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 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:

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

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

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

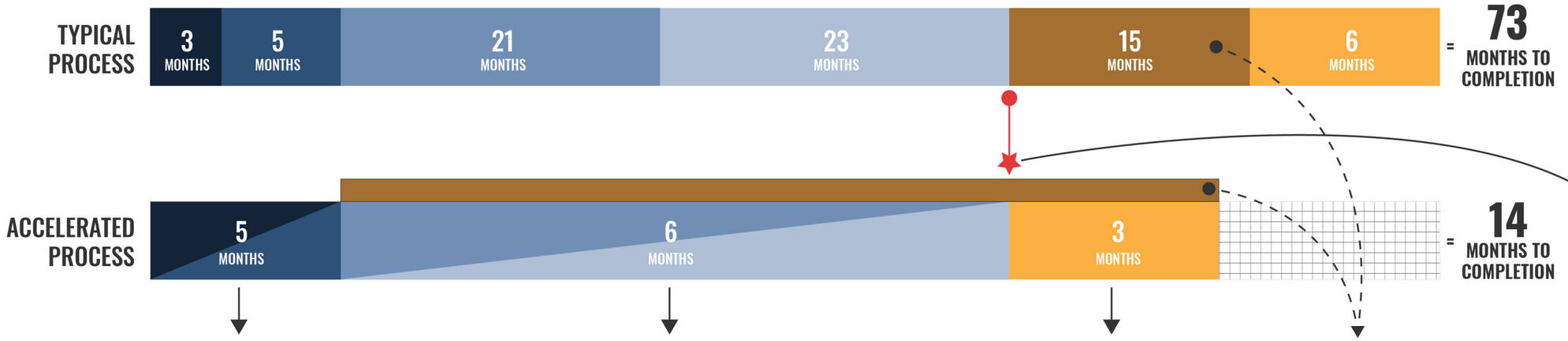
DISTRIBUTION FACILITIES
Vaccines & associated ancillary kits (syringes, needles, and alcohol swabs) will be shipped concurrently to distribution depots and facilities

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

PHARMACOVIGILANCE (FDA & CDC)
24 month post trial monitoring for adverse effects/additional safety feature

OPERATION WARP SPEED
ACCELERATED VACCINE PROCESS

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



1

A typical 8-month process is accelerated by:

- Creating vaccine candidates immediately after viral genome sequence is available.
- Using vaccine platforms developed for other diseases.

2

A typical 42-month process is accelerated by:

- Large scale Phase III clinical trials of 30,000 volunteers allowing for rapid collection and earlier analysis of safety and efficacy data of demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.
- Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.
- The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

4

A typical 6-month process is accelerated by:

- A tiered approach based on CDC recommended allocation methodology used as part of pandemic flu planning and the COVID-19 response will be used to determine vaccine distribution.

3

A typical 15-month process is accelerated by:

- Planning for infrastructure and distribution before the vaccines are approved or authorized.
- CDC leading distribution planning with DoD augmentation.

5

A typical 12-month FDA review for EUA approval or licensure is accelerated by:

- Providing continuous safety and efficacy data collected in large Phase III clinical trials.

R&D + Preclinical Trials Vaccine Candidate/s Identified
Phase I Clinical Trials
Phase II Clinical Trials
Phase III Clinical Trials
Manufacturing
Distribution

COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name | First Name | MI

Date of birth | Patient number *(medical record or IIS record number)*

Vaccine	**Product Name/Manufacturer** **Lot Number**	**Date**	**Healthcare Professional or Clinic Site**
1st Dose COVID-19		____/____/____ *mm dd yy*	
2nd Dose COVID-19		____/____/____ *mm dd yy*	
Other		____/____/____ *mm dd yy*	
Other		____/____/____ *mm dd yy*	

Reminder! Return for a second dose!
¡Recordatorio! ¡Regrese para la segunda dosis!

Vaccine	**Date / Fecha**
COVID-19 vaccine Vacuna contra el COVID-19	_____/_____/_____ mm dd yy
Other Otra	_____/_____/_____ mm dd yy

Bring this vaccination record to every vaccination or medical visit. Check with your health care provider to make sure you are not missing any doses of routinely recommended vaccines.

For more information about COVID-19 and COVID-19 vaccine, visit **cdc.gov/coronavirus/2019-ncov/index.html**.

You can report possible adverse reactions following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) at **vaers.hhs.gov**.

Lleve este registro de vacunación a cada cita médica o de vacunación. Consulte con su proveedor de atención médica para asegurarse de que no le falte ninguna dosis de las vacunas recomendadas.

Para obtener más información sobre el COVID-19 y la vacuna contra el COVID-19, visite **espanol.cdc.gov/coronavirus/2019-ncov/index.html**.

Puede notificar las posibles reacciones adversas después de la vacunación contra el COVID-19 al Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) en **vaers.hhs.gov**.

YOU CALL THE SHOTS

Vaccine Administration: Needle Gauge and Length

Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions. Needle selection should be based on the:

- Route
- Age
- Gender and weight for adults *(19 years and older)*
- Injection site

The following table outlines recommended needle gauges and lengths. In addition, clinical judgment should be used when selecting needles to administer injectable vaccines.

Route	Age	Needle gauge and length	Injection site
Subcutaneous injection	**All ages**	23–25-gauge 5/8 inch (16 mm)	Thigh for infants younger than 12 months of age[1]; upper outer triceps area for persons 12 months of age and older
Intramuscular injection	**Neonate, 28 days and younger**	22–25-gauge 5/8 inch (16 mm[2])	Vastus lateralis muscle of anterolateral thigh
	Infants, 1–12 months	22–25-gauge 1 inch (25 mm)	Vastus lateralis muscle of anterolateral thigh
	Toddlers, 1–2 years	22–25-gauge 1–1.25 inches (25–32 mm)	Vastus lateralis muscle of anterolateral thigh[3]
		22–25-gauge 5/8[2]–1 inch (16–25 mm)	Deltoid muscle of arm
	Children, 3–10 years	22–25-gauge 5/8[2]–1 inch (16–25 mm)	Deltoid muscle of arm[3]
		22–25-gauge 1–1.25 inches (25–32 mm)	Vastus lateralis muscle of anterolateral thigh
	Children, 11–18 years	22–25-gauge 5/8[2]–1 inch (16–25 mm)	Deltoid muscle of arm[3,5]
	Adults, 19 years and older ▪ 130 lbs (60 kg) or less ▪ 130–152 lbs (60–70 kg) ▪ Men, 152–260 lbs (70–118 kg) ▪ Women, 152–200 lbs (70–90 kg) ▪ Men, 260 lbs (118 kg) or more ▪ Women, 200 lbs (90 kg) or more	22–25-gauge 1 inch (25 mm[4]) 1 inch (25 mm) 1–1.5 inches (25–38 mm) 1–1.5 inches (25–38 mm) 1.5 inches (38 mm) 1.5 inches (38 mm)	Deltoid muscle of arm[3,5]

[1] May be administered into the upper outer triceps area if necessary
[2] If the skin is stretched tightly and subcutaneous tissues are not bunched
[3] Preferred site
[4] Some experts recommend a 5/8-inch needle for men and women weighing less than 60 kg, if used, skin must be stretched tightly and subcutaneous tissues must not be bunched.
[5] The vastus lateralis muscle in the anterolateral thigh can also be used. Most adolescents and adults will require a 1- to 1.5-inch (25–38 mm) needle to ensure intramuscular administration.

Reference: Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

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