Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation

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COVID-19 Vaccine Development Portfolio

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BARDA/ASPR/HHS

Vaccines and Related Biological Products Advisory Committee
22 October 2020

UNCLASSIFIED

ASPR Mission

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

Pandemic Preparedness Principles

Flexible Agreements

Platforms for Faster Development

Expand Access

Sustainable

Improved Delivery

Production Capacity

Pandemic Influenza Preparedness

Emerging Infectious Diseases Preparedness

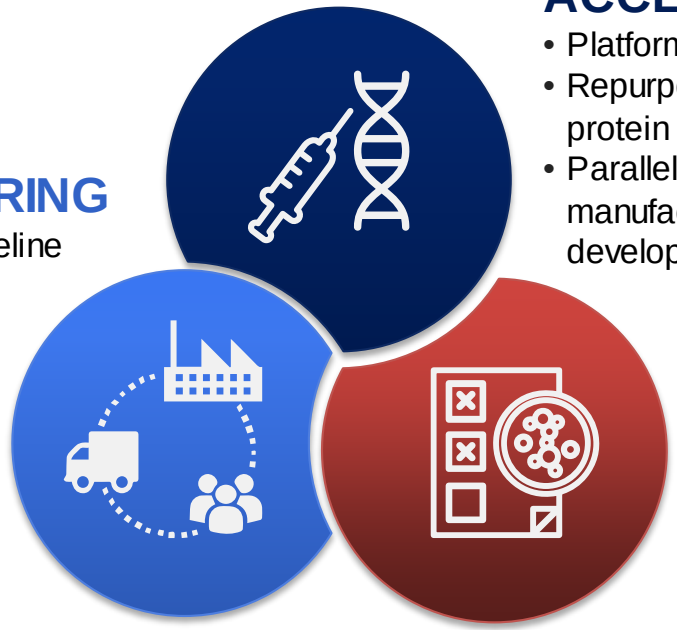
BARDA Pandemic Vaccine Preparedness and Response Strategy

ACCELERATE DEVELOPMENT

- Platform technologies (mRNA, Ad26, VSV)
- Repurpose licensed products (recombinant protein expression vectors; adjuvants)
- Parallel, not sequential, activities (large scale manufacturing in parallel with clinical development)

DOMESTIC MANUFACTURING

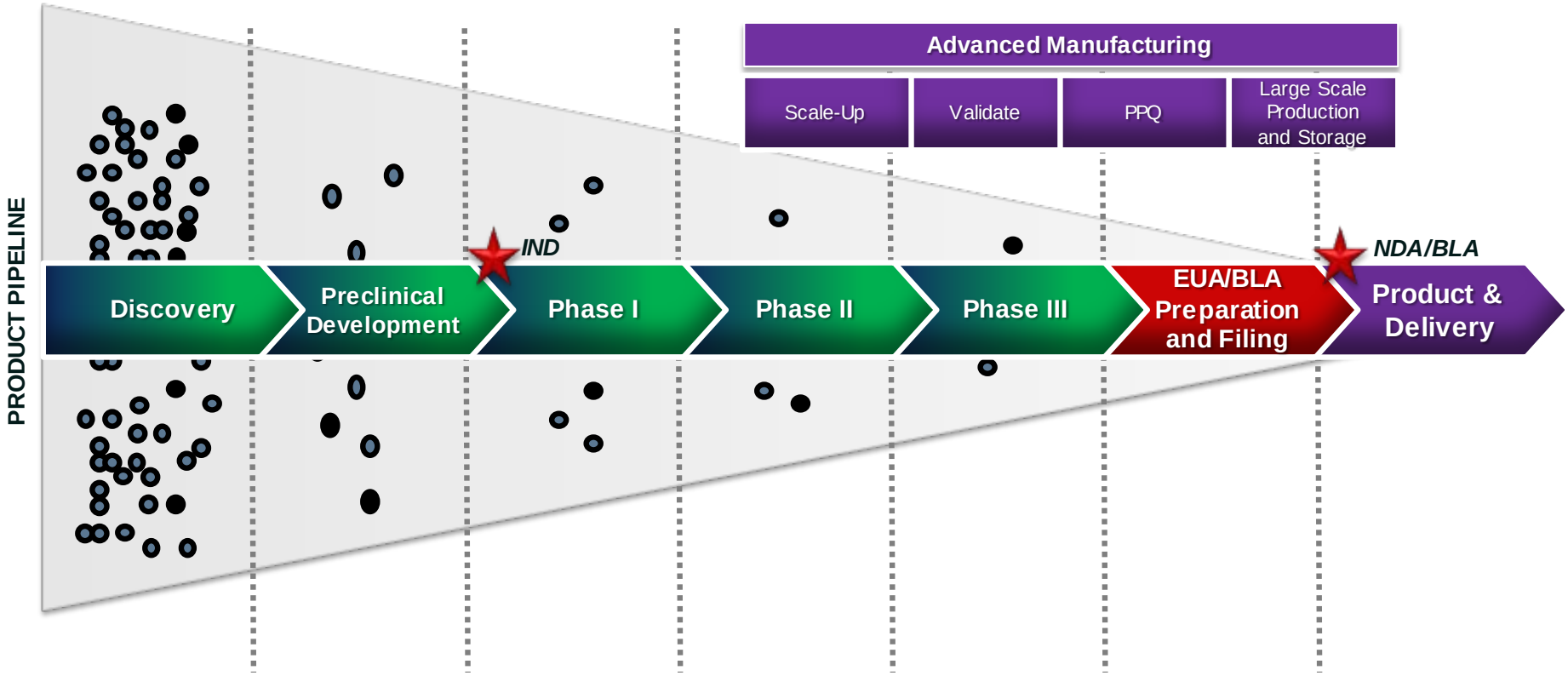
- Scale Up & Scale Out Capability/Timeline (Proven Platform Technologies)
- Raw materials and supply chains
- Leverage existing facilities (CIADMs)



