National Medical Device Evaluation System: CDRH's Vision, Challenges, and Needs

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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…

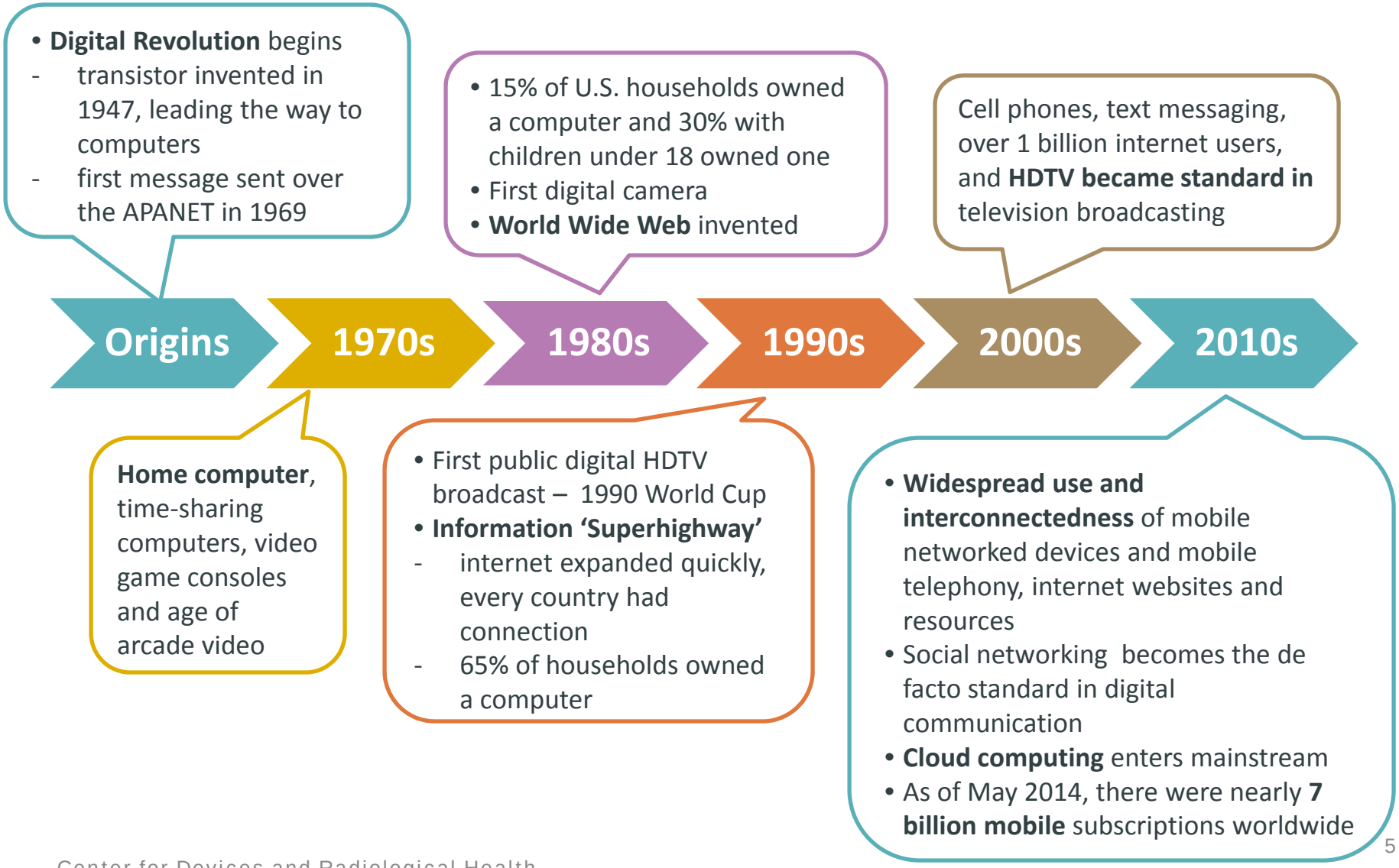
device development, assessment, review, manufacturing, monitoring, and reimbursement – **without compromising the reasonable assurance of safety and effectiveness standard**

