Center for Veterinary Medicine Office of Research Strategic Priorities

FY 2018 - 2022

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Introduction

The Center for Veterinary Medicine (CVM)¹ is a specialized product and research center that works to fulfill the U.S. Food and Drug Administration's (FDA) public health mission. Research is conducted primarily at the CVM's Office of Research (OR) in collaboration with a variety of stakeholders to provide research solutions that ensure the safety of animal derived food and animal health products. These research activities support the needs of FDA's animal health regulators, on current and evolving issues including pre-market drug review, compliance, post-approval monitoring, and animal feed safety.

The OR maintains internationally recognized research programs in these areas:

- Analytical evaluation of compounds which pose a potential health risk if found in animal tissue or feed.
- Applied and basic research in animal health and medicine in support of current and evolving regulatory issues.
- Applied and basic research involving the isolation, identification, and characterization of microorganisms potentially harmful to animals and humans.

In addition, the OR has oversight over the following two surveillance programs:

- The National Antimicrobial Resistance Monitoring System (NARMS): is a
 collaborative project of state and local public health departments, the FDA, the
 Centers for Disease Control and Prevention (CDC), and the U.S. Department of
 Agriculture (USDA). NARMS data are used by FDA to make regulatory decisions
 designed to preserve the effectiveness of antibiotics for humans and animals. Its main
 function is to serve FDA CVM as a source of data for the approval of new animal
 antibiotics and for the post-approval safety monitoring of these compounds.
- CVM Veterinary Laboratory Investigation and Response Network (Vet-LIRN): The
 mission of Vet-LIRN is to promote human and animal health by collaborating with
 veterinary diagnostic laboratories in order to provide scientific information, build
 laboratory capacity for routine and emergency response, and train scientists. Further,
 the Vet-LIRN helps CVM investigate potential problems with CVM regulated products
 (animal feeds and animal drugs).

FY 2018-2022 OR Strategic Priorities sets a clear direction of how OR research activities will support and address animal and public health challenges faced by CVM and the FDA in next five years. The plan includes the new OR mission and vision, critical goal areas, and specific objectives with strategies that are appropriately focused and in alignment with Food and Veterinary Medicine (FVM) 2016-2025 Strategic Plan and CVM's Key Initiatives.

¹ http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm

FVM Mission

Promote public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products

CVM Mission

Protecting Human and Animal Health

OR Mission

Protecting human and animal health by providing meaningful research to support regulatory decision making about food, feed, and drugs

OR Vision

We are the leader among internationally recognized research programs ensuring the safety of feed, animal derived food, and animal health products.

OR Goals and Objectives

FY 2018-2022 OR Strategic Priorities plan identifies the following three core goals along with the key objectives and strategies to ensure that the research activities adequately support our mission of protecting and promoting human and animal health.

Goal #1 - Increase the use of regulatory science to inform standards development, analysis, and decision-making to enhance oversight of FDA regulated animal food and health products.

Objective 1.1 Strengthen detection and surveillance of problems with FDA-regulated animal food and feed, animal-derived food, and animal health products.

- Strategy 1.1a: Improve data analysis and collaboration with food and feed safety stakeholders including industry, academia, and other domestic and foreign regulatory bodies.
- Strategy 1.1b: Foster development of tools and models to assess the safety of unapproved animal drugs, including compounded animal drugs.
- Strategy 1.1c: Collaborate with federal and state agencies to identify and address illegal drug residues in animal-derived food.

Objective 1.2 Reduce risks in the manufacturing, production, and distribution of FDA-regulated animal health products.

- Strategy 1.2a: Increase coordination with federal, state, local, tribal, and private stakeholders and enhance monitoring of antimicrobial drug use practices and resistance data to support efforts to foster judicious use of medically important antimicrobials in food producing animals
- Strategy 1.2b: Support research to better understand the emergence, persistence, and spread of antimicrobial resistance

- Objective 1.3 Monitor and assess emerging nutrition science as well as changes in the composition of animal foods in the marketplace in relation to the nutritional and health status of animals and humans.
- Strategy 1.3a: Enhance the capacity to gather and analyze the composition and labeling of animal food (i.e., pet food, animal feed, and raw materials and ingredients) in the marketplace.
- **Objective 1.4** Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.
- Strategy 1.4a: Evaluate and mitigate the risks of chemical exposures in food and feed products that pose public health or regulatory concerns.
- Strategy 1.4b: Evaluate and mitigate the risks of microbiological hazards in food and feed products.
- **Goal #2 -** Increase regulatory science capacity to effectively evaluate food, feed, and animal health products.

