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

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• **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

Prepare → Respond → Recover

Prepare

Respond

Recover
## Priority Research Areas

| Identifying, developing, and qualifying | Tools to assess safety and efficacy of MCMs  
In silico predictive models and in vitro assays to assess safety and efficacy of MCMs |
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<tbody>
<tr>
<td>Validating</td>
<td>NGS-based IVD platforms</td>
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<tr>
<td>Developing</td>
<td>Reference materials related to facilitate development of MCMs</td>
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<td>Assessing</td>
<td>The performance, design, and reuse of emergency medical equipment including PPE</td>
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<td>Enhancing</td>
<td>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 &amp; Assessment)</td>
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<tr>
<td>Advancing</td>
<td>Tools, technologies, and platforms that can improve the manufacturing efficiency, consistency, and quality of MCMs</td>
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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
More Information

On the web: www.fda.gov/MedicalCountermeasures including sign up for MCMi email newsletter

Questions? AskMCMi@fda.hhs.gov

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