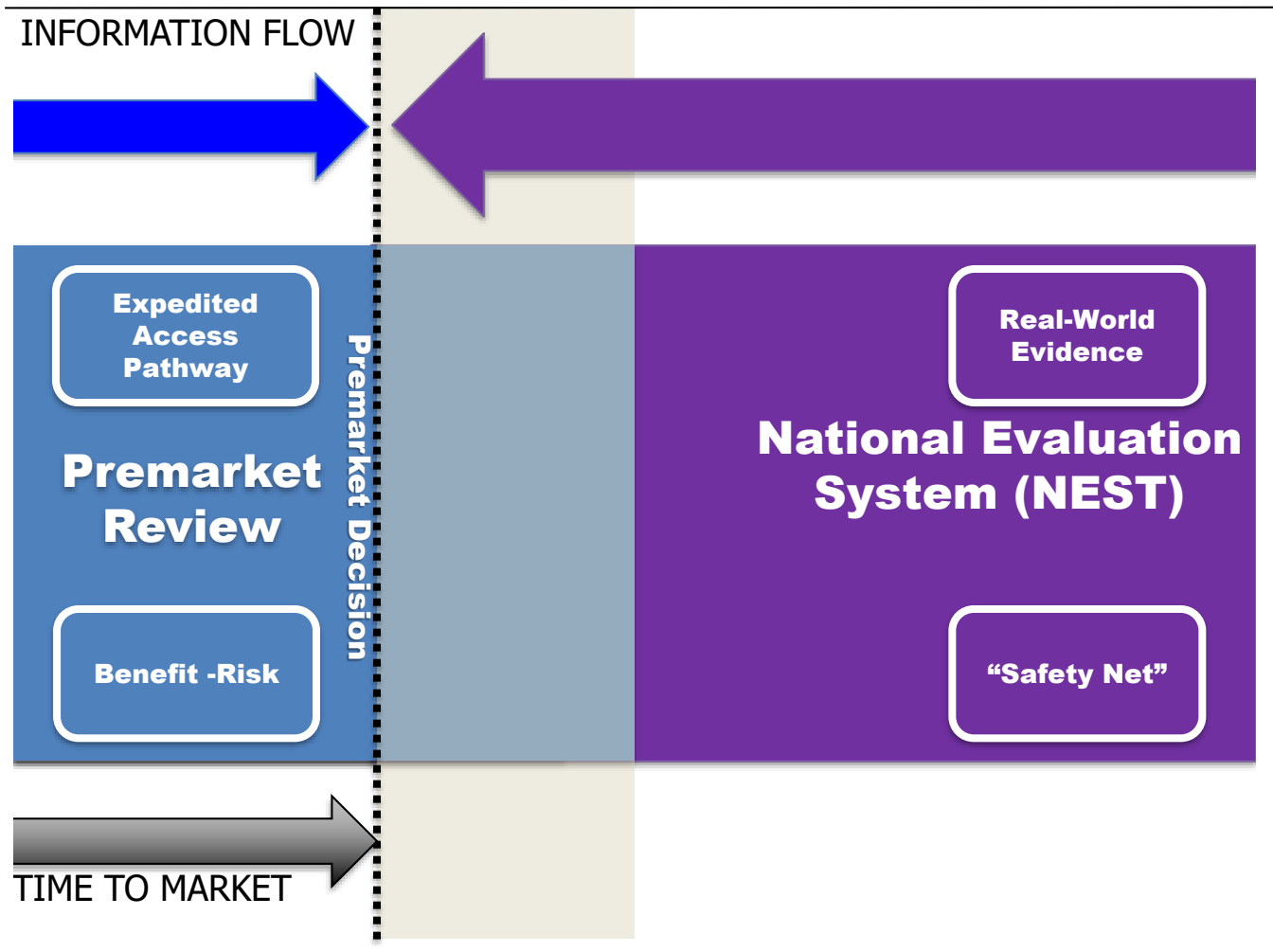
Total Product Life Cycle (TPLC) Framework



