

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

REGULATORY SCIENCE PRIORITIES (FY2016)



Executive Summary

October 20, 2015

The Regulatory Science Subcommittee (RSS) of the CDRH Center Science Council assessed and prioritized the Center's regulatory science needs, after collecting regulatory science needs/gaps from CDRH Offices. The following top 10 needs, all of equal importance, were identified by the RSS:

- Leverage “Big Data” for regulatory decision making
- Leverage evidence from clinical experience and employ evidence synthesis across multiple domains in regulatory decision making
- Improve the quality and effectiveness of reprocessing reusable medical devices
- Develop computational modeling technologies to support regulatory decision making
- Enhance performance of Digital Health and medical device cybersecurity
- Incorporate human factors engineering principles into device design
- Modernize biocompatibility / biological risk evaluation of device materials
- Advance methods to predict clinical performance of medical devices and their materials
- Advance the use of patient reported outcome measures (PROMs) in regulatory decision making
- Collect and use patient experience/preference in regulatory decision making

If you need additional information please e-mail CDRHRegScience at:
CDRHRegScience@fda.hhs.gov .

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

TABLE OF CONTENTS

I. INTRODUCTION	3
WHAT IS REGULATORY SCIENCE?	3
II. WHAT DRIVES REGULATORY SCIENCE AT CDRH?	4
III. WHAT IS THE PURPOSE OF IDENTIFYING CDRH REGULATORY SCIENCE PRIORITIES?	5
HOW DOES THE CENTER ENVISION USING THESE PRIORITIES?	5
IV. HOW DID CDRH GENERATE FY2016 REGULATORY SCIENCE PRIORITIES?	5
V. CDRH REGULATORY SCIENCE PRIORITIES FOR FY2016	6
LEVERAGE “BIG DATA” FOR REGULATORY DECISION MAKING:	6
LEVERAGE EVIDENCE FROM CLINICAL EXPERIENCE AND EMPLOY EVIDENCE SYNTHESIS ACROSS MULTIPLE DOMAINS IN REGULATORY DECISION MAKING:	7
IMPROVE THE QUALITY AND EFFECTIVENESS OF REPROCESSING REUSABLE MEDICAL DEVICES:	7
DEVELOP COMPUTATIONAL MODELING TECHNOLOGIES TO SUPPORT REGULATORY DECISION MAKING:	8
ENHANCE PERFORMANCE OF DIGITAL HEALTH AND MEDICAL DEVICE CYBERSECURITY:	8
INCORPORATE HUMAN FACTORS ENGINEERING PRINCIPLES INTO DEVICE DESIGN:	8
MODERNIZE BIOCOMPATIBILITY / BIOLOGICAL RISK EVALUATION OF DEVICE MATERIALS:	8
ADVANCE METHODS TO PREDICT CLINICAL PERFORMANCE OF MEDICAL DEVICES AND THEIR MATERIALS:	8
ADVANCE THE USE OF PATIENT REPORTED OUTCOME MEASURES (PROMs) IN REGULATORY DECISION MAKING:	9
COLLECT AND USE PATIENT EXPERIENCE/PREFERENCE IN REGULATORY DECISION MAKING:	9

I. INTRODUCTION

FDA's Center for Devices and Radiological Health (CDRH) is responsible for assuring the safety, effectiveness, performance and quality of medical devices and radiation-emitting products used to treat, prevent, and diagnose disease.

The mission¹ of CDRH is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

To support this mission, regulatory science at CDRH is aimed at improving the assessment of the safety, effectiveness, performance and quality of medical devices and radiation-emitting products throughout the product life cycle thereby reducing the time to market, improving safety, and making the process least burdensome. CDRH regulatory science also aims at advancing our nation's public health by helping to facilitate device innovations and ensuring that devices using state-of-the art technologies are available to improve and maintain Americans' health.

