

# COVID-19 Vaccines Development and Distribution Planning

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# Clinical & Preclinical Stage Vaccine Pipeline

 BARDA / DoD funding

 OWS funded

 Jointly developed



Source: Biomedtracker, Biocentury, BIO Industry Analysis

1. PrEP Biopharm vaccine dsRNA, all others mRNA

Oxford, Astrazeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.

Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)

*Info as of Nov 10, not exhaustive*

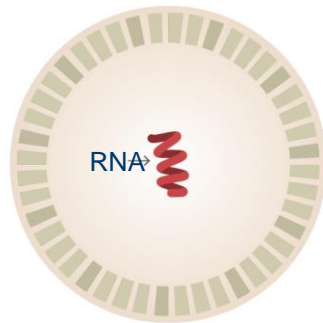
# Types of Vaccines for SARS-COV2

## Recombinant Protein Vaccine



Yeast or other cells can be engineered to carry a virus's gene and spew out viral proteins, which are then harvested and put into a vaccine. A coronavirus vaccine of this design would contain whole spike proteins or small pieces of the protein.

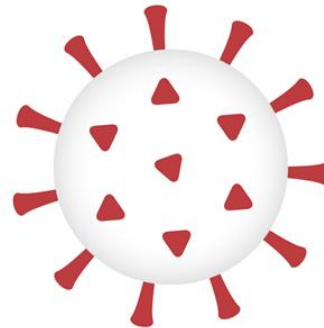
## Genetic Vaccine (DNA or RNA)



**DNA Vaccines:** A circle of engineered DNA is delivered into cells. The cells read the viral gene, make a copy in a molecule called messenger RNA, and then use the mRNA to assemble viral proteins. The immune system detects the proteins and mounts defenses.

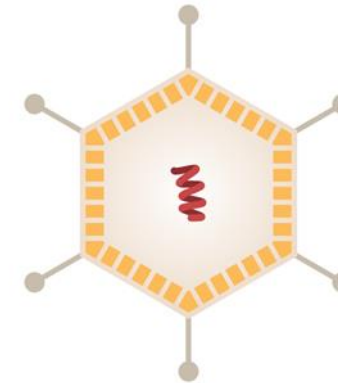
**RNA Vaccines:** Delivers messenger RNA into cells. The cells read the mRNA and make spike proteins that provoke an immune response.

## Virus-like or Nanoparticle Vaccine



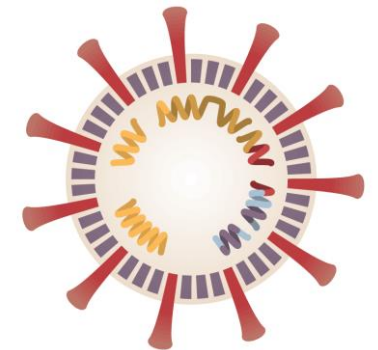
These vaccines are particles that contain pieces of viral proteins. They can't cause disease because they are not actual viruses, but they can still show the immune system what coronavirus proteins look like.

