

Strengthening Regulatory Science to Advance the Development of Medical Countermeasures for Emerging Infectious Diseases

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MCMi Regulatory Science Program

- **Goal**
 - Develop the tools, standards, and approaches to assess MCM safety, efficacy, quality, and performance
 - Translate cutting-edge science and technology into innovative, safe, and effective MCMs
- **Activities**
 - Intramural research
 - Extramural research
 - Scientific collaborations



Science Preparedness & Response



Priority Research Areas

Identifying, developing, and qualifying	<p>Tools to assess safety and efficacy of MCMs</p> <p>In silico predictive models and in vitro assays to assess safety and efficacy of MCMs</p>
Validating	<p>NGS-based IVD platforms</p>
Developing	<p>Reference materials related to facilitate development of MCMs</p>
Assessing	<p>The performance, design, and reuse of emergency medical equipment including PPE</p>
Enhancing	<p>Emergency preparedness and response capabilities including risk communication and the capability to evaluate the safety and clinical benefit of MCMs used during public health emergencies (Monitoring & Assessment)</p>
Advancing	<p>Tools, technologies, and platforms that can improve the manufacturing efficiency, consistency, and quality of MCMs</p>

Preparedness

- Correlates of Protection against Ebola Virus Predictive of Vaccine Efficacy in Humans
- Comparison of EBOV Infection and Ebola Virus Disease in Animals and Humans and Assessing Animal Models for MCM Development
- Development of Assays and Models for Evaluation of Pandemic Influenza Vaccines
- Personal Protective Equipment Decontamination



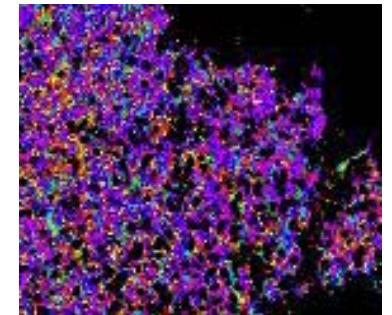
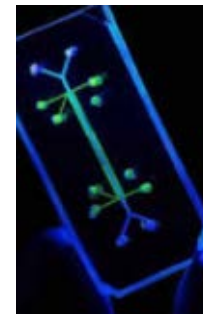
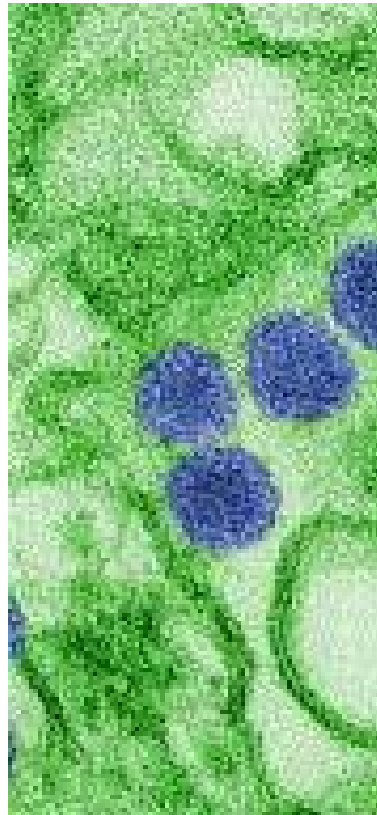
Response

- SHIELD: Real-Time Infectious Disease Outbreak Monitoring
- FDA Sentinel Initiative
- Rapid assessment of acute illness and injury to enhance the U.S. response to public health emergencies
- Field Laboratory Testing of Ebola Assays in Sierra Leone
- Companion Studies to Define the Distribution and Duration of Zika Virus in Non-Human Primates



Regulatory Science Research Tools

- Cross-species immune system reference
- FDA-ARGOS (FDA Database for Regulatory Grade Microbial Sequences)
- Zika virus reference materials for diagnostic developers



Scientific Engagement



Public Health
England



More Information

On the web:

www.fda.gov/MedicalCountermeasures

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Questions? AskMCMi@fda.hhs.gov

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