This document provides a summary of the identified CDRH top ten regulatory science needs/priorities for FY2016. It also provides an overview of the process that CDRH used to generate these priorities.

What is Regulatory Science?

CDRH defines regulatory science as science in the service of regulation. It helps ensure that regulatory decisions are well-founded and achieve desired impact on public health, by developing and applying tools, standards and methodologies to study the safety, effectiveness, quality and performance of medical devices and radiation-emitting products under the total product life cycle framework. In addition it facilitates good decision-making in the areas of premarket evaluation, postmarket surveillance, compliance, and education; and it embraces a broad range of disciplines including engineering, medicine, chemistry, toxicology, epidemiology, statistics and social sciences.

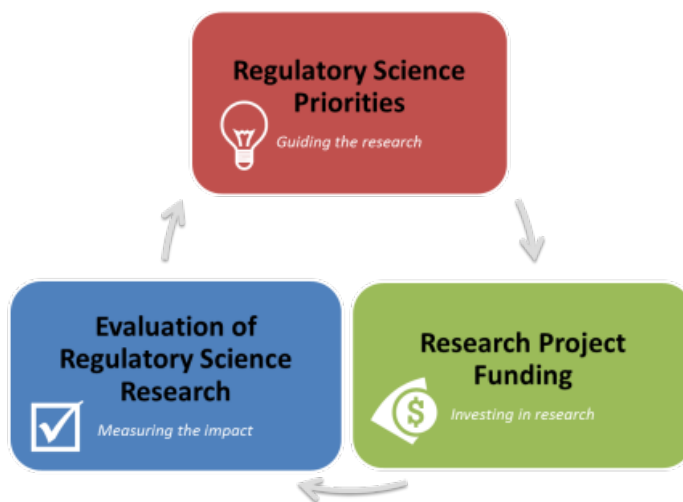
¹ <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm>



II. WHAT DRIVES REGULATORY SCIENCE AT CDRH?

Regulatory science at CDRH aligns with and supports the Center's [mission and vision](#).

CDRH regulatory science is intended to be proactive and anticipatory on regulatory and public health issues, while being responsive to emerging public health and regulatory issues. It covers the continuum of medical device regulatory science research needs ranging from investing in infrastructure (software, hardware, data capacity and sources, lab equipment); developing evaluative tools, approaches or methods; addressing long standing questions (such as topics that consistently raise deficiencies or questions during regulatory review); and addressing emerging issues.



The overarching goal of CDRH regulatory science is to foster the development and application of tools, standards and methodologies to study the safety, effectiveness, performance and quality of devices. It is intended to facilitate medical device innovation, as well as, transparent and predictable decision-making in the areas of

premarket evaluation, postmarket surveillance, compliance, and education. It also aims to expedite the availability of novel safe and effective medical devices in the U.S. marketplace.

In response to the 2011 510(k) Working Group and Utilization of Science in Regulatory Decision Making Task Force reports, CDRH created an action plan to implement recommendations made in these reports. This plan included the formation of the [Center](#)

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

[Science Council \(CSC\)](#), an advisory body comprised of Center leadership and CDRH staff, to help the Center meet its public health goals. In accordance with the CSC Charter, the Regulatory Science Subcommittee (RSS) was created in 2013. The RSS is charged with proactively enhancing medical device innovation, development, safety, quality and effectiveness through developing policies and practices that promote the identification and incorporation of new science and technology into regulatory decision making. These activities support and promote regulatory science at CDRH.

III. WHAT IS THE PURPOSE OF IDENTIFYING CDRH REGULATORY SCIENCE PRIORITIES?

The CDRH regulatory science priorities serve to accelerate improving the safety, effectiveness, performance and quality of medical devices and radiation-emitting products, and to facilitate introducing innovative medical devices into the marketplace. It helps the Center address the most important regulatory science gaps or needs. These priorities will be reassessed and updated periodically to reflect current regulatory science needs.



