

# **COVID Vaccine Planning Update**

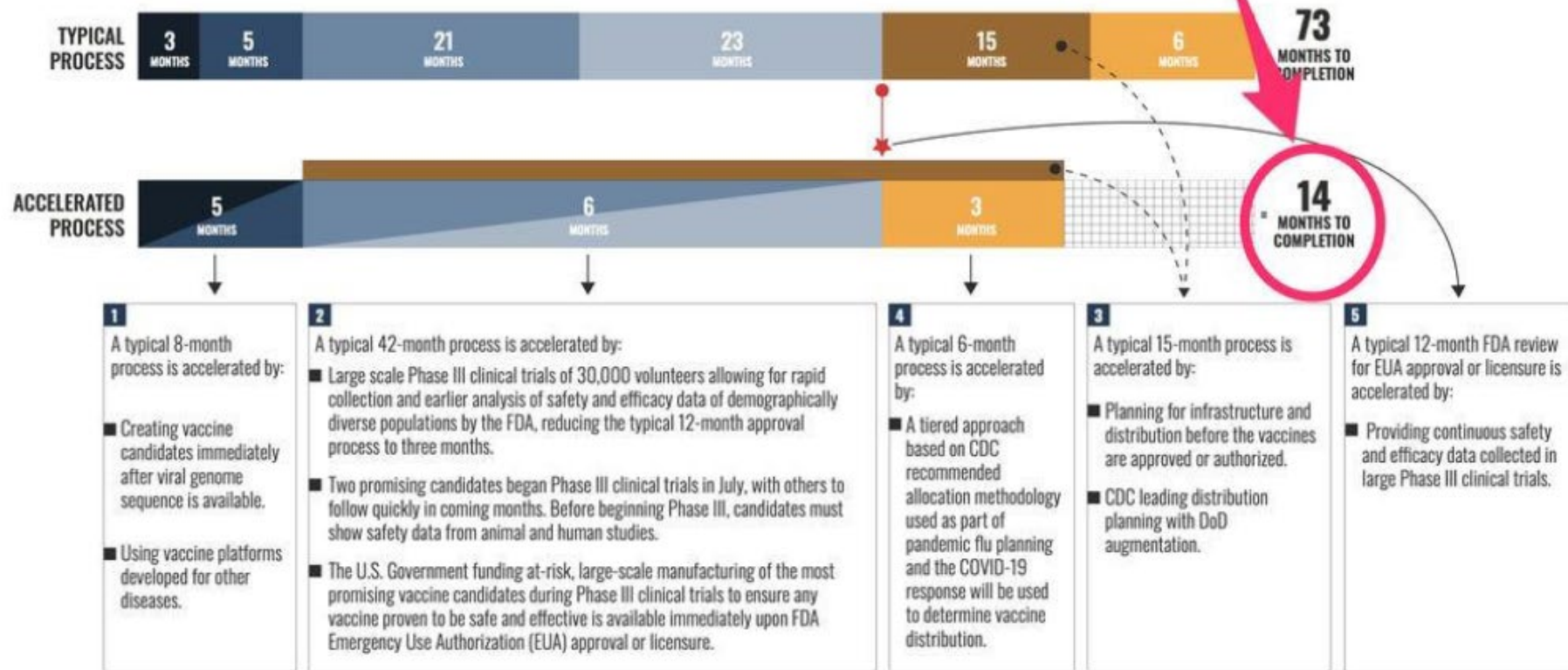
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**SHPR Quarterly Meeting - Aug. 19, 2020**



# OPERATION WARP SPEED ACCELERATED VACCINE PROCESS

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



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



# FDA Published Standards for COVID Vaccine Trials

- June 2020 FDA Published [“Guidance for Industry”](#)
- Key Principles
  - Phase 3 trials should be Randomized, Placebo-controlled Efficacy Trials
  - ~30,000 volunteers
  - Study population: Diverse,  $\geq 18$  yo, with subsets in high risk groups
  - Primary Endpoint: Prevention of symptomatic COVID-19 disease
    - Primary efficacy endpoint at least 50%
  - Common Data Safety Monitoring Board (DSMB) across all trials (NIAID)

# Front Runner Vaccine Candidates

Company	Candidate	Platform	Current Phase	OWS Funding	Dose commitment
AstraZeneca/Oxford Univ.	AZD1222	Viral vector	3	\$1.2B	300M
Moderna	mRNA-1723	mRNA	3	\$1.5B	100M
Johnson & Johnson (Janssen)	Ad26 SARS-CoV-2	Viral vector	1/2	\$1.5B	100M
Novavax	NVX-CoV2373	Protein subunit	1/2	\$1.6B	100M
Pfizer/BioNTech	BNT162	mRNA	2/3	\$1.95B	100M
GlaxoSmithKline/Sanofi	-----	Protein subunit	Pre-clinical	\$2.1B	100M

# Interested in participating in a COVID Vaccine Trial?

[COVID-19 Prevention Network – Volunteer Registry](#)



