



# COVID-19 Vaccine Landscape Update

Presented by Aon

Issue Date: November 9<sup>th</sup>, 2020

# Overview

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- Phases of Vaccine Development
- Clinical Trial Status
- Issues that influence making vaccinations available and effective for the population
- Geographic Considerations
  - US
  - EMEA
  - Approach for other countries

Note: Since many clients have a footprint that spans 2 or more countries, it is helpful to understand differences
- Appendix
  - Immunity, Dosing and Coverage Considerations
  - Sourcing, Manufacturing and Distribution Considerations
  - Operationalizing at Scale – Simultaneous Workstreams for Vaccine Development, Manufacturing and Distribution
  - Pandemic Vaccine Distribution: CDC Depiction and Guidelines (2018 and 2020)
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# Phases of Vaccine Development – Updated as of November 9<sup>th</sup>, 2020

- Data Collection
- Involves only non-human testing
- Toxicity and pharmacological effects are tested

**Pre-clinical phase**  
(135+ vaccines in this stage)

**Clinical Phase I**  
(38 vaccines in this stage)

**Clinical Phase II**  
(14 vaccines in this stage)

**Clinical Phase III**  
(11 vaccines in this stage)

**Regulatory Review (RR)**  
(6 vaccines approved for use\*)

**Clinical Phase IV**

- Researches the safety and efficacy of a drug
- Dosing and scheduling of doses are examined here
- Usually takes up to 3 years. Estimated to take just 8 months
- “The experimental drug or treatment is administered to a larger group of people (100–300)”<sup>3</sup>

- Government Agency reviews the results of trials and lab results
- Manufacturing can occur concurrently
- Process expedited to a few months for COVID-19

- Small sample of healthy people
- Purpose is to evaluate the immune response to drug
- This process in typical drug development can take up to 2 years, for COVID-19 testing purposes it is taking 3 months
- “An experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects”<sup>3</sup>

- Study of 1000’s of people
- Safety and efficacy continue to be studied
- This process usually takes 2-4 years, Phases II and III are being combined for COVID-19 vaccine development purposes
- “The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments”<sup>3</sup>

- Testing begins after drug is released to the general public
- Monitor effectiveness in real-world environments
- “After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use”<sup>3</sup>

\* no vaccines have been approved in the US

Source:

1. <https://www.covid-19vaccinetracker.org/><sup>1</sup>
2. <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html?searchResultPosition=1><sup>2</sup>
3. National Institutes of Health (for Clinical Trial Phase definitions)<sup>3</sup>

# Clinical Trial Status for Top 10 Global Vaccine Candidates

Based on phase of testing and promising lab results as of November 9<sup>th</sup>, 2020

Phase of Testing	Clinical Trial Testing Lab	Projected Advancement to Next Clinical Trial Phase	Company estimated timeline for transition to Manufacturing Status
III	Univ. Of Oxford/AstraZeneca	Plans for distribution have begun, in late phase studies	<u>End of 2020</u>
III	Wuhan Inst./Sinopharm	Phase III in United Arab Emirates	<u>End of 2020</u>
III	Sinovac/Instituto Butantan	Phase III trials in Brazil	
III	Moderna	Expected to obtain efficacy data in November	<u>Starting 2021</u>
III	Beijing Inst./Sinopharm	Just started Phase III	<u>End of 2020</u>
III	Gamaleya Research Institute	Late stage data target date end of October	<u>End of 2020</u>
III	Cansino Biologics	Plans to launch Phase III trials in Saudi Arabia	
III	Janssen (J&J) Pharma	Began Phase III trials end of September	<u>Early 2021</u>
III	Novavax	Plan to have Phase III trials in the fall	<u>2021 Second Quarter</u>
III	BioNTech/Fosun/Pfizer	Pfizer releases promising trial data	<u>End of 2020</u>

Source:

1. [Fierce Pharma C19 Vaccine Tracker](#)
2. <https://www.covid-19vaccinetracker.org/>

# Newsworthy Candidates in the United States

## Pfizer

A vaccine being developed in collaboration with BioNTech a German pharmaceutical company and Fosun a Chinese pharmaceutical company