2014 - 2015 CDRH Strategic Priorities

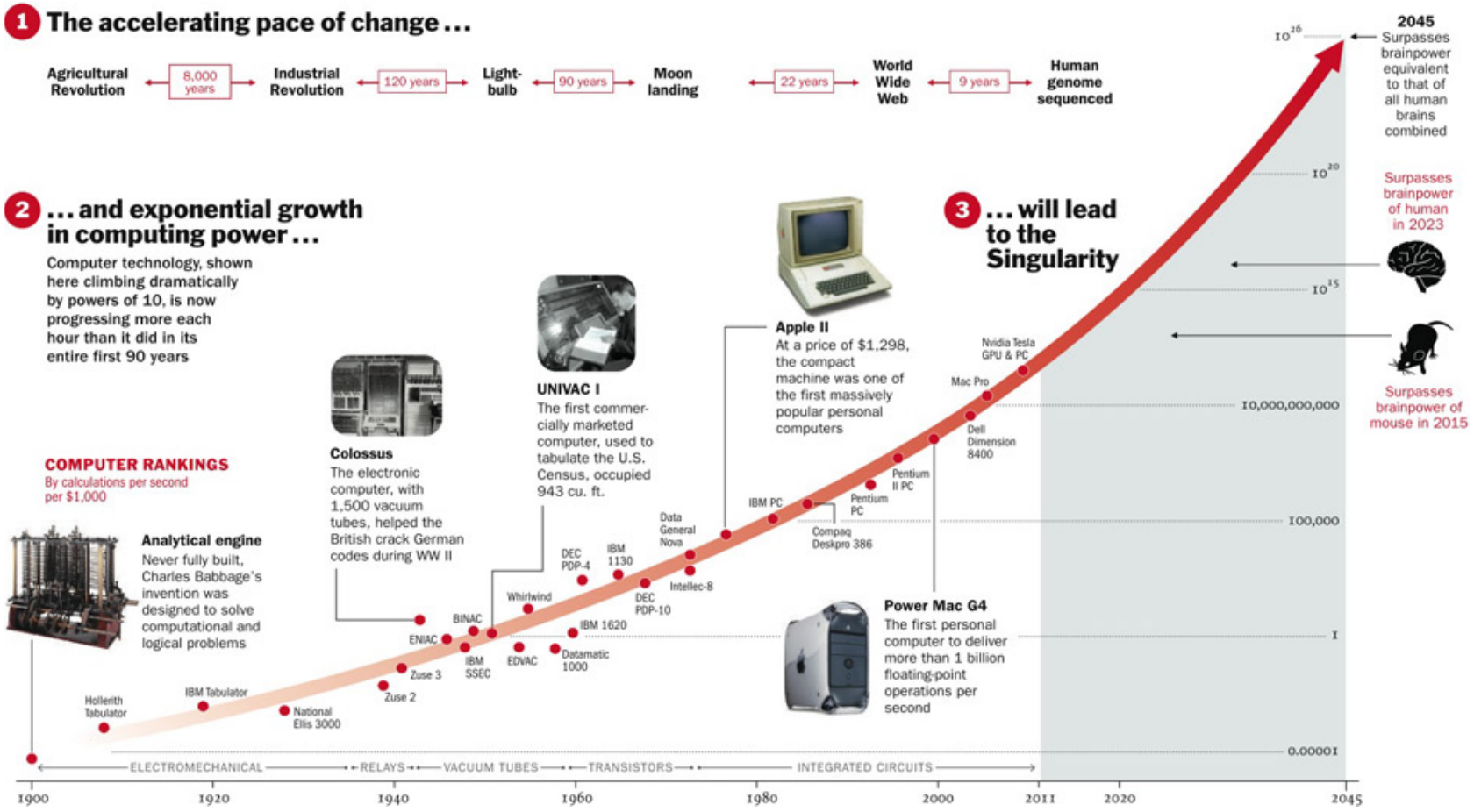
- Strengthen the Clinical Trial Enterprise
- Strike the Right Balance Between Premarket and Postmarket Data Collection
- Provide Excellent Customer Service

We and our partners have tried to go as far as we can in the world of today

Digital Revolution and the Information Age



The Accelerating Pace of Change



http://content.time.com/time/interactive/0,31813,2048601,00.html

Digital Revolution and the Information Age

Benefits and Costs

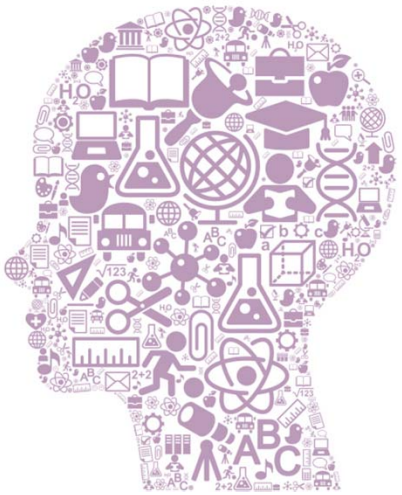
Benefits

- Access to more information and people
- Faster creation of new information
- Longitudinal connection of data