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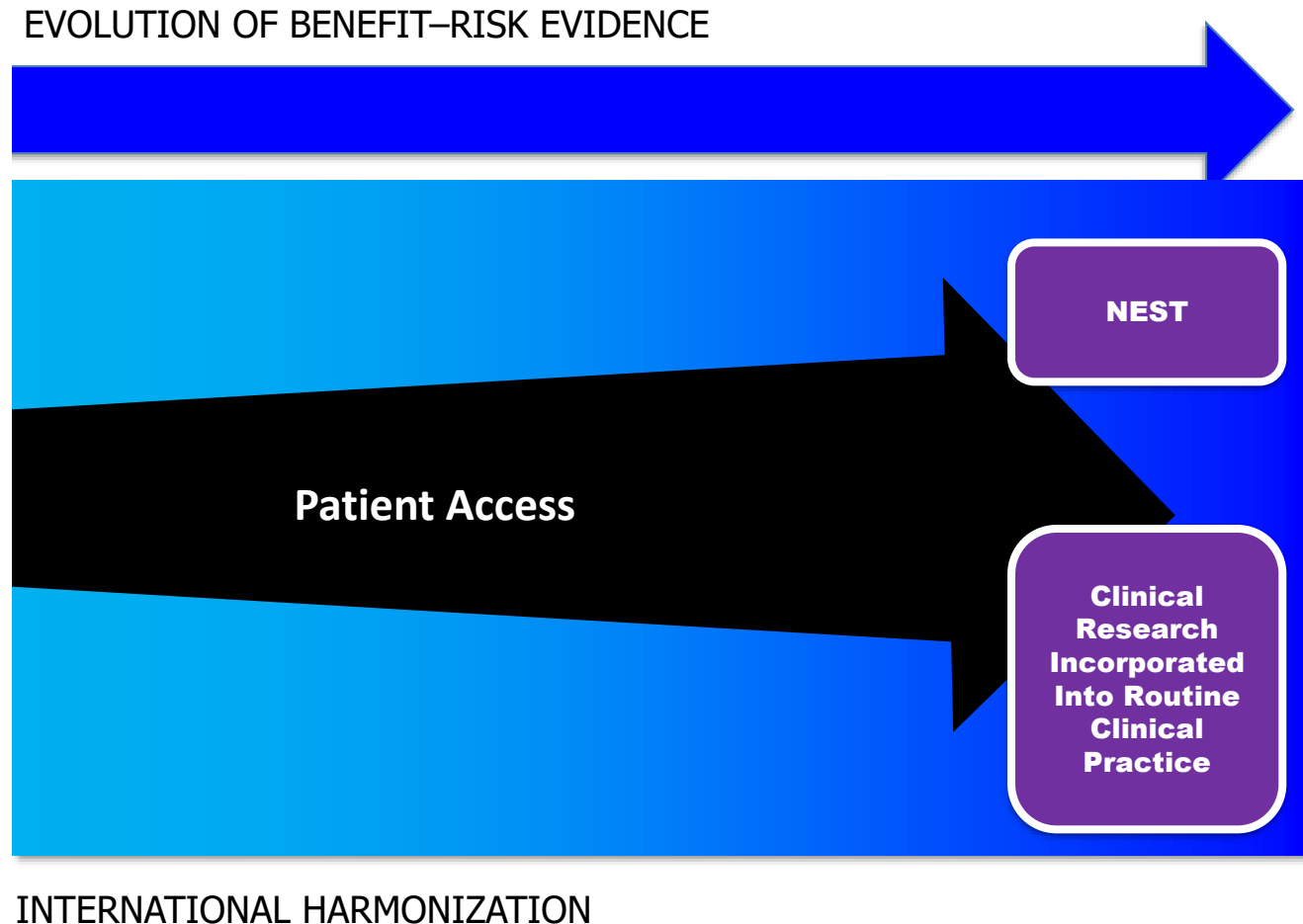


