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

Jeff Shuren
Director, CDRH
Food and Drug Administration
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

- **Digital Revolution** begins
  - transistor invented in 1947, leading the way to computers
  - first message sent over the APANET in 1969

1970s
- Home computer, time-sharing computers, video game consoles and age of arcade video

1980s
- First public digital HDTV broadcast – 1990 World Cup
- **Information ‘Superhighway’**
  - internet expanded quickly, every country had connection
  - 65% of households owned a computer

1990s
- 15% of U.S. households owned a computer and 30% with children under 18 owned one
- First digital camera
- **World Wide Web** invented

2000s
- Cell phones, text messaging, over 1 billion internet users, and **HDTV became standard in television broadcasting**
- **Widespread use and interconnectedness** of mobile networked devices and mobile telephony, internet websites and resources
- Social networking becomes the de facto standard in digital communication

2010s
- **Cloud computing** enters mainstream
- As of May 2014, there were nearly 7 **billion mobile** subscriptions worldwide

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The Accelerating Pace of Change

1. The accelerating pace of change...
   - Agricultural Revolution: 8,000 years
   - Industrial Revolution: 150 years
   - Lightbulb: 60 years
   - Moon landing: 22 years
   - World Wide Web: 9 years
   - Human genome sequenced: 10 years

2. ...and exponential growth in computing power...
   - Computer technology, shown here climbing dramatically by powers of 10, is now progressing more each hour than it did in its entire first 90 years.

3. ...will lead to the Singularity
   - UNIVAC I: The first commercially marketed computer, used to tabulate the U.S. Census, occupied 943 cu. ft.
   - Apple II: At a price of $1,298, the compact machine was one of the first massively popular personal computers.
   - Power Mac G4: The first personal computer to deliver more than 1 billion floating-point operations per second.

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 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

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

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Flexible Regulatory Paradigms
Continuum of Clinical Study Onset and Market Entry Points

- Early Feasibility Study Paradigm Guidance (2013)
- 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)
- “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 make curated information available to a community to do research, and generate and apply new knowledge.

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

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.
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

Diagram showing the processes and tools involved in the national surveillance system, including UDI incorporation into EHI, evidence generation, administrative and claims data, other tools, FDA discretionary studies, postmarket surveillance studies, post-approval studies, medical device reporting (MDR), medical product safety network (MEDSUN), and post-approval studies.
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
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

• Build on existing information systems
• Link registries to longitudinal data (claims data, Sentinel, PCORnet, EHRs)
• Establish “Coordinated Registry Networks”
• Remain flexible to accommodate evolution of parts (IT, medical device development, science, health care delivery system)
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

INFORMATION FLOW

Premarket Review
- Expedited Access Pathway
- Benefit Risk

TIME TO MARKET

Premarket Decision

“Real World” Data

Postmarket Surveillance System

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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