



The Integrated National Biodefense Medical Countermeasures (MCM) Portfolio Initiative

GHSI Public Health Emergency Medical Countermeasures Workshop

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Integrated National Biodefense Medical Countermeasures Portfolio: *Purpose*



- **HHS and DoD both develop and procure medical countermeasures for CBRN threats**
- **An integrated, end-to-end national biodefense portfolio for medical countermeasure products is needed to leverage investments and achieve success.**
- **Supports the MCM planning and alignment called for in Homeland Security Presidential Directive “Medical Countermeasures against WMD” and the vertical and horizontal coordination echoed in Homeland Security Presidential Directive “Public Health and Medical Preparedness”**



Integrated National Biodefense Medical Countermeasures Portfolio

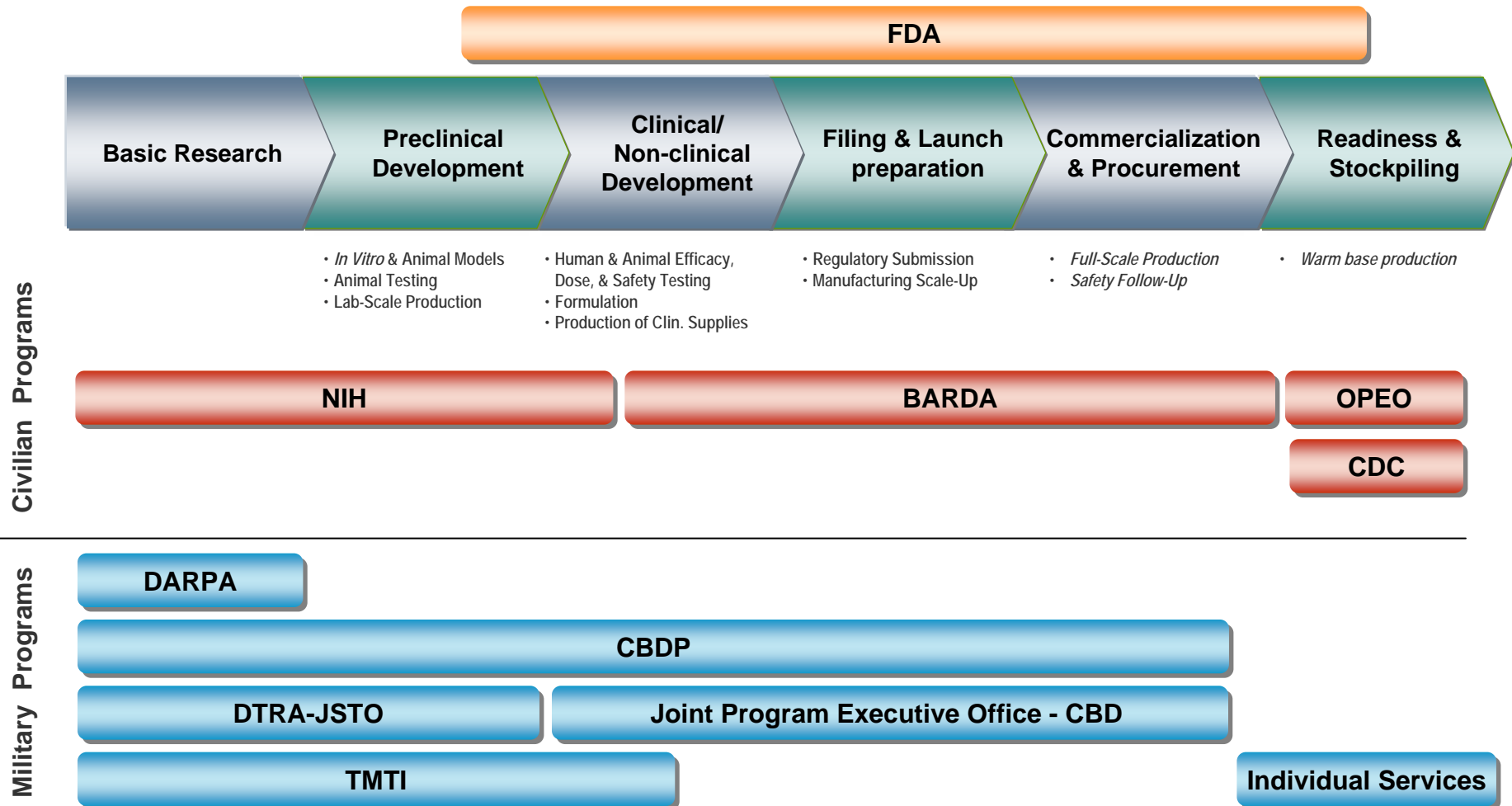


- A collaboration among program components of the Department of Health and Human Services (HHS) and the Department of Defense (DoD)