Costs

- Quality of information
- Too many silos as information became a commodity
- Content and structure of databases, as well as difficulties and costs of creating and maintaining comprehensive databases

Knowledge



Knowledge resides in the user...happens only when human experience and insight is applied to data and information

http://www.tlainc.com/articl134.htm

Knowledge refers to a deterministic process where patterns within a given set of information are ascertained

http://www.differencebetween.net/language/difference-between-knowledge-and-information

Knowledge Age

A new mindset is required, one that can take into account the new meaning of knowledge and the new contexts and purposes for using that knowledge:

- Information is a resource, something we use to learn (or think) and create knowledge
- We use knowledge to create new knowledge and new applications for existing knowledge
- Information and resulting knowledge are in a constant state of flux, and therefore, must be rapidly identified, analyzed, applied, and communicated

The Three Waves of the Internet

Steve Case, Washington Post May 30, 2015

First Wave (1980s – 2000)

Connecting people

Key Activities: Building infrastructure, connections and awareness

Second Wave (2001-2015)

Creating new ways for people to access information and one another

Key Activities: Developing mobile apps and social media

Third Wave (about to break)

Integrating the Internet into everyday life

Key Activities: Partnerships to drive change in critical economic sectors, such as health care

Huge Data and Smarter Systems Driving Intelligent Healthcare

- **Big data revolution is just beginning to touch the most sacred aspect of our lives: our health**
- **Health data may empower understanding our health like never before**

It has been estimated that as much **as 90% of all data** in the world has been generated **in the past two years**

Key Challenges for 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 interoperability
  - Inadequate data quality and completeness
  - Inadequate methodologies
- Data Silos
  - Competition over data rather than only over what we do with the data, such making better technologies

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 darn much and change won't come easy

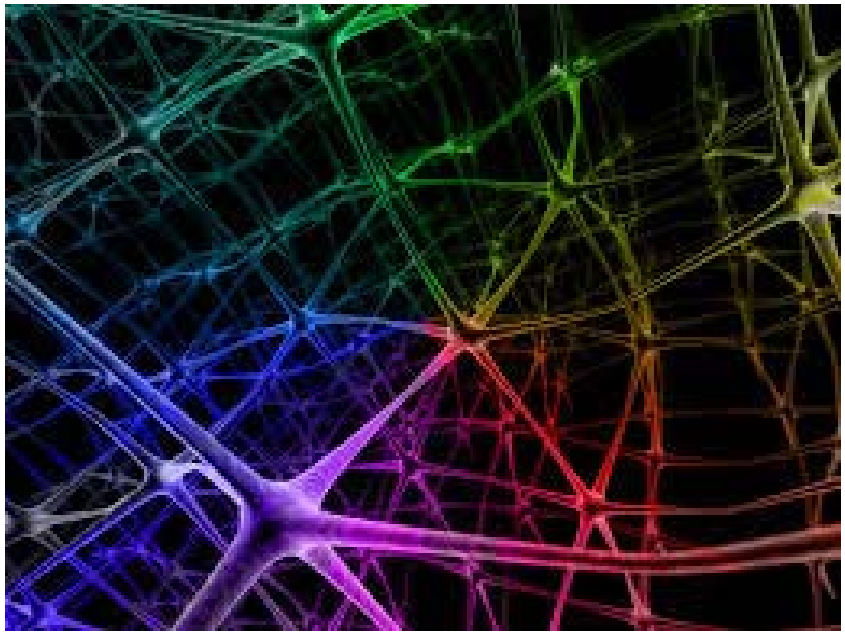
What do we need to do?

We need to invest in a new approach and infrastructure to create new knowledge and make better use of knowledge, integrating people, health information technologies, data repositories, and systems

Learning Medical Device Ecosystem: A Neural Network

Flexible regulatory paradigms combined with knowledge commons and a national evaluation system (plus supportive reimbursement models) can lead to a paradigm shift for the medical device ecosystem

This approach can incentivize the development and use of important new devices and other technologies that improve the health and the quality of life of patients while increasing the return on investment of our healthcare dollars



Regulatory Innovation Can Drive Technological Innovation

Traditional Regulatory Paradigm	New Regulatory Paradigm
Premarket vs Postmarket	Extent of Patient Access
Stage-Gate Approach to Device Assessment	TPLC Data Development Plans
Light Switch Model for Approval Decisions	Flexible Decision Points
Regulate Because It's a Device	Regulate Because It's Value Added

Flexible Regulatory Paradigms

Continuum of Clinical Study Onset and Market Entry Points

- **PMA, De Novo Benefit-Risk Determination Framework Guidance (2012)**
- **Early Feasibility Study Paradigm Guidance (2013)**
- **IDE Benefit-Risk Determination Framework Draft Guidance (2015)**
- **Patient Preference Information Draft Guidance (2015)**
- **Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project**
- **Expedited Access Pathway Program (2015)**

Should we have a progressive/conditional approval pathway?