Total Product Life Cycle (TPLC) Framework

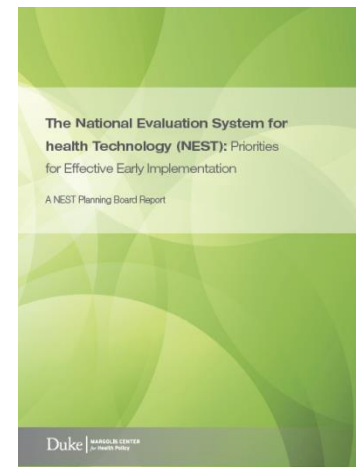
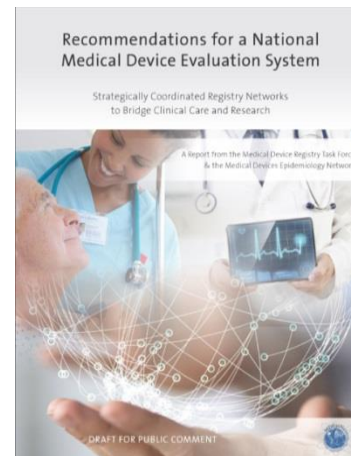
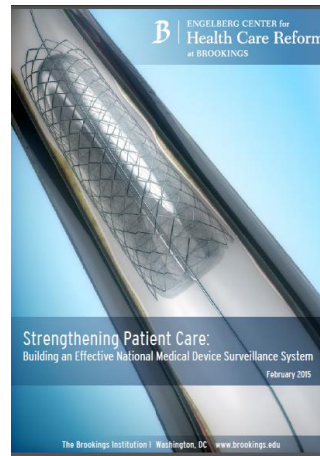
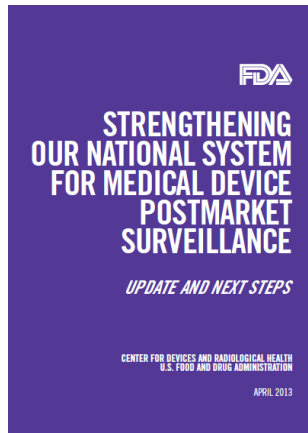
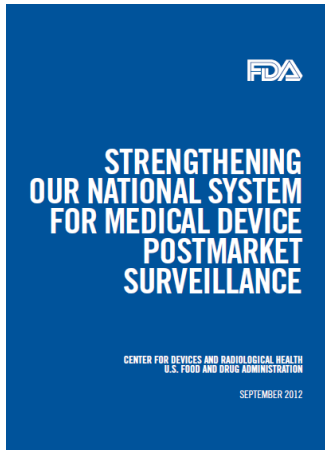


Learning Medical Device Ecosystem

Total Product Life Cycle (TPLC) Framework



Foundational Work



Use of Real-World Data

Real-World Data Sources

Claims Data

EMRs/EHRs

Prospective
Observational
Data

Patient
Pathways

Surveillance

Mortality
Database

Primary and
Secondary
Care Data

Administrative
Data

Disease and
Device
Registries

Pharmacy
Data

Cost Studies

Mobile
Devices

Consumer
Data

Social Media

Real-World Evidence

Identifying Unmet Needs

Natural History

Comorbidities

Burden of Illness

Incidence and
Prevalence

Disease
Mechanisms

Clinical Practice
Patterns

Real-World Evidence

Informing Clinical and Policy Decisions

Utilization Patterns

Outcome
Predictors

Benefit/Risk in
Subgroups

Pharmacovigilance

Population-level
Impact

New Indications

Adapted from Galson S and Simon G.

Available at: <https://nam.edu/wp-content/uploads/2016/10/Real-World-Evidence-to-Guide-the-Approval-and-Use-of-New-Treatments.pdf>

Potential Benefits of Better Leveraging Real World Evidence



More Efficient and Timely Data Collection

Reduce Cost of Evidence Generation

Bring Devices to Patients More Quickly

Better Reflection of Real World Performance

Reduce Other Regulatory Burdens

Meet Other Stakeholder (Patient, Clinician, Payer, etc.) Needs

Evolving Use of Registries



Postmarket Surveillance



Leverage Infrastructure for Premarket Studies



“Real World” Use to Support Expanded Indications



Link to Other Databases - EHR, Claims, etc.



