FDA Perspective on a National Evaluation System for Medical Devices

To successfully harness the diverse set of real-world evidence

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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

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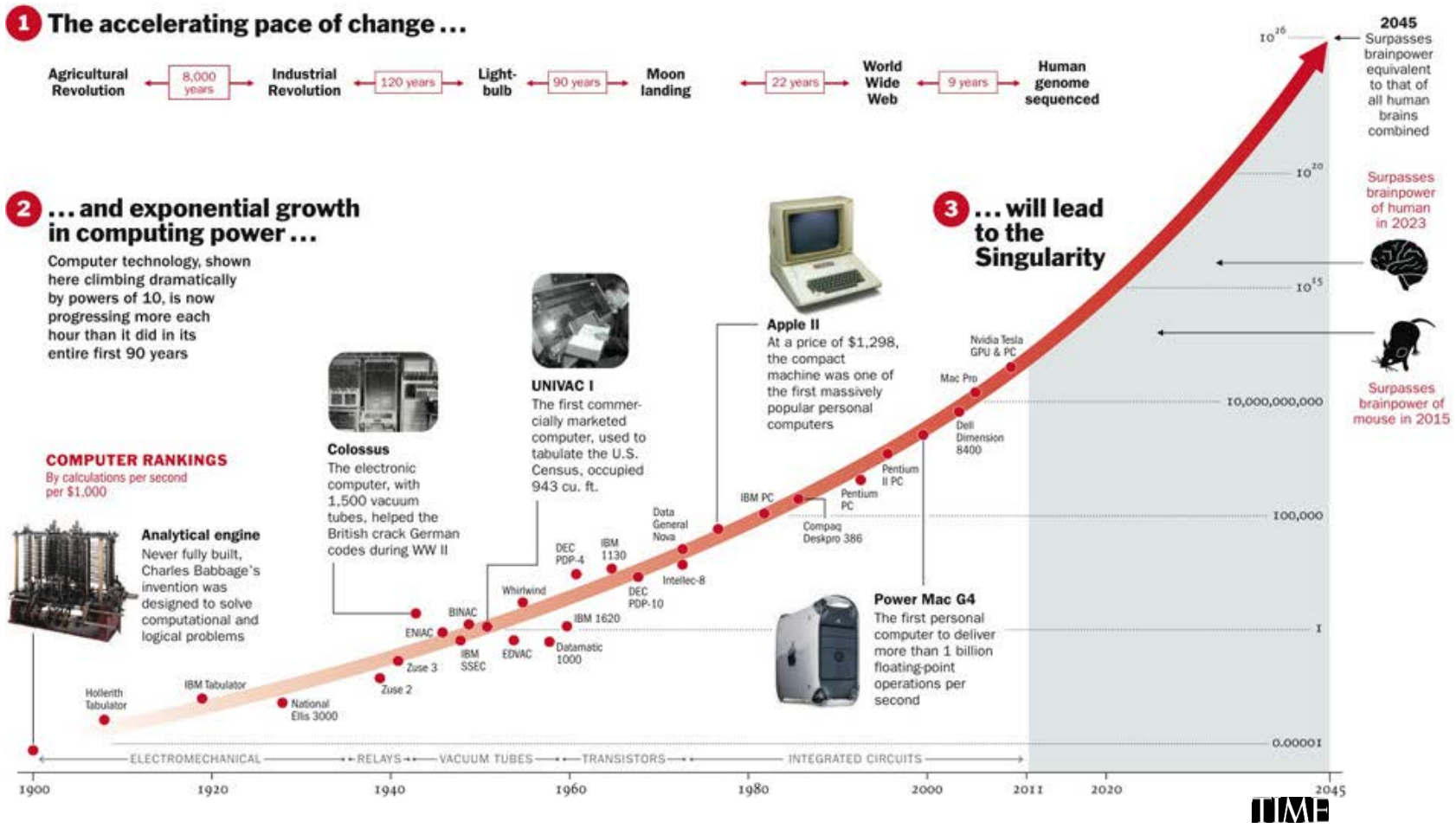
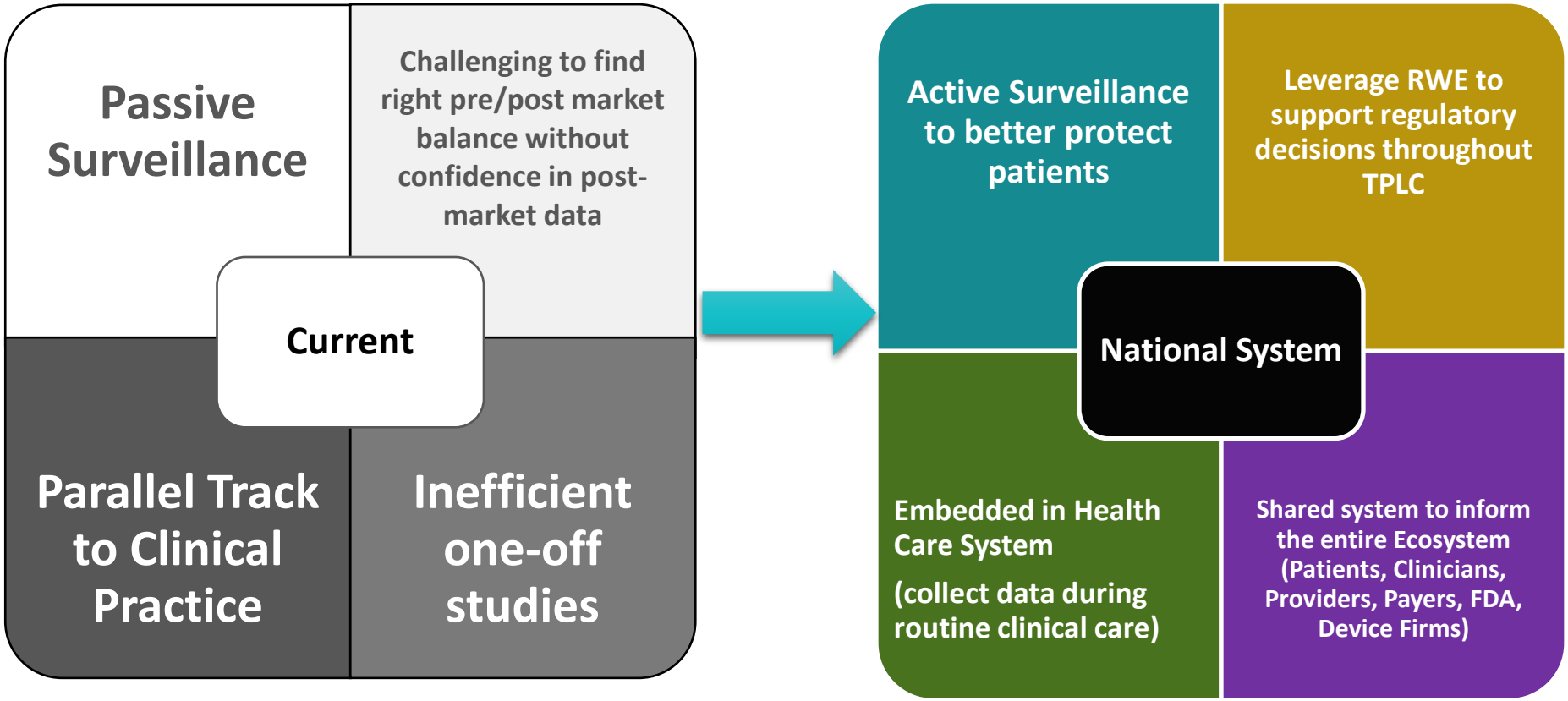
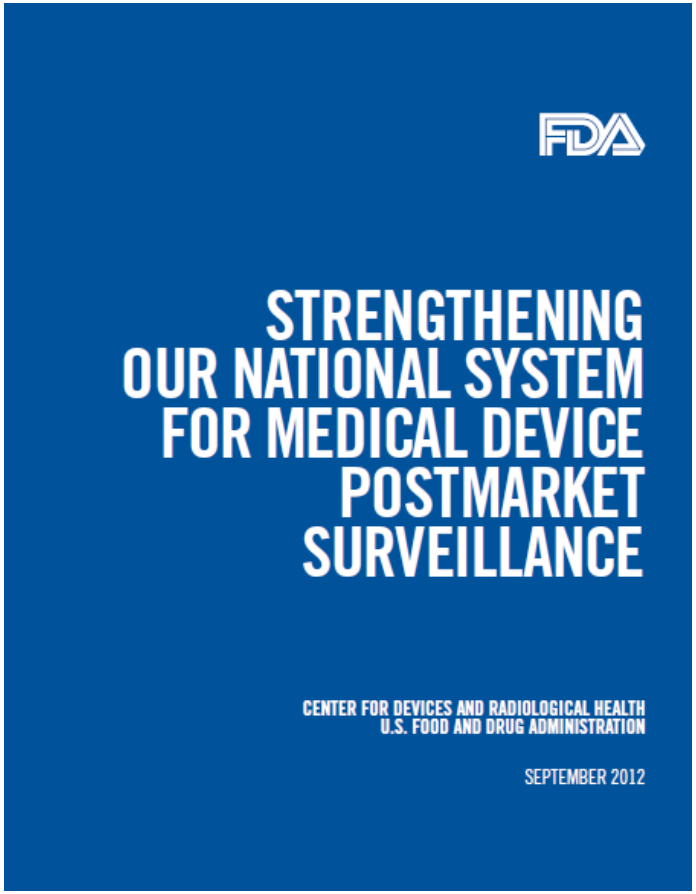
The Accelerating Pace of Change
Information Age and Digital Revolution