- First meetings on the concept of an integrated portfolio for Biodefense MCMs were held in March 2008
- A core working group has driven this cooperative effort:
 - Biomedical Advanced Research and Development Authority
 - DoD Chemical Biological Defense Program
 - Joint Program Executive Office (Chemical Biological Medical Systems)
 - National Institute of Allergy and Infectious Diseases
 - Joint Science and Technology Office (Chem/Bio)
 - Deputy Assistant To Secretary of Defense (Chemical Biological Defense)
- A series of working meetings and briefs to the Homeland Security Council and Office of Management and Budget were held over the summer of 2008.

To institutionalize the Integrated National Biodefense MCM Portfolio, the working group formed a Portfolio Advisory Committee composed of government organizations that fund and manage CBRN MCM R&D programs.



No Single Agency has Visibility into the Entire Development Portfolio





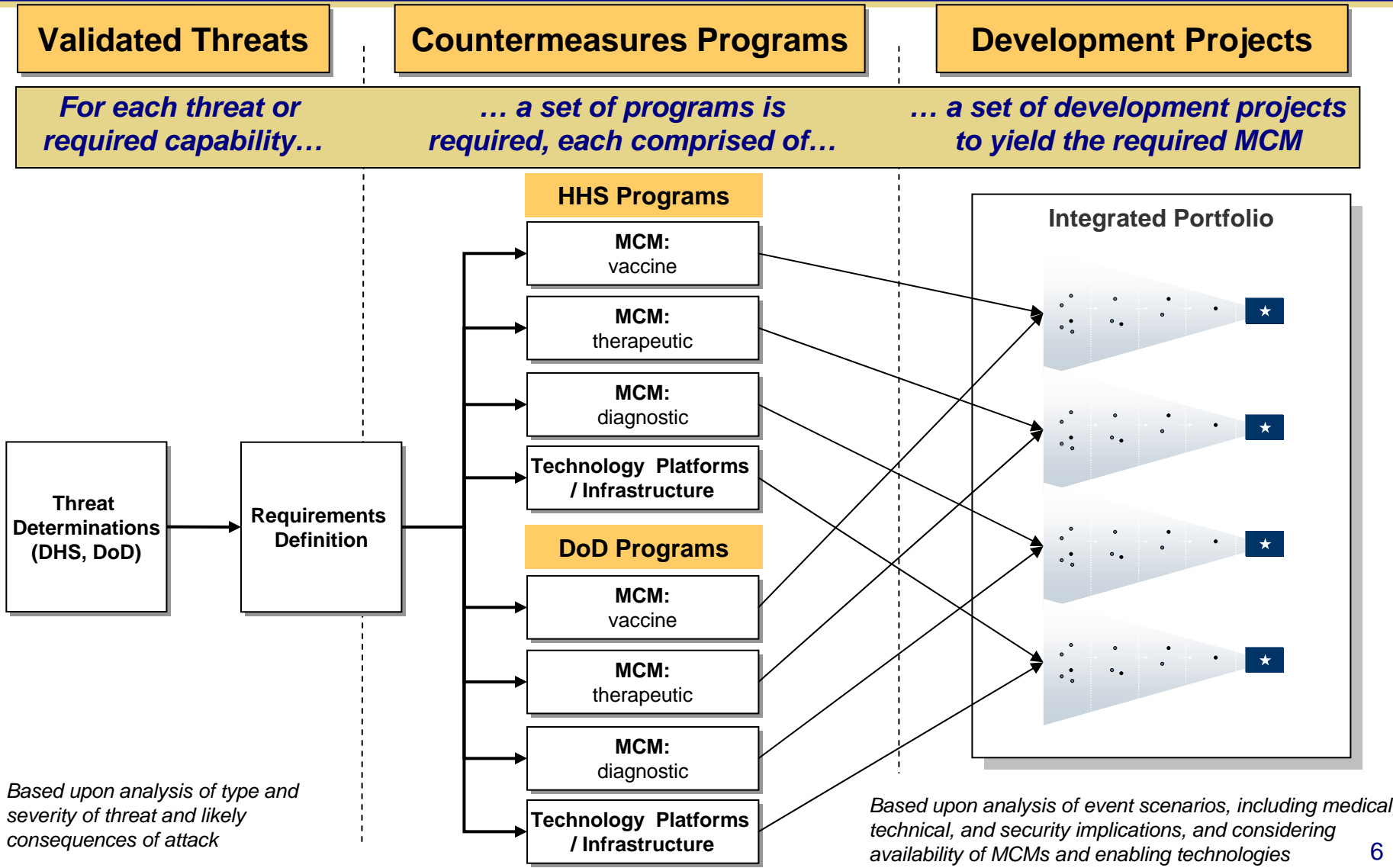
Objectives for the Integrated National Biodefense MCM Portfolio