## Viral Vector Vaccine



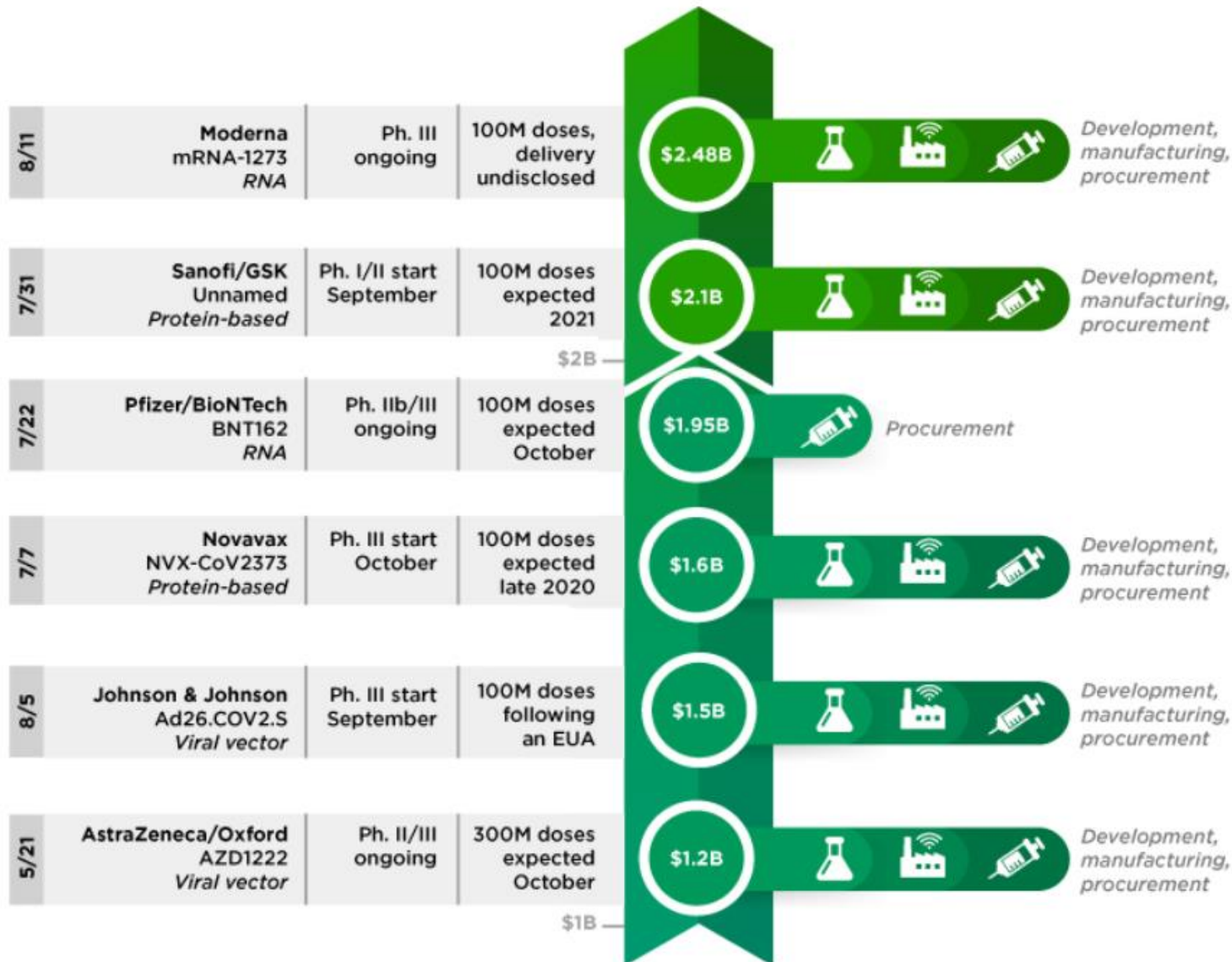
To create a coronavirus vaccine, several teams have added the spike protein gene to a virus called an adenovirus. The adenovirus slips into cells and unloads the gene. Because the adenovirus is missing one of its own genes, it cannot replicate and is therefore safe.

## Whole-Virus Vaccine



Incorporates an inactivated or weakened form of a virus that is not able to cause disease. When immune cells encounter them, they make antibodies.