### Considerations:

- Enrolled the youngest clinical trial participant at age 12<sup>1</sup>
- Two doses are required
- An analysis found the vaccine was more than 90% effective in preventing the disease among trial volunteers who had no evidence of prior coronavirus infection<sup>2</sup>
- Vaccine will have to be chilled to minus 70 degrees Celsius (minus 94 degrees Fahrenheit) until it's ready to be injected<sup>5</sup>
- U.S. government provided \$1.95 billion funding to secure 100 million doses of the vaccine, if effective, and right to request up to 500 million more doses<sup>3</sup>

### Manufacturing:

Pfizer is advancing its vaccine manufacturing programs and expected to be able to provide 100 million doses by March 2021, enough for 50 million people. 40 million of the 100 million doses are likely to be available by the end of this year.<sup>4</sup>

1. <https://www.nbcnews.com/news/us-news/meet-youngest-participants-covid-19-vaccine-trials-teens-tweens-n1244957>
2. <https://www.nytimes.com/2020/11/09/health/covid-vaccine-pfizer.html>
3. <https://ctmirror.org/2020/10/25/who-decides-when-vaccine-studies-are-done/>
4. <https://www.fiercepharma.com/pharma/coronavirus-tracker-novavax-boasts-billion-plus-shot-capacity-by-2021-russia-s-world-first>
5. <https://globalbiodefense.com/2020/10/05/the-challenges-of-vaccine-cold-chain-distribution-must-be-met-to-end-the-pandemic/>

## Moderna

Moderna is setting an aggressive manufacturing schedule while Phase III of clinical trials is underway<sup>1</sup>

### Considerations:

- Early studies have shown that vaccine promotes creation of neutralizing antibodies in older adults at comparable rates to younger adults<sup>2</sup>
- Two doses are required
- Clinical trial specific plans released to assure public vaccine is not aligned with politically motivated timelines<sup>3</sup>
- Vaccine will have to be chilled to minus 20 degrees Celsius (minus 4 degrees Fahrenheit) until it's ready to be injected<sup>4</sup>

### Manufacturing:

The company and its partners are working to produce millions of doses at three sites for the U.S. market. Moderna is manufacturing vaccine for the U.S. market at its Massachusetts facility and in New Hampshire in conjunction with its partner Lonza.<sup>5</sup>

1. <https://www.wbur.org/commonhealth/2020/10/29/moderna-vaccine-end-of-year>
2. <https://medcitynews.com/2020/09/modernas-covid-19-vaccine-shows-antibody-t-cell-responses-a-month-after-second-dose-in-interim-phase-i-data/?rf=1>
3. <https://www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html>
4. <https://globalbiodefense.com/2020/10/05/the-challenges-of-vaccine-cold-chain-distribution-must-be-met-to-end-the-pandemic/>
5. <https://www.fiercepharma.com/pharma/moderna-has-started-producing-commercial-covid-19-vaccines-at-risk-ceo>

## J&J

Pharmaceutical giant Johnson & Johnson is developing a single-dose COVID-19 vaccine<sup>1</sup>

### Considerations:

- The vaccine does not need to be frozen; making distribution simpler
- It is a single dose instead of a two-dose series; making it easier to receive an effective dose more quickly
- Reportedly the lowest cost vaccine<sup>2</sup> (refer to slide 8 for reported manufacturer's price per dose)

### Manufacturing:

The pharmaceutical company struck a deal to supply 100 million doses of its candidate, Ad26.COV2.S, if the shot is cleared for use by the FDA.<sup>3</sup>

1. <https://www.inj.com/johnson-johnson-initiates-pivotal-global-phase-3-clinical-trial-of-janssens-covid-19-vaccine-candidate>
2. <https://observer.com/2020/08/covid19-vaccine-price-comparison-moderna-pfizer-novavax-johnson-astrazeneca/>
3. <https://www.fiercepharma.com/pharma/j-j-scores-1b-contract-from-u-s-to-deliver-100-million-coronavirus-vaccine-doses>

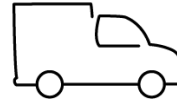
# Issues that Influence Making Vaccination Available and Effective for the Workforce

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## Immunity, Dosing & Coverage

- Immunity post-infection
- Immunity post-immunization
- Safe size of dose, as well as number of doses needed for a person to achieve immunity
- Frequency of inoculation to maintain immunity level



