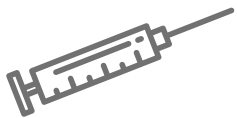




OPERATION WARP SPEED VACCINE DELIVERY MILESTONES

AUTHORIZATION - APPROVAL



Phase 3 Trials

Randomized, double-blind, placebo-controlled studies with more than 30k participants each, including diverse populations, providing rapid data collection



Data Safety Monitoring Board

Independent board evaluates data from ongoing Phase 3 trial, advises manufacturer whether pre-specified success criteria is met



Emergency Use Authorization (EUA)

Granted by the FDA following a recommendation by the Vaccines and Related Biological Products Advisory Committee and an independent analysis of drug manufacturing facilities, processes and drug product data

Biologics License Application (BLA)

Includes safety and efficacy data along with product, manufacturing and clinical studies information to consider full approval, potentially following six months of additional monitoring

PRIORITIZATION - ALLOCATION



National Academies of Science, Engineering and Medicine

Informs the CDC Advisory Committee on Immunization Practices (ACIP) on which populations receive priority for vaccines



Vaccine Priority

ACIP recommends vaccine priority to the CDC director, who reviews and recommends to the HHS Secretary



HHS Secretary

Endorses recommendation and staffs policy for approval to National Security Council



Allocation

Distribution based on census data for prioritized groups; drives the delivery of available doses to states, tribes, territories, localities and federal agencies



Jurisdictions/Federal Agencies

Execute federal priority guidance to identify points for vaccine delivery and administration



Delivery

Begins 24 hours after EUA, first doses available within 96 hours

DISTRIBUTION - ADMINISTRATION

Initial dose administered at various locations:



MANUFACTURERS
Produce products



SUPPLIES
Needles, syringes, alcohol swabs, etc.



KITTING
Preassembles and packages in ready-to-ship kits



DISTRIBUTOR
Delivers vaccine and supplies to administration sites

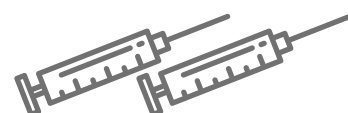
Administration sites

- Pharmacy
- Public health clinic
- Long term care facility
- Hospital
- Federally qualified health center
- Healthcare provider (doctors' office)
- Mass vaccination site
- Indian Health Service
- Home health
- Mobile site
- Other federal sites



Data IT/Systems

Jurisdictions provide dosing information to CDC data clearing house through immunization information systems and partner systems; patient data is de-identified with no personal identifying or health information



Second Dose Tracking

As most vaccines require two doses – 21 to 28 days apart from the same manufacturer, second dose reminders will be generated through existing IT systems



Pharmacovigilance

Post-vaccination monitoring continues for 24 months to detect, assess, understand, and prevent adverse effects; coordinated with vaccine companies, the CDC and FDA through multiple vaccine safety systems and V-SAFE