Flexible Regulatory Paradigms

Data Generation: There's More than One Way to Skin a Cat

- **Bayesian Statistics Guidance (2010)**
- **Adaptive Clinical Trial Design Draft Guidance (2015)**
- **"Real World" Observational Data Draft Guidance under development**
  - Critical to address "noise" and biases, such as by imbedding randomization into the system
- **Medical Device Innovation Consortium (MDIC) Computer Modeling Project**
- **Use of Modeling in Clinical Trials Paper under development**
- **But, regardless of the approach, the data must be sufficiently robust**

Flexible Regulatory Paradigms

Smart Regulation When You Need It
No Regulation When You Don't

Extensive deregulation of low-risk digital health technologies

- Mobile Medical Apps Guidance (2013)
- Medical Device Data Systems Guidance (2015)
- General Wellness Claims Draft Guidance (2015)

New framework for Software as a Medical Device under development intended to meet the needs of rapid innovation cycles

Knowledge Commons

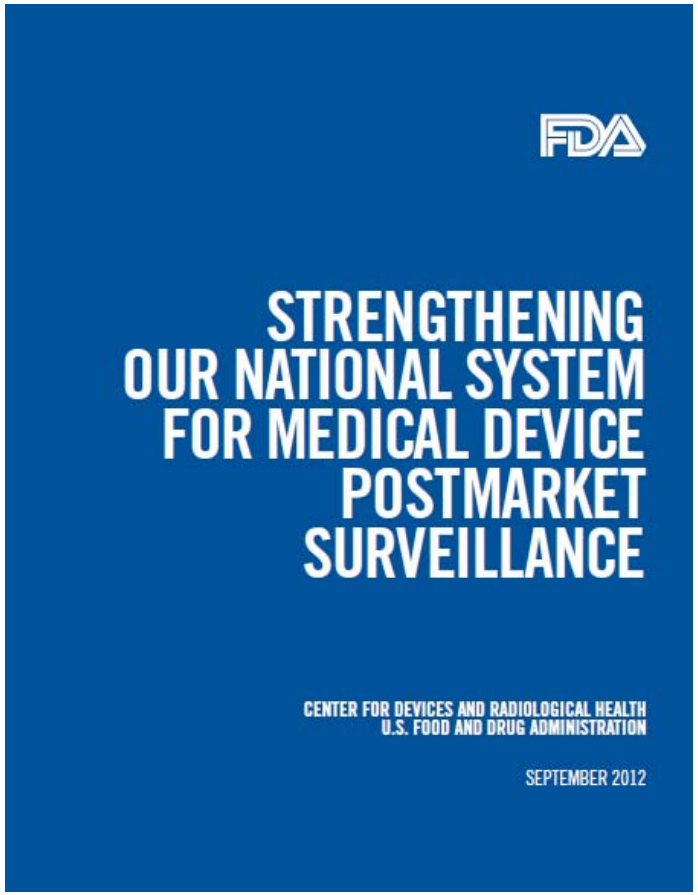
Adapting regulatory framework to address new technologies: Next Generation Sequencing (NGS)

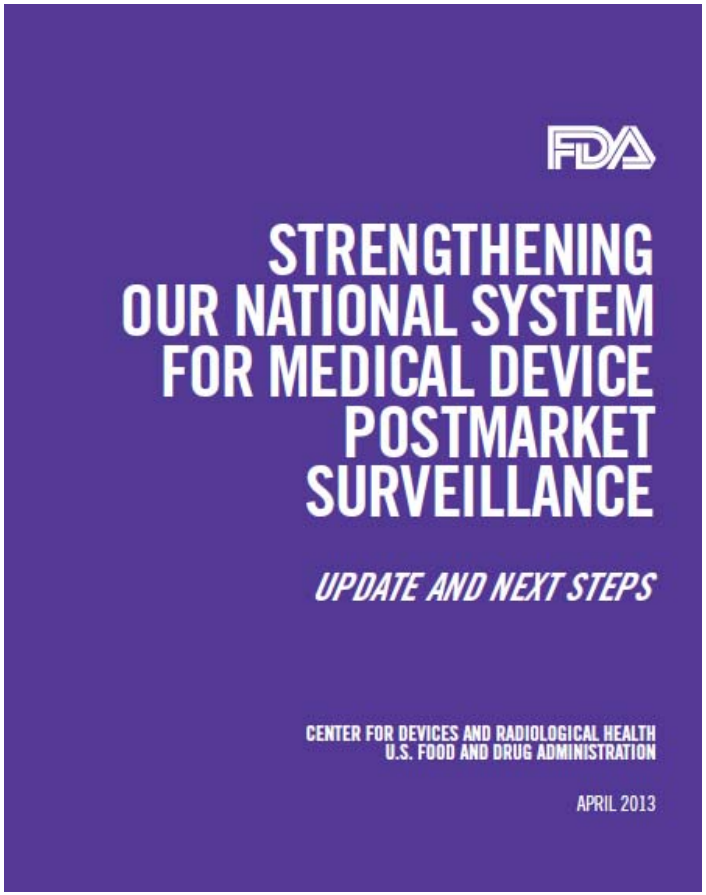
Knowledge Commons make curated information available to a community to do research, and generate and apply new knowledge