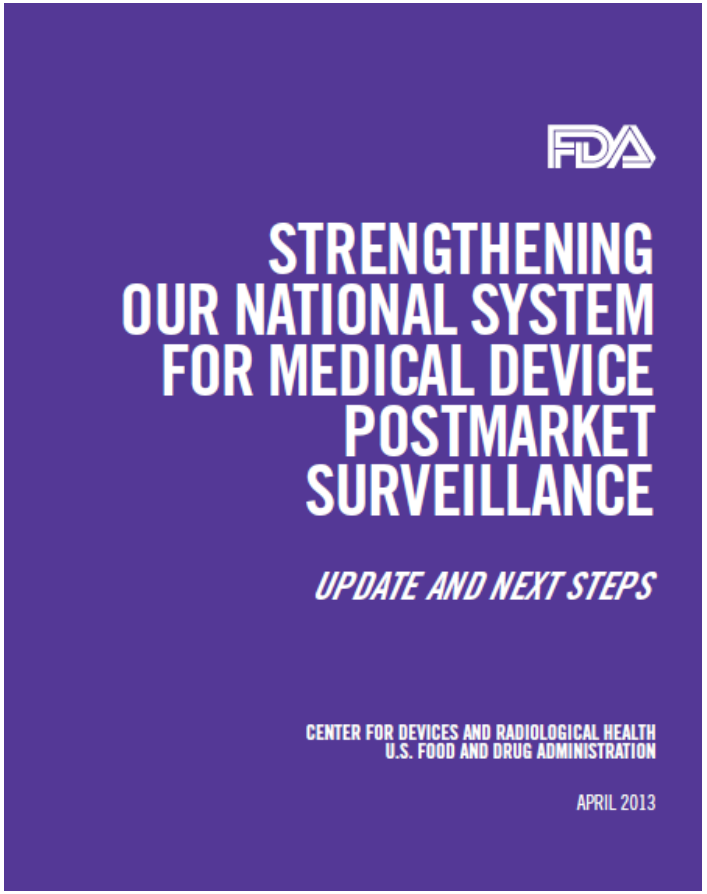


National System Paradigm Shift



Strengthening Our National System
Taking the Next Steps





FDA's Vision for a National System

For the Ecosystem, Governed by the Ecosystem

- Develops and communicates an evolving understanding of device benefits and risks throughout their marketed life using high-quality, linked electronic health information
- Identifies potential safety signals in near real-time from a variety of privacy-protected data sources serving as a safety net
- Reduces burdens and costs of medical device postmarket surveillance
- Facilitates clearance and approval of new devices or new uses of existing devices