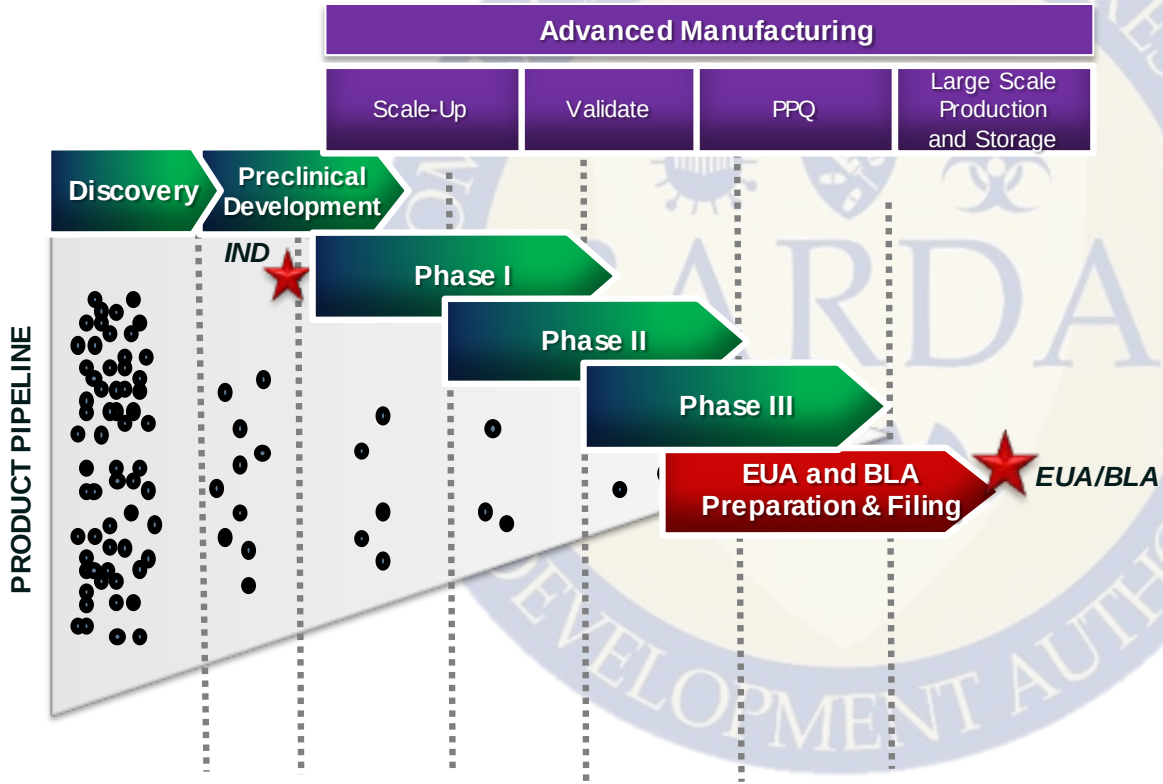
MITIGATE RISK

- Multiple technologies
- Multiple Facilities
- Redundancy

Traditional Pathway – Early Development to Large Scale Production

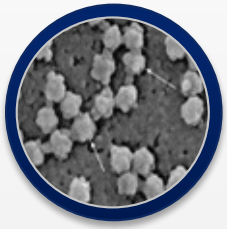


Accelerating Development of Safe and Effective Vaccines

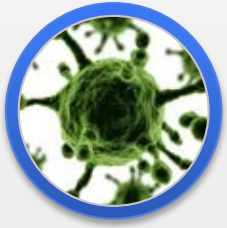


- Platform Technologies
- Multiple Candidates
- Large Scale Manufacturing in Parallel with Clinical Trials
- Large Phase III Trials

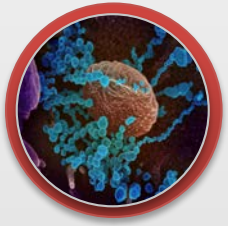
21st Century Novel Human Coronavirus Outbreaks



SARS | 2002
SARS emerged in China, CFR 11%



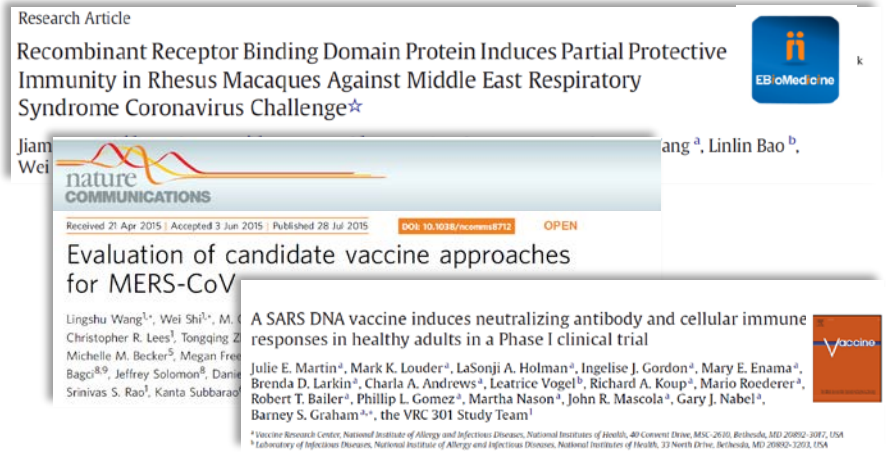
MERS | 2012
MERS first identified in Saudi Arabia



COVID-19 | 2019
COVID-19 emerged in Wuhan

16 YEARS

3rd Coronavirus Outbreak
No Licensed vaccines



Research Article

Recombinant Receptor Binding Domain Protein Induces Partial Protective Immunity in Rhesus Macaques Against Middle East Respiratory Syndrome Coronavirus Challenge☆

EBioMedicine

Jiam … ang [a], Linlin Bao [b], Wei …

nature COMMUNICATIONS

Received 21 Apr 2015 | Accepted 3 Jun 2015 | Published 28 Jul 2015 DOI: 10.1038/ncomms8712 OPEN

Evaluation of candidate vaccine approaches for MERS-CoV

Lingshu Wang[1,*], Wei Shi[1,*], M. … Christopher R. Lees[1], Tongqing Z… Michelle M. Becker[5], Megan Fre… Bagci[8,9], Jeffrey Solomon[8], Danie… Srinivas S. Rao[1], Kanta Subbarao…

A SARS DNA vaccine induces neutralizing antibody and cellular immune responses in healthy adults in a Phase I clinical trial

Vaccine

Julie E. Martin[a], Mark K. Louder[a], LaSonji A. Holman[a], Ingelise J. Gordon[a], Mary E. Enama[a], Brenda D. Larkin[a], Charla A. Andrews[a], Leatrice Vogel[b], Richard A. Koup[a], Mario Roederer[a], Robert T. Bailer[a], Phillip L. Gomez[a], Martha Nason[a], John R. Mascola[a], Gary J. Nabel[a], Barney S. Graham[a,*], the VRC 301 Study Team[1]