2014 FDA White Paper outlines possible approach to advance these technologies that would greatly reduce time and cost by leveraging data in high-quality, curated genetic databases as an alternative to conducting new clinical trials, thereby letting the clinical community crowdsource data to demonstrate clinical validity based on levels of evidence and expert review

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 variety of privacy-protected data sources**
- **Reduces burdens and costs of medical device postmarket surveillance**
- **Facilitates clearance and approval of new devices or new uses of existing devices**

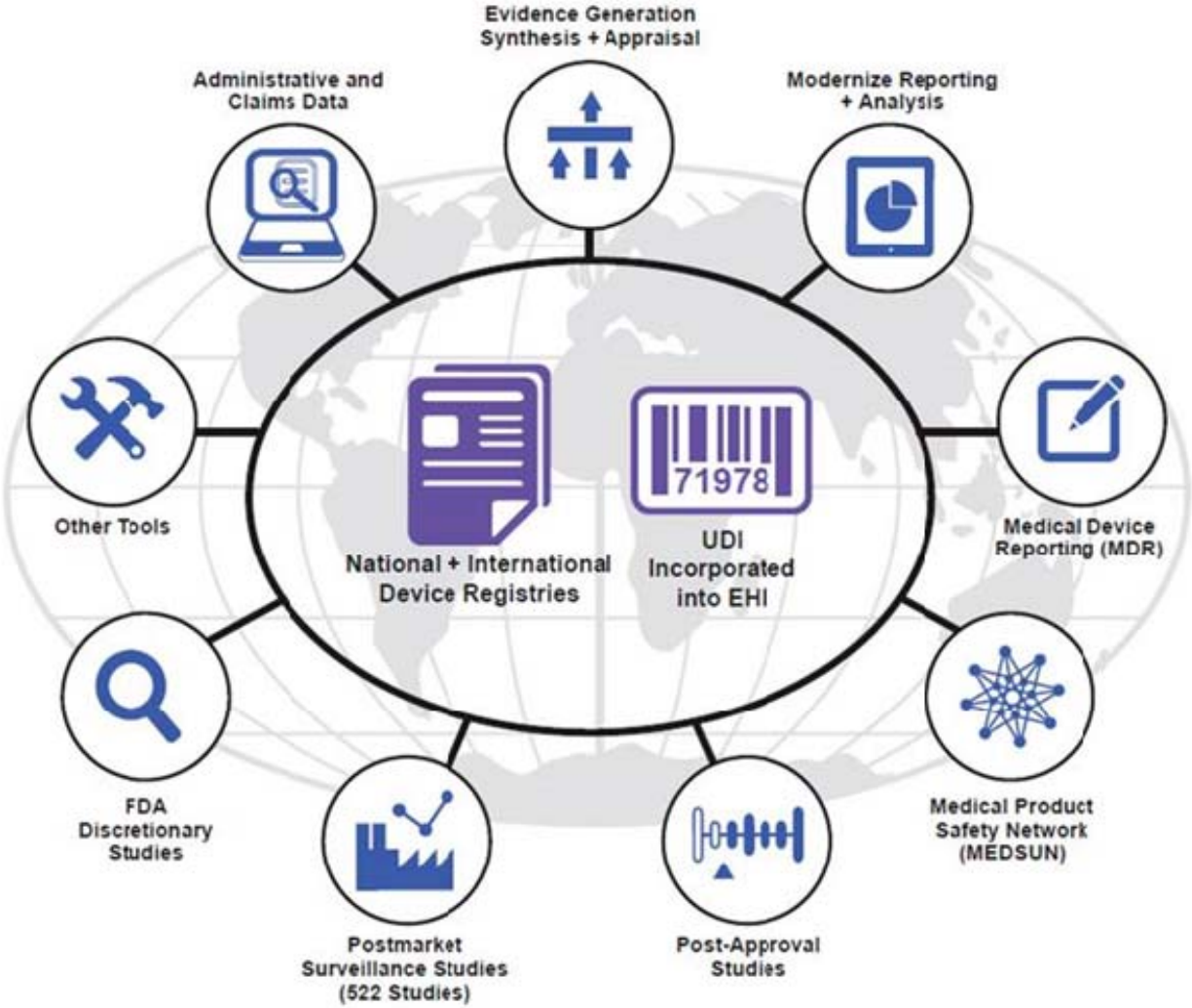
National "Surveillance" System

2012 Strategy

- **Establish a Unique Device Identification system and promote its incorporation into electronic health information**
- **Promote the development of national and international device registries for selected products**
- **Modernize adverse event reporting and analysis**
- **Develop and use new methods for evidence generation, synthesis, and appraisal**

National "Surveillance" System

2012 Strategy



Proof of Concept

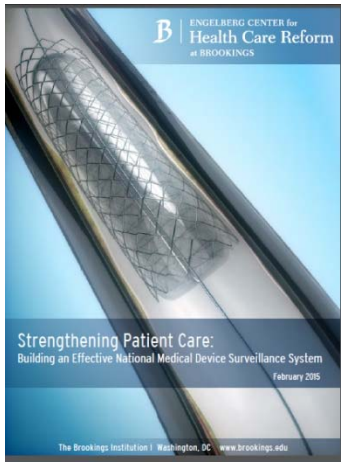