The Value Proposition

- Patients would have more timely access to safer, more effective devices
- Clinicians would have better information about the use of a given device in practice.
- Hospitals, clinical practices, and integrated health systems would benefit from improved quality, reliable assurances of safety, and, possibly, relief from multiple reporting requirements
- Payers would benefit from access to high-quality evidence on device performance in clinical practice, either alone or compared with other therapies

The Value Proposition

- Device manufacturers would be able to provide high-quality evidence at lower cost and in less time to support premarket approval, clearance, and payer coverage, coverage with evidence development and reimbursement decisions, to enable informed decisions about when devices should be used in particular patients and how to mitigate risk across the device's lifecycle, and to meet postmarket study and adverse event reporting requirements
- In cases where the potential public health value of the device is high, some data that would otherwise be collected in the premarket setting could be responsibly collected after market entry instead, owing to strong assurances that additional postmarket data would be generated
- The system may obviate the need for FDA premarket review of some device modifications because more timely and informative evaluations of the impact of those changes would occur in the course of routine data collection
- In fact, the FDA has already taken some of these steps for a handful of device types

FDA Investments 2011-2015

UDI Established a Unique Device Identification (UDI) System

50 Completed or engaged in over 50 projects, including the creation of new RWE data sources, demonstration of proof of concept for use of RWE, development and use of advanced analytics

$20,000,000 Invested over $20 million

What is left to do?

Key Contributions of the National Evaluation System

To drive down the time and cost and increase the value and use of real-world evidence through:

- Governance
- Coordination
- Standardization

National Evaluation System Planning Board

In February 2015, the multi-stakeholder Planning Board, convened by Brookings Institution, issued a report with recommendations for how to establish the national system

- Provides a pathway to realizing a national system that harnesses novel data sources, modern analytical techniques and the participation of all stakeholders to optimize patient care
- Recommends as a core strategy to use registries linked to longitudinal data systems
- Sets out an organizational structure and directions for pilots
- Developed consensus of stakeholders