# Vaccines with Operation Warp Speed Funding

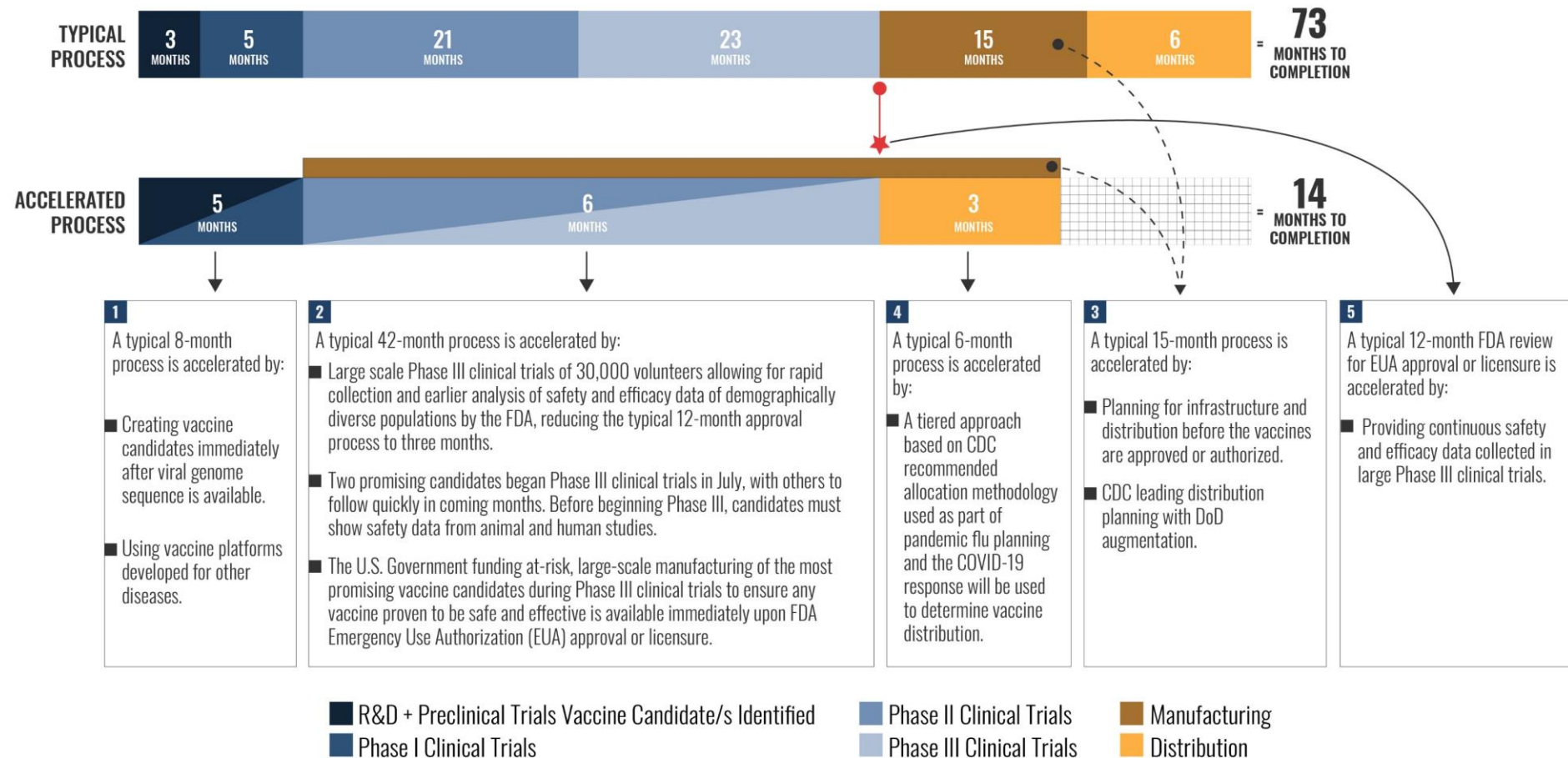


- OWS funding includes purchase of doses of vaccine
- As with H1N1 pandemic, vaccines will be provided free of charge to all Americans
- Efforts underway to also help patients with provider administration fees



