

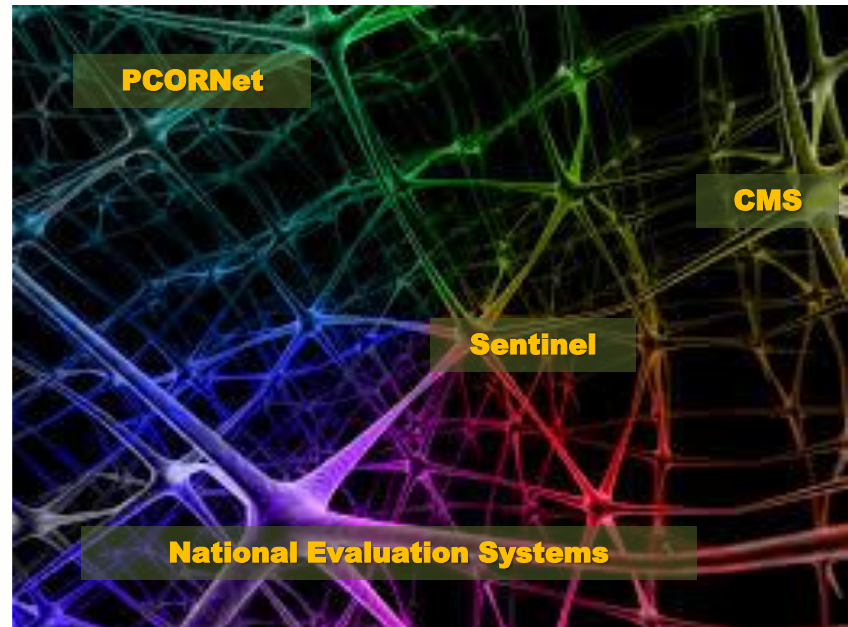
FDA Perspective

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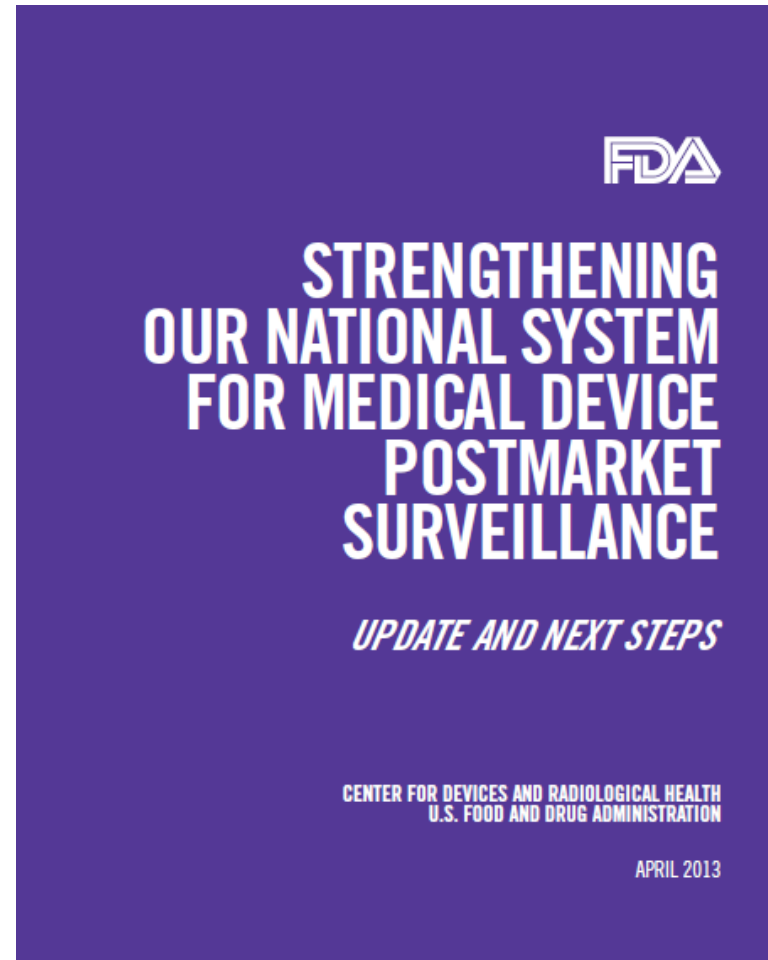
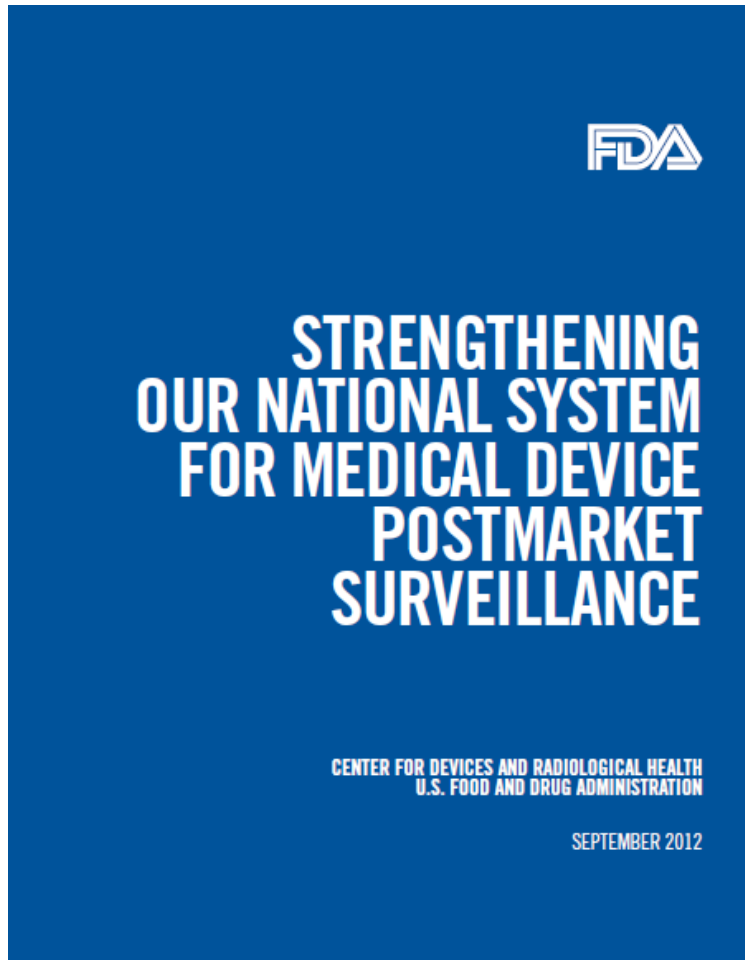
The Learning Health Care System: investing in a new infrastructure to make better use of knowledge generated by health information technologies, repositories, and systems.

