



ASPR

Partnerships for Getting Ahead of the Curve

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Government-University-Industry Research Roundtable
National Academies of Sciences, Engineering, and Medicine

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UNCLASSIFIED

ASPR Mission

**Save Lives
and Protect
Americans from
21st Century
Health Security
Threats**



The BARDA Model

BARDA develops and makes available medical countermeasures (**MCMs**) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



Flexible, nimble authorities

Multi-year funding

Cutting edge expertise

Facilitate partnerships

Promote innovation

Our Government Partners



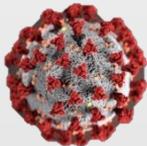
55 FDA Approvals, Licensures, and Clearances



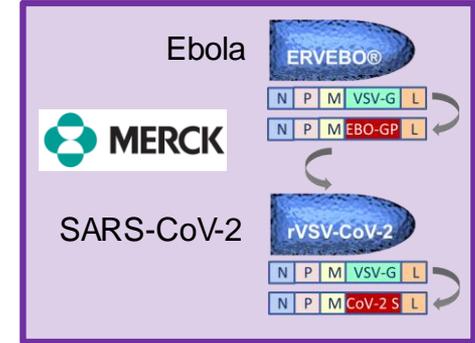
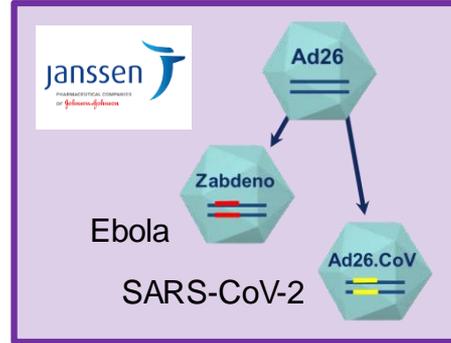
CBRN Pandemic Preparedness and Platform Technologies

RAPID RESPONSE

A decade of investments in platform technologies under flexible agreements facilitated BARDA's rapid pivot to developing COVID-19 MCMs



