



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

JPEO-CBRND

SMALLPOX COUNTERMEASURES BRIEF TO THE NATIONAL ACADEMIES OF SCIENCE, ENGINEERING AND MEDICINE (NASEM)

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PROGRAMS EXECUCED ON BEHALF OF THE CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM



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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

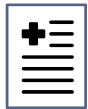
Repurposed Drugs



Rapid Acquisition and Investigation of Drugs for Repurposing (RAIDR) - Repurposing proven medicines to provide a first line of defense



- **Demonstrated safety**, lowering risk of failure
- **Established manufacturing** processes
- **Faster and cheaper path to deploy**, building from prior development efforts
- Provides **broad-spectrum MCMs to bridge** between threat emergence and targeted therapy development



Clinical Practice Guidelines-informed development

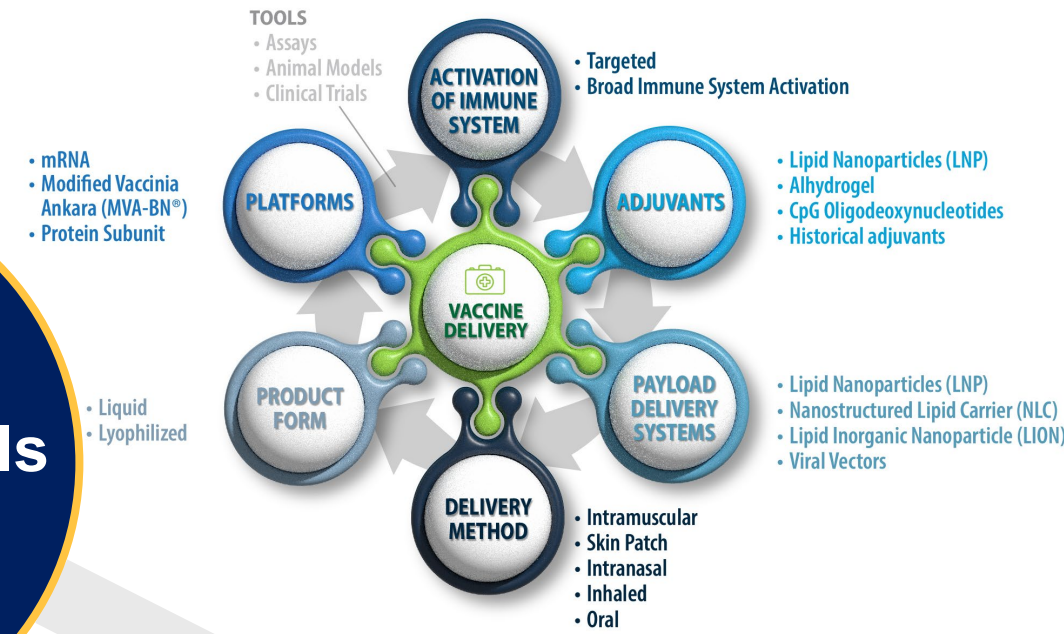
Accelerated Defense Pharmaceuticals

Leveraging lessons learned from COVID-19 to respond rapidly to threats

Platform Vaccines



Vaccine Acceleration by Modular Progression (VAMP) - Developing a systems of systems approach to advance vaccines with proven partners



Flexible contracts and fit-for-purpose agreements

Assays and Pathogen Characterization



- **Surveillance and Pathogen Characterization (SPCHAR)** program
- Assay refinement and validation are critical for obtaining data needed to deliver MCMs
- Aligns test and evaluation across multiple development efforts