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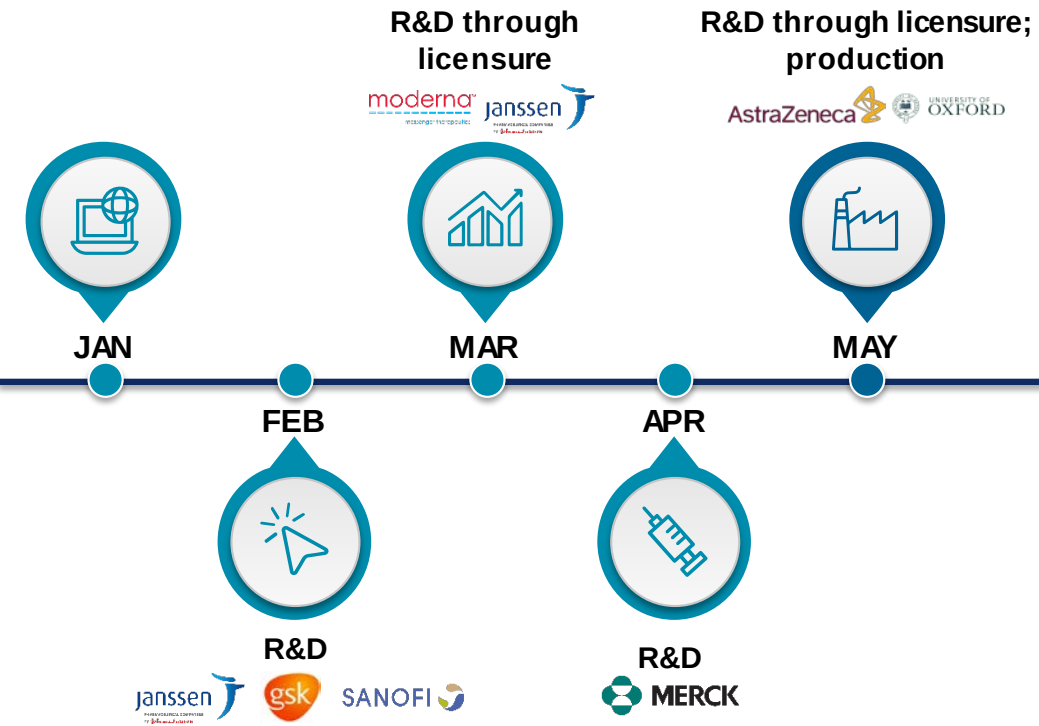
[b] Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 33 North Drive, Bethesda, MD 20892-3203, USA