- Collect and report on overall state of Integrated National Biodefense Portfolio
- Evaluate portfolio probability of success and articulate required investment
- Identify portfolio gaps and overlaps
- Develop recommendations for portfolio (“Implementation Planning”)
- Implement Joint Portfolio Oversight
- Enhance intra-Departmental and inter-Departmental collaboration
- Build portfolio plan into budget planning



The Integrated Portfolio has Developed a Framework for Structured Portfolio Analysis

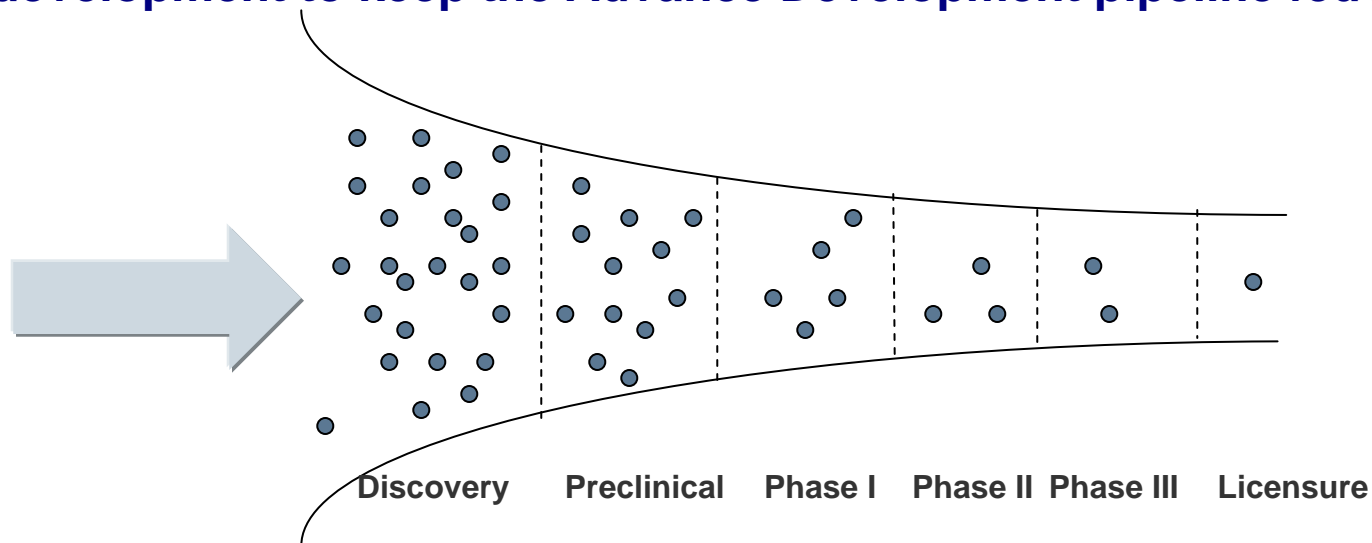




Typical portfolio costs, timeframes, and success rates can be estimated for a set of MCM development projects