## Manufacturing & Distribution

- Availability/sourcing of supplies, preparation, process & resources
- Shelf-life, storage & shipping requirements
- Regulations



## Balancing Demand & Supply

- National & global regulations
- Health & safety oversight
- Hierarchy of population risk (essential workers, general underlying health risks)
- Funding and pricing
- Coverage

# Geography Considerations – US Overview

## Coronavirus Aid, Relief, and Economic Security (CARES) Act for US

### CARES Act Requires Coverage of COVID-19 Vaccine/Immunization

#### What's required?

- An employer-sponsored group health plan must cover (without cost-sharing) any Qualifying Coronavirus Preventive Service

#### What is the deadline for coverage?

- Within 15 business days of the recommendation by the USPSTF (U.S. Preventive Services Task Force) or the ACIP (Advisory Committee on Immunization Practices)

#### Any additional information?

- No guidance from the agencies to date, but based on statutory language, it appears that the requirement will apply to most employer-sponsored medical/Rx plans and *likely* will apply only in-network
- *Pending guidance to the contrary*, we anticipate that the following types of plans will not be required to cover the vaccine/immunization without cost-sharing:
  - Retiree only (fewer than 2 current employees in legal plan on first day of plan year)
  - Grandfathered group health plans

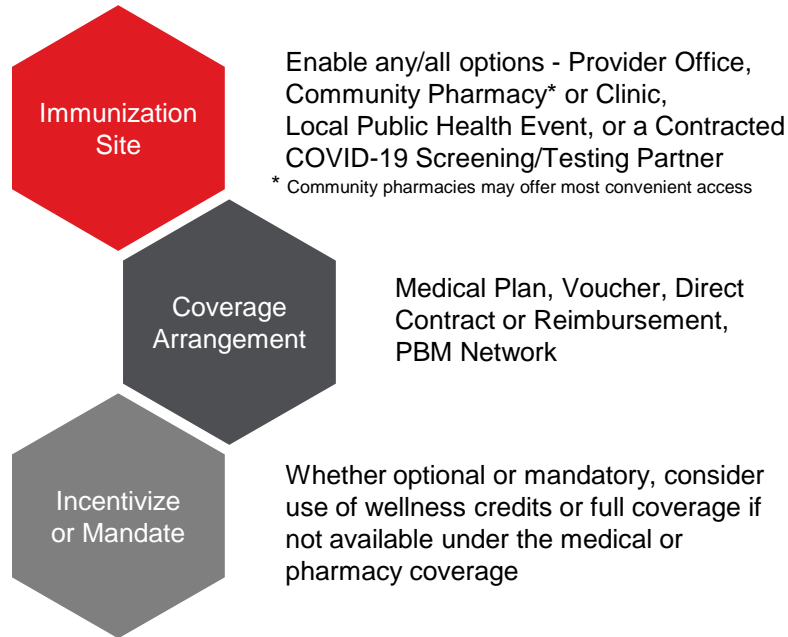
**Qualifying Coronavirus Preventive Service means an item, service or immunization that mitigates COVID-19 AND is:**

An evidence-based item or service that has a rating of “A” or “B” in the U.S. Preventive Services Task Force recommendations (USPSTF)

**OR**

An immunization that has a recommendation from the Advisory Committee on Immunization Practices (ACIP)

# Provider Delivery Considerations and Pricing – US



## Sampling of *Potential* Vaccine Providers & Pricing

Prices exclude administration fees

- Pfizer/BioNTech- \$19.50 a dose (two doses necessary)<sup>1</sup>
- Moderna- \$35 a dose (two doses necessary)<sup>2</sup>
- Janssen- \$10 a dose<sup>3</sup>

In an article published by the Wall Street Journal it is speculated that most doses of the COVID-19 vaccine will be between \$10 and \$37, with most manufacturers requiring a 2 dose series.<sup>4</sup>

*“Sharing finite supplies strategically and globally is actually in each country's national interest.”*

WHO, Aug 18, 2020

Vaccine distribution will be influenced by supply, funding and regulation

Source:

1. <https://www.barrons.com/articles/covid-19-vaccine-makers-could-be-heroes-but-not-if-the-price-tag-is-too-high-51595623222><sup>1</sup>
2. <https://www.cbsnews.com/news/coronavirus-vaccine-moderna-charging-more-rival-treatments/><sup>2</sup>
3. <https://scrip.pharmaintelligence.informa.com/SC141970/COVID19-Vaccine-Could-Cost-As-Little-As-10-A-Dose-Says-Janssen><sup>3</sup>
4. <https://www.wsj.com/articles/covid-19-vaccine-makers-signal-prices-11596648639><sup>4</sup>



# Geography Considerations – US

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## Operation Warp Speed (OWS) for US

### **Operation Warp Speed is a collaborative effort to accelerate vaccine development, manufacturing and distribution for US**

- Entities involved: HHS (Dept. of Health and Human Services), CDC, FDA, NIH, DOD (Dept. of Defense), and BARDA (Biomedical Advanced Research and Development Authority)
- Goal: Invest in and streamline COVID-19 vaccination development efforts and deliver a safe and effective drug to the general US public by the end of 2020<sup>1</sup>

Note: It is not certain that all vaccine candidates will be effective; too early to tell

- Funding: \$10 billion of funding (\$6.5 billion for countermeasure efforts and \$3.5 billion for research)

OWS is only choosing the manufacturers of the top 7 contenders who show promising results in initial trials, research, and technology capabilities<sup>2</sup>:

- Novavax (\$1.6 billion)
- Pfizer Inc (\$1.95 billion)
- AstraZeneca (\$1.2 billion)
- Moderna (\$430 million)
- Merck and IAVI (\$38 million)
- Protein Sciences, a Sanofi company (\$30 million)
- Janssen (\$457 million)

Source:

1. <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>
2. <https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx2>

# COVID Vaccine Injury Program – US

## *Addressing the concern of potential COVID-19 vaccine injury*

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Occasionally, a pandemic, epidemic, or security danger threatens the US. To combat these threats, the government supports the development of countermeasures such as vaccines. The Countermeasures Injury Compensation Program (CICP) was created so that in the unlikely event a person experiences a serious injury from a covered countermeasure, the person may be considered for benefits. COVID-19 vaccine is such a countermeasure. See: <https://www.hrsa.gov/cicp>



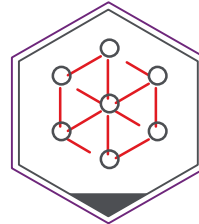
### **Countermeasures Injury Compensation Program (CICP):**

- Program run by Health and Human Services (HHS)
- Covers harm resulting from vaccine used in a pandemic, epidemic, security danger
- High threshold for proving a relationship between an injury and the vaccine
- No-fault system



### **Employers:**

- Vaccine Sponsor
- Vaccine Campaigns
- Required or Voluntary
- Injury claims already emerging



### **Vaccine Court:**

- Orders payouts for claims
- Mandated to pay awards quickly and easily

Note: The above description of CICP only applies to US. COVAX Facility has its own approach to addressing vaccine injury for COVAX member countries; we will include discussion of COVAX Facility in our next update.

Source: <https://www.hrsa.gov/cicp>

# Geography Considerations – EMEA

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## EU Strategy for COVID-19 vaccines:

Mid-June, the European Commission presented a strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19. Under this strategy the commission is supporting efforts to accelerate the development and availability of safe and effective vaccines in a timeframe of 12-18 months<sup>1</sup>

- Initial investment of €2.7 billion has been committed in advanced purchase commitments<sup>1</sup>
- European Commission is envisaging a contract with Sanofi-GSK for COVID-19 vaccines which would provide an option for all EU Member States to purchase the vaccine. Commission would have a contractual framework in place for the purchase of 300 million doses once an effective vaccine has been developed<sup>4</sup>
- European Commission is also currently in negotiations with the following organizations for advanced purchase commitments for vaccine: Sanofi, Moderna, Johnson & Johnson, BioNTech and CureVac

## Inclusive Vaccine Alliance:

France, Germany, Netherlands and Italy have joined together to form the Inclusive Vaccine Alliance. The alliance is focused on achieving faster vaccine development and pharma companies promise that such vaccine development must be accessible, available and affordable. The alliance is also working on making a portion of vaccines available to low-income countries, including those in Africa.<sup>2</sup>

- This alliance has reached an agreement with AstraZeneca to supply up to 400 million doses of University of Oxford's COVID-19 vaccine with an advanced purchase commitment of €750 million<sup>3</sup>.

