FDA’s Center for Devices and Radiological Health: Strategic Priorities for 2017 and Beyond

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U.S. Food and Drug Administration
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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
# Time Is Money

Estimated Cost of FDA Decisions on a 30 Employee Company

<table>
<thead>
<tr>
<th>Description</th>
<th>Expense to Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 Week Delay in Scheduling a Meeting</td>
<td>$1.8 M</td>
</tr>
<tr>
<td>Additional 20 Animal Study (6 months)</td>
<td>$5.5 M</td>
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<tr>
<td>Extra Year in Negotiating an IDE</td>
<td>$10.8 M</td>
</tr>
<tr>
<td>Additional 100 patient study with 1 year Follow-up (24 months)</td>
<td>$24.1 M</td>
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</tbody>
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Versant Ventures
Almost 4-fold Increase in # of Novel Device Approvals

* Novel devices include original PMAs, panel track supplement PMAs, and de novos
Since late 2009, CDRH has both continuously improved and transformed the way we do business through a series of culture, policy and process changes as well as legislative improvements and increased user fee funding.
Moderate Risk Innovative Devices (De Novo)

64% REDUCTION in Total Time to Decision

De Novo Average Total Time to Decision*

*Average Time to Grant, Decline, or Withdrawal

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Clinical Trials (IDEs)

>90% Reduction in Time to IDE Approval

Median number of days to full IDE approval

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Median Days</th>
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<tbody>
<tr>
<td>2011</td>
<td>442</td>
</tr>
<tr>
<td>2013</td>
<td>215</td>
</tr>
<tr>
<td>2014</td>
<td>101</td>
</tr>
<tr>
<td>2015</td>
<td>30</td>
</tr>
<tr>
<td>2016</td>
<td>30</td>
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CDRH Strategic Priorities

**2014-2015**
- Strengthen the Clinical Trial Enterprise
- Strike the Right Balance Between Premarket and Postmarket Data Collection
- Provide Excellent Customer Service

**2016-2017**
- Establish a National Evaluation System for Medical Devices (NEST)
- Partner with Patients
- Promote a Culture of Quality and Organizational Excellence

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21st Century Cures Implementation

- Establish Breakthrough Device Pathway
- Change HDE Limit to 8000 Patients
- Streamline Process for 510(k) Exemptions
- Modifications to Classification Panels
- Allow for Central IRBs
- Update CLIA Waiver Guidance
- Recognition of Standards
- Train and Audit Least Burdensome
- Clarify Medical Software Regulation
- Cleaning and Validation Data
MDUFA 4 Implementation

- Add Performance Goals for Presubmissions and De Novo
- Reduce 510(k) and PMA Avg Total Time to Decision
- PMA Approvable and Post-Panel Decisions
- Improve Deficiency Letter Writing
- Enhance Use of Consensus Standards
- Establish Digital Health and Quality Management Programs
- Independent Assessment/Auditing
- Patient Engagement
- Real World Evidence

Launch Date: October 1, 2017
Flexible Regulatory Paradigms
Applied Across the Total Product Life Cycle

CDRH Vision

Patient-Centered, TPLC Approach
Benefit-Risk Tradeoffs

Postmarket Benefit-Risk Guidance (2016)

Evidence Generation

Clinical Trials
Early Feasibility Study Paradigm Guidance (2013)

Regulatory Science
MDDT Pilot Program

Real-World Evidence
RWE Draft Guidance (2016)
Unique Device Identification Final Rule (2013)

Premarket-Postmarket Balance

Expedited Access Pathway Program (2015)

Science of Patient Input

Patient Preference Information Guidance (2016)
Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project

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Flexible Regulatory Paradigms

• Design the regulatory paradigm around the type of technology rather than push the technology down a one-size-fits-all pathway

• Direct-to-Consumer Genetic Health Risk Tests
  – One-time pre-check via 510(k)
  – No submissions for almost all future claims if meet special controls

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NEST

MDIC

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Benefit-Risk Tradeoffs

We have a risk-based framework but we need a benefit-risk-based framework

- Relevance of the Deficiency
- Clinically Significant vs Statistically Significant
- Least Burdensome Approach
- Patient Preferences
- Uncertainty
Least Burdensome Approach

Traditional Application

• Update guidances
• Train employees
• Streamline approach to deficiencies
  – Optimize interactive review
  – Provide rationale in Additional Information and Major Deficiency Letters
• Explain in summaries of significant decisions how the least burdensome approach was applied
• Conduct audits
• Establish process controls and implement decision support tools, such as eSubmission templates for industry and SMART templates for CDRH reviewers
Least Burdensome Approach
Expanded Application Incorporates Benefit-Risk Tradeoffs

• Stop regulating if FDA oversight is not sufficiently value added
  – Deregulated scores of software-based functions (2013)
  – Proposed to exempt over 1,000 Class II devices and 72 Class I device types from 510(k) (2017)

• International harmonization and convergence

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Use of Real-World Data

Adapted from Galson S and Simon G.
Benefits of Unique Device Identifiers (UDI)

- Improve Patient Safety
- More Accurate Understanding of Device Benefit-Risk Profile
- Facilitate Device Innovation and Patient Access
Foundational Work
NEST – Next Steps

Awarded $3 Million FDA Grant to establish NEST Coordinating Center

Proposed MDUFA IV User Fee Agreement

Pilot projects funded to determine the usability of RWE for PMA and 510(k) devices for:
- Expanded indications for use
- New clearances/approvals
- Improved malfunction reporting
NEST Coordinating Center Approach

1. Phase 1: Define needs and stand up organization
   - Conduct **Landscape Analysis**
   - Hire **Executive Director**
   - Establish NESTcc **Governing Committee** with representation from patients, federal agencies, industry, clinicians, hospitals, and health plans

2. Phase 2: Start demonstration projects
   - Initiate focused **demonstration projects** centered on high-risk category devices that require tracking and EHR data from hospital systems that use modern means of data collection

3. Phase 3: Establish Sustainability
   - Demonstration projects will **establish sustainability** of the NESTcc to the broader medical technology ecosystem
Real-World Evidence Heat Map

To gain a better understanding of the activity of RWE application across the TPLC, a heat map was developed using case studies shared by stakeholders and or collected during research.

RWE Applications Across Total Product Lifecycle

- Disease Area
  - Anesthesiology, General Hospital, Respiratory, Infection Control, & Dental
  - Cardiovascular
  - Cross-Cutting
  - In Vitro Diagnosis
  - Neurological & Physical Medicine
  - Ophthalmic and Ear, Nose, & Throat
  - Orthopedics
  - Reproductive, Gastro-Renal, & Urological
  - Surgical

- Number of Cases
  - 0
  - 26
Make Evidence Generation, Evidence Evaluation, and Device Oversight Global Enterprises
International Medical Device Regulators Forum

• Unique Device Identification
• National Competent Authority Report Exchange Program
• Regulated Products Submission
• Adverse Event Reporting
• Device Registries
• Software as a Medical Device
• Medical Device Single Audit Program
• Premarket Review

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Thank You