National Coordinated Registry Network (CRN) Think-tank

The Value of 'Real World Data' for Innovation within FDA

What can CRNs offer?

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It's About the Patients

And ACCESS to Safe and Effective Medical Devices

2014 - 2015 CDRH Strategic Priorities

Strike the Right the Right Balance Between Premarket and Postmarket Data Collection

Expedited Access Pathway* Launched the Expedited Access Pathway Program in April 2015 for breakthrough devices

- Eligible devices are those subject to a PMA or de novo intended to treat or diagnose a **life-threatening or irreversibly debilitating disease and address an unmet need**
- Early, ongoing, and extensive interaction with review team, engagement by senior management, assignment of a case manager, and **collaborative creation of a Data Development Plan**
- Where appropriate, **some premarket data collection shifted to the postmarket setting for PMA devices**

*EAPMA final guidance issued Apri13, 2015:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm393879.htm

2016 - 2017 CDRH Strategic Priorities

Establish a National Evaluation System for Medical Devices

Next Areas of Focus include

- **Developing a framework for:**
  - **accessing evidence from clinical experience**
  - **assessing the quality of the evidence from clinical experience**
  - **using evidence from clinical experience**
    - **for a variety of regulatory purposes**
    - **for other stakeholder's purposes**

LOOKING FORWARD INTO THE FUTURE

The most important means to successful market entry, adoption, and safe use is knowledge gained through evidence generation and experience

Key Challenges for Knowledge Generation in the Medical Device Ecosystem

- Significant Inefficiency in Our Healthcare System: We do not make good use of data and knowledge generated every day as a part of routine healthcare
  - Inadequate data **quality** and completeness
  - Inadequate **methodologies**
  - Different **definitions**
- Data Silos
  - Competition over data rather than only over what we do with the data, such as making better technologies
- Inadequate interoperability
  - Our Data systems do not communicate

Key Challenges for the Medical Device Ecosystem

- Regulatory paradigms are out of step with rapid technology innovation cycles and data generation
- Rapid technological innovations without adequate knowledge about their impact on people
- Reimbursement models that do not encourage knowledge generation and smart innovation

Overall, the whole system costs too much and change won't come easy

Where Could (Should) We Go?

How can CRNs Stimulate Medical Device Innovation?

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

Why CRNs?

- Building a de novo national system for devices:
  - **Cost prohibitive**
  - **Diversity prohibitive**
  - **Perception prohibitive**
  - ***Outdated by launch***
- Of current & emerging e-health information sources (registries, EHRs, administrative, moblie apps, etc.) ***registries provide most robust content & operational predicates***
- ***No single registry suffices*** for benefit/risk & safety for all devices
- *Strategic data sharing interoperability* ***(linking) complementary sources could mitigate single source deficiencies: CRNs***

Why CRNs?

Small steps to big changes

- Priority device focus
- Opportunistic, successful first steps
- Immediate device-specific & generalizable deliverables
- National System should actively catalogue lessons learned & data sharing solutions for use/re-use, accelerating development of CRNs in additional device areas
- Build momentum, consistency & confidence

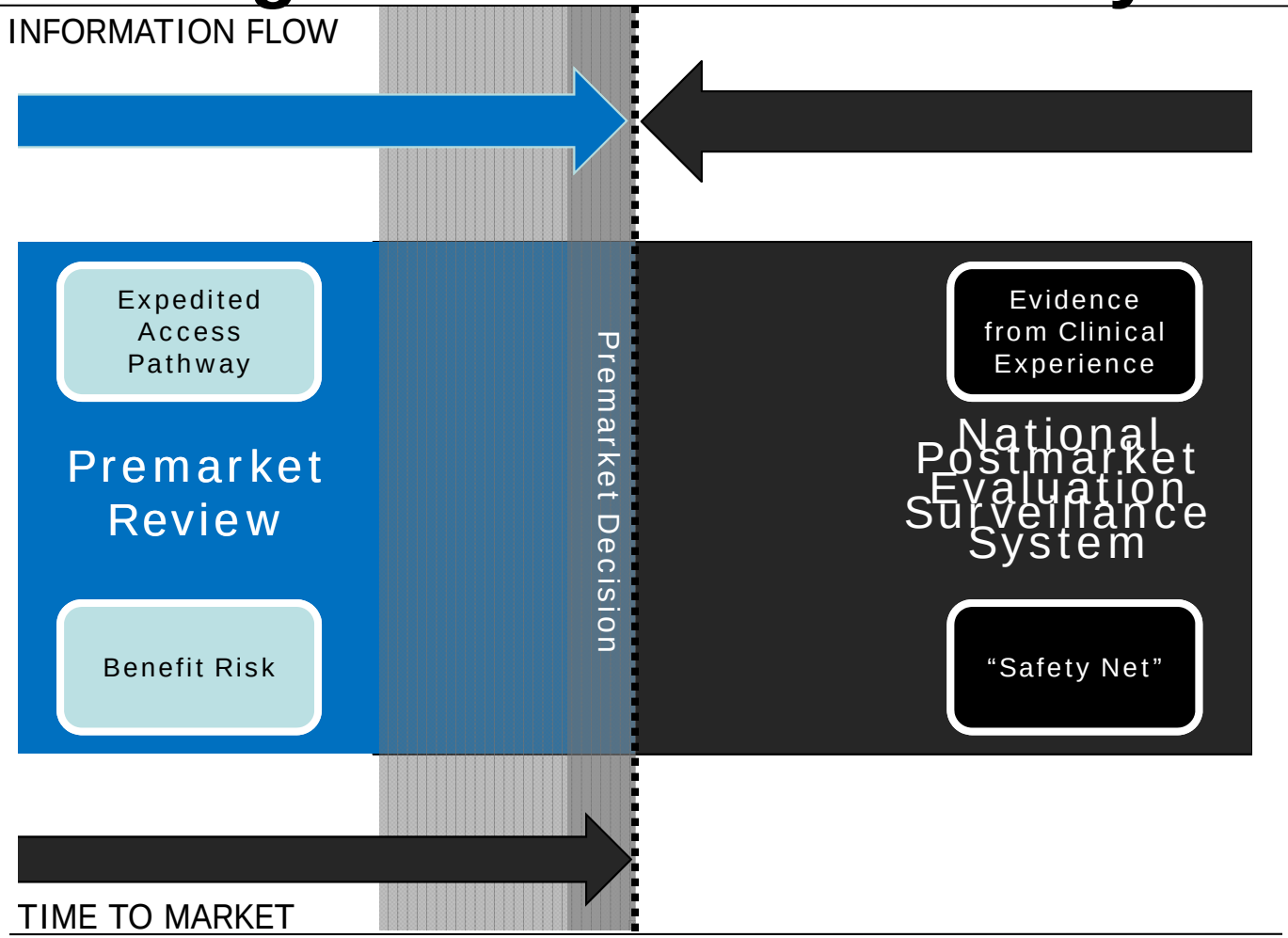
NESMD: Value Proposition

- **Patients** would have more timely access to safer, more effective devices
- **Clinicians** would have better and more timely 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

NESMD: Value Proposition

- **Manufacturers** develop high-quality evidence at lower cost/less time to support premarket approval, clearance, and payer coverage, CED and reimbursement decisions, 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
- **FDA** could shift some data collection from the premarket setting to the postmarket instead, owing to strong assurances that additional postmarket data would be generated
- **FDA** may reduce premarket review of some device modifications as 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

Learning Medical Device Ecosystem



Thank You