Source:

1. [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_1103](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1103)

2. <https://www.government.nl/latest/news/2020/06/03/france-germany-italy-and-the-netherlands-working-together-to-find-a-vaccine-for-countries-in-europe-and-beyond>

3. <https://institute.global/sites/default/files/2020-06/Tony%20Blair%20Institute%2C%20Towards%20a%20Global%20Covid-19%20Vaccine%20Strategy.pdf>

4. [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_1439](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1439)

# Geography Considerations – EMEA

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## EMEA & Public Health Organizations Overview

### UK<sup>1</sup>

- Sanofi and GSK have reached an agreement, subject to final contract, with the UK government for the supply of up to 60 million doses of a COVID-19 vaccine
- 90 million vaccine doses from the BioNTech/Pfizer alliance and Valneva with more in the pipeline as part of its strategy to build a portfolio of promising new vaccines to protect the UK from COVID-19
- In addition, treatments containing COVID-19-neutralising antibodies have been secured from AstraZeneca to protect those who cannot receive vaccines

### COVAX Facility<sup>2</sup>

- Lead by Gavi, World Health Organization (WHO) and Coalition for Epidemic Preparedness Innovations (CEPI) – The COVAX Facility has been created to guarantee rapid, fair and equitable access to COVID-19 vaccination worldwide. Their goal is to deliver 2 billion doses of vaccines with regulatory approval and WHO prequalification, with prioritization of healthcare workers of the participating 165 countries, followed by rest of the population
- COVAX Facility is an important part of ACT-Accelerator; a dedicated framework the European Commission helped establish for enhancing global collaboration in speeding up the development and universal deployment of the tools required to fight COVID-19<sup>3</sup>
- 7 partners have been supported by COVAX Facility, with an advanced market commitment of US \$2 billion
- AstraZeneca has committed to COVAX Facility a supply of 300 million doses of COVID-19 vaccine

Source:

1. <https://www.gov.uk/government/news/millions-could-be-vaccinated-against-covid-19-as-uk-secures-strong-portfolio-of-promising-vaccines>
2. <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>
3. [https://ec.europa.eu/info/sites/info/files/communication-eu-strategy-vaccines-covid19\\_en.pdf](https://ec.europa.eu/info/sites/info/files/communication-eu-strategy-vaccines-covid19_en.pdf)

# Geography Considerations – Emerging Vaccine Distribution Guidelines

## US

### Approach:

- A phased approach (Phases 1-3) from the CDC
- Phase 1: Potentially limited supply of COVID-19 vaccine doses available
- Phase 2: Large number of vaccine doses available
- Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses)

### Prioritizing populations:

- Healthcare personnel (paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials)
- Non-healthcare essential workers
- Adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness
- People 65 years of age and older (including those living in long-term care facilities (LTCFs))

### State response:

- The CDC released the “Jurisdiction Operations Playbook” to operationalize the phased approach on a state level. Rhode Island, Washington State, North Carolina, Illinois, and Tennessee are a few of the states who have started planning based on CDC guidance.

[https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)

## COVAX Facility

### Approach:

- For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as a number of higher-income self-financing countries that have no bilateral deals with manufacturers
- All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021
- Funded countries will receive enough doses to vaccinate up to 20 per cent of their population in the longer term

### Prioritizing populations:

- Allocated to all participating countries at the same rate, proportional to their total population size
- 5% of the total number of available doses will be kept aside to build a stockpile to help with acute outbreaks and to support humanitarian organizations, for example to vaccinate refugees who may not otherwise have access
- No country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this amount