# OPERATION WARP SPEED ACCELERATED VACCINE PROCESS

**MISSION:** Deliver 300 million doses of safe and effective vaccine by 1 January 2021.



# Regulatory Pathways for COVID-19 Medicines

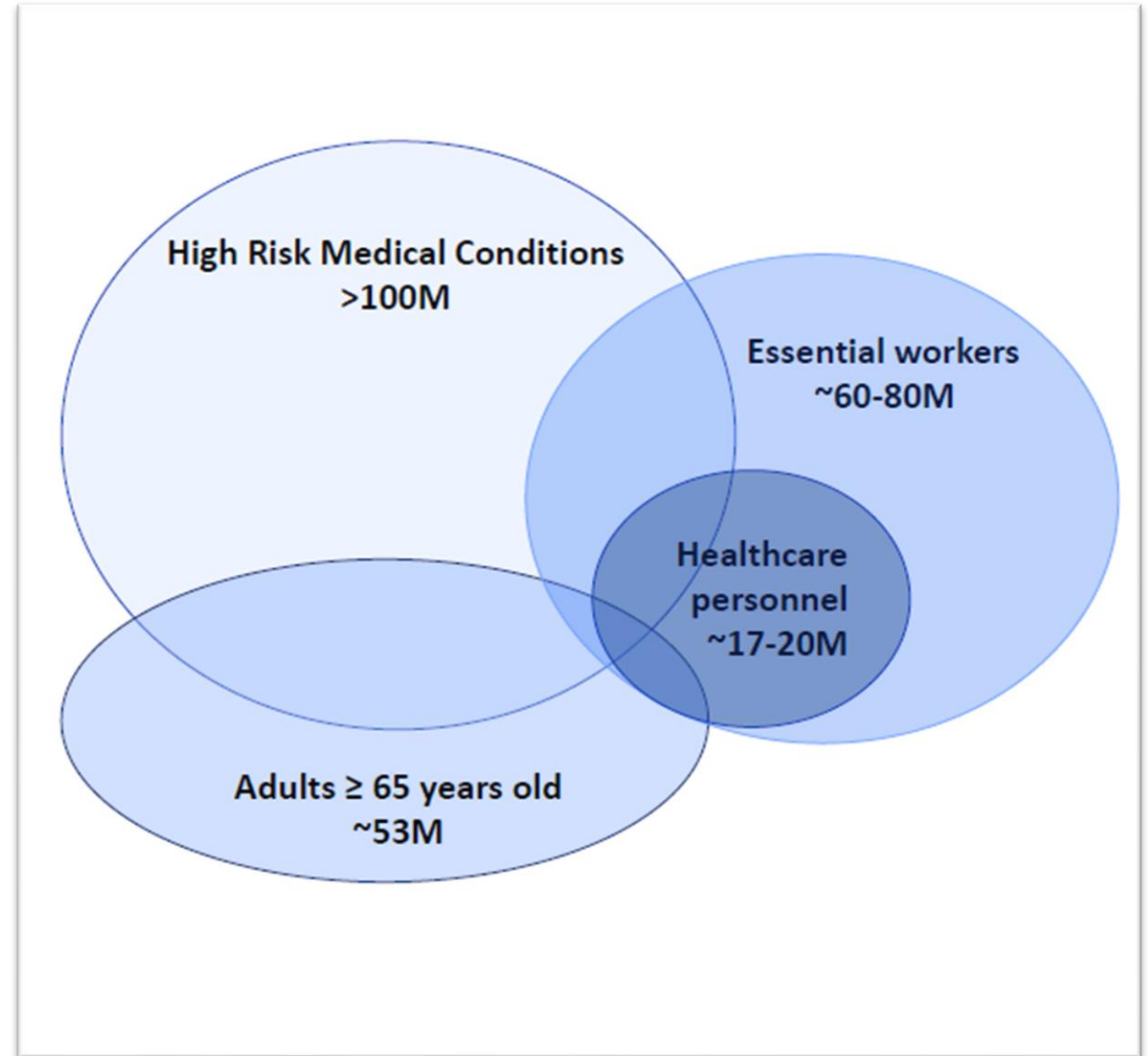
- **Biologics License Application (BLA):** Full licensure granted if FDA determines there is substantial evidence of safety and effectiveness from adequate and well-controlled trials.
- **Emergency Use Authorization (EUA):** The legal threshold for FDA to grant an EUA is that a product may be effective and its benefits outweigh known and potential risks
  - In the past EUA has been used for products developed against priority bio-threats such as smallpox and anthrax
- **FDA issued guidances for industry on COVID-19 in June and October 2020**
  - Regulatory requirements for EUA of COVID-19 vaccines are very similar to requirements for BLA of COVID- 19 vaccines.
  - Primary differences are in period of follow up and some requirements on manufacturing inspections.