How does the Center envision using these priorities?

CDRH envisions a cyclical regulatory science prioritization and implementation model to best serve the Center's mission, vision and use of Center resources.

The regulatory science priorities serve as a precept for making strategic intramural research funding decisions to ensure that CDRH research is focused on issues/gaps/needs that are relevant and critical to the regulatory science of medical devices and radiation-emitting products. The research projects that are funded through intramural sources are evaluated periodically using our metrics rubric to ensure the projects are meeting their regulatory science goals and ultimately impacting public health and/or regulatory decision-making.

We envision that our external stakeholders can use these priorities to better target their regulatory science resources as well complement these activities. In addition, we believe that collaboratively we can work to maximize the impact of regulatory science research investments.

IV. HOW DID CDRH GENERATE FY2016 REGULATORY SCIENCE PRIORITIES?

The regulatory science priorities were generated by the RSS under the direction of the Center Director and the RSS co-chairs, using a systematic and scientific process as described below.

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

The RSS conducted a Center-wide call for regulatory science needs. The collection methodology included a standard form with guidelines that provided a structured framework and helped submitters think through and describe how a regulatory science need aligned with the Center's regulatory mission and/or vision.

The RSS then processed the information collected through a systematic, stepwise, interactive and scientific procedure to compile, categorize, rank and prioritize the regulatory science needs. The result is the Center's top-10 regulatory science needs for FY2016, listed in Section V.

During the assessment process, each proposed regulatory science need was assessed for its ability to address the following pre-specified criteria:

1. Will addressing the need facilitate medical device innovation and bring new technology to market?
2. Will addressing the need enhance or expedite the availability of medical devices and radiation-emitting products while maintaining their safety and effectiveness?
3. Will addressing the need facilitate rapid identification of problems, improve our postmarket understanding of the benefit-risk profile of devices or radiation-emitting products and aid future premarket device clearance or approval?
4. What is the public health impact of the need?
5. Is it a need that other organizations will not or cannot address?

V. CDRH REGULATORY SCIENCE PRIORITIES FOR FY2016

The top 10 CDRH regulatory science priorities/needs, all of equal importance, are listed below.

Leverage "Big Data" for regulatory decision making:

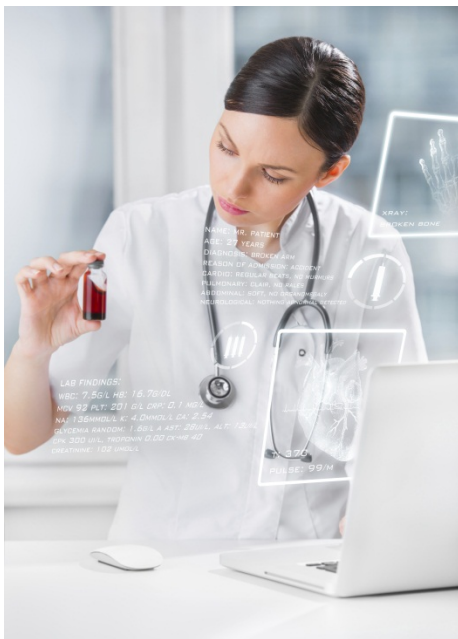
Big Data warehouses such as the human genome sequence database and clinical trials database contain a wealth of scientific and clinical information relevant to the safety, performance and/or quality of medical devices. However, these data sources are under-utilized in regulatory decision making. Harvesting, validating, organizing and disseminating information in these data warehouses, when appropriate, can potentially enhance the quality and effectiveness of regulatory decision making. In addition, harvesting and analyzing information from data warehouses such as these may aid the regulatory process by streamlining scientific review and identifying potential emerging post-market issues earlier in the process. Therefore, it is important to develop appropriate informatics capabilities and information technology/software tools to

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

collect, store, and analyze Big Data relevant to enhancing safety, performance, and/or quality of medical devices.