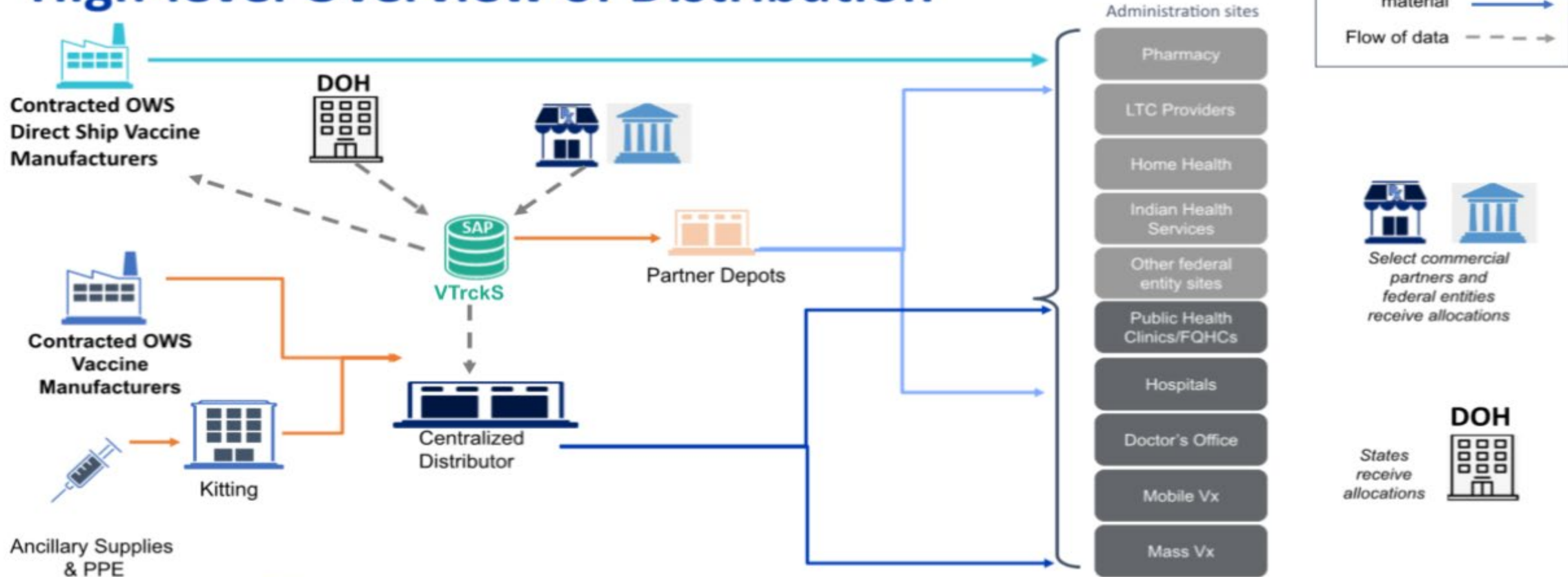
# COVID-19 Vaccine Planning Assumptions

- **Limited COVID-19 doses will be available in fall of 2020**
  - October is target for CDC to have plans ready
- **Initial populations recommended for COVID-19 vaccination will likely be:**
  - Healthcare Workers
  - Those that maintain essential functions of society
  - Residents and staff at LTC facilities
- **Initial doses may be authorized under EUA from FDA**
- **Likely 2 doses will be needed**
  - $\geq 21$  or  $\geq 28$  days apart
  - Both doses will need to be same product

## COVID-19 Vaccine Planning Assumptions cont'd

- All vaccine candidates require some level of cold chain mgmt.
- Some candidates currently require ultra low cold chain (ULC)
  - ULC means  $\leq -70^{\circ}\text{C}$
- Recommendation for target groups subject to change based on vaccine supply and characteristics
- Planning should include high demand and low demand scenarios
- Routine immunization programs must continue

# High-level Overview of Distribution



OWS coordination cell

## System needs to allow for:

- ✓ **Control:** Targeted populations
- ✓ **Tracking:** Where the vaccine is (End-to-End visibility)
- ✓ **Uptake:** Know when shots are administered



## **Current Federal Level Planning Activities:**

- **Building model plans, by working with select state/local jurisdictions that will be shared**
- **Collaborating with various agencies to determine priority groups**
- **Establishing MOAs with nationwide providers (large chain drug stores and federal providers)**

# Current State Level Vaccine Planning Activities:

- **Forming COVID vaccine planning team**
- **Reviewing existing mass vaccination plans**
- **Reviewing H1N1 lessons learned**
- **Assessing current status of**
  - **Vaccine storage capabilities**
  - **Pharmacy distribution**
  - **Immunization registry**
  - **Onboarding process for new users**

## **Current suggestions for local planning activities:**

- **Form local COVID vaccine planning team**
- **Assess existing mass vaccination plans**
- **Review H1N1 lessons learned**
- **Think about high-risk groups in your community and ways to reach them**
- **Stay current with the latest information**
  - Weekly LHD call



## **A few notes about Seasonal Flu:**

- **Increase Flu vaccine coverage among adults**
  - Target those at high risk for complications
  - Reduce strain on healthcare system
- **For the 2020-2021 Flu Season ONLY**
  - NCIP providers can use 2-way borrowing policy for flu vaccine
  - Amount of flu vaccine that can be borrowed between stocks is not limited to a certain amount
- **LHD's should expect communication from State IB soon**

# **Vaccine Planning Resources (Pre-COVID)**

*2019-2024 Public Health Emergency Preparedness (PHEP) Notice of Funding Opportunity – Supplemental Guidance and Resources*

*Domain 4: Key Components of Pandemic Influenza Operational Readiness*

**CDC - March 2019**

*Interim Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic*

**CDC – December 2018**

# Additional Sources of Information

[Advisory Committee on Immunization Practices \(ACIP\)](#)

[FDA COVID-19 Website](#)

[Clinicaltrials.gov](#)

[CDC COVID-19 Website](#)

[North Carolina COVID-19 Dashboard](#)

[WHO – Draft Landscape of COVID-19 Candidate Vaccines](#)

# Questions?

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