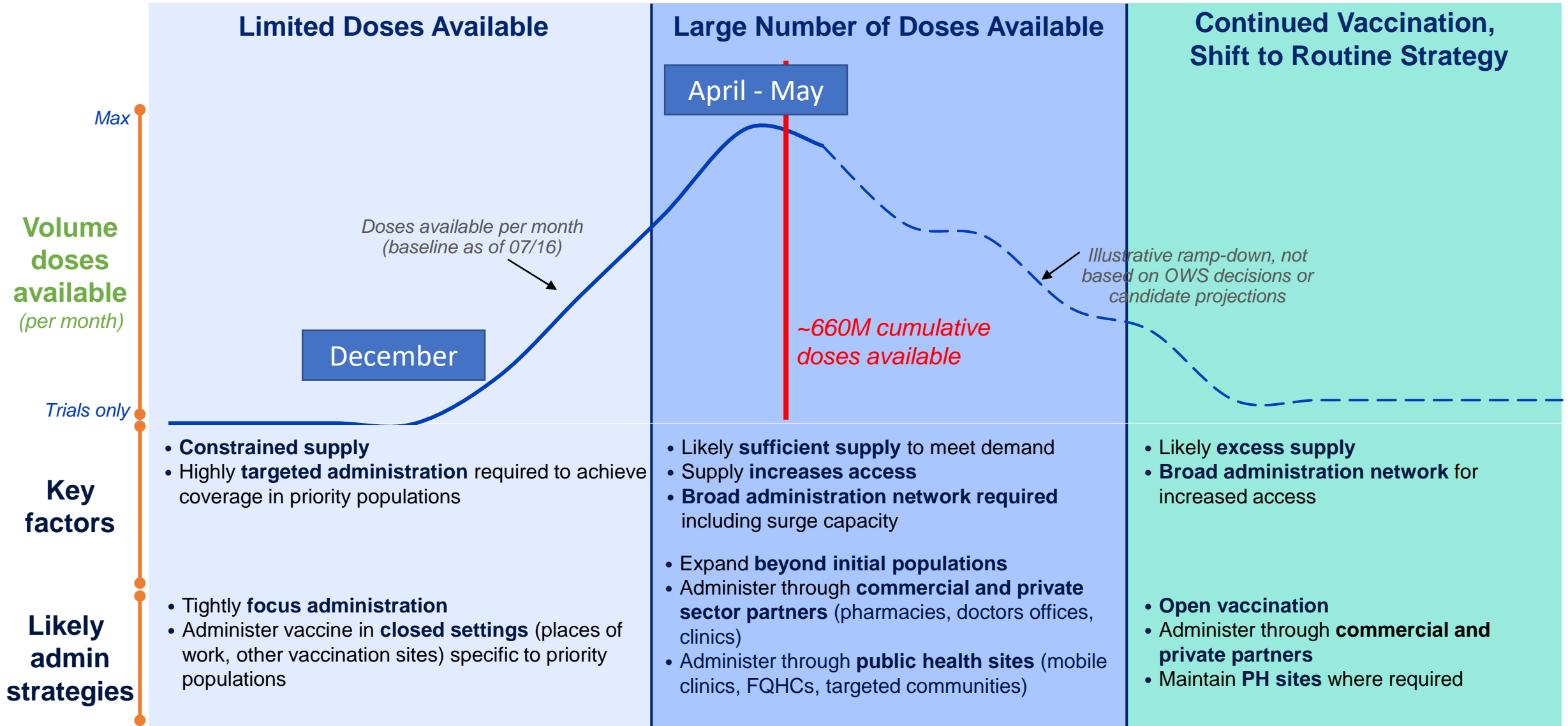
# CDC's Advisory Committee on Immunization Practices (ACIP) Prioritization Framework

## Groups prioritized for early phase vaccination

- ❑ Overlapping groups with significant heterogeneity
- ❑ Communities of color are significant portion of each population
- ❑ Accounts for > half of U.S. adults
- ❑ Framework informed by National Academies and Johns Hopkins frameworks



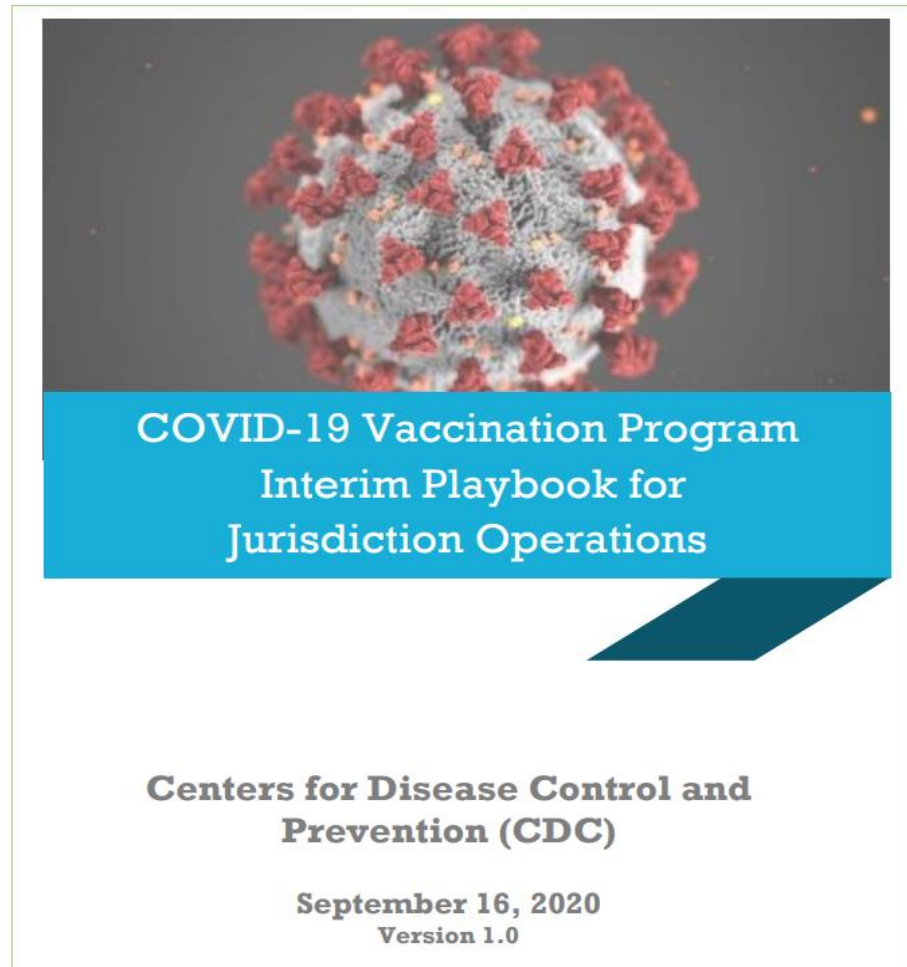
# Distribution will adjust as volume of vaccine doses increases



