YOU DRIVE INNOVATION,
WE’LL NAVIGATE

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Innovating Within Regulation

Technologies of the Heart – September 12, 2014
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OVERVIEW

- Regulations – Why do they exist?
- FDA – What do they do?
- Bench to Bedside – How do I get there?
- Innovation in Regulation – Can I get there faster?
- Speed Bumps - What will slow me down?
- The Medical Device Ecosystem
- The Future
REGULATIONS
THE REGULATORS

Department of Health and Human Services

Food and Drug Administration

Office of Medical Products and Tobacco

Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
WHAT DO THEY DO?

FDA PROCESS FOR APPROVING NEW DRUGS...

APPROVED!

ART • DAN BERGER

CONCEPT • MIKE ADAMS

WWW.NATURALNEWS.COM
NO, REALLY. WHAT DO THEY DO?

FDA Mission:

To protect and promote the public health.
DEVICE RISK

Eenie, meenie, mynie, moe, in which bin should the tongue depressor go?
Class I and II

Class III

http://www.samaras-assoc.com/regulatory.htm
MULTIDISCIPLINARY

• Bench Testing
  - Fatigue testing
  - Accelerated wear testing
  - Dynamic failure mode
  - Stress/Strain curves
  - Failure Modes and Effects Analysis
  - Pressure/Flow
  - Flex testing
  - .....and more!

• Human Factors

• Computational Modeling
  - Finite element analysis
  - Shear stress
  - Fluid dynamics

• Animal Model
  - Biocompatibility/Genotoxicity
  - Implant/delivery testing
  - Histology
  - Pathology

• Trial Design
  - Clinical Endpoints
  - Sample size
  - Power
  - Significance
  - Human Factors

• Patient protection
  - Informed consent
  - Ethics of trial participation
LOTS OF DATA, LOTS OF PEOPLE

- Review Team
  - Lead Reviewer
  - Scientific reviewers (engineers, scientists – multidisciplinary)
  - Medical Officers (physicians, veterinarians)
  - Statisticians (biostatisticians from OSB)
  - Consultants from CDER, CBER (combination products)
  - Nurses
  - Epidemiologists
  - Manufacturing
- Experienced versus Inexperienced
- Regulator versus Innovator
BENCH TO BEDSIDE – TOTAL PRODUCT LIFE CYCLE
CURRENT PARADIGM

• Pre-Clinical
  - Bench Testing
  - Animal
  - Computational

• Clinical Study
  - Feasibility
  - Pivotal
CAN YOU GET THERE FASTER?
SHIFTING THE PRE-CLINICAL PARADIGM

• Pre-clinical testing
  - Challenge: Accelerated wear test takes too long
  - Solution: Begin clinical study while certain pre-clinical tests are ongoing

• Computational Modeling (Personalized Medicine)
  - Challenge: Few patients in which to test device and make changes
  - Solution: Leverage computational modeling to design devices, assess in patients in early feasibility trial, and pursue any changes
SHIFTING THE CLINICAL AND POST-MARKET PARADIGM

• Clinical Study
  - Challenge: Unreasonable to conduct large patient study

  - Solution: Conduct clinical study and assess additional data in a post-market study

• Post-market
  - Challenge: Limited post-market data available because device is used off-label

  - Solution: Submit data from existing registry in support of label expansion
THE FUTURE

• Changing paradigm for pre-clinical/clinical requirements prior to approval

• Consider transfer of some risk assessment from FDA/government to patients (need appropriate education plan)

• Leverage post-market data into an approval package

• Encouragement for first in human, FIRST in US

• Globalization and greater acceptance of OUS data

• Improved alignment with other organizations (Centers for Medicare and Medicaid Services, professional societies, etc.)
SUMMARY - LEAST BURDENSOME PATH TO MARKET

• Talk to FDA – early and often

• Need to know versus want to know

• Plan a reasonable strategy – EARLY
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Thank you!
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