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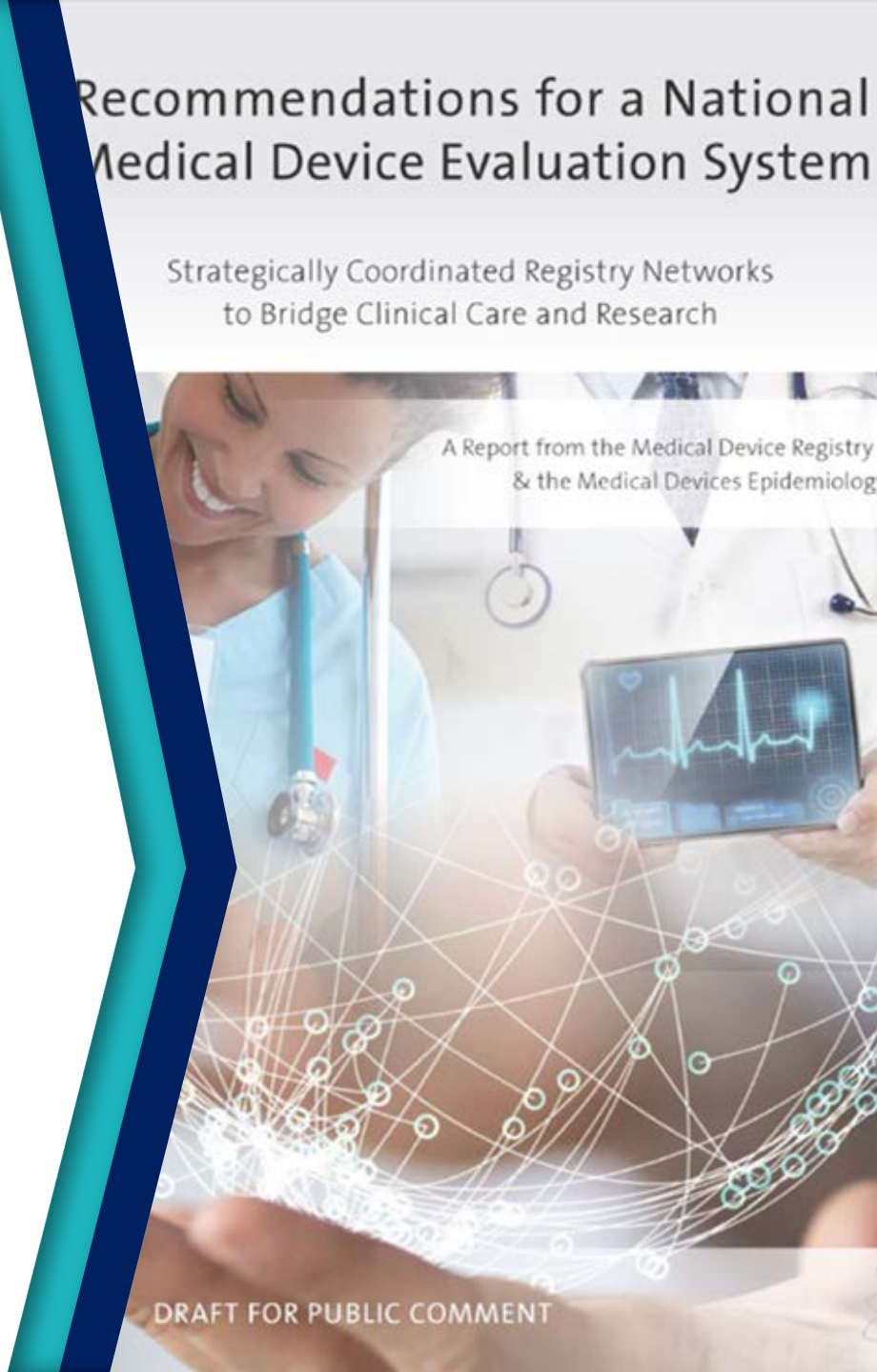
Medical Device Registry Task Force

In August 2015, the multi-stakeholder Registry Task Force, convened by Duke, issued a report that:

- Builds on the core strategy of White Papers and Planning Board Report
- Provides a direction for the future of registries
- Describes the role registries in the evolving National Medical Devices Evaluation System
- Recommends the creation of “CoordinatedRegistry Netowrks”



Phase 2 of Planning Board

- **CDRH asked the Brookings Institution, now the Duke Margolis Center, to reconvene the Planning Board to:**
  - Develop the organizational structure and governance of the national system
  - Develop a financial/sustainability plan
  - Develop an implementation plan
- **Planning Board expanded to support the new task**
- **Pending the outcome of user fee discussions, select a coordinating center and establish the governing board**

2016 - 2017 CDRH Strategic Priorities

- **Establish a National Evaluation System for Medical Devices**
- **Partner with Patients**
- **Promote a Culture of Quality and Organizational Excellence**

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2016-2017 CDRH Strategic Priority #1

GOAL
Increase Access to Real-World Evidence to Support Regulatory Decision Making

- By December 31, 2016, gain access to 25 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification
- By December 31, 2017, gain access to 100 million electronic patient records with device identification

2016-2017 CDRH Strategic Priority #1

GOAL
Increase Use of Real-World Evidence to Support Regulatory Decision Making

- By December 31, 2016, increase by 40 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)
- By December 31, 2017, increase by 100 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)

