

Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research

Region V: Illinois, Indiana, Ohio, Michigan, Minnesota, Wisconsin
National Institute of Allergy and Infectious Diseases

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Mission of the RCE Network

To facilitate rapid translation of basic research findings to medical counter measures for biodefense

- **Commitment:** Discovery and early development of new vaccines, therapeutics and diagnostics to counteract bio-threat agents.
- **Approach:** Combined research excellence of interdisciplinary scientists.
- **Main focus:** Top priority CDC Category A - C agents
 - Development of animal models of disease
 - Target identification and characterization
 - Host-pathogen interactions; mechanism of immunity to disease or mechanism of action of therapeutics
- **Implementation:**
 - Solicitation of applications from premier research institutions and scientists;
 - Review applications for scientific merit and focus on biodefense research goals;
 - Promote collaborations, state-of-the-art technologies, interactions with biotech and government;
 - Ensure strategic plan is in alignment with national priorities



Challenges to RCE network

Engage academia in MCM product development pathway

- Academia must advance discovery through early/ mid development
 - Funding stream for product development of biodefense MCM is unclear, especially for the lower priority threats;
 - Commitment and understanding that optimal products takes time;
 - How far should a discovery be developed to be eligible for BioShield?
- Opacity in BioShield creates uncertain market for RCE discoveries
 - Interest in patenting and licensing technologies limited
 - Lack of interest from pharmaceutical industry
 - Opacity in specifications leads to unfocused efforts
 - Are all BioShield dollars committed?
 - Do new discoveries in biodefense have a place in BioShield?
 - Are failures of existing purchases a prerequisite for future procurements?
 - Incentives for improving technologies unclear



Needs of RCE Network

To enhance efficiency and success of MCM development

- Transparency in threat selection and MCM prioritization
 - Currently moving target
 - What about lower priority threats?
 - Fragmented Responsibilities
 - NIAID – Research Infrastructure, Countermeasure Specification
 - OPHEMC – Procurement
 - FDA – Regulatory Approval
 - CDC – Stockpiling, Detection & Response
 - DHS – Threat Evaluation & Scenarios
 - DHS – Determination of Material Threat
 - DOD – Alignment not clear
 - If agencies disagree, is contractor or researcher penalized?
 - Are optimal solutions across whole system generated?



Needs of RCE Network

To enhance efficiency and success of MCM development

- Knowledge of material threat process
 - To inform research and development focus
 - Input into feasibility and likelihood of successful intervention of MCM
- Access to research facilities, resources and infrastructure for early and mid development
 - Select Agent rule / Patriot Act
 - Good laboratory practice
 - Animal Rule
- Transparent funding avenues for development activities
 - Stabilization of market to sustain biotech industry interest in new discoveries for MCMs