Objective 2.1 Improve access to safe and effective animal drug products

- Strategy 2.1a: Identify and develop new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new drug development.
- Strategy 2.1b: Facilitate the introduction of innovative products and processes by enhancing the predictability of regulatory evaluation processes of animal drug products.
- Objective 2.2 Increase collaboration, training, and information-sharing with the scientific community, industry, and other regulatory bodies
- Strategy 2.2a: Use existing and new tools and methods to acquire needed capabilities through partnership with academia and non-regulated private industry, and other Govt. entities
- Objective 2.3 Foster evidence-based decision making through collaboration, training, and information-sharing with the scientific community, industry, and other regulatory bodies
- Strategy 2.3a: Establish and maintain partnerships within CVM, FVM, FDA centers, and other government agencies to jointly address ongoing and emerging food, feed, and animal health issues.
- **Objective 2.4** Develop and maintain effective internal communication, horizontally and vertically, within CVM, FVM, FDA, and with other government departments and agencies
- Strategy 2.4a: Develop plans and mechanisms for sharing information from conferences and training

Goal #3 Enhance Organizational Excellence

Objective 3.1 Achieve optimal risk-informed resource allocation.

- Strategy 3.1a: Fully implement a risk-informed resource allocation framework, linking risk-informed program priorities to spend plans and budget execution.
- Strategy 3.1b: Leverage information technology systems and processes to support risk-informed decision making, evaluation of public health impact, and strategic resource planning.
- Strategy 3.1c: Improve efficient use of resources to enhance productivity while maintaining program.
- Strategy 3.1d: Expand comprehensive data- informed planning models that connect performance measures and outputs to public health outcomes.

Objective 3.2 Optimize the scientific expertise and organizational capacity

- Strategy 3.2a: Adopt innovative, risk-informed approaches to ensure scientific research is directed at mitigating priority hazards and advances public health.
- Strategy 3.2b: Establish collaborative arrangements with the public health community, including academia, industry and other regulatory agencies, to leverage existing knowledge and improve innovation in areas including product development, food safety, and analytic methods.
- Strategy 3.2c: Foster the development of rapid and advanced technologies to accurately identify biological and chemical hazards through expansion of scientific expertise and laboratory capacity

Objective 3.3 Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission

- Strategy 3.3a: Recruit, develop, train, and strategically manage a talented and diverse workforce by investing in leadership and human capitol infrastructures.
- Strategy 3.3b: Promote an organizational culture of quality, cooperation, innovation, and accountability by enhancing open communication, encouraging creativity, and supporting employee recognition.
- Strategy 3.3c: Enhance leadership development through continuous learning, performance management, and effective succession planning
- Strategy 3.3d: Increase leveraging of resources through collaboration with external stakeholders, including academia, industry, and other regulatory bodies.

IMPLEMENTATION

The OR Strategic Priorities will be implemented through annual tactical planning at the office/division level. Research goals and objectives will continue to be prioritized and strategically aligned annually with CVM's Science and Research Committee (SRC), and FVM's Science and Research Steering Committee (SRSC). The strategies will be reassessed biennially, accompanied by reexamination of broader Strategic Goals and Objectives.

The OR Tactical Plan is updated annually and reflects alignment with OR Strategic Priorities.

Next Steps:

- Develop meaningful indicators/performance measures for excellence in goal areas
- Connect the OR Strategic Priorities to Division and Staff levels
- Integrate OR Strategic Priorities into OPI starting in FY 2018
- Coordinate an ongoing process of communication and engagement with OR staff, SRC, CEB, OFVM, and external stakeholders to refine the plan and substantiate the thoughtful dynamism of the framework—ensuring that OR work advances the mission of CVM, FVM, and FDA.
- Share successes and report outcomes