Use of Real World Evidence to Expand Minimally Invasive Heart Value Replacement Indications

Society of Thoracic Surgeons (STS) and American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry

- **Used for regulatory decision making: expansion of use, label change**
- **Linked to claims data for longitudinal study of transcatheter aortic value replacement**
- **Increased speed and efficiency of studies**

National "Surveillance" System

Planning Board



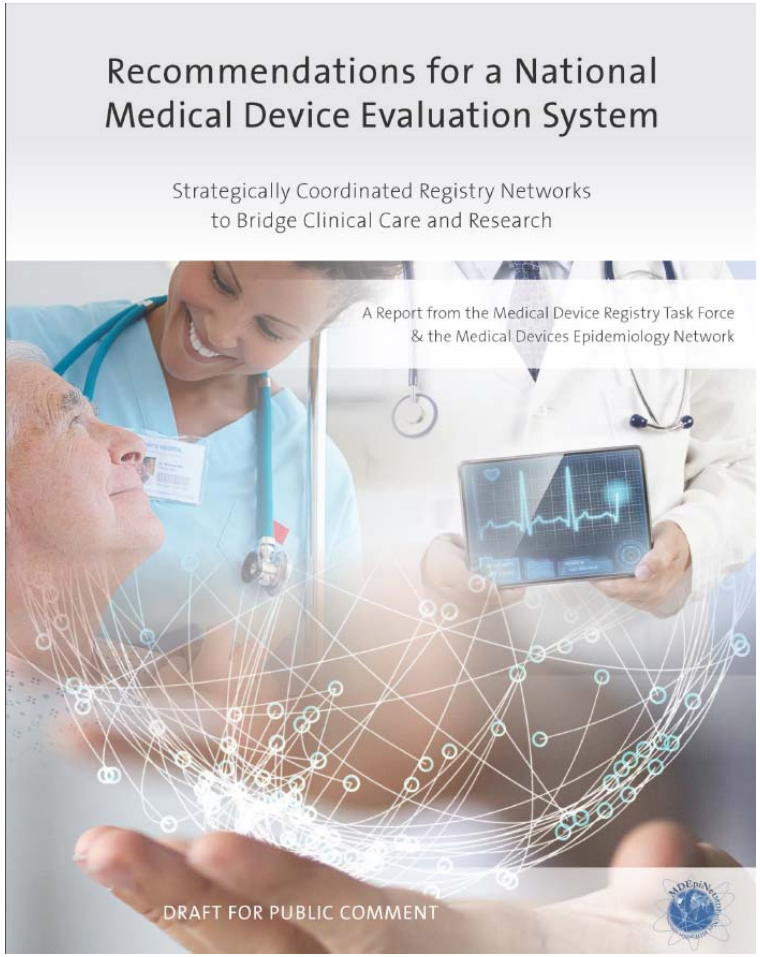
In February 2015, the multi-stakeholder Planning Board, convened by Brookings Institution, issued a report with recommendations for how to establish the national system

- 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.
- Set out an organizational structure and directions for pilots
- Proposed next steps

National "Surveillance" System

Current step: Medical Device Registry Task Force Report

- **Builds on the core strategy of the White Papers and the Planning Board Report**
- **Discusses the role of registries in the evolving National Medical Device Evaluation System**
- **Provides a direction for the future of registries**