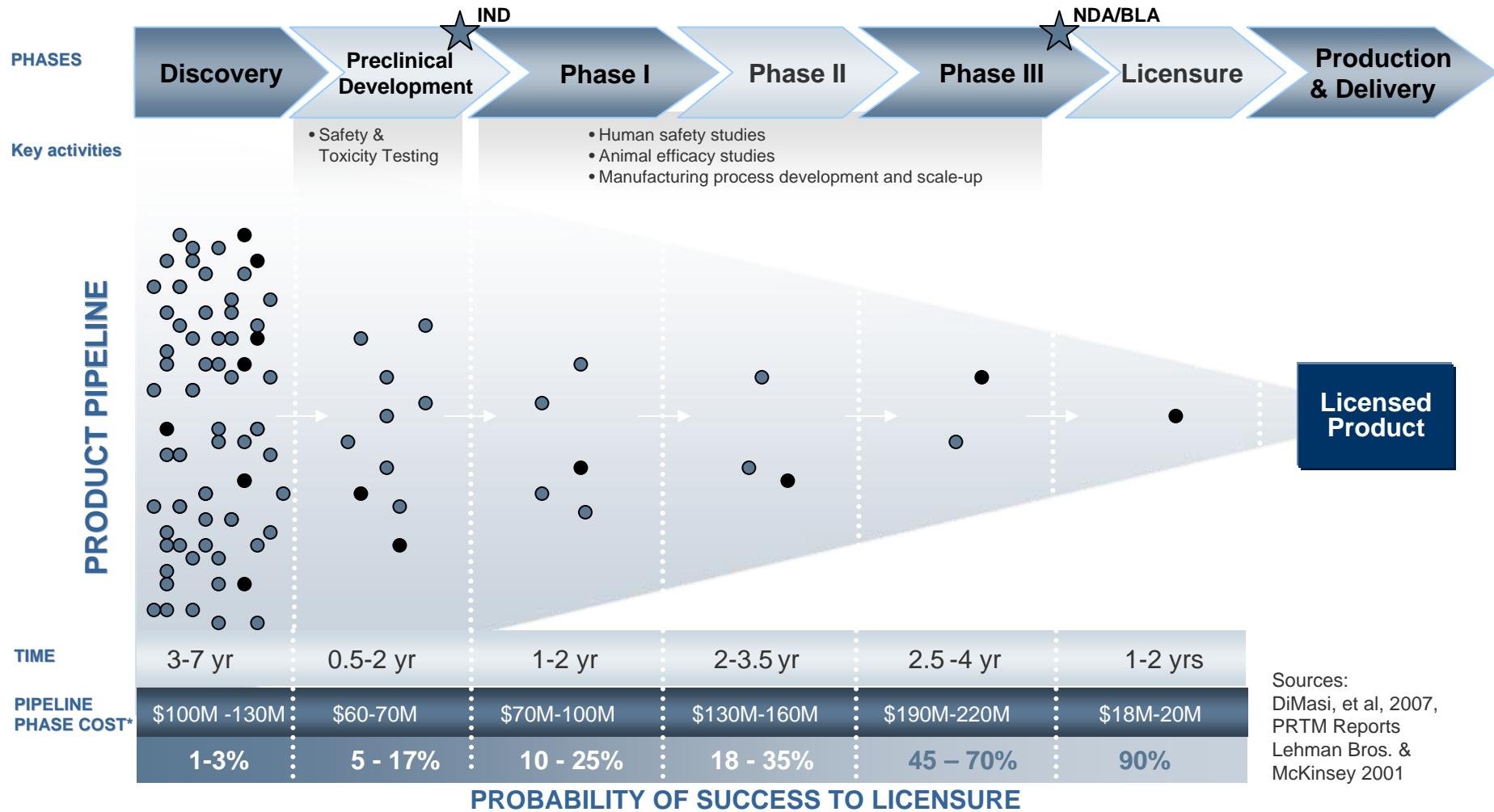


- **The Portfolio Planning Model uses a Monte Carlo Simulation to estimate:**
 - How many candidates should be in the pipeline concurrently to yield a successful product within the desired time horizon?
 - How likely is it we will develop all the products we desire?
 - What will it cost to support the complete portfolio?
 - How many candidates do basic research labs need to provide to clinical development to keep the Advance Development pipeline fed?





