



The Integrated National Biodefense Portfolio Initiative

“One-Portfolio”

Advance Planning Briefing for Industry May 7, 2009

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The Integrated National Biodefense Portfolio Initiative



“One-Portfolio”

- An effort to integrate Medical Countermeasures (MCM) efforts
- Primary partners are the Department of Defense (DoD) and Department of Health and Human Services (HHS) with participation by agencies who’s mission involves medical countermeasures
- The vision is government-wide coordination of research and development (R&D) of medical countermeasures for biological, chemical, radiation and nuclear threats.
- The working group formed A Portfolio Advisory Committee of government organizations that fund and manage MCM R&D



“One Portfolio” Objectives

- **An integrated, end-to-end national Biodefense portfolio for medical countermeasure products is needed to leverage investments and maximize preparedness**
- **Major Objectives:**
 - Describe state of the National Biodefense Portfolio
 - Evaluate risk and required investment
 - Identify portfolio gaps and overlaps
 - Develop recommendations for portfolio
 - Implement Joint Portfolio Oversight
 - Enhance intra-Departmental and inter-Departmental collaboration
 - Build portfolio plan into budget planning

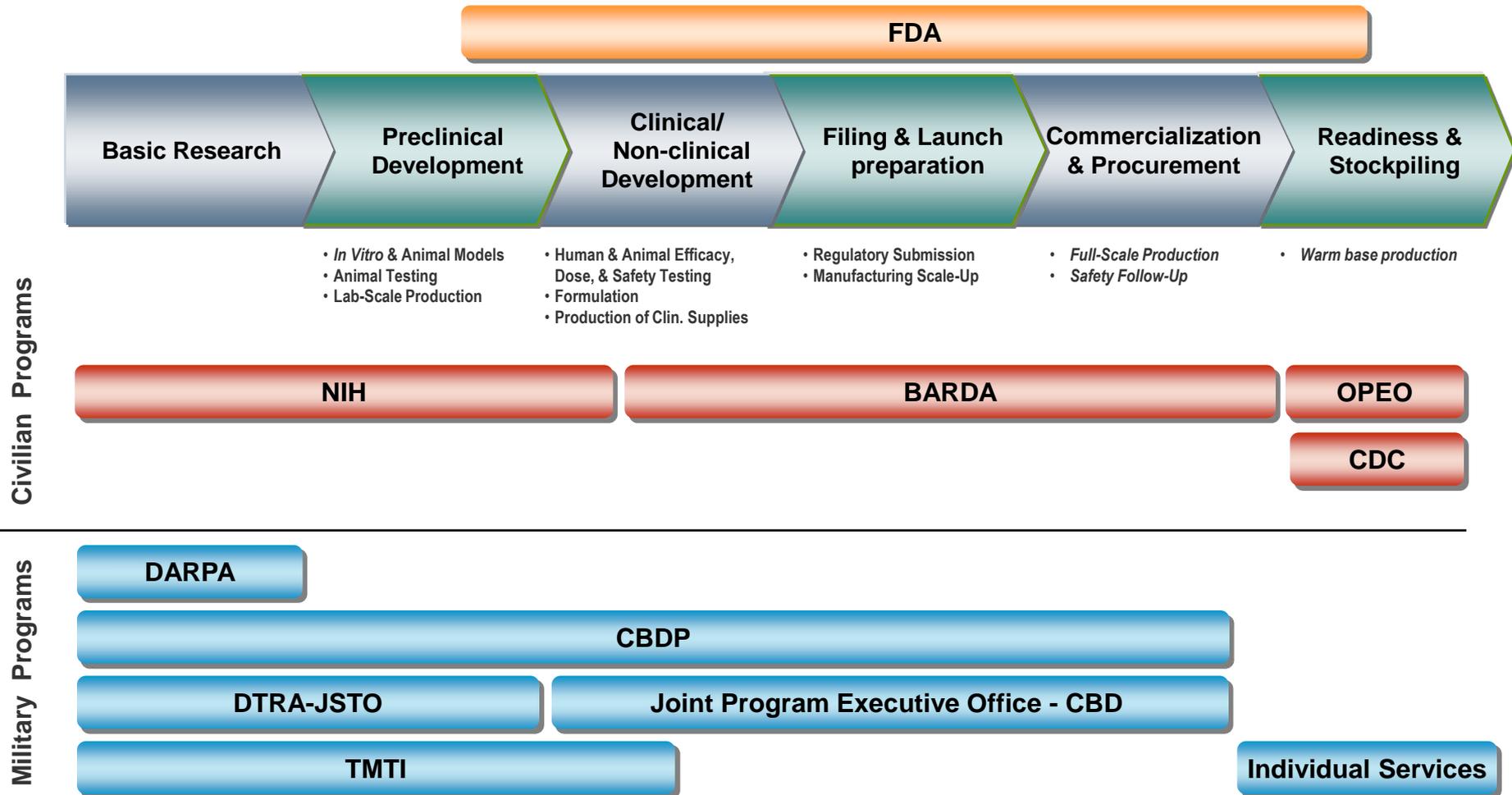


Unified National Portfolio: Membership

- **Department of Health and Human Services**
 - Office of the Secretary
 - **Biodefense Advanced Research and Development Agency**
 - National Institutes of Health/National Institute of Allergy and Infectious Diseases
 - Food and Drug Administration
- **Department of Defense**
 - **Chemical/Biological Defense Program, Office of the Secretary of Defense**
 - **Joint Program Executive Office for Chemical/Biological Defense**
 - Joint Staff, Joint Requirements Office
 - Office of the Assistant Secretary of Defense for Health Affairs
 - Defense Threat Reduction Agency
- **Other government agencies participating/attending**
 - Executive Office of the President
 - Homeland Security Council
 - Office of Science and Technology Policy
 - Office of the Vice-President
 - Office of Management and Budget
 - Department of Homeland Security
 - Department of Veterans' Affairs



