

JPEO-CBRND & & & & & JPL CBRND ENABLING BIOTECHNOLOGIES OVERVIEW

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AN ENABLER IN THE MEDICAL COUNTERMEASURES DEVELOPMENT SPACE





MISSION

To provide medical solutions during a crisis and against future threats.

VISION

The nation's premier service provider enabling rapid development, manufacture, and fielding of safe and effective countermeasures for preparedness, prevention, protection, response, and recovery from CBRN threats.

WHAT EB DOES:

- Develop capability in response to directed requirements
- Provide incremental capabilities
- Enable rapid product development by lowering risk and increasing maturity
- Increase readiness posture of Defense and Homeland Security
- Improve preparedness, feasibility of rapid response to biological incident
 - Take products through Phase I clinical trials

WHAT EB DOESN'T DO:

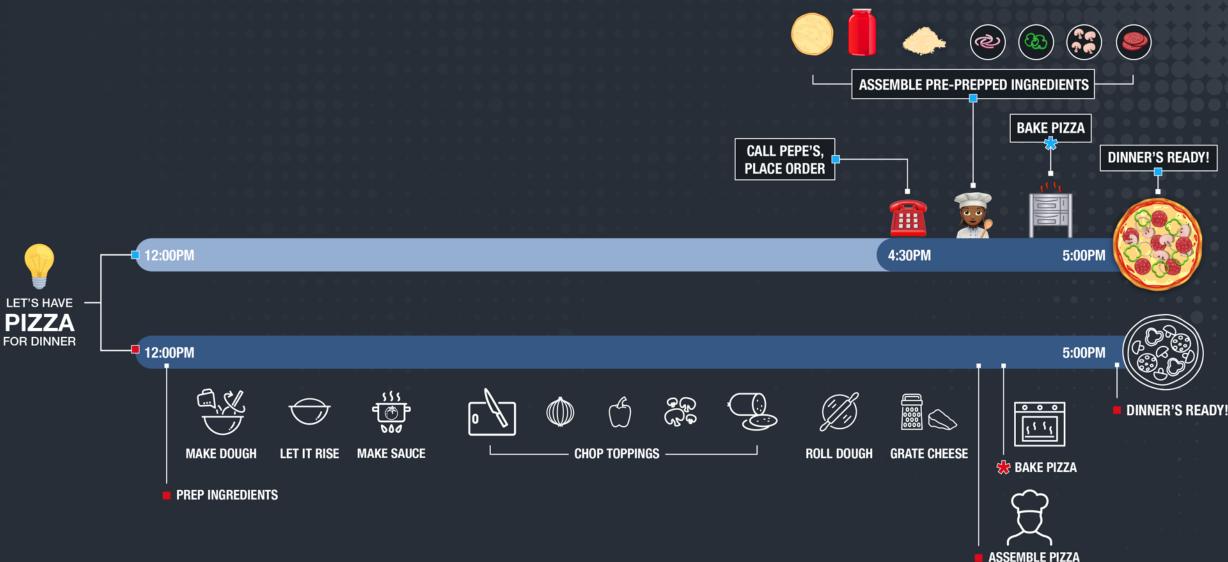
- × Perform traditional acquisition
- Field or sustain traditional defense equipment or fully developed medical countermeasures (MCM)
- Directly address Joint Capabilities Integration and Development System (JCIDS) requirements



JPL CBRND EB ACCELERATES MEDICAL COUNTERMEASURES

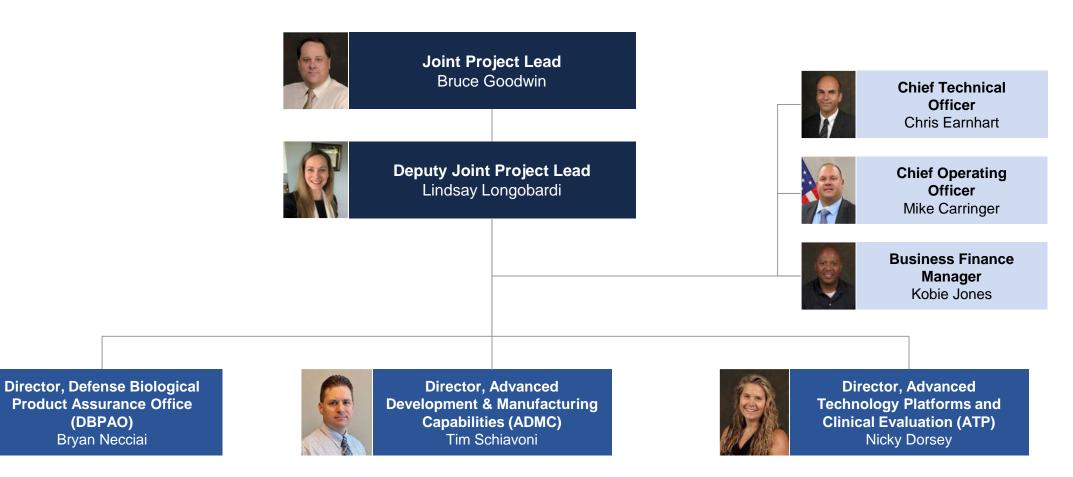
ENABLERS = FASTER MCM SOLUTIONS





LEADERSHIP ORGANIZATION



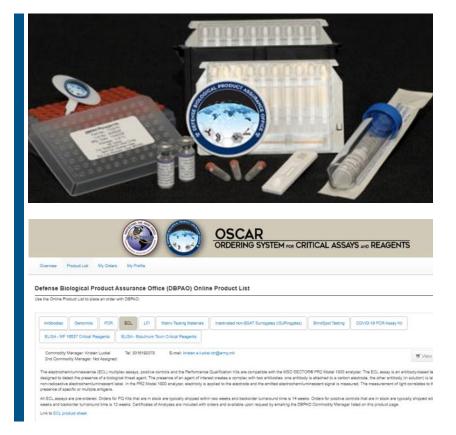


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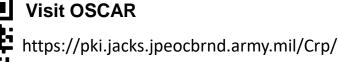
DEFENSE BIOLOGICAL PRODUCT ASSURANCE OFFICE (DBPAO)