National Biodefense R&D Portfolio must be Informed by Industry Benchmarks for MCM Development



Sources:
 DiMasi, et al, 2007,
 PRTM Reports
 Lehman Bros. &
 McKinsey 2001

* Out of pocket costs from Discovery through Licensure to develop a single successful product (includes attrition)



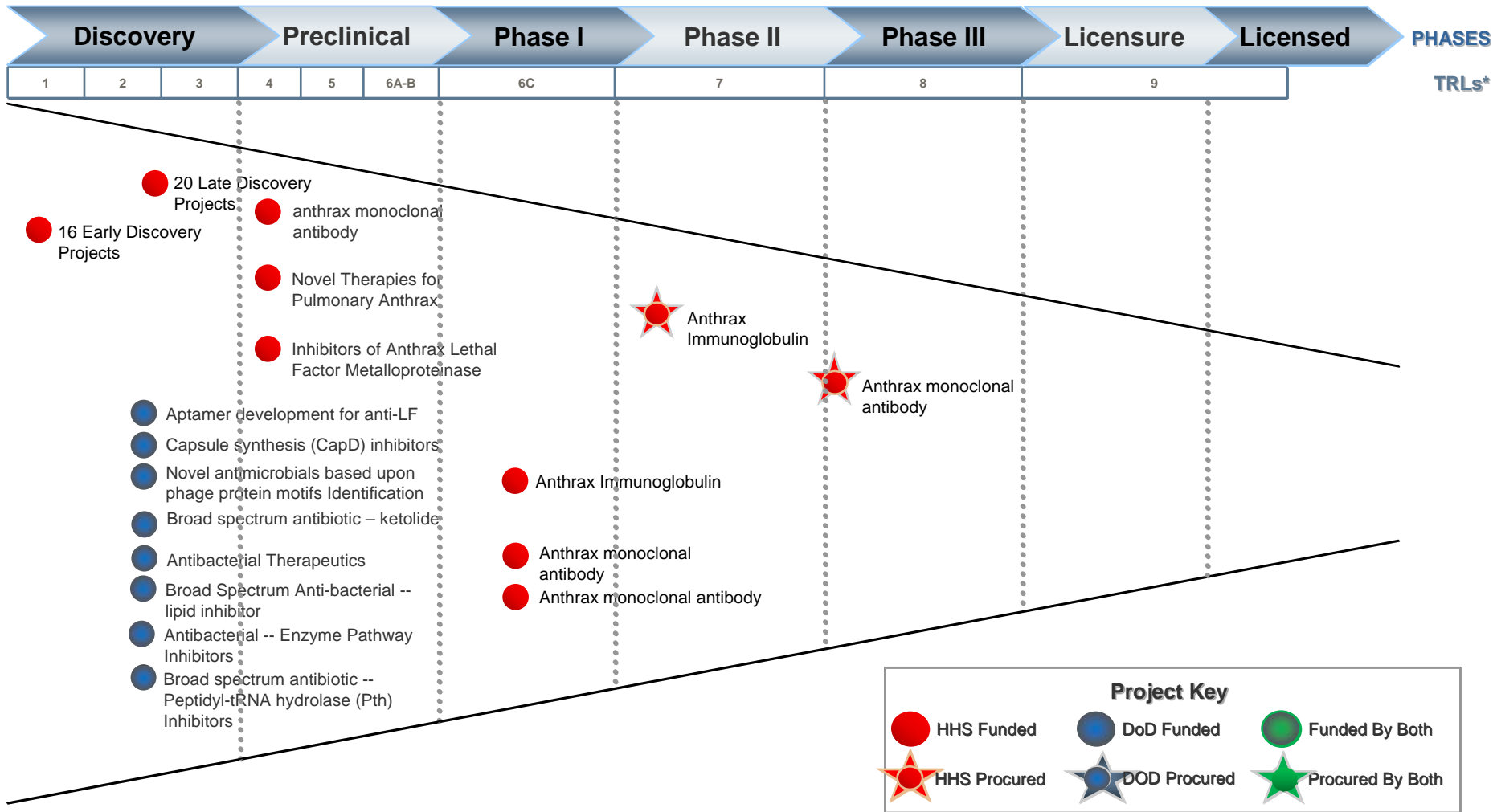
Analyze Portfolio Probability of Success, Gaps and Funding Needs