Useful to Multiple Stakeholders

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

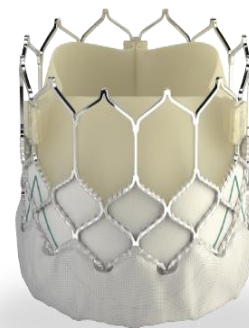
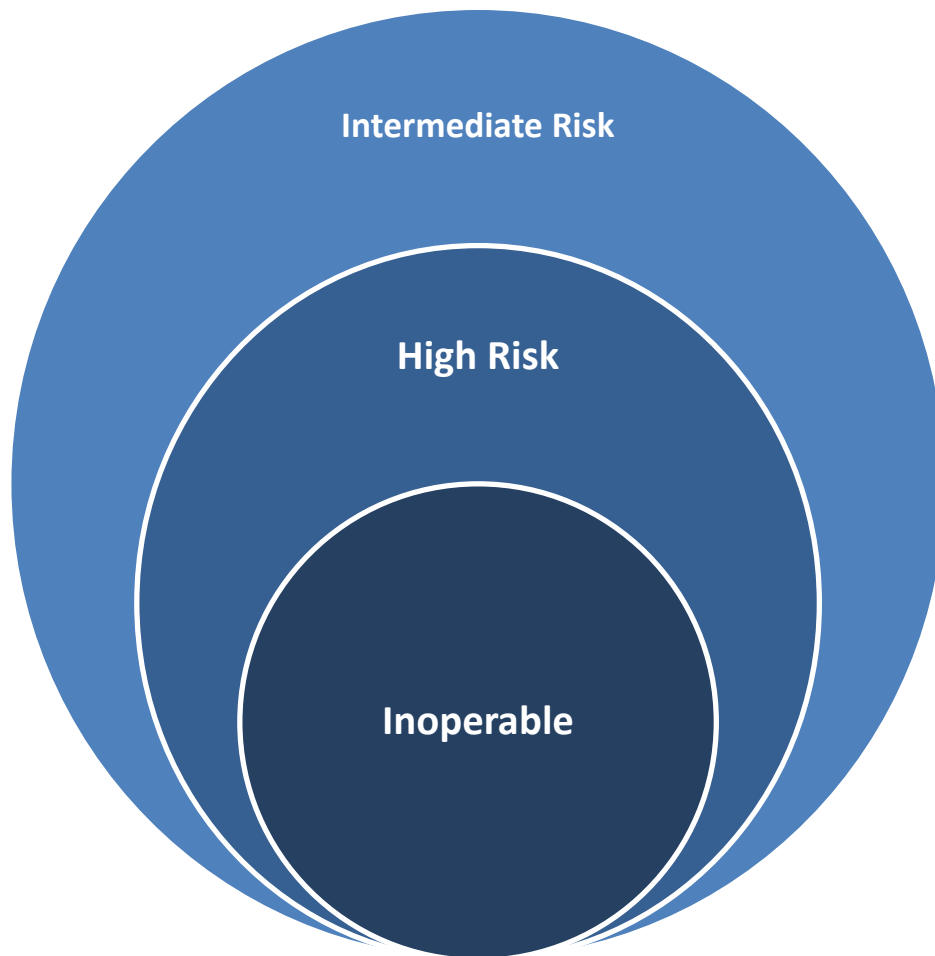
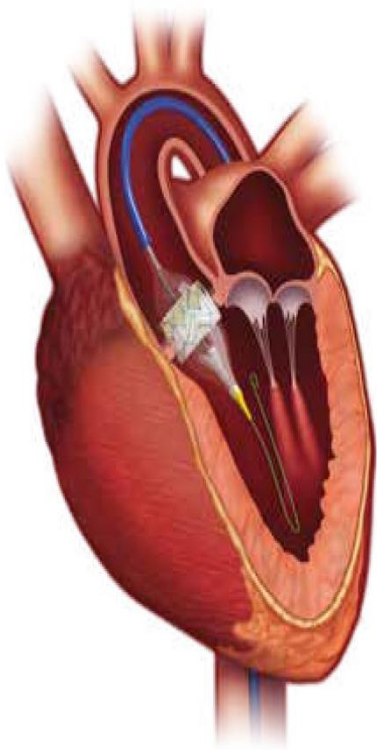
Medical Device Industry