Implementation of Vaccine Response Strategy

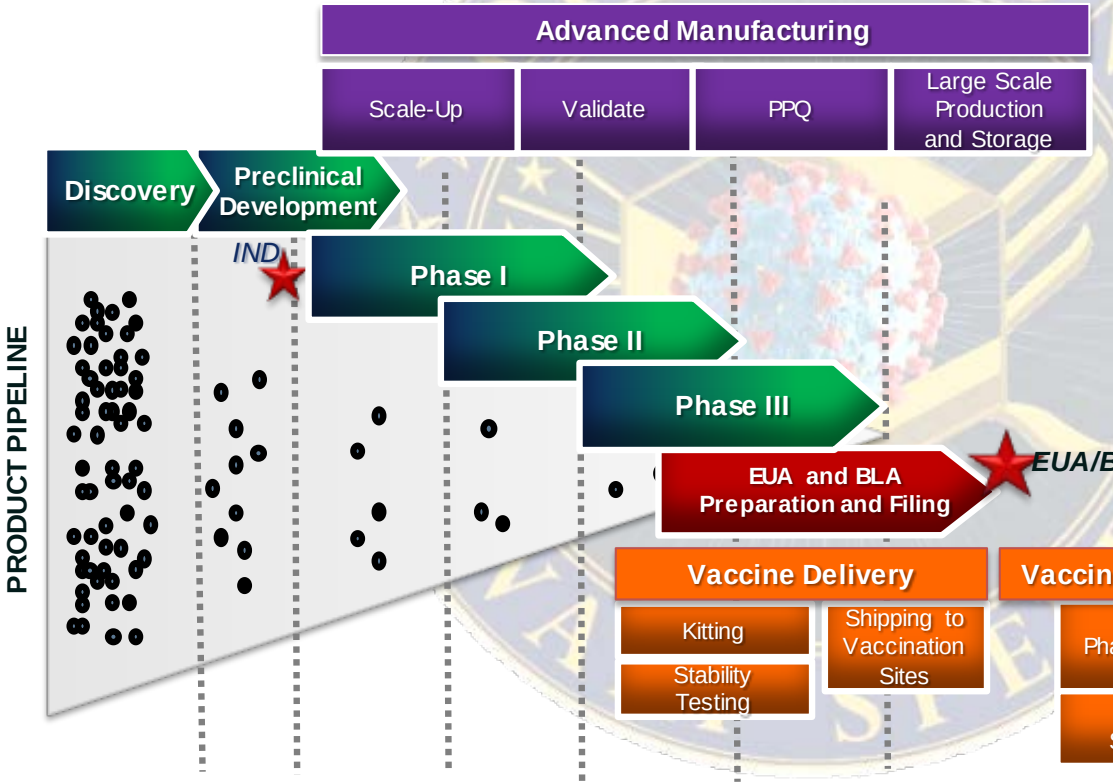


Operation Warp Speed

HHS and DoD working collaboratively with other federal partners as “One Government entity” to address the largest health security threat our nation has faced in a century.

Partnering with the biotech and pharmaceutical industry to develop, manufacture, deliver and administer safe and effective vaccines, and therapeutics to prevent and treat COVID-19 that will mitigate the effects of COVID-19 in the United States.

Accelerating Development of Safe and Effective Vaccines



- Platform Technologies
- Multiple Candidates
- Large Scale Manufacturing in Parallel with Clinical Trials
- Large Phase III Trials
- End-to-End Solution
- Expertise/Resources

Vaccines Leadership

Project Coordination Teams	Clinical & Development	Manufacturing & Quality Assurance	Distribution & Administration
University of Oxford AstraZeneca			
janssen			
moderna			
NOVAVAX			
BIONTECH Pfizer			
gsk SANOFI			