Leverage evidence from clinical experience and employ evidence synthesis across multiple domains in regulatory decision making:

Currently most regulatory decisions are based on information provided by manufacturers. The vast amount of observational data on device use after-marketing can be found in sources such as healthcare databases. This data is often underdeveloped and underutilized. Research to develop and leverage reliable clinical evidence / observational data is necessary to use these data to enhance the quality of regulatory decision making. Similarly, there is need for further development and application of evidence synthesis of scientific literature and other disparate data domains.



Improve the quality and effectiveness of reprocessing reusable medical devices:

Reuse of devices introduces the risk of infection transmission to patients between uses. Reusable devices are commonly used in patient care and many reusable devices have evolved into more complex designs, making them more challenging to reprocess. To minimize patient harm from inadequately reprocessed devices and to enhance the safety, effectiveness, performance, and/or quality of these devices, it is critical to develop a comprehensive approach to address the effectiveness of reprocessing techniques. Approaches should encompass the areas of device design; human factors; reprocessing instructions; reprocessing methodologies; validation methods for reprocessing including cleaning and high level disinfection; validated markers of successful reprocessing; and surveillance of reprocessed devices in healthcare facilities.

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

Develop computational modeling technologies to support regulatory decision making:

Computational modeling and simulations are being increasingly used for device development, testing and validation. However, the application of these in regulatory decision making lags behind device development. Developing representative modeling/simulation techniques in conjunction with appropriate validation methodologies together with guidance on assessing their credibility may help devices enter the marketplace utilizing least burdensome approaches.

Enhance performance of Digital Health and medical device cybersecurity:

Digital Health and cybersecurity are some of the fastest growing areas impacting medical devices. Devices are being increasingly used in networked environments and are expected to communicate with one another securely and accurately. To ensure these technologies and technological environments achieve the desired public health impact, research is needed to enhance performance and security of medical devices and interoperability, and to understand the impact of software modifications on device performance.

Incorporate human factors engineering principles into device design:

Many device recalls and adverse event reports reflect underlying human factors engineering problems including usability issues and preventable design problems. To address these issues, it is important to develop tools and methodologies for assessing device design and usability. For example, human factors research could be important to reduce alarm fatigue.

Modernize biocompatibility / biological risk evaluation of device materials:

The typical biological risk / biocompatibility assessment approach for devices would benefit from considering alternative approaches to the standard biocompatibility battery of tests. For example, the development of improved tools/methods to assess and predict biological risk factors of devices as well as the integration of chemical characterization, computational or *in silico* modeling could translate into lessening the dependence on animal testing.

Advance methods to predict clinical performance of medical devices and their materials:

There is a gap in the availability of tools and methodologies to assess the impact of various materials and material types on the quality, performance and safety of medical devices, particularly when trying to predict long-term clinical outcomes. There is a need to improve the nonclinical assessment of physicochemical and mechanical performance of devices. Methodologies and tools to more accurately predict the clinical impact of new materials and technologies such as surface coatings, materials corrosion and additive manufacturing, on device quality, performance and safety, could promote the

CDRH REGULATORY SCIENCE PRIORITIES (FY2016)

development of alternative materials, enhance predictability of nonclinical performance to represent longer-term performance and increase safety in device design.

Advance the use of patient reported outcome measures (PROMs) in regulatory decision making:

Although there is a growing trend to use PROMs in medical product development, the quality and validity of PROMs is highly variable. To better incorporate data from PROMs in regulatory decision making, it is important to develop and validate PROM instruments which generate high quality, relevant data on outcomes of importance to patients.

Collect and use patient experience/preference in regulatory decision making:

Patients are increasingly interested in providing their views to spur patient-centric medical product development and to inform patient-centric regulation. To utilize patient experience/preference information, CDRH needs to better understand and/or develop methods/tools to elicit and collect high quality patient experience data, as well as to incorporate such data appropriately into regulatory decision making.