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Introduction

The U.S. Food and Drug Administration (FDA) plays a vital and active role protecting the United States from chemical, biological, radiological, nuclear (CBRN), and emerging infectious disease threats (such as Zika virus, Ebola virus, and pandemic influenza). The FDA is responsible for assessing the safety and effectiveness of medical countermeasures (MCMs) – including diagnostic tests, drugs, and vaccines – that are needed to counter these threats. In addition, the FDA works closely with interagency partners and product developers to advance the development and availability of investigational MCMs. In 2010, the FDA established its Medical Countermeasures initiative (MCMi) focusing increased resources on promoting the development of MCMs by establishing clear regulatory pathways for MCMs, instituting effective regulatory policies and mechanisms to facilitate timely access to available MCMs, and advancing MCM regulatory science to create the tools, standards, and approaches that support regulatory decision-making.

MCMi Regulatory Science Program

The MCMi Regulatory Science Program supports a robust intra- and extramural research portfolio focused on helping to translate cutting-edge science and technology into innovative, safe, and effective MCM. The mission of the MCM regulatory science program is to foster MCM regulatory science initiatives to:

1. Develop solutions to complex regulatory science problems,
2. Facilitate incorporation of cutting-edge science into the regulatory review process and
3. Make product development more efficient and predictable.

This program is being implemented through partnerships, and support of intra- and extra-mural research projects. The intramural research program, which began in 2011, has enhanced and expanded existing MCM research efforts at FDA. In 2012, the extramural program was initiated using the FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science (FDABAA-16-00122). <http://go.usa.gov/x8XEs>

MCMi Regulatory Science Priority Research Areas

- Developing animal models and tools to evaluate safety and efficacy
- Identifying and qualifying biomarkers for safety and efficacy
- Using protein engineering to stabilize vaccine proteins
- Developing methods to assess medical countermeasure product quality and related product release assays
- Validating next-generation *in vitro* diagnostics platforms
- Assessing the performance of emergency medical equipment
- Enhancing emergency preparedness and response capabilities, including risk communication and tracking and evaluating the safety and clinical benefit of medical countermeasures used during public health emergencies

Ebola Research

In response to the 2014-2015 Ebola outbreak in West Africa, FDA made substantial investments in both the intra- and extramural research programs to address scientific gaps specifically related to Ebola MCMs (Table 1).

Table 1. MCMi Regulatory Science Research – Ebola Projects

Project Area	Project Title	Principle Investigator(s) Affiliation	Program
Animal Models	Animal models to evaluate Filovirus T cell responses	Dr. Marian Major FDA, Center for Biologics Evaluation and Research	Intramural
Assay Development	Supporting field lab testing of Ebola antibodies in Sierra Leone	Dr. Gerardo Kaplan FDA, Center for Biologics Evaluation and Research	Intramural
		Dr. Maria Capobianchi National Institute for Infectious Diseases “Lazzaro Spallanzani” (INMI), Rome, Italy	Extramural
Vaccines	Developing tools for better understanding human response to Ebola vaccines	Dr. Surender Khurana FDA, Center for Biologics Evaluation and Research	Intramural
Therapeutics	Novel clinical trial designs for investigational (therapeutic) agents	Dr. Dionne Price FDA, Center for Drug Evaluation and Research	Intramural
Diagnostics	Providing regulatory-grade filovirus nucleic acid sequences to support diagnostic development	Dr. Heike Sichtig FDA, Center for Devices and Radiological Health	Intramural
		Dr. Lisa Sadzewicz University of Maryland	Extramural
Biomarkers (Immune Characterization)	Analyzing samples from Ebola survivors to better understand long-term sequelae of Ebola Virus Disease	Dr. Miles Carroll Public Health England	Extramural
	Sequae and Immunopathology of Ebola Virus Infections	Dr. Garry Nolan Stanford University	Extramural



Scientist processing Ebola virus disease samples at Donka Hospital in Conakry, Guinea as part of the EVIDENT project. (Image: EVIDENT)