### Participants:

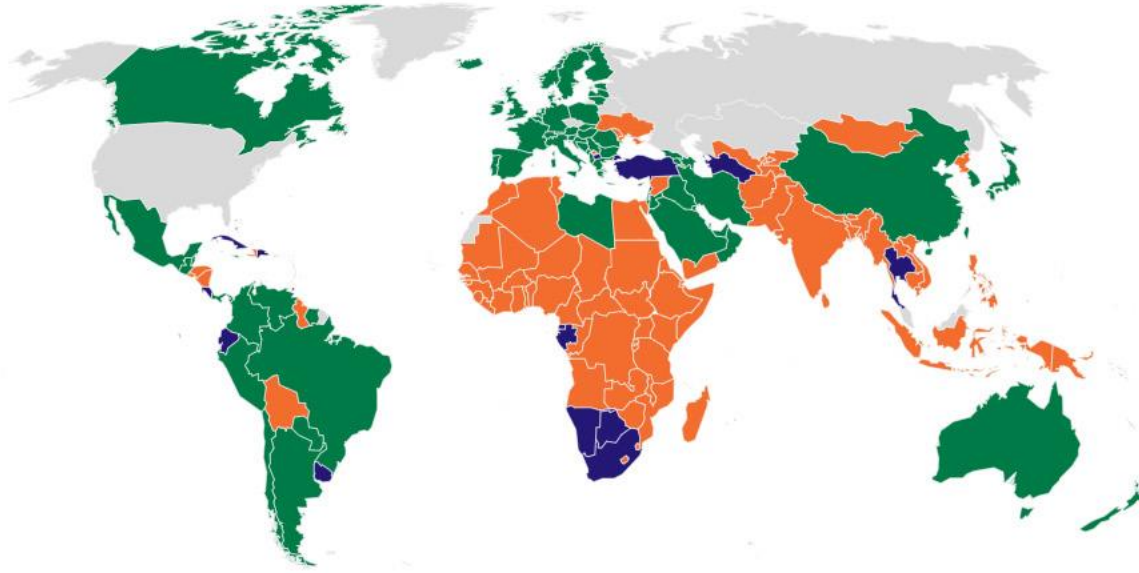
- All countries participating in the COVAX facility are listed on slide 14

<https://www.gavi.org/vaccineswork/covax-explained>

# Distribution of COVID-19 Vaccine(s) may be the Defining Global Challenge of 2021

## COVAX vaccine initiative participants

■ Committed participants ■ Interested countries  
■ Subsidized access



184 Countries participating in COVAX (approximately 93% of world's population)

Countries that are not participating:

- US\*
- Russia
- Belarus
- Kazakhstan
- Malaysia
- 5 small island countries or micro-states

\*US is the only country to have publicly rejected COVAX initiative outright; instead, invested in 6 vaccine candidates through Operation Warp Speed<sup>1</sup>

# Geography Considerations – Global Approach

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## Combination of approaches available for countries throughout the world:

- Pursue their own contract arrangements with Clinical Trial labs/manufacturers/distributors (such as Oxford/AstraZeneca), and/or
- Participate in WHO's ACT-Accelerator ("ACT" is "Access to COVID-19 Tools") and have access to vaccines available to the world (also acts as a safety net in case the vaccine candidates involved in a country's own contract arrangements do not prove effective)
- Note: It is not certain that any vaccine candidates being considered will be effective; too early to tell

## ACT-Accelerator<sup>1</sup>

- Participating global health organizations include the [Bill & Melinda Gates Foundation](#), [CEPI](#), [FIND](#), [Gavi](#), [The Global Fund](#), [Unitaid](#), [Wellcome](#), the [WHO](#), the [World Bank](#) and [Global Financing Facility](#)
- ACT-Accelerator is a framework for collaboration; it is NOT a decision-making body. It has 4 pillars: Diagnostics, Treatment, Vaccines, Health System Strengthening
- Vaccine pillar is the COVAX Facility discussion described on the previous slide

Source:

1. <https://www.who.int/initiatives/act-accelerator>



# Appendix



# Immunity, Dosing and Coverage Considerations

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## Immunity considerations:

- 2 paths to achieving immunity: (1) Vaccines, (2) Infections<sup>1</sup>
- Herd immunity – Occurs when large portion of a community becomes immune to a disease, thereby making the further spread of disease unlikely. As a result, the whole community becomes protected; not just those who are immune
  - To achieve herd immunity, community's target % immune threshold varies with how contagious a disease is; for instance, typical view is 70% immunity needed, but for measles (which is highly contagious), 94% is needed; targeting 70% for COVID-19<sup>1</sup>
  - It is not certain these vaccine candidates will be successful in producing immunity; Clinical Trial process helps gauge success, but even vaccine candidates that pass might not achieve the same success in a real-world community with a large illness burden
- If immunity is produced, it is not certain *how long* such immunity will be sustained<sup>2</sup>
  - It is too early to tell how long immunity resulting from infections lasts
  - Not clear how long vaccine-induced immunity will last – will it be durable, or will re-vaccination be needed? If so, how soon?