*Illustrative scenario for planning purposes; will be adapted based on the clinical / manufacturing information on all OWS candidates and vaccine prioritization*



# OWS / CDC Jurisdictional “Playbook” Leads to State Plans

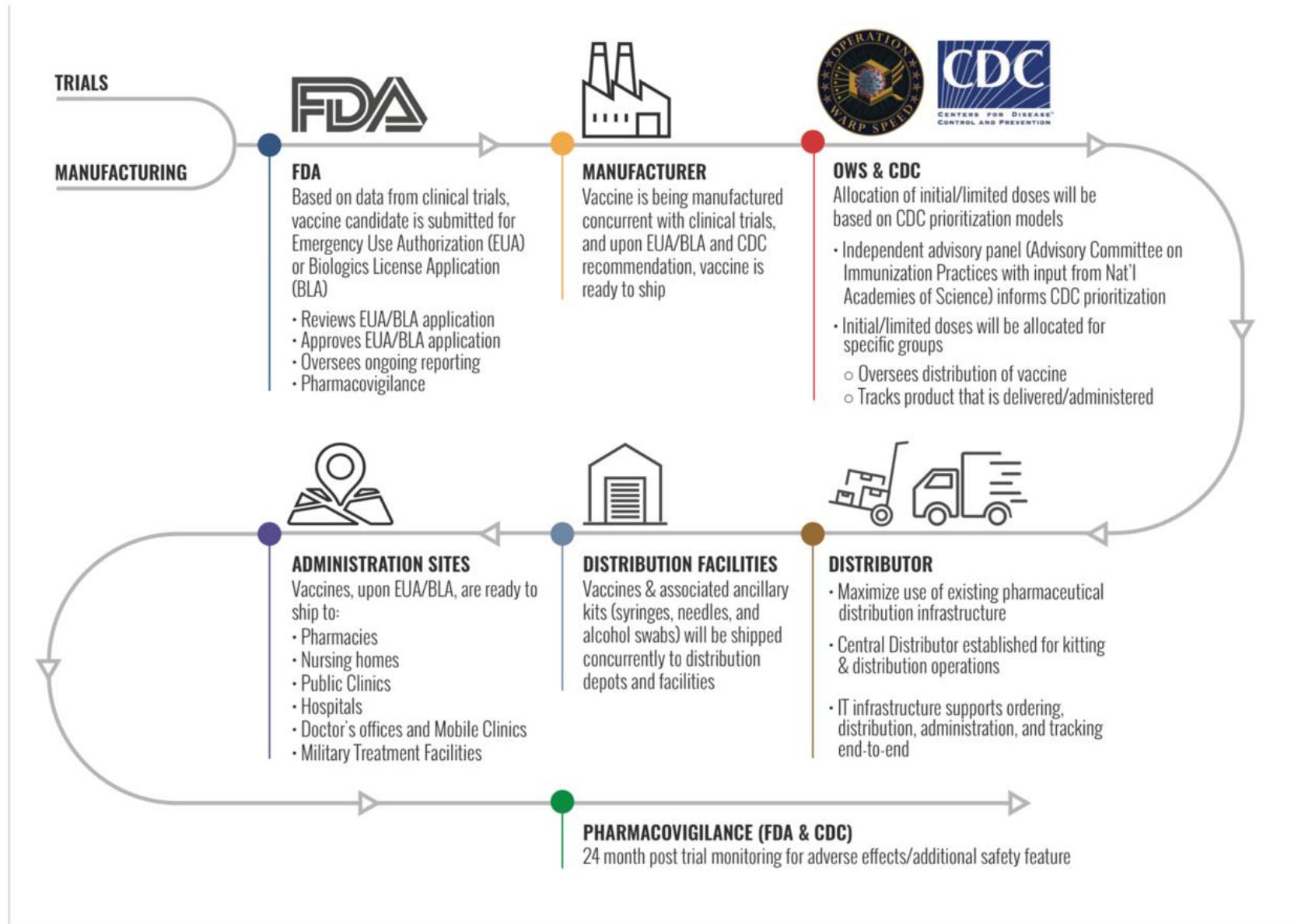


- CDC Playbook released September 16th
  - Locating Critical Populations
  - Vaccination Provider Recruitment, Enrollment and Training
  - Vaccination Program Communication
  - Vaccine Ordering and Distribution
  - Vaccine Storage and Handling (preliminary)
  - Vaccine Safety Monitoring (preliminary)
  - CDC Dashboards
- State and jurisdictional plans submitted to CDC October 16<sup>th</sup>
  - Many states established distribution / implementation committees
  - Several states established clinical review committees



[https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)

