



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

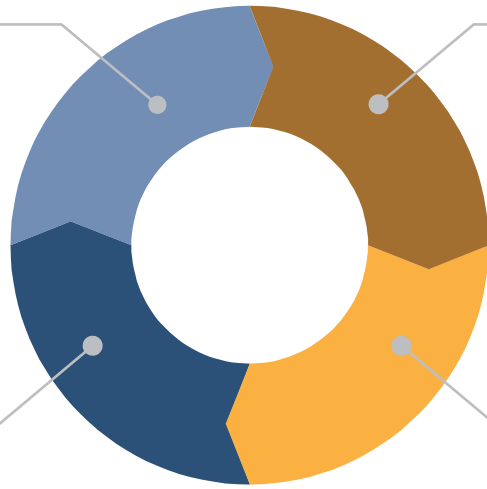
UPTAKE

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

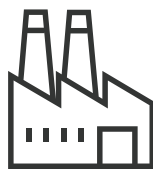
MANUFACTURING



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 and CDC recommendation, 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