## Dosing and coverage considerations<sup>3</sup>:

- Experts expect 1 or 2 doses will be required, depending on the vaccine
- Coverage implications, using US as example and assuming an estimated 2-dose regimen:
  - Estimated number of doses to achieve herd immunity (70% of US population): 462 million doses for US (estimate only)
  - Estimated number of doses to achieve full coverage (100% of US population): 660 million doses for US (estimate only)
- Global need (not just a US need), so coverage implications exponentially larger than just for US

# Sourcing, Manufacturing and Distribution Considerations

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## Fill-finish process is important to achieving necessary coverage<sup>1</sup>:

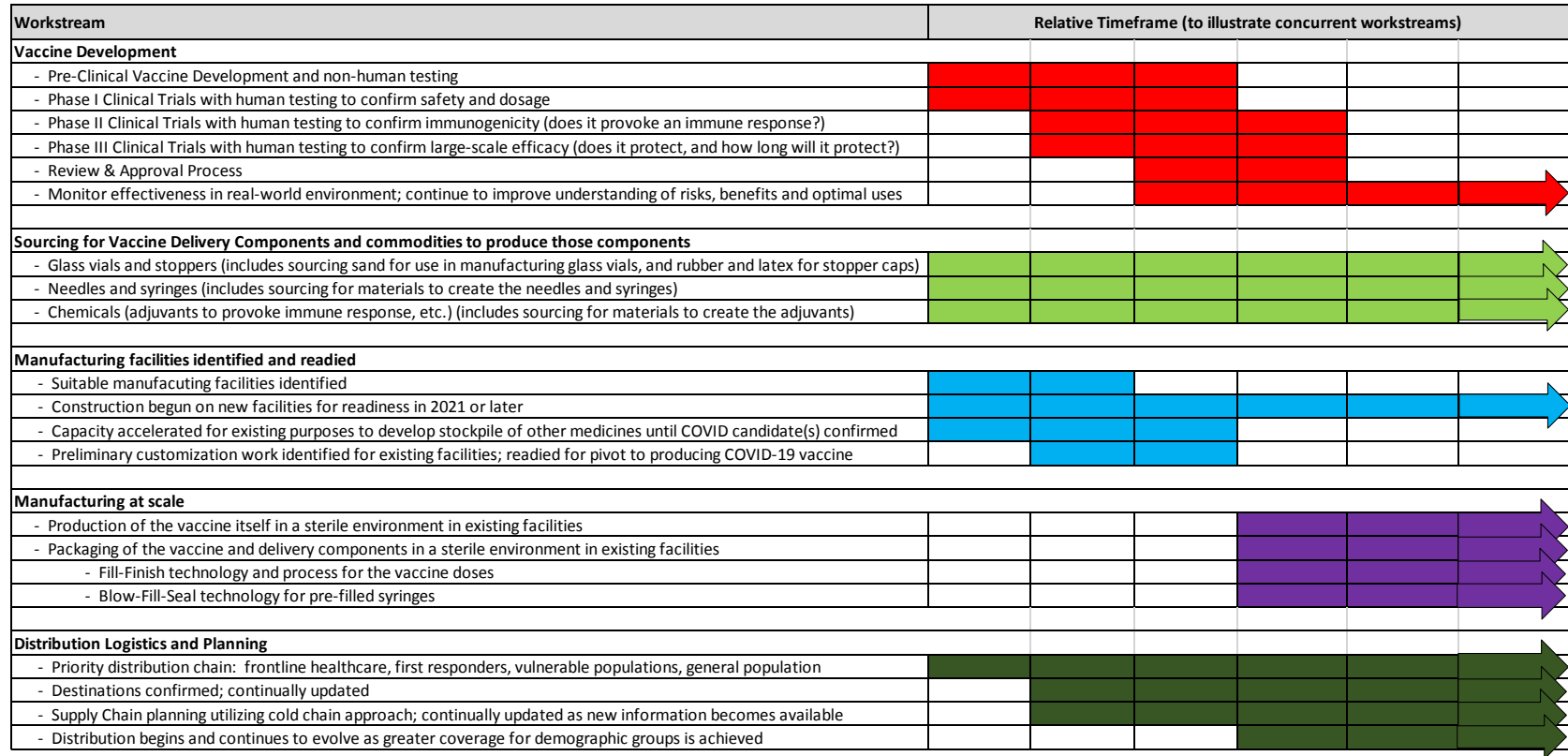
- Fill-finish is process of filling vials and syringes and packaging them in highly sterile conditions
- Fill-finish is a major hurdle on the path to vaccine distribution

