UNCOMPROMISING INTEGRITY ✦ RESPECT FOR ALL ✦ COMMITTED TO EXCELLENCE ✦ ALWAYS READY

JPEO-CBRND

JPL CBRND ENABLING BIOTECHNOLOGIES – MCM CAPABILITIES TO THE NASEM

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PROGRAMS EXECUTED ON BEHALF OF THE CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM

P.A.I.D. U.P.

PEOPLE first

ADAPT to the Joint Force's needs

INTEGRATE layered CBRN defense

DELIVER on our commitments

UNITY of command/effort

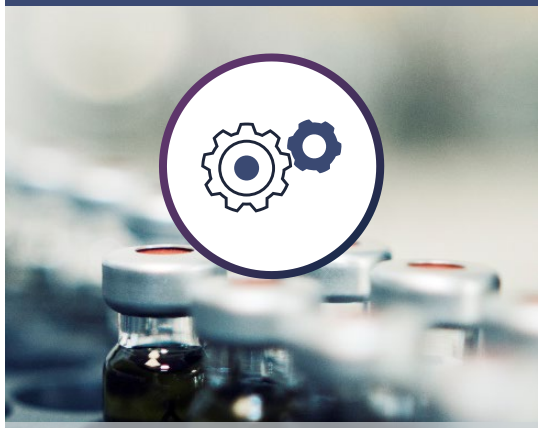
PIVOT to incremental capability

ENABLING BIOTECHNOLOGIES
FROM INFORMATION TO INJECTION

Characterize threat

Sequencing and analytics to understand threat

Accelerate MCM development



Portfolio of platform technologies to enable rapid MCM development against range of threats

Maintain network to manufacture MCMs

Network of DoD priority access manufacturers for rapid MCM production

Support clinical trials

Infrastructure and portable technologies to enable agile and remote clinical trials

Ensure forward-looking technical posture by continuously scanning the landscape

ADVANCED TECHNOLOGY PLATFORMS (ATP)

"PLATFORM" = **Proven Technology**  + **Validated Process**   ;

- Improves speed of medical response
- Ensures platforms produce valid, effective MCMs
- Pre-positions platforms at facilities within the ADMC Network

Medical Countermeasures Platform Technologies (MCMPT)

- Streamlined approach that enables rapid response and accelerates MCM delivery through reducing developmental risks
- Reduces risk through using standardized discovery, design, manufacturing, and testing processes

Generative Unconstrained Intelligent Drug Engineering (GUIDE)

- EB-led partnership with Defense Advanced Research Projects Agency and Department of Energy
- Artificial Intelligence -based capability
- Enables unprecedented acceleration of drug development cycle
  - Faster, cheaper, and safer
  - Targeted MCMs for emerging threats
  - Use data from existing MCMs to design new

Accelerated Antibodies (AA)

- Focused Interagency effort
- Significantly reducing time to develop, manufacture MCMs
  - Develop antibodies against prioritized targets
  - Establish strategic reserve of antibodies at Phase 1 approval

Rapid Access to Products in Development (RAPID)

- Strategic reserve for Medical Countermeasure prototypes that are still in development and not FDA licensed
- A "tiered" approach to broad preparedness
- Will include data packages for prototypes at different maturity levels
- Will include storage of actual doses of products in the final tier which will enable an interim fielding capability

ACCELERATED ANTIBODIES PROTOTYPES AND DELIVERABLES

On going MCM development

	Target	Performer/Sponsor	Phase of development
1	Plague	JUST-Evotec	IND enabling nonclinical and CMC
2	Nipah/Hendra	Mapp Bio	IND enabling nonclinical and CMC
3	Rift Valley	IDBIO	IND enabling nonclinical and CMC
4	Pan-Ortho[1]	JUST-Evotec	Lead Candidate Selected (all 4); Process Development

For each mAb based MCM the accelerated antibody initiative will deliver…

- Completed Phase 1 Clinical Trial
- Large Scale Manufacturing Process in place
- 5,000-10,000 cGMP phase 2 compliant ready doses
- Regulatory Plan for Emergency Use (EUA or EA)
- Near instant onset of protection with intended 6 months of duration
- Ability to proceed to advanced development and licensure based on desire and availability of funding

1. Pan-Ortho covers: M-Pox, Cowpox, Variola, Vaccinia

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