- 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



Transcatheter Heart Valves

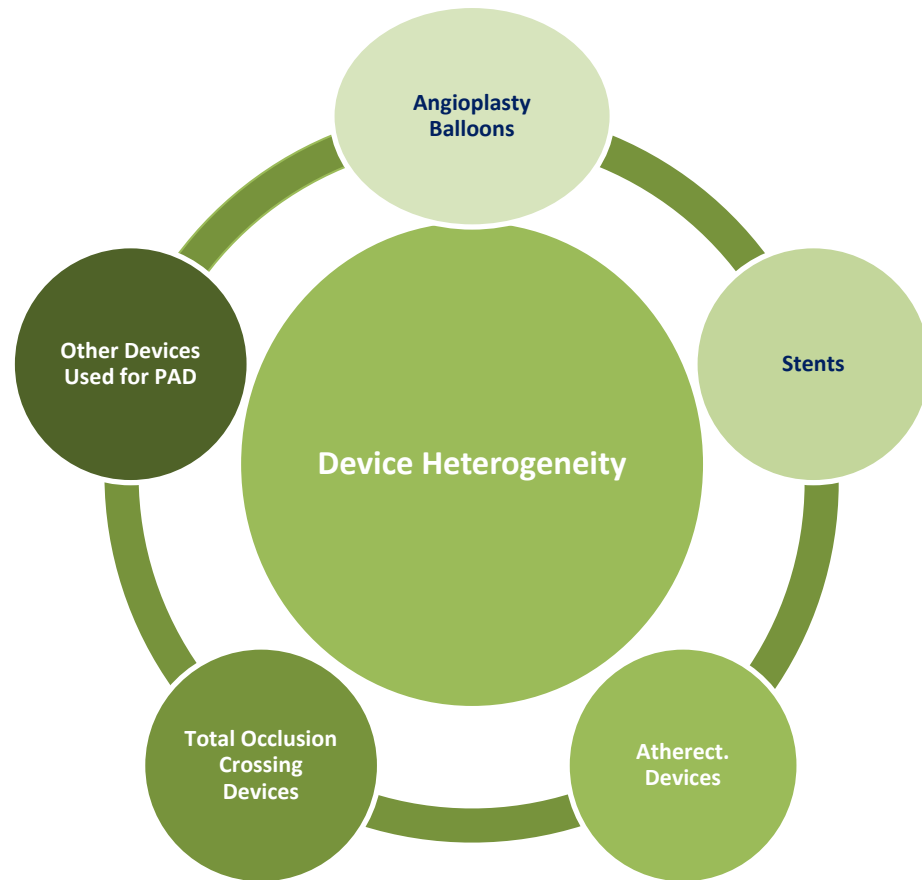
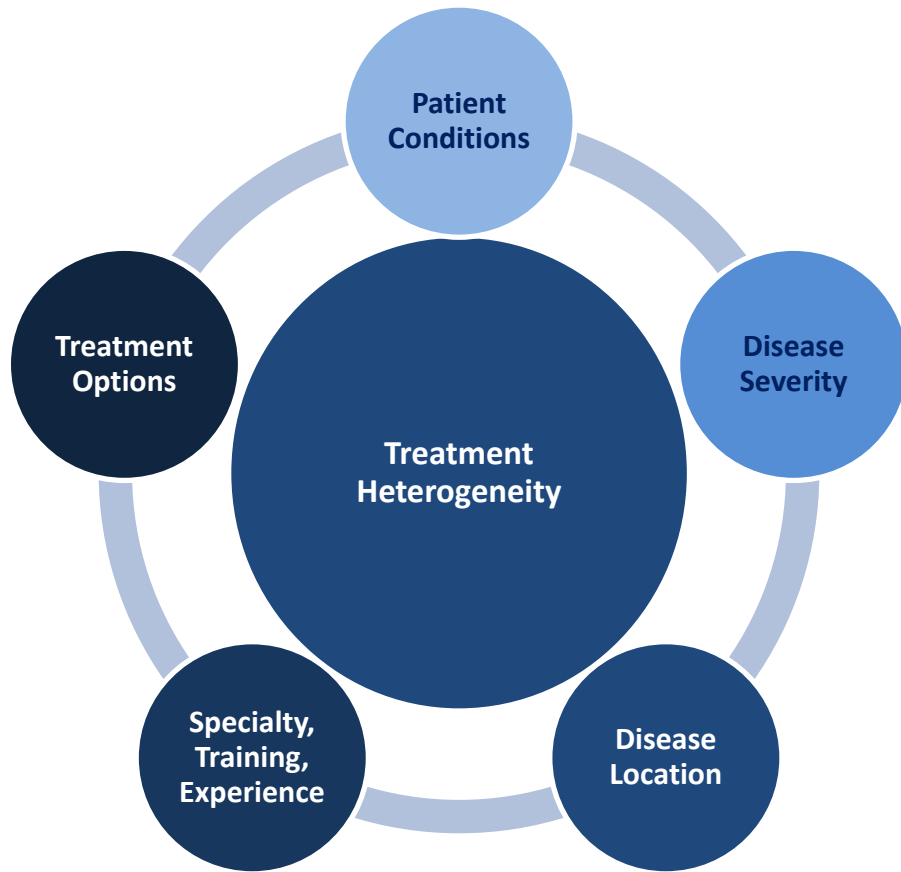
Use of Registry Data for Post Market Surveillance and Label Expansion



Registry Assessment of Peripheral Interventional Devices



Infrainguinal Arterial Occlusive Disease



Other Uses of Registry Data

Proof of Concept

Control arm for pivotal clinical study

- Left ventricular assist devices
- Stent grafts
- Surgical mesh

Post approval study

- Post-approval study of Thoracic Endovascular Aortic Repair (TEVAR) device using the Vascular Quality Initiative Registry enrolled patients twice as fast as expected

Adverse event reporting

- Pilot on using registry data in lieu of submitting Medical Device Reports for on-label adverse events

NEST – Next Steps



Awarded \$3 Million FDA
Grant to establish NEST
Coordinating Center

MDUFA IV User Fee Agreement

Pilot projects funded to determine the usability of RWE for:

- Expanded indications for use
- New clearances/approvals
- Improved malfunction reporting

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