Clinical Trials

Manu-facturing

Supply, Production & Distribution

Plans, Operations & Analysis

Distribution

Infra-structure

Information

Security & Assurance

Personnel

Public Affairs

Legislative Affairs

Chief of Staff

Finance & Contracting

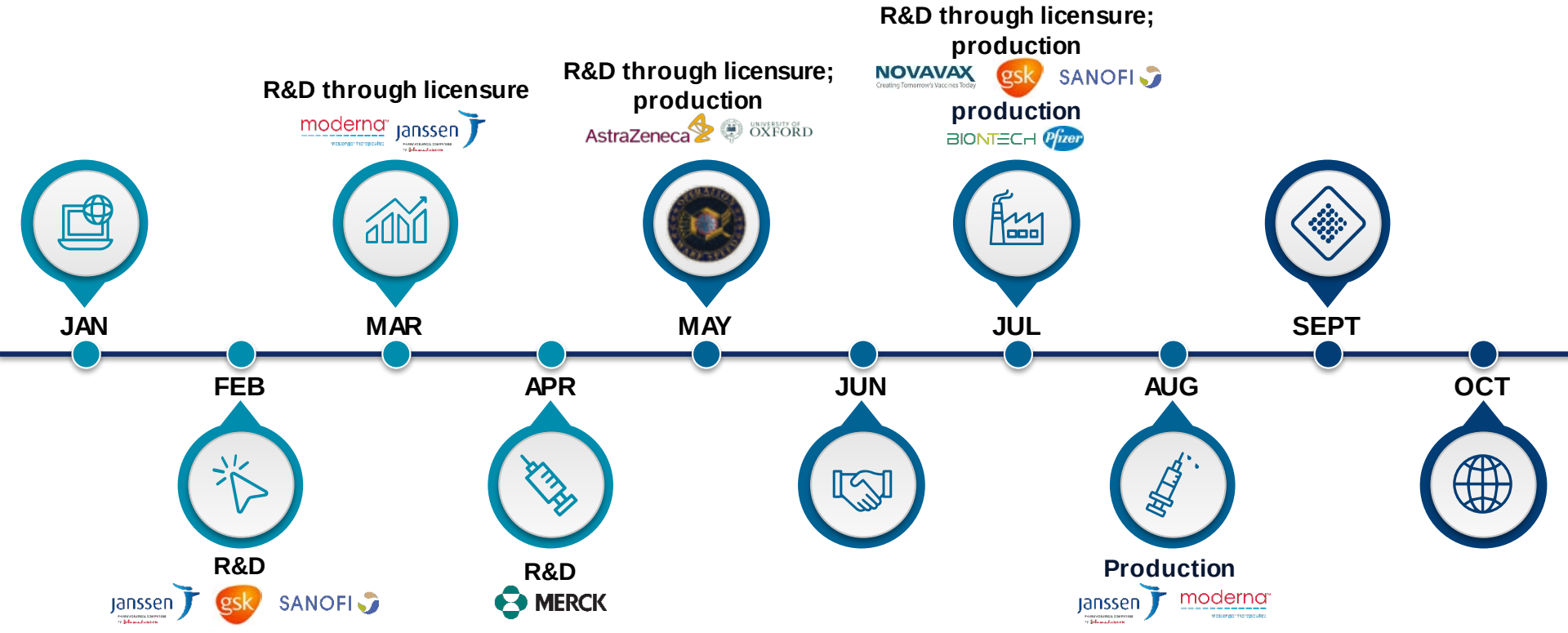
Office of General Counsel

Chief Operating Officer

Chief Science Advisor

A similar organizational structure supports COVID-19 therapeutic development

OWS/BARDA/JPEO COVID-19 Vaccine Research, Development, and Production Efforts



OWS/BARDA Vaccine Candidates

Developer	Platform	Doses/ Regimen	Non-clinical Results	Phase 1/2 Trial Start Dates	Clinical Phase
moderna	mRNA-1273 mRNA encapsulated in a lipid nanoparticle	2	• Neutralizing antibodies • Strong Th1 response • Protection from challenge	Phase 1: 3/16 start (18+) Phase 2: 5/29 start (18+)	Phase 3 7/27 start
BIONTECH Pfizer	BNT162b2 mRNA encapsulated in a lipid nanoparticle	2	• Neutralizing antibodies • Strong Th1 response • Protection from challenge	Phase 1: 5/5 start (18-85) Phase 2/3: 7/27 start (18-85)	Phase 3 7/27 start
UNIVERSITY OF OXFORD AstraZeneca	AZD1222 Non-replicating chimp adenovirus	2	• Neutralizing antibodies • Strong Th1, Th2 response • Protection from challenge	Phase 1: 4/23 start (18-55) Phase 2: 5/22 start (5-12, 18-70+)	Phase 3 8/31 (US)
janssen	JNJ-78436725 Non-replicating human adenovirus	1	• Neutralizing antibodies • Strong Th1, Th2 response • Protection from challenge	Phase 1/2: 7/24 start (18+)	Phase 3 9/23
NOVAVAX Creating Tomorrow's Vaccines Today	NVX-CoV2373 Protein subunit Matrix M adjuvant	2	• Neutralizing antibodies • Protection from challenge	Phase 1: 5/25 start (18-55) Phase 2: 8/24 start (18-84)	Phase 2 8/24
gsk SANOFI	Protein subunit AS03 adjuvant	2	• TBD	Phase 1/2: 9/3 start (18+)	Phase 1/2 9/3

OWS Tenets for BARDA Supported Phase 3 Trials

Harmonization

- Primary and secondary endpoints
- Common DSMB
- Immune Assays
- Work with CoVPN Network
- Statistical Analysis Plan
- Protocol Oversight Group
  - Developer
  - NIH
  - BARDA