National Evaluation System

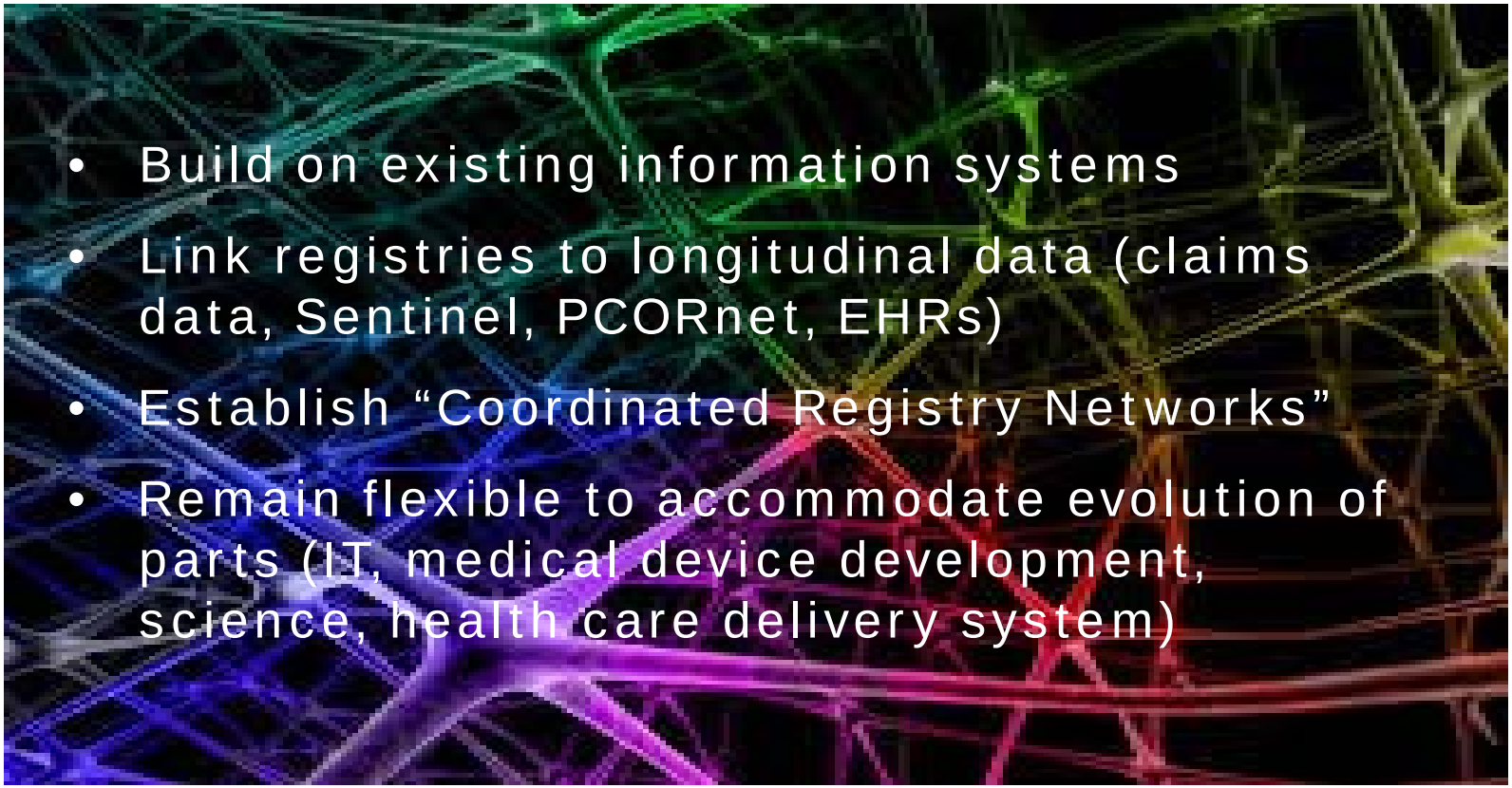
Transition from a "surveillance" to an "evaluation" system

- CDRH White Papers proposed a national system for multiple uses (not just for the FDA)
  - Comparative effectiveness, cost studies, premarket studies, and others
- But the word "surveillance" stuck

The report of the National Medical Device Registry Task Force has moved us forward setting out "evaluation" as a more inclusive term that brings all stakeholders into the system