No Single Agency has Visibility into the Entire Development Portfolio



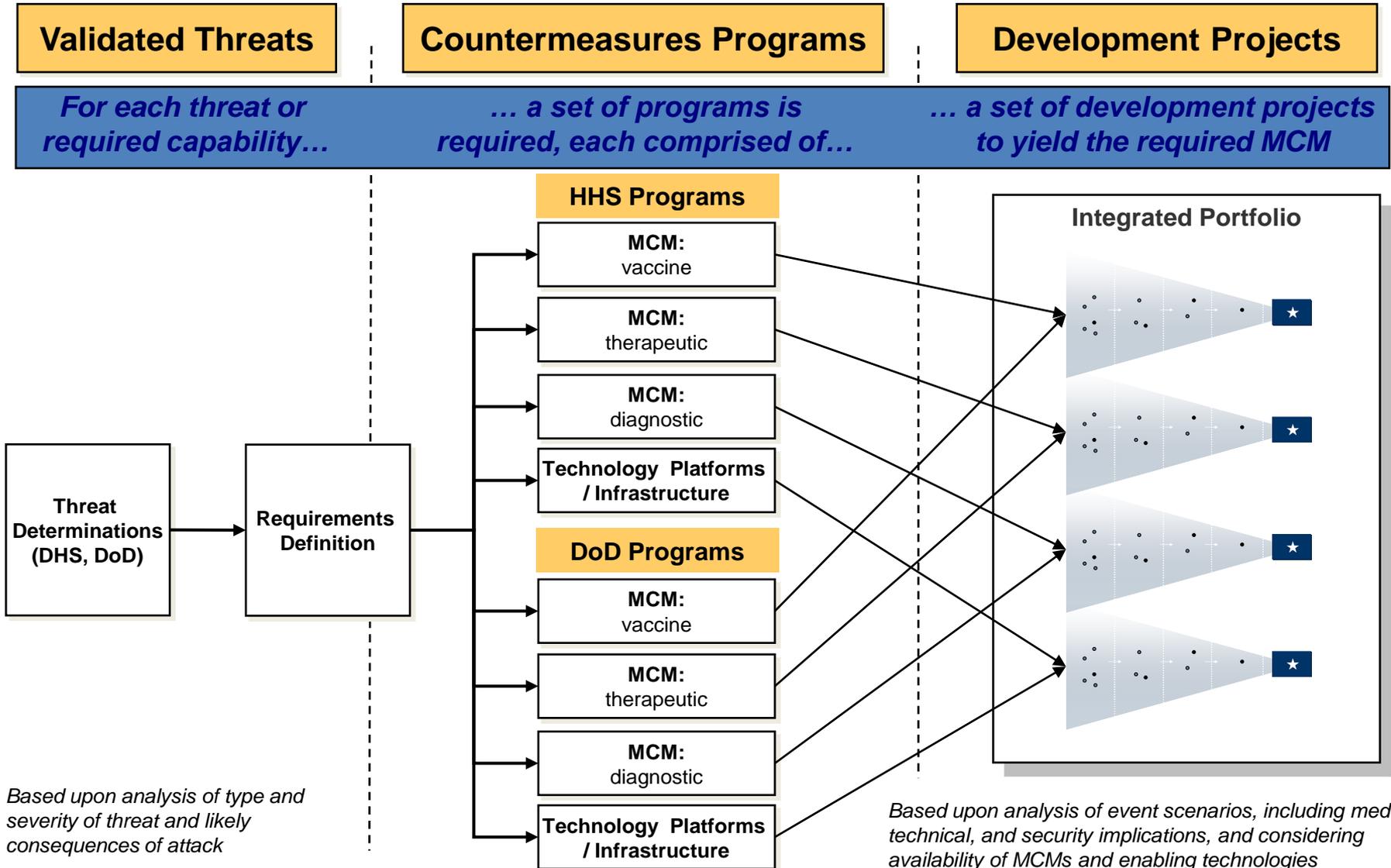


Progression and Scope of Portfolio Analysis

- **Progression of analysis:**
 - Biological threats
 - [Chemical, Radiological / Nuclear threats]
 - [Diagnostics]
- **Scope Includes:**
 - Medical Countermeasures (Vaccines, Therapeutics, & Diagnostics)
 - Technology Platforms
 - Infrastructure to support MCM development
- **Currently Not Addressing:**
 - Non-Medical Countermeasures
 - Pandemic Influenza and other naturally occurring Emerging Infectious Diseases
 - Environmental detection



Framework for Structured Portfolio Analysis



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Integrated National Biodefense MCM Portfolio Requirements – Unique and Convergent



DoD-Unique

- Brucellosis Vx
- VEE/EEE/WEE Vx & Rx
- Plague Vx
- Botulism Vx
- SEB Vx & Rx
- Tularemia Vx
- Ricin Vx & Rx
- (other, unfunded)

Common

- Anthrax Vx & Rx
- Smallpox Vx & Rx
- Ebola / Marburg Vx & Rx
- Tularemia Rx
- Botulism Rx
- Radiation Rx
- Nerve agent Vx & Rx

HHS-Unique

- Smallpox Vx for special populations
- Burkholderia sp. Rx
- Junin Rx
- Plague Rx

DoD focus is on protecting forces prior to exposure. HHS focus is on response to threats to general civilian population after exposure

V_x = Prophylaxis R_x = Therapeutic

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Integrated Portfolio Accomplishments to Date

- DoD and HHS have harmonized a common set of Technology Readiness Levels
- An improved understanding of the expected impact of animal rule on biodefense product development
- Pipelines for several biological threat MCMs have been mapped and are ready for top down / bottom up analysis
- MCM development “projects in common” have been identified and further coordinated between DoD and HHS and across HHS
- Discuss approaches to portfolio integration
 - *Cost-sharing*
 - *Knowledge sharing*
 - *Program sharing*