



# OPERATION WARP SPEED VACCINE DISTRIBUTION PROCESS

IN SUPPORTING THE DISTRIBUTION & ADMINISTRATION OF COVID-19 VACCINES, OWS HAS FOUR KEY GOALS, TENETS, AND ARCHITECTURE



Ensure safety and effectiveness of COVID-19 vaccines



Reduce morbidity and mortality of COVID-19 disease through effective and efficient distribution of COVID-19 vaccines



Support rapid vaccine distribution based on CDC guidance for states immunizations services



Assist with the return to pre-pandemic quality of life

## DISTRIBUTION AND ADMINISTRATION OF A COVID-19 VACCINE FOUR KEY TENETS

### CONTROL/VISIBILITY

Where vaccines and secondary item kits are at all times in the process of distribution and ensuring the vaccines go to prioritized groups as determined by policy

### COVERAGE

Deliver vaccines beyond the normal brick and mortar facilities, including potential mobile or on-site delivery of vaccine to long-term healthcare facilities and other hard to reach populations

### UPTAKE

How many vaccines were administered per location per day to match supply with demand

### TRACEABILITY

Confirm which of the approved vaccines were administered:

- Regardless of location (private/public)
- Reminder to return for second dose
- Administer the correct second dose



### TRIALS

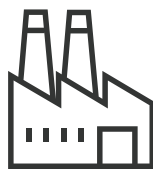
### MANUFACTURING



#### FDA

Based on data from clinical trials, vaccine candidate is submitted for Emergency Use Authorization (EUA) or Biologics License Application (BLA)

- Reviews EUA/BLA application
- Approves EUA/BLA application
- Oversees ongoing reporting
- Pharmacovigilance



#### MANUFACTURER

Vaccine is being manufactured concurrent with clinical trials, and upon EUA/BLA, vaccine is ready to ship



#### OWS & CDC

Allocation of initial/limited doses will be based on CDC prioritization models

- Independent advisory panel (Advisory Committee on Immunization Practices with input from Nat'l Academies of Science) informs CDC prioritization
- Initial/limited doses will be allocated for specific groups
  - Oversees distribution of vaccine
  - Tracks product that is delivered/administered



#### ADMINISTRATION SITES

Vaccines, upon EUA/BLA, are ready to ship to:

- Pharmacies
- Nursing homes
- Public Clinics
- Hospitals
- Doctor's offices and Mobile Clinics
- Military Treatment Facilities



#### DISTRIBUTION FACILITIES

Vaccines & associated ancillary kits (syringes, needles, and alcohol swabs) will be shipped concurrently to distribution depots and facilities



#### DISTRIBUTOR

- Maximize use of existing pharmaceutical distribution infrastructure
- Central Distributor established for kitting & distribution operations
- IT infrastructure supports ordering, distribution, administration, and tracking end-to-end

#### PHARMACOVIGILANCE (FDA & CDC)

24 month post trial monitoring for adverse effects/additional safety feature