- Provides assays, reagents, and biologics for agents of concern in support of Chem Bio defense efforts and emerging products
- Consolidates Government product needs, leveraged for Better Buying Power and cost reductions through economies of scale
 - At-cost products paid for by purchasing organization
 - Advance development, sourcing, quality assurance, market research paid for with Congressional funds (per DoD Financial Management Regulation)
- Certifies our products through verification and validation to industry-equivalent quality standards
- Has several partnerships with DoD organizations and other Government agencies
- Maintains Ordering System for Critical Assays and Reagents (OSCAR) a.k.a. "Amazon for Assays"







ADVANCED DEVELOPMENT & MANUFACTURING CAPABILITIES – PHARMACEUTICAL INFRASTRUCTURE (ADMC-PI)





- Priority access to a network of domestic, trusted, and secure pharmaceutical manufacturing facilities
 - Enables the rapid production and deployment of medical countermeasures
- Partnerships with both Industry and other USG Stakeholders make it possible
 - National Resilience (DoD-ADM facility)
 - JUST / Evo-Tec (JPOD facility)
 - ^o Bio-Manufacturing Partnership (BioMaP) with HHS/BARDA
- Continuing to expand the network to leverage additional manufacturing capacities and capabilities for the DoD

"PLATFORM" = Proven Technology

ADVANCED TECHNOLOGY PLATFORMS (ATP)

- Platforms are used to develop medical countermeasures (MCMs) quicker than traditional methods
- Improves speed of medical response
- Ensures platforms produce valid, effective MCMs
- Pre-positions platforms at facilities within the ADMC Network



- 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
 - $\circ~$ Faster, cheaper, and safer
 - Targeted MCMs for emerging threats
- Use data from existing MCMs to design new

Accelerated Antibodies (AA)

• Focused Interagency effort

Validated Process

- 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



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GENERATIVE UNCONSTRAINED INTELLIGENT DRUG ENGINEERING (GUIDE)

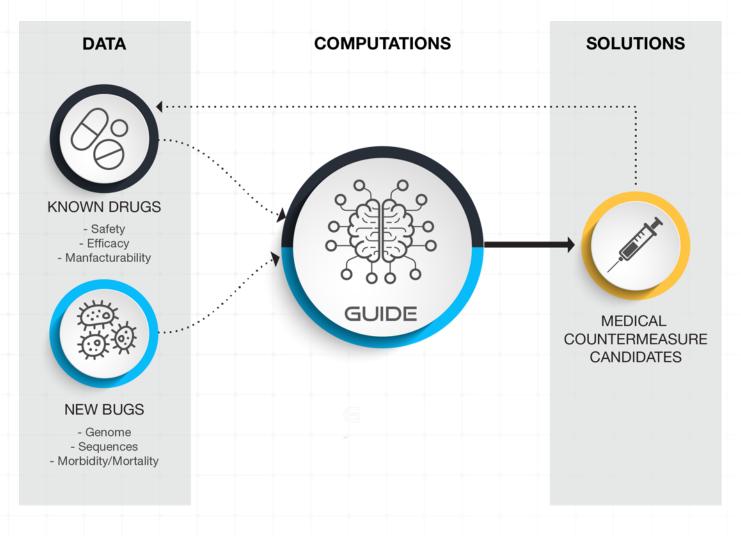


JPL CBRND EB-led partnership with the Defense Advanced Research Projects Agency and the Department of Energy



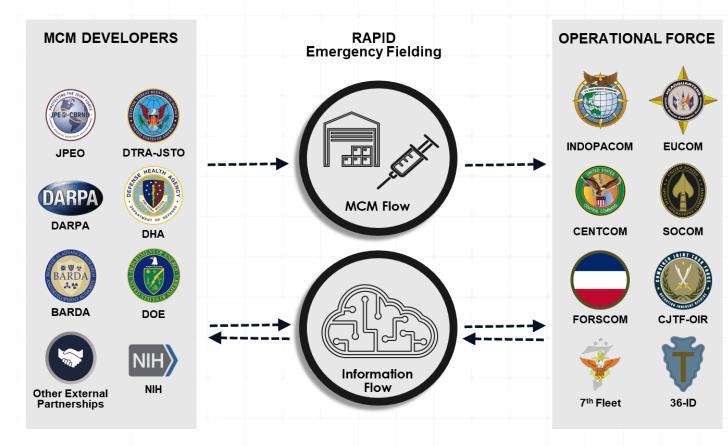


- Artificial Intelligence-based defense capability
- Improves speed of medical response by accelerating design of new MCMs
- Enables unprecedented acceleration of drug development cycle
 - Faster, cheaper, and safer
 - Targeted medical countermeasures for emerging threats
 - Use data from existing MCMs to design new



RAPID ACCESS TO PRODUCTS IN DEVELOPMENT (RAPID)





CHALLENGE: Protect against diverse, dynamic and regionally distinct threats

JPL CBRND EB-led initiative to provide the force with emergency medical countermeasures in response to an actual or potential CBRN attack

- Virtual 'shelf' of products in development
- 5-10K GMP doses pre-positioned
 - Known safety profile
 - Stability tested
 - Contingency fielding plans
- Enables rapid response across broad threat space



CONTACT

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