- **“Top Down” Analysis (*Provides rough order of magnitude cost estimates*)**
 - Exercise Portfolio Planning Model to estimate cost, time and probability of success for portfolio
- **“Bottom Up” Analysis (*Provides insight for practical decision making*)**
 - Round out Pipeline Maps with additional candidates to achieve required products
- **Comparison of “Top Down” and “Bottom Up” results to suggest portfolio recommendations**



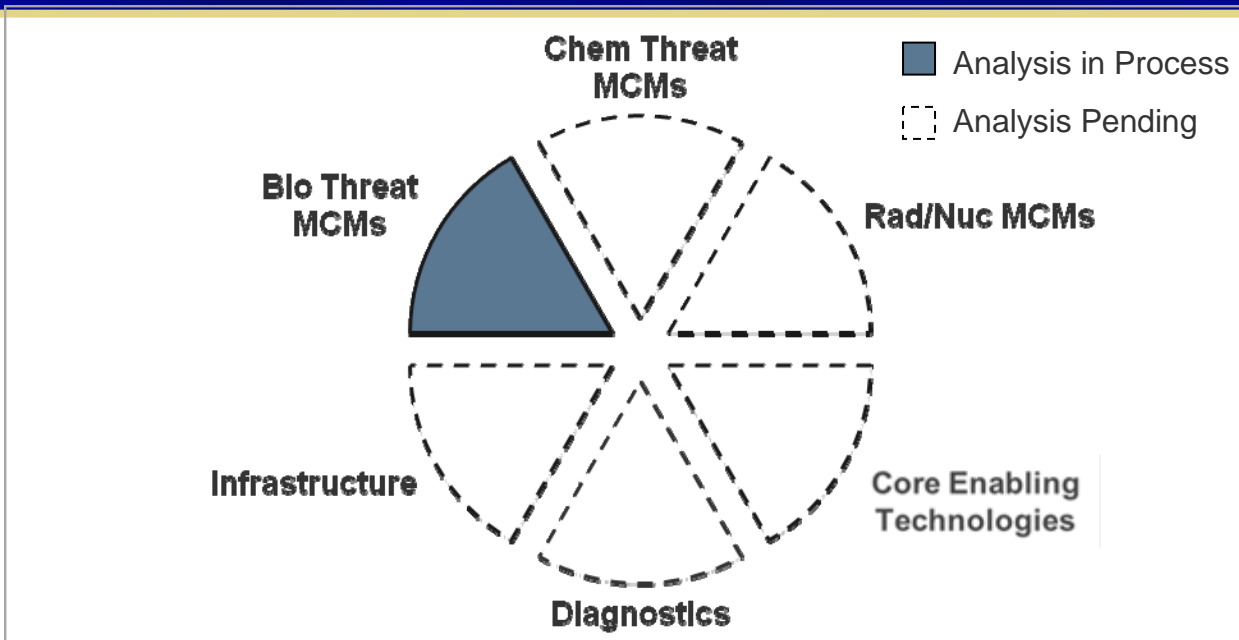
Draft Pipeline Map: Anthrax Therapeutic Program





Integrated National Biodefense MCM Portfolio

Analysis Progress To Date



Analysis to be completed for each area:

- ❖ Pipeline maps
- ❖ Characterization of projects (current status, technology types)
- ❖ Product lifecycle strategy
- ❖ Estimates of portfolio cost, risk, timelines
- ❖ Recommendations to add, subtract, defer projects



Integrated Portfolio Accomplishments to Date:



- DoD and HHS have harmonized a common set of Technology Readiness Levels to define research pipeline and candidate maturity
- An improved understanding of the expected impact of animal rule on biodefense product development
- Pipelines for several biological threat MCMs have been mapped and analyzed; others are in progress
- Program Officers have now established focused networks with colleagues in other agencies
- MCM development “projects in common” have been identified and further coordinated between DoD and HHS and across HHS
- Approaches to portfolio integration are being implemented (*cost-sharing, knowledge sharing, program sharing*)
- Established MOUs between agencies to facilitate cooperation