Partnerships at the Center for Devices and Radiological Health

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Center for Devices and Radiological Health,
U.S. Food and Drug Administration

FDA Health Professional Organization Conference
May 14, 2014
"Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety." --CDRH Vision Statement
Medical Devices are Critical to Our Nation’s Health…

Medical Device Development

The Total Product Life Cycle

Faster, Cheaper, Safer
2014 - 2015 Strategic Priorities

- Strengthen the clinical trials enterprise
- Strike the right balance between premarket and postmarket data collection
- Provide excellent customer service
Network of Experts

- Tool to provide rapid access to experts in science, engineering, and medicine to answers questions affecting core mission activities
NofE Partnerships

- American Urological Association (AUA)
- Infectious Disease Society of America (IDSA)
- American Gastroenterological Association (AGA)
- Association for Molecular Pathology (AMP)
- American Academy of Ophthalmology (AAO)
- American Society of Plastic Surgeons (ASPS)
- American Academy of Orthopaedic Surgeons (AAOS)
- American Glaucoma Society (AGS)
- American Academy of Neurology (AAN)
- American College of Nursing-Midwives (ACNM)
- American Dental Association (ADA)
- American Society of Anesthesiologists (ASA)
- American Academy of Pediatrics (AAP)
Improvements

1. Outreach
2. Focus on customer service
3. Simplify the process
4. Address clearance bottleneck
5. Improve scheduling
6. Transcription
7. Better document management
8. Stronger Communication
1) Initial Request and Clearance

Requestor (CDRH Staff) → Question for Network of Experts [Email: NetworkOfExperts@fda.hhs.gov]

Meeting to clarify the question(s) for Experts (within 2 weeks)

Office Clearance by NofE Office Liaison → Issue Outline

Center Clearance by CDRH NofE Coordinator

2) Experts Requested

CDRH NofE Coordinator sends request to Network Organization(s)

Requestor receives experts CVs and COIs and decides which expert(s) they would like to speak with

Organization has 7 working days to respond to the request

Signed COI and CVs of Experts

3) Call and Writeup

Requestor schedules telecon with experts

Telecon with Expert(s) → Summary of Call or Transcript created

Upload to NofE SharePoint
Network of Experts Day

May 14, 2014
1:00pm to 3:30pm
Bldg 66 Atrium

An opportunity to meet experts and to learn more about the expertise of their organization!

- American Academy of Neurology (AAN)
- American Association of Neurological Surgeons (AANS)*
- American College of Cardiology (ACC)*
- American Institute for Medical and Biological Engineering (AIMBE)
- Association of Public Health Laboratories (APHL)*
- American Society for Gastrointestinal Endoscopy (ASGE)
- American Society of Nephrology (ASN)
- American Society of Plastic Surgeons (ASPS)*
- American Society for Radiation Oncology (ASTRO)
- American Urological Association (AUA)
- American-European Congress of Ophthalmic Surgery (AECOS)
- Association for Molecular Pathology (AMP)*
- Infectious Disease Society of America (IDSA)
- The Society of Thoracic Surgeons (STS)
- International Congress of Oral Implantologists (ICOI)*
- American College of Gastroenterology (ACG)
- American Society of Anesthesiologists (ASA)*
How Does It Work?

Medical Device Discovery and Development Path

Basic Research → Proof of Concept or Invention → Early-stage Technology Development → Product Development → Production and Marketing

- NSF, NIH Corporate Research, SBIR Phase I
- Angel Investors, Corporations, Technology Labs, SBIR Phase II

Precompetitive Space
- Standards, data and processes that are common across an industry

Competitive Space
- Data, processes and know-how specific to a product

Regulatory science develops tools, methods, and standards to aid in this step
Reduce time and cost of device development and review

Key
- Source frequently funds this technological stage
- Source occasionally funds this technological stage

FDA, MDIC, Non-Profit, Industry

People
- Patients
- Providers
- Academia

Intellectual Control

Resources

Industry
The Power of Collaboration

- The most effective way to advance medical device regulatory science is through collaboration.

- Regulatory science is big science. In the current fiscal climate, we need to pool people, resources, and ideas to drive breakthroughs.

- The Medical Device Innovation Consortium will promote these collaborations by establishing an independent non-profit that brings together industry, government, and other stakeholders to this end.

- The MDIC will vastly expand our capacity for device-related regulatory science by creating a safe space for facile, creative, and ambitious medical device collaborations.
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1. Computational Modeling and Simulation, Randy Schiestl
   • Development
   • Assessment
   • Review

2. Clinical Trial Reform, Rick Kuntz, MD
   • Large Simple Trials
   • Post Market Surveillance
   • Data Transparency
   • Clinical Trial Efficiency

3. Patient Centeredness and Risk Management, Ross Jaffe, MD
   • Validation strategies for measuring patient views on device benefits and risks
   • Provide suggestions on how to utilize this data in the regulatory setting

Align • Achieve • Accelerate
Patient Engagement Panel
Possible Disease Representation

- Rare diseases
- Diabetes
- Osteoporosis
- Heart disease
- Epilepsy
- Obesity
- Pediatrics
- Ob/Gyn
- Hematology/Oncology
- Parkinson's
- Geriatrics
- Women’s Health
- Innovation
- General Patient Advocacy
For additional information, please contact

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* Annie Saha
* Michelle McMurry-Heath

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