COVID-19 vaccine candidates



COVID-19 monoclonal antibody candidate



IEIDD Preparedness Principles



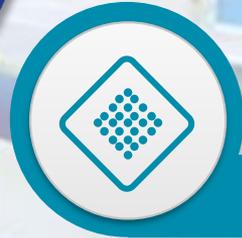
Flexible Agreements



Sustainable



Platforms for Faster Development



Improved Delivery

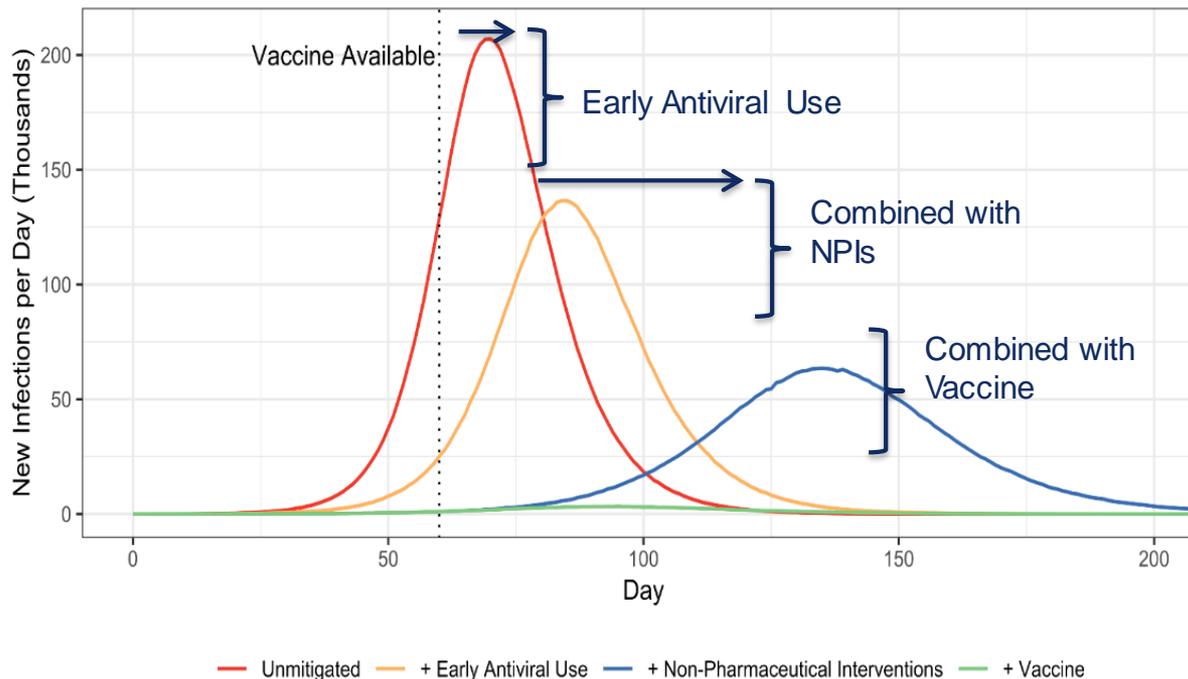


Expand Access



Production Capacity

Defeating the Pandemic Curve

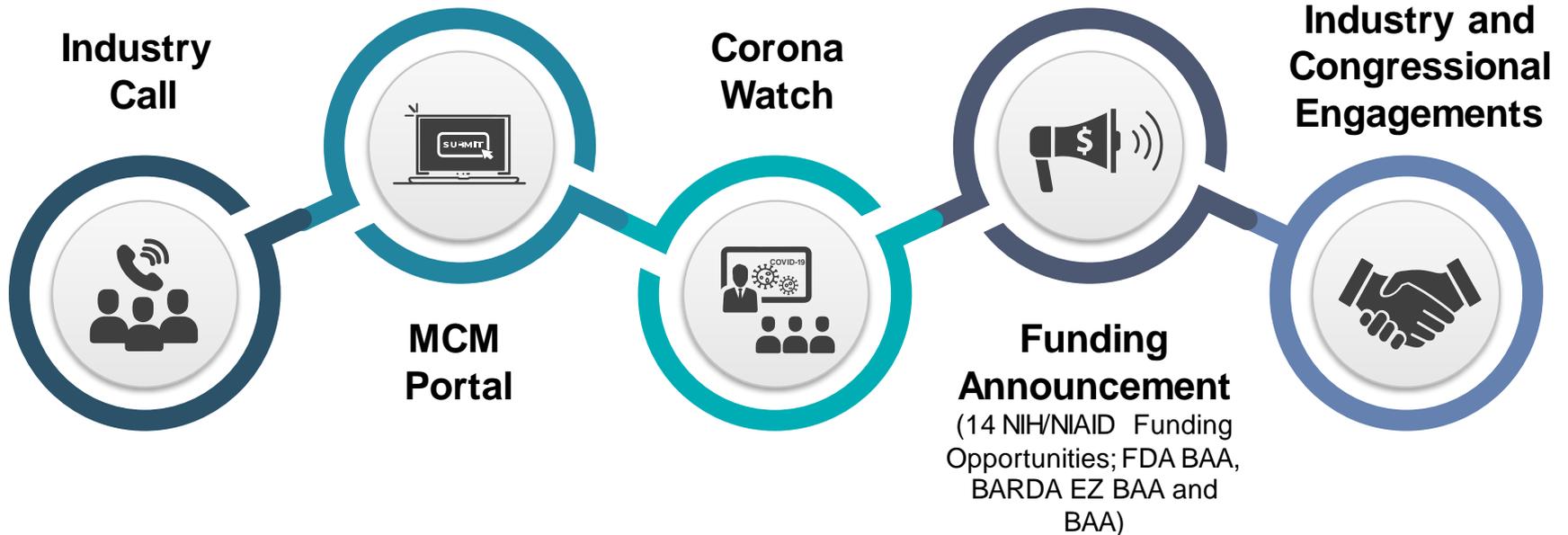


BARDA Agent-Based Simulation of DC, MD, and VA | Asher, Arguello, Durham, Romero

16
Years

3rd Coronavirus Outbreak
No Licensed products

Agency-Wide Engagement with Developers



COVID-19 Market Research Portal Submissions

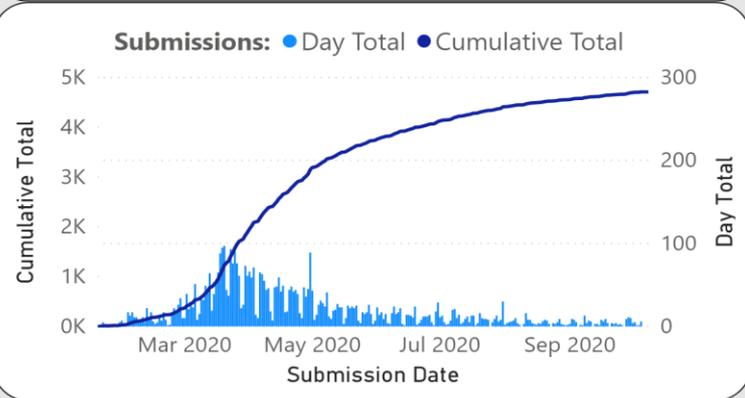
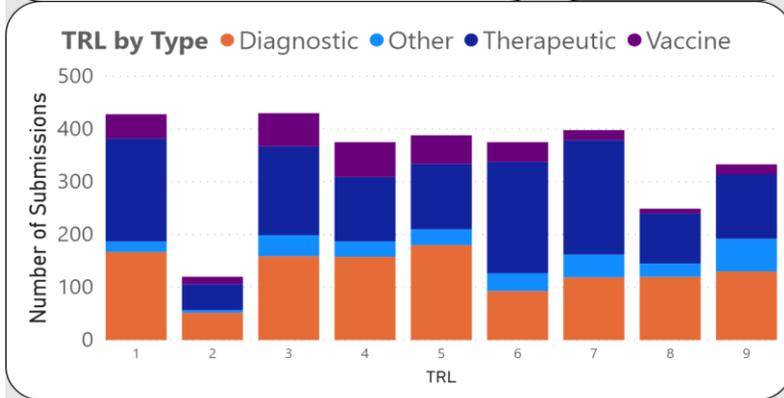
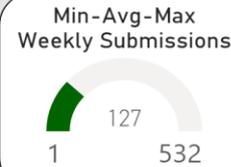
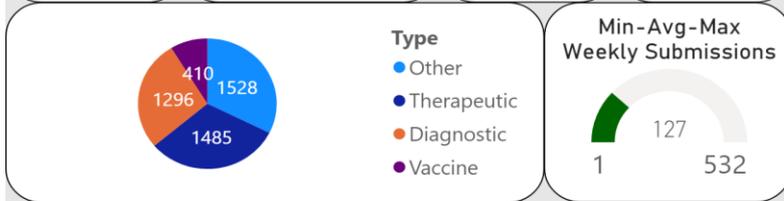
BARDA COVID-19 Submissions Report - **Overview**

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Last Refreshed



Market Research Contacts	Total	Dx	Tx	Vx	Other
TechWatch Held	512	189	194	68	61
All Contacts	3866	842	1342	346	1336



COVID-19 MEDICAL COUNTERMEASURE DEVELOPMENT STRATEGY



ACCELERATE DEVELOPMENT

- Platform technologies
- Repurpose licensed products
- Parallel, not sequential activities

MITIGATE RISK

- Multiple technologies
- Multiple targets
- Redundancy

DOMESTIC MANUFACTURING

- Scale Up & Scale Out
- Raw materials and supply chains
- Leverage existing facilities

COVID-19 Medical Countermeasures Task Force

Align and prioritize MCM development across interagency partners to avoid duplication of effort, identify opportunities for synergy, and fill potential gaps