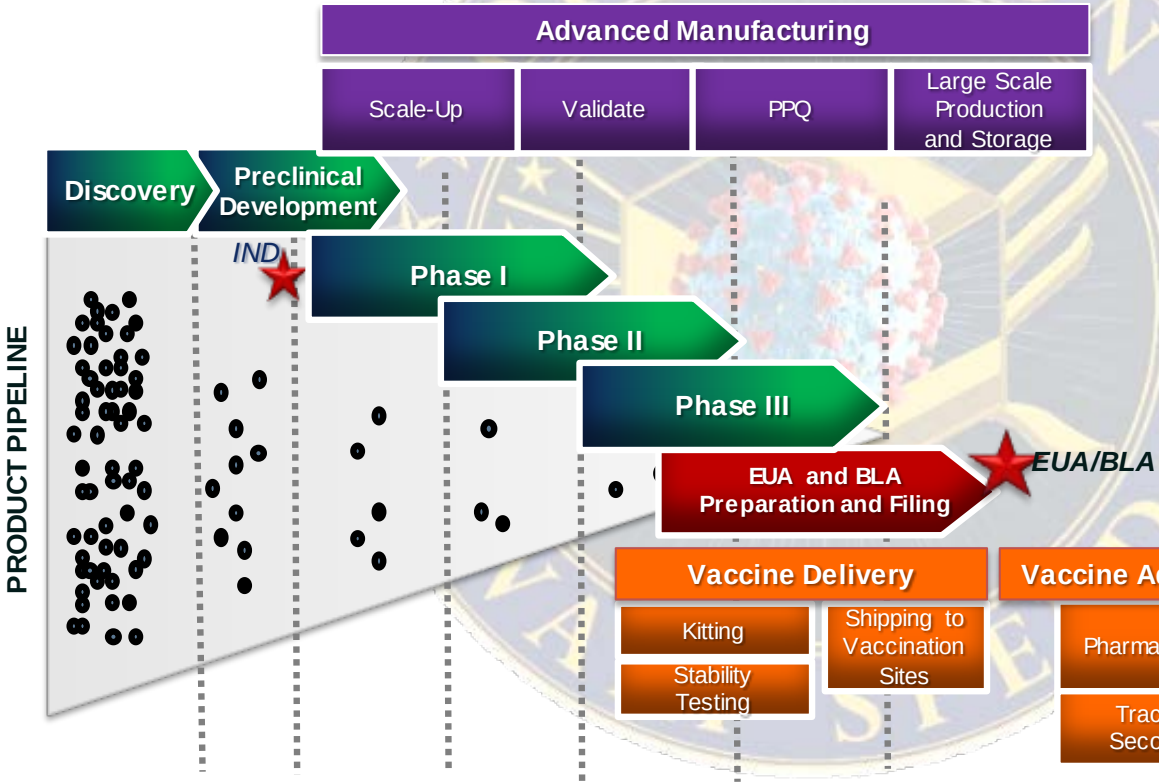
OWS Responsibility

- Overall Oversight Responsibility
- DSMB secretariat
- Protocol Approval
- Contract Oversight Responsibility

Developer Responsibility

- IND Sponsor
- Site Selection/Monitoring/ Oversight
- Sample/Data Management

Accelerating Development of Safe and Effective Vaccines



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OWS/BARDA Vaccine Manufacturing Portfolio

Vaccines

- Johnson & Johnson / Janssen — Ad26 Vector Mfg.Demo
- Sanofi Pasteur / GSK — Recombinant Protein + AS03 Adjuvant Mfg. Demo
- AstraZeneca — AZD1222 (ChAdOx1) Mfg.Demo
- Moderna — mRNA-1273 Commercial Scale Mfg.
- Novavax — NVX-CoV2373 Mfg. Demo
- Pfizer — BNT162 (mRNA) mRNA Mfg. Demo

Vaccine Supporting Efforts

- Marathon Medical — Needles & Syringes
- Emergent BioSolutions — Manufacturing Capacity & Vial Filling
- Smiths Medical — Needles & Syringes Manufacturing Capacity Expansion
- Cytiva — Manufacturing of Pharmaceutical Consumables
- BD — Needles & Syringes + Manufacturing Capacity Expansion
- Corning — Vial Manufacturing Capacity
- Grand River Aseptic Manufacturing — Domestic Fill/Finish Capacity Expansion
- Ology Bioservices — Manufacturing Capacity Reservation & Expansion
- Retractable Technologies, Inc — Needles & Syringes + Manufacturing Capacity Expansion
- SiO2 Materials Science — Vial Manufacturing Capacity
- The Texas A&M University System — Manufacturing Capacity Reservation & Expansion
- Snapdragon Chemistry — Raw Materials for mRNA Vaccine Manufacturing
- patheon by Thermo Fisher Scientific — Fill/Finish Capacity

Mfg = ≥100M doses

Visualize the END STATE

Solutions to Secure the Future

How to Contact BARDA

medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

beta.sam.gov/
Official announcements and info for all government contract solicitations

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

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