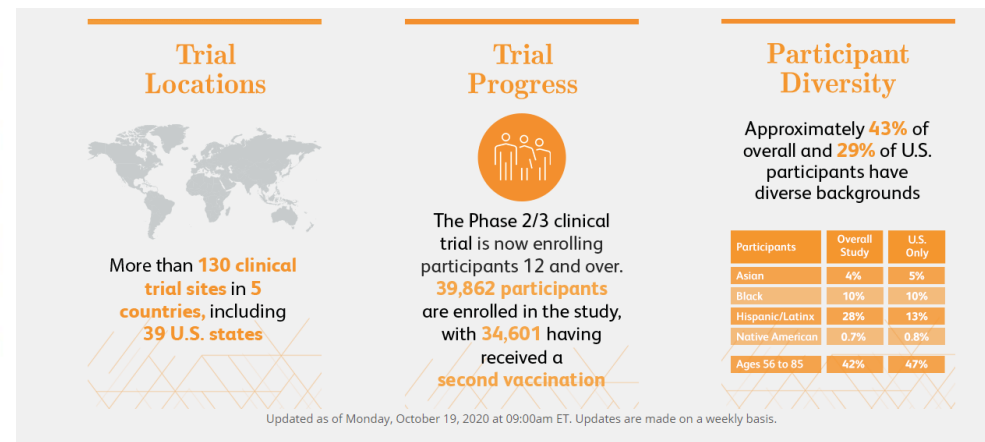
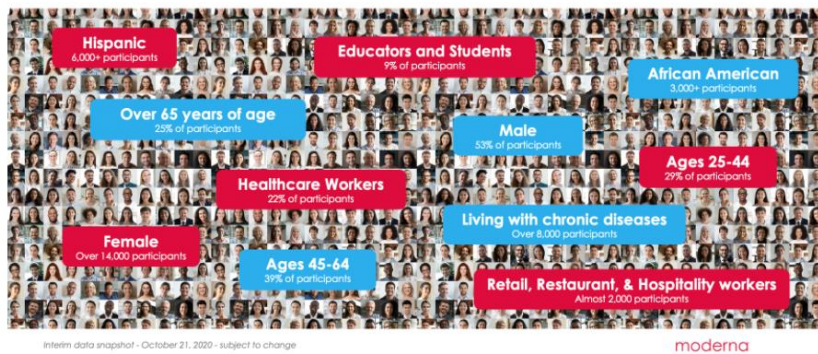
# OWS Vaccines Distribution Process



# Industry Commitment to Scientific Rigor, Transparency and Diversity

- Companies post weekly Phase 3 enrollment updates with breakdown in diversity
- Biopharmaceutical companies (CEOs) public pledge on scientific rigor, evidence and safety
- Companies have published their Phase 3 clinical trial protocols
- Companies have been submitting data for all trials for rapid peer-review by scientific journals and sharing more extensive scientific data in press releases closer to publication

A vaccine for everyone...find yourself in the Cove study



# BIO Resources

<https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus>

<https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>