medicalcountermeasures.gov



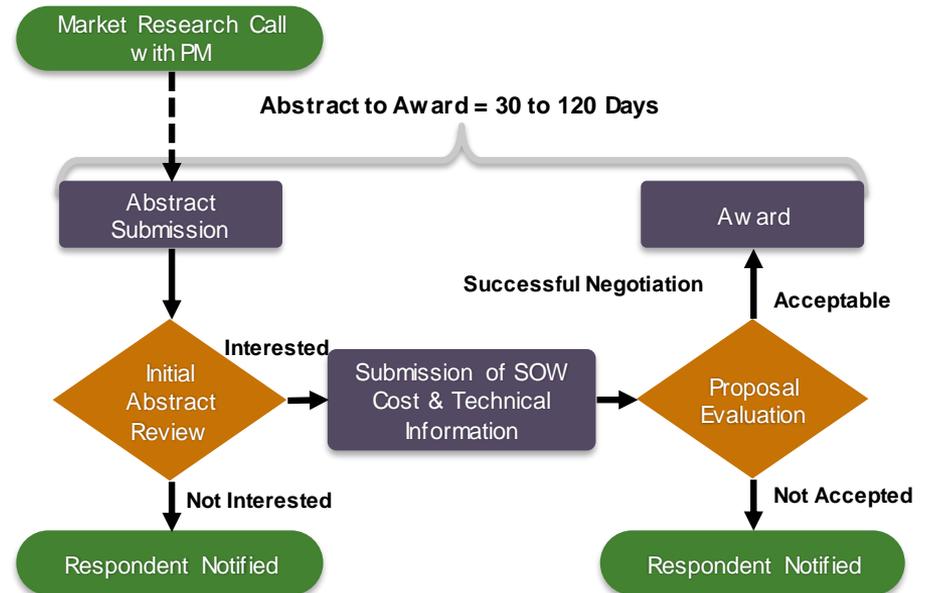
Medical Countermeasures.gov



DRIVE EZ BAA Funding Vehicle

- Easy Broad Agency Announcement (EZ-BAA) is designed to be fast, easy-to-use, and flexible
- Inspired by DARPA – Piloted in DRIVE
- \$749,999 max & 30-50% cost share requirement
- Can go from posting solicitation to award within 30 days