Flexible regulatory paradigms combined with national evaluation systems and information commons can lead to a true TPLC approach to devices.

This approach will incentivize the development of new devices and technologies to generate and make better use of knowledge.



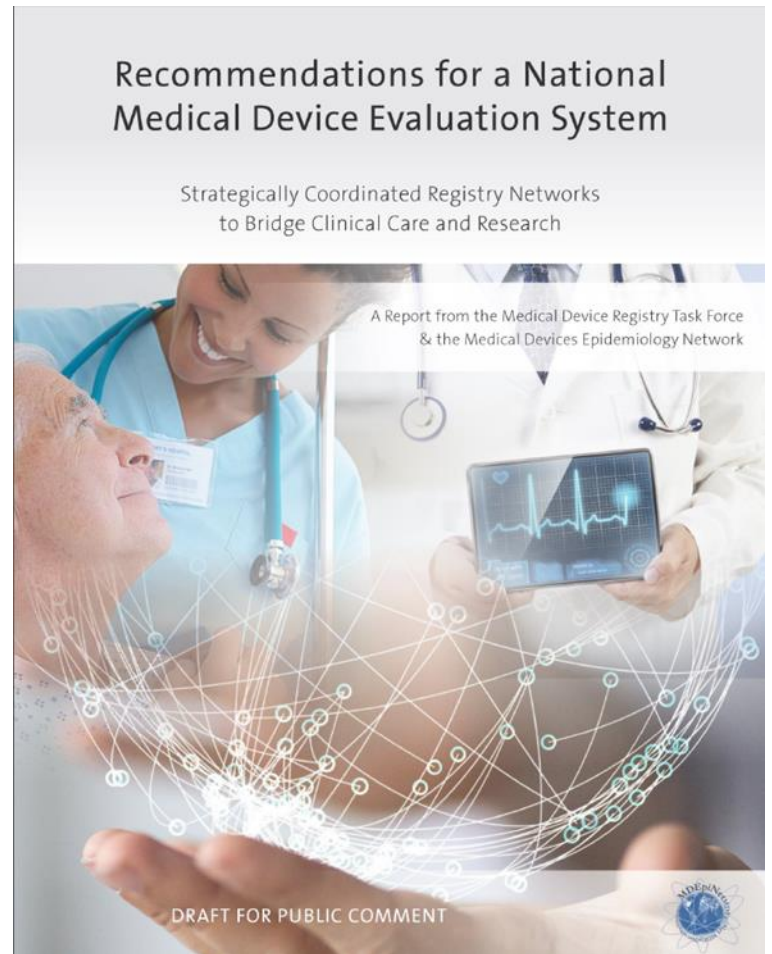
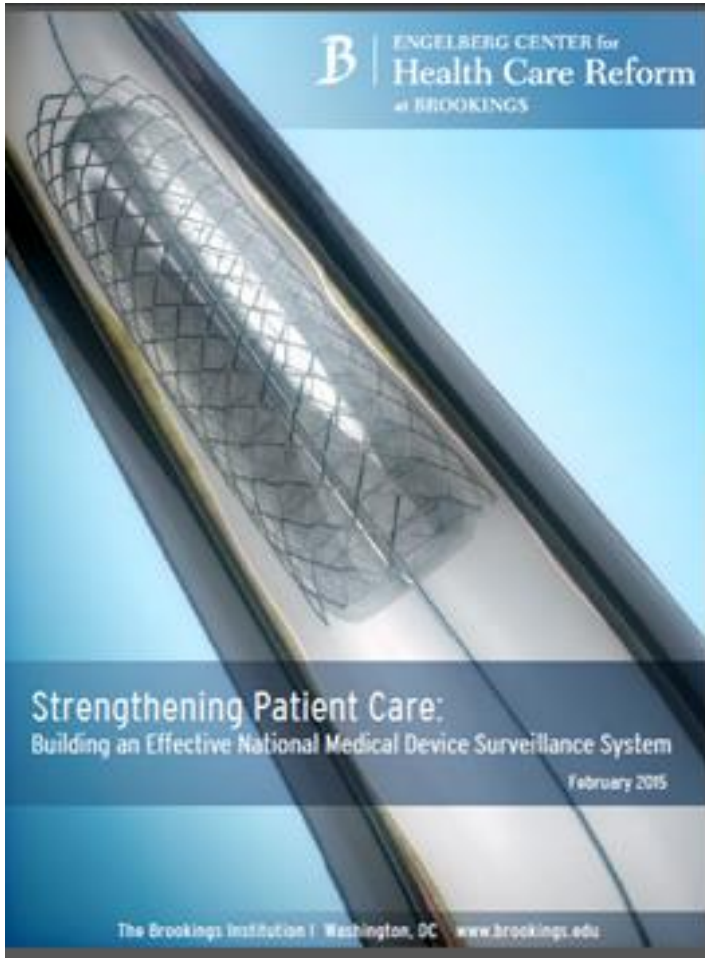
Strengthening Our National System