National Evaluation System

Core Strategy



Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices

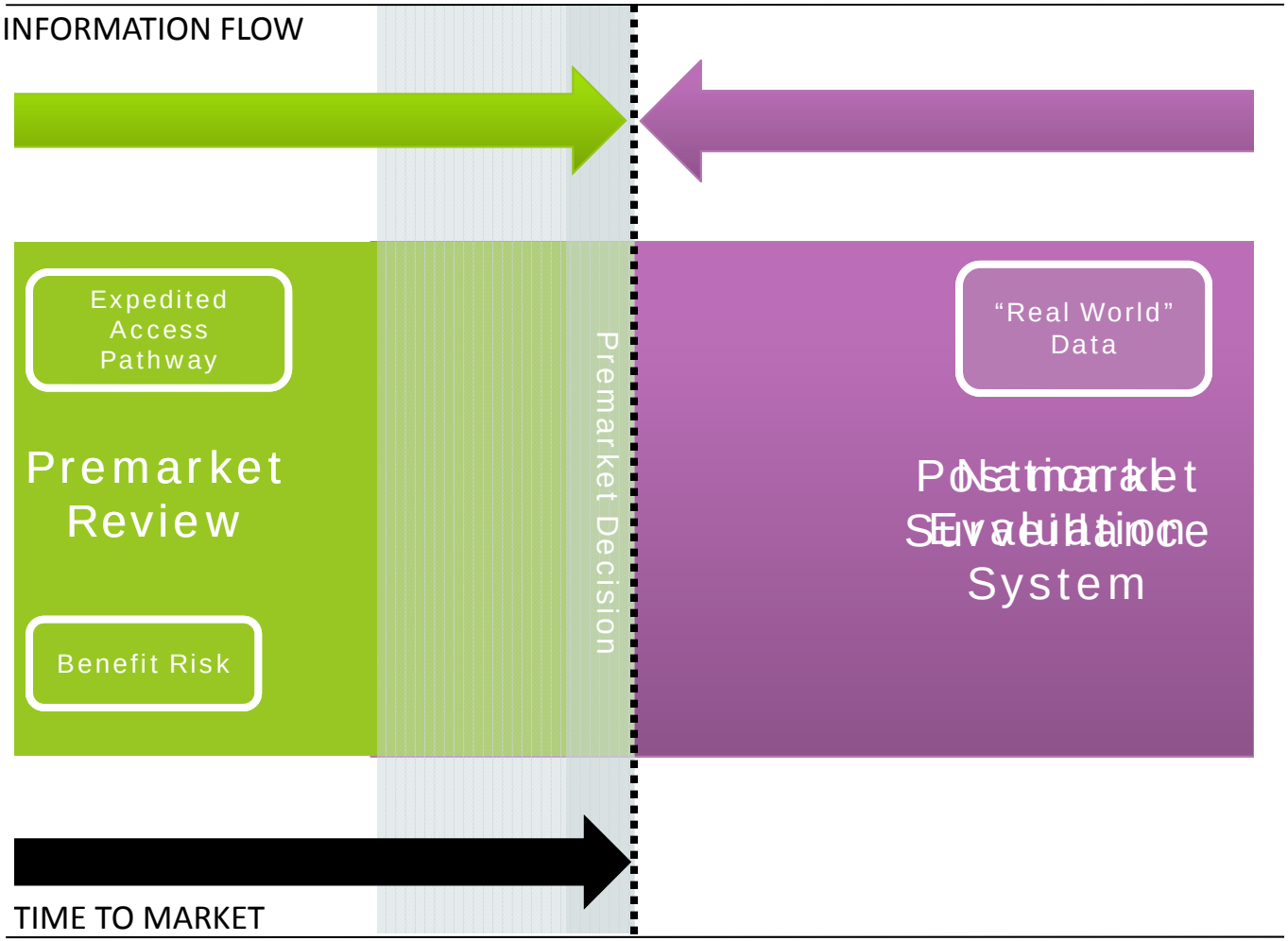
http://www.nber.org/papers/w20981

According to the authors, "For the set of devices on which we have data, we estimate that the US is close to the optimal policy"

Finding: FDA required clinical studies drive device use but also delay patient access and increase market access costs

Conclusion: "Some FDA reform proposals advocate for more relaxed premarket requirements but enhanced postmarket surveillance. The logic behind this proposal is straightforward…. We…find that if post-approval learning rates approach those we observe from clinical trials at a comparable cost, the benefits from such a policy change are substantial."

Learning Medical Device Ecosystem



What Will It Take to Succeed

- **It starts with trust among the medical device ecosystem members: "It Takes an Ecosystem"**
- **Shared commitment**
- **Shared responsibility**
- **Shared governance (with leadership)**
- **Sharing financial support**
- **Sharing data and expertise … and knowledge**
- **(And we can have different needs as long as we all get value out of the system)**

If we build it together, we have arrived

Thank You