EZ BAA Abstract Review Process Flow Chart





**SOLUTIONS TO SECURE
THE FUTURE**

OWS Oversees

Vaccine



Kitting/Distribution



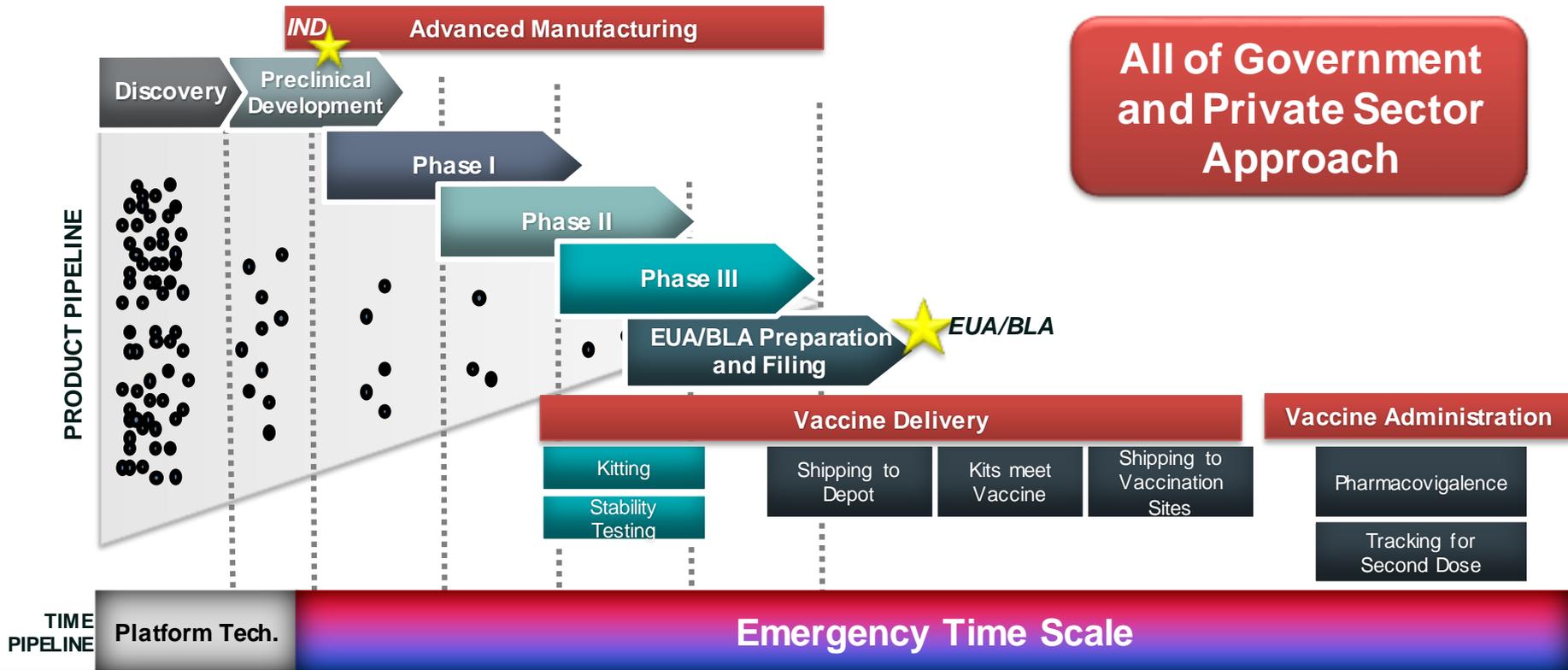
Therapeutic



Capacity



Accelerating Vaccine Development



BARDA Medical Countermeasures Response

Portfolio

Therapeutics

 Janssen Anti-viral Library Screening CT	 REGENERON REGN-COV2 Mfg. Demo CT	 SAB BIOTHERAPEUTICS Polyclonal Abs CT	 DARPA Anti-SARS-CoV-2 mAb Combination CT
 IL22Fc/aST2 CT	 GRIFOLS Hyperimmune Globulin, Convalescent Plasma	 emergent biosolutions Hyperimmune Globulin	 Expanded Access Treatment Protocol – Convalescent Plasma CT
 Famotidine + HCQ Clinical Trial CT	 PPD HCQ + CQ – EUA REVOKED	 REGENERON Anti-IL6R mAb (Kevzara®) – BARDA no longer supporting	 Anti-IL6R mAb (Actemra®) – BARDA no longer supporting
 Phlow US-Based Advanced Manufacturing (Non-COVID-19)	Convalescent Plasma CT EUA		

Rapidly Deployable Capabilities

 Sepsis Diagnostic	 evidation COVID-19 Detection & Forecasting Model	 Host Response Test for Sepsis
 cerus INTERCEPT Blood System	 BECKMAN COULTER Sepsis Detection Algorithm	 SEPSIS ALLIANCE Sepsis COVID-19 Webinars
 vitalconnect Vista Solution Remote Patient Monitoring	 PHILIPS Healthcare AI-Based Ultrasound to Assess Lung Injuries	 empatica Early Monitoring Platform
 Early Detection of Respiratory Infections at Home	 98point6 Text-Based Virtual Care for COVID-19 [Telehealth + AI & Machine Learning]	

Vaccines

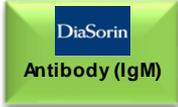
 Ad26 Vector Mfg. Demo CT	 SANOFI PASTEUR Recombinant Protein + AS03 Adjuvant Mfg. Demo CT
 AZD1222 (ChAdOx1) CT	 moderna mRNA-1273 Commercial Scale Mfg. CT
 NOVAVAX NVX-CoV2373 Mfg. Demo CT	 MERCK rVSV Vector
 Pfizer BNT162 (mRNA) Commercial Scale Mfg. CT	

CT = In Clinical Trials

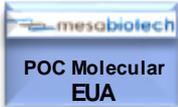
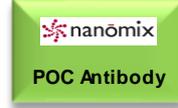
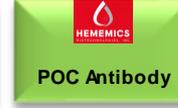
BARDA Medical Countermeasures Response Portfolio

COVID-19 Diagnostics

Laboratory

 Molecular Panther Fusion EUA	 Molecular EUA	 Molecular NxTAG EUA	 Molecular NxTAG Respiratory Pathogen Panel
 Molecular Panther EUA	 Molecular - Aries EUA	 Molecular QIAStat Panel EUA	
 LAB & POC Molecular GeneXpert EUA	 Molecular EUA (v2.0)	 GenMark Dx Molecular Panel	
 Antibody - Centaur EUA	 Antibody EUA	 Ortho Clinical Diagnostics Improved IgG Antibody	 Antibody - Advanced Serology Assay
 Antibody - Atellica EUA	 Antibody	 Ortho Clinical Diagnostics Improved Total Antibody	 Antibody (IgM)

Point of Care

 POC Molecular EUA	 POC Molecular EUA	 POC Molecular
 POC Antibody		
 POC Antigen Panel	 POC Antigen	 POC Antigen
 POC Antibody	 POC Antibody	 POC Antibody
 POC Antigen	 POC Antibody	 POC Antigen