## Components for fill-finish, and sourcing concerns for these components<sup>1</sup>:

- Glass vials and stoppers:
  - Shortage of sand to make glass vials – takes 2 years to produce # of glass vials needed for COVID-19 vaccines<sup>1</sup>
  - Stoppers (rubber or latex components) can't interact with chemicals inside the vial<sup>1</sup>
- Needles and syringes
- Chemicals and vaccine components
  - Adjuvants (adjuvant strengthens the body's immune response to inoculation)<sup>1</sup>  
Note: one adjuvant comes from bark of a special tree in South America that is only harvested November-January<sup>1</sup>
  - Many of the needed chemicals come from China and India<sup>1</sup>
- Additional concern: Segregate COVID-19 needs from needs of other medicines to minimize disruption to other medicines<sup>1</sup>
- Cold-chain distribution needs<sup>2</sup>:
  - Most vaccines must be kept at 2 degrees to 8 degrees Celsius (35.6 degrees to 46.4 degrees Fahrenheit); however, Pfizer and Moderna vaccines must be kept at ultra-cold temperatures:
    - Pfizer = minus 70 degrees Celsius (minus 94 degrees Fahrenheit)
    - Moderna = minus 20 degrees Celsius (minus 4 degrees Fahrenheit)
  - Each step in the distribution chain must maintain consistent temperature in that range without interruption

# Operationalizing – Vaccine Development, Manufacturing and Distribution at Scale

## Importance of simultaneous workstreams; timing doesn't allow for sequential process



Source:

- <https://www.who.int/initiatives/act-accelerator>
- <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/#nref-488196-11>
- <https://science.sciencemag.org/content/368/6494/948>

# Pandemic Vaccine Distribution: CDC Depiction & Guidelines (2018 & 2020)



## National Center for Immunization and Respiratory Diseases Pandemic Vaccine Program Distribution, Tracking, and Monitoring

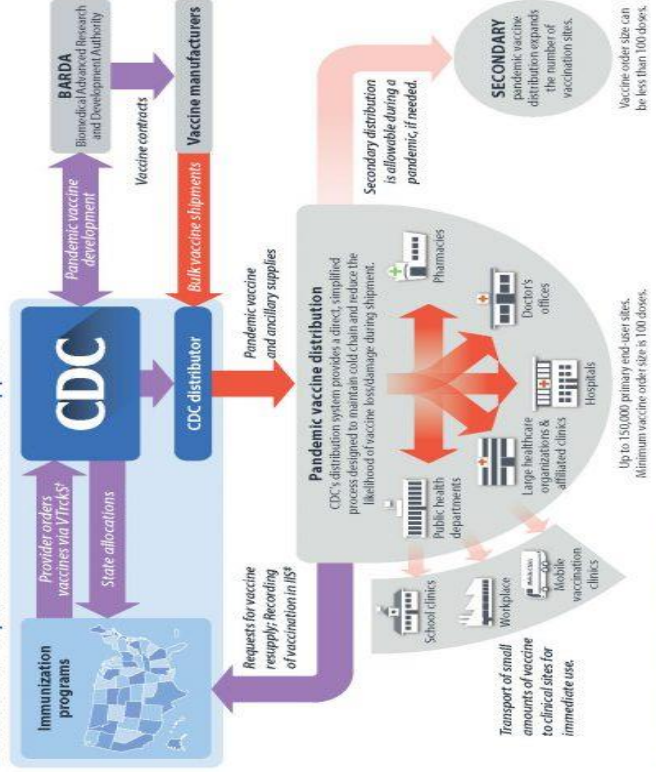
During a pandemic, CDC will scale up existing vaccine distribution, tracking, and monitoring systems to support the response.



### Vaccine handling, distribution, and tracking

Secure storage and safe and efficient distribution of vaccine are the cornerstones of a successful vaccination program. CDC's vaccine distribution system, which transfers products to sites where