MDEpiNet RAPID Think Tank

Update on National Evaluation System for Health Technologies (NEST)

William H. Maisel, MD, MPH
Deputy Director for Science
FDA/CDRH

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.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.
- Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

NEST Foundational Work

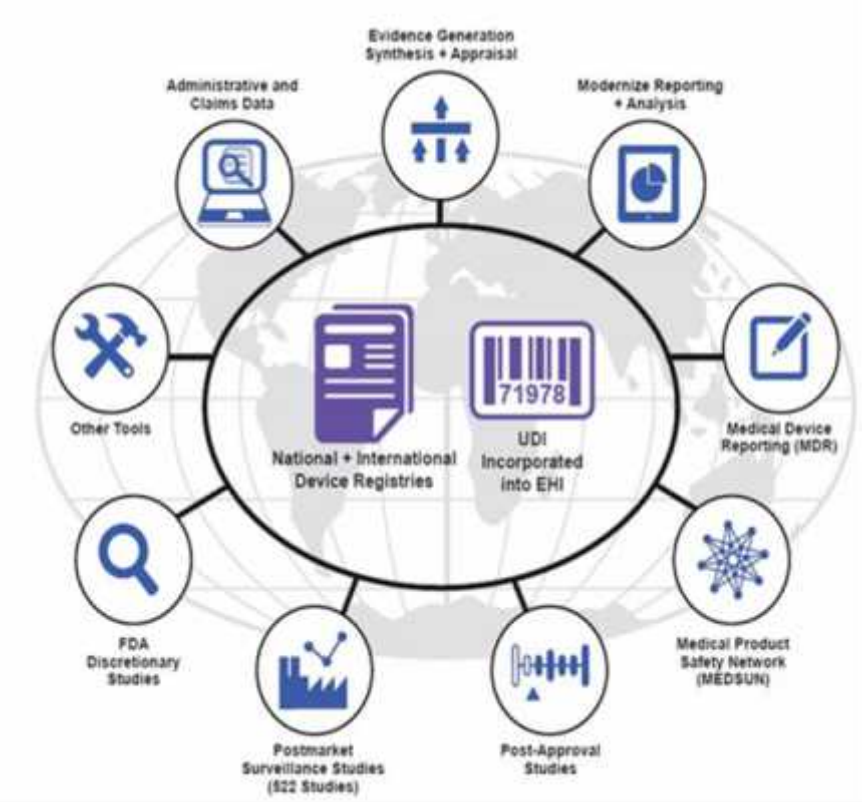
2012

2016

MDIC
Medical Device Innovation Consortium
Align • Achieve • Accelerate

NEST Coordinating Center

Core Strategy: Leverage Real-world Evidence



Data sources:

- Registries
- Medical Claims
- Electronic Health Records (EHR)
- Others

Work collaboratively with:

- Patients/consumers
- Professional societies and Registries
- Academia
- Payers/Health care industry
- Device industry

Why?

- More efficient and timely achievement of our public health goals -- assuring safe and effective devices
- Bring life sustaining, health promoting devices to patients more quickly
- Improve our ability to detect safety issues by moving to more active surveillance
- Expand our ability to study how devices perform in diverse populations and better understand how devices behave in the real world.

Why now?

By leveraging real world data collected as part of routine clinical care we more fully realize the potential of the digital revolution for the device space.

The national system is transformative, a paradigm shift.

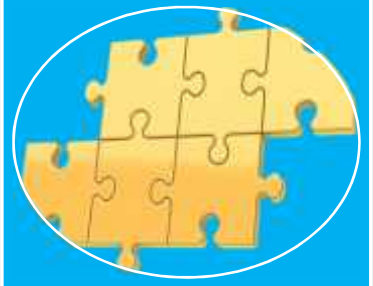
“To successfully harness from the diverse set of real-world evidence (digital information collected from clinical experience) in an efficient manner, the U.S. must develop the necessary infrastructure – a National Evaluation System for medical devices.”

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

Core Strategy: Linking Real-World Evidence

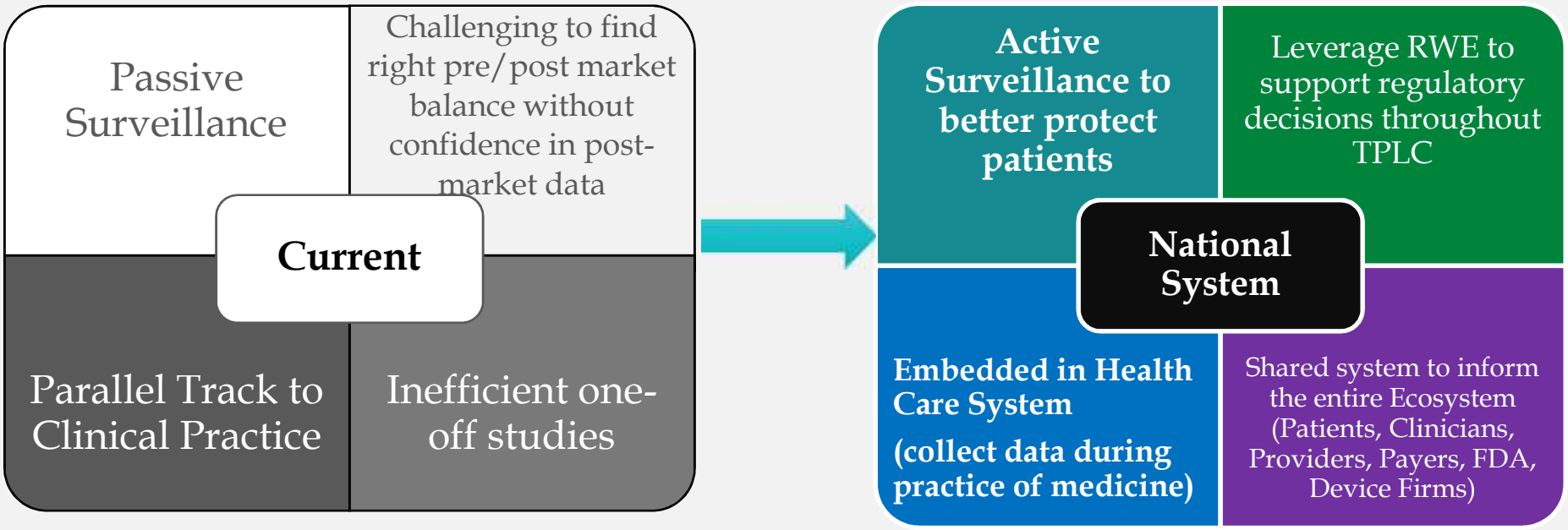
- Create cohorts of patients who receive implants out of data from registries which uniquely identify devices
- Link registry data to longitudinal data systems (e.g. medical claims) for outcomes to conduct studies for surveillance and evaluation of these devices
- Over 20 studies of this type are done or under way leveraging work of MDEpiNet.

In the future
Implementation of unique device identifiers (UDI) in electronic health records and medical claims will enable further development of the national evaluation system (e.g., non-implantables, devices without registries)

To accomplish these goals, CDRH will take several steps including the following:

- Establish an organizational structure for the National Evaluation System
- Develop a framework for the incorporation of real-world evidence into regulatory decision making.
- Develop “real-world evidence” education and training for CDRH staff and industry.
- Develop metrics to track progress on building of a national medical device evaluation system.

National System Paradigm Shift



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