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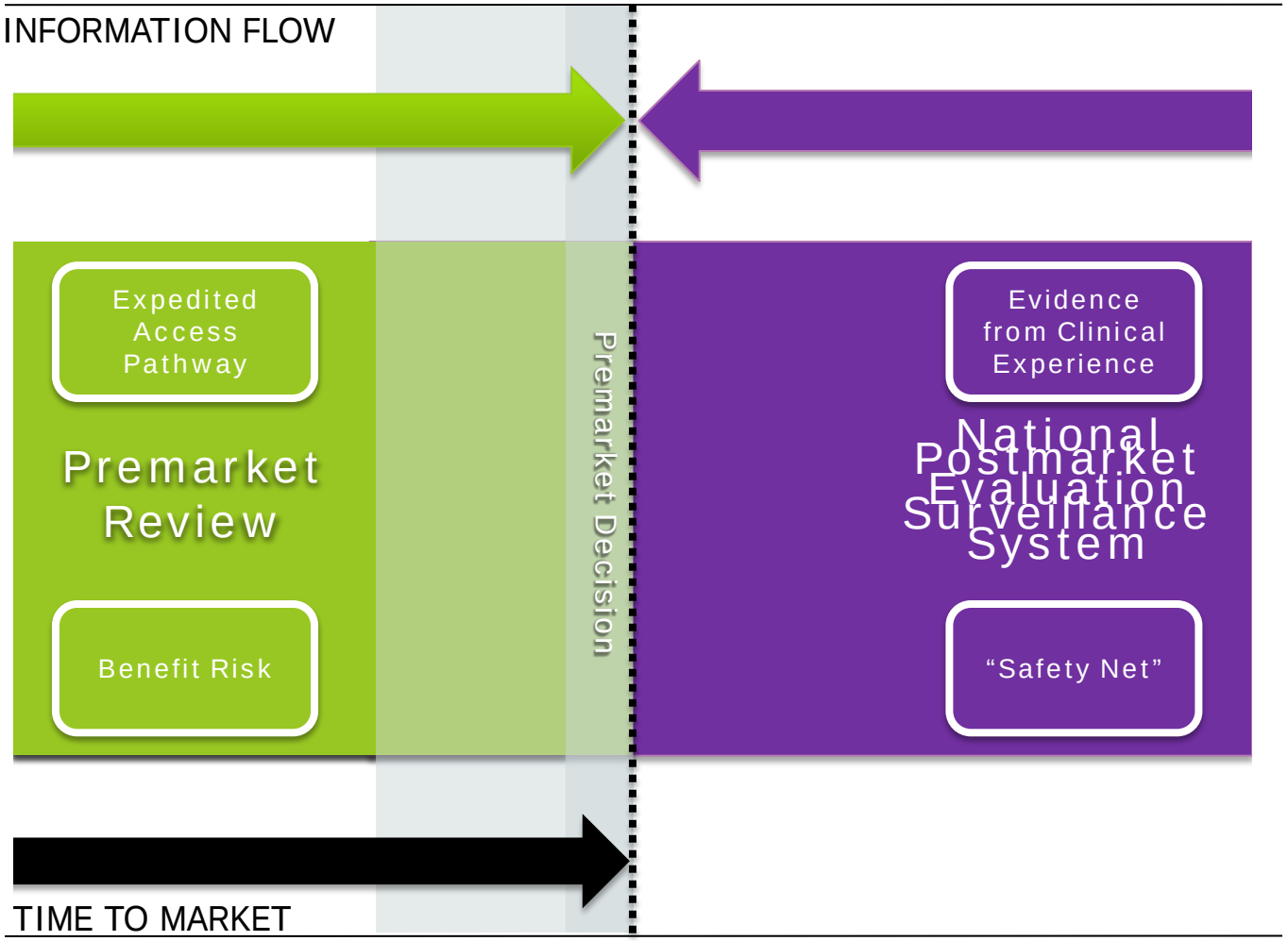
Learning Medical Device Ecosystem



Thank You

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