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

- **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

- **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

- **Administration sites**
  - Pharmacy
  - Public health clinic
  - Hospital
  - Federally qualified health center
  - Healthcare provider (doctors' office)
  - Mass vaccination site

- **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