BARDA Medical Countermeasures Response

Portfolio

Supporting Efforts

 <p>BATTELLE</p> <p>Animal Model Development</p>	 <p>UNIVERSITY OF MARYLAND</p> <p>Therapeutic Screening and Animal Model Dev.</p>	 <p>Marathon Medical</p> <p>Needles & Syringes</p>	 <p>emergent biosolutions</p> <p>Manufacturing Capacity & Vial Filling</p>	 <p>smths medical</p> <p>Needles & Syringes Manufacturing Capacity Expansion</p>	 <p>America's Blood Centers It's About Life.</p> <p>Convalescent Plasma Collection Systems</p>	 <p>BCA Blood Centers OF AMERICA</p> <p>Convalescent Plasma Collection</p>	 <p>BROAD INSTITUTE</p> <p>Convalescent Plasma Titering</p>	 <p>Berry Consultants Integrated Services</p> <p>Statistical Support</p>	 <p>APPLIED RESEARCH & ANALYTICAL, INC.</p> <p>Filtration Media</p>
 <p>MIGROBaid Molecular Diagnostics</p> <p>Animal Model Development</p>	 <p>ENVIGO</p> <p>Animal Model Support</p>	 <p>BD</p> <p>Needles & Syringes + Manufacturing Capacity Expansion</p>	 <p>CORNING</p> <p>Vial Manufacturing Capacity</p>	 <p>GRAND RIVER SEPTEL MANUFACTURING</p> <p>Domestic Fill/Finish Capacity Expansion</p>	 <p>Cantor BioConnect</p> <p>Convalescent Serum Collection</p>	 <p>American Red Cross</p> <p>Convalescent Plasma Collection</p>	 <p>Mount Sinai</p> <p>Convalescent Plasma Titering</p>	 <p>CSOFT</p> <p>Protocol Translation</p>	 <p>Swab Kits Air Bridge e</p>
 <p>LOVELACE BIOMEDICAL</p> <p>Animal Model Development</p>	 <p>RETRACTABLE TECHNOLOGIES, INC.</p> <p>Needles & Syringes + Manufacturing Capacity Expansion</p>	 <p>sio2 MATERIALS SCIENCE</p> <p>Vial Manufacturing Capacity</p>	 <p>THE TEXAS A&M UNIVERSITY SYSTEM</p> <p>Manufacturing Capacity Reservation & Expansion</p>	 <p>ICON</p> <p>Convalescent Serum Collection</p>	 <p>NYU</p> <p>Clinical Sample Collection</p>	 <p>MITRE</p> <p>Convalescent Plasma Outreach</p>	 <p>Colorado State University</p> <p>SolaVAX Virus Inactivation Process</p>	 <p>Reagent prep to support diagnostic development</p>	
 <p>SR SOUTHERN RESEARCH</p> <p>Animal Model Development</p>	 <p>patheon by Thermo Fisher Scientific</p> <p>Fill/Finish Capacity</p>	 <p>SNAPDRAGON CHEMISTRY</p> <p>Raw Materials for mRNA Vaccine Manufacturing</p>	 <p>ology BIOSERVICES</p> <p>Manufacturing Capacity Reservation & Expansion</p>	 <p>Whole Blood Samples</p>	 <p>Veterans Medical Research Foundation</p>	 <p>ATCC</p> <p>Short-Term Sample Storage</p>	 <p>UCONN UNIVERSITY OF CONNECTICUT</p> <p>Novel Vaccine Tech. Microneedle Patch</p>	 <p>VAXESS technologies</p> <p>Novel Vaccine Tech. Microneedle Patch</p>	
							 <p>Vermdari</p> <p>Novel Vaccine Tech. Microneedle Patch</p>	 <p>Esperovax</p> <p>Novel Vaccine Tech. Oral Delivery</p>	

How to Contact BARDA



Medical Countermeasures.gov

[medicalcountermeasures.gov](https://www.medicalcountermeasures.gov)

Portal to BARDA: **Register to request a TechWatch meeting!**



[beta.sam.gov/](https://beta.sam.gov)
Official announcements and info for all government contract solicitations



phe.gov/BARDA
Program description, information, news, announcements



drive.hhs.gov
Learn about DRiVe, including our Accelerator Network and EZ BAA



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