FDA's Vision for a National System

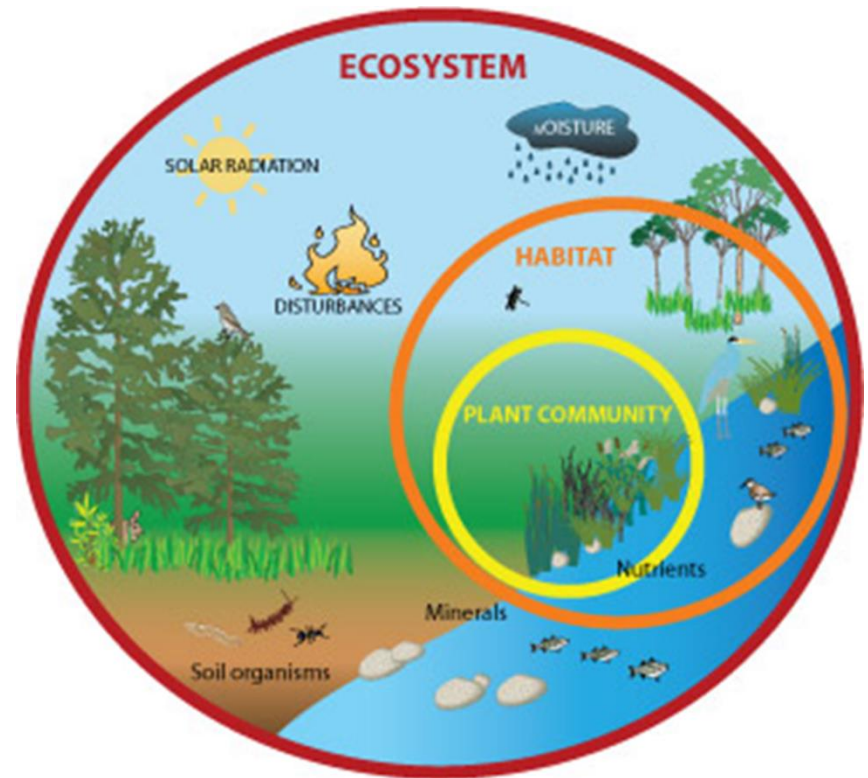
For the Ecosystem, Governed by the Ecosystem

- 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 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



Alignment

- Critical next steps to ensure that MDEpiNet and the Planning Board are aligned
- MDEpiNet is building components/tools for the national system.
- Planning Board is move forward the organizational structure and governance.



A more home spun metaphor

**Building the
National Medical Device Evaluation System:
a strong house brick by brick**



New methods (e.g., DELTA)

**Linkage of
data sets**

Coordinating Center

**Clinical registries,
EHR, and longitudinal
data that may be
incorporated in future
(Sentinel, PCORnet,
claims)**

**Foundation of the national system
demonstrated by the numerous
studies TVT and others.**

Thank you