ORTHOPOX VIRUS BIOLOGICAL DEFENSE

JPEO CBRN MEDICAL CAPABILITIES AND PARTNERSHIPS



Existing Capabilities

Capability	Product	Status/Field Use
Pre-exposure prophylaxis (PrEP)	Approved Vaccines: <ul style="list-style-type: none"> • Jynneos (Bavarian Nordic) <ul style="list-style-type: none"> • DOD primary SPX vaccine • ACAM2000 (Emergent) 	<ul style="list-style-type: none"> • Vaccination prior to deployment, but not available for Field Use. • Jynneos can be given to a broader population than ACAM2000
Post Exposure Prophylaxis (PEP)	<ul style="list-style-type: none"> • ACAM 2000 - Vaccination within 5 days post exposure • No licensed product 5-17 days post exposure 	<ul style="list-style-type: none"> • ACAM 2000 has been reported to have cardiovascular adverse events • TPOXX available as PEP for orthopox including Mpox under FHP EAP IND to treat in 5-17 day window
Treatment	Approved Treatments: <ul style="list-style-type: none"> • TPOXX (SIGA) <ul style="list-style-type: none"> • Also used to treat adverse reactions to ACAM2000 • TEMBEXA (black box warning) 	<ul style="list-style-type: none"> • TPOXX: Oral capsule or IV Formulation Capsules are pre-positioned in COCOMS

TPOXX Stockpile

Contract	Doses	Location
W911SR-22-C-0039	21,727	SriSai
W911SR-22-C-0051	14,677	SriSai
W911SR-22-C-0051	14,576	Murtech
Total Purchased	50,980	

TPOXX is forward deployed OCONUS to:

- Landstuhl Regional Medical Center, Landstuhl, German
- Naval Hospital Okinawa, Okinawa, Japan
- Naval Hospital Guam, Guam
- Brian Allgood Army Community Hospital, South Korea
- Yokota Air Base, Japan
- 35th Medical Group, Misawa, Japan
- 51st Medical Group, Osan Air Base, South Korea
- US Naval Hospital Naples, Naples, Italy



In Development

- Evaluate PEP efficacy of smallpox antiviral TPOXX when given at a timeframe of known or suspected exposure to smallpox.
- A **Phase 2**, open label (JYNNEOS), double blind (TPOXX & Placebo), multicenter, randomized, placebo-controlled, drug-vaccine interaction study
 - To examine whether simultaneously administering JYNNEOS with TPOXX affects immunogenicity of JYNNEOS in healthy adult subjects
- A **Phase 3** multicenter, double blind randomized, placebo-controlled study
 - To assess the safety, tolerability, and pK of 600 mg TPOXX (oral) when administered for 28 days in adult subjects
- TPOXX PEP sNDA submission NLT July 2024

Research and Development Mechanisms

- Contracts
 - Contract with SIGA to support on-going clinical trials
 - TPOXX Procurement Contract with SIGA
 - Vendor Managed Inventory with MURTECH
- Interagency Agreements
 - U.S. Army Medical Materiel Development Activity
- CRADAs
 - SIGA



ORTHOPOX DIAGNOSTICS

BIOFIRE FILMARRAY CAPABILITIES

Existing Capabilities

- BioFire FilmArray diagnostic system fielded to DoD labs as part of the Next Generation Diagnostic System program
 - Sample-to-answer testing
 - Multiplex PCR format



- Sentinel Panel – Multiagent Biothreat panel
 - Environmental sample types (i.e. air, water, surface swab etc.)
 - Targets for Orthopox and Variola viruses
 - Orthopox and Variola testing performed at the CDC
 - Currently available to DoD and LRN

Available Testing Networks

- DoD – >1500 FilmArray systems
- LRN – 36 labs have FilmArray biothreat testing capability
- RESPTC – 10 Regional Hospitals have FilmArray Biothreat testing capability adjacent to containment units
- Commercial – >15000 FilmArray systems in US

In Development

- OPX diagnostic prototype (6 month effort)
 - Design based on FDA Mpox EUA template
 - Sample type- skin swab (VTM, UTM)
 - Optimized based on in silico analysis and live organism testing (Variola used synthetic targets)
 - FY24-FY25 pre-EUA testing planned at CDC

Table 1. Prototype BioFire Orthopoxvirus Panel v0.2

Target	# of Assays
Orthopoxvirus spp.	2
Non-variola Orthopoxvirus spp.	2
Variola virus	4
Monkeypox virus (clade I & II)	1
Monkeypox virus clade II	1
Human Sample Adequacy Control	1

Research and Development Mechanisms

- Contracts
 - BioFire Defense LLC - Development and Procurement contract
 - Interagency Agreements
 - CDC/NCEZID/DHCPP – Testing and validation
 - CDC/DLS – LRN FilmArray collaboration
- CRADAs
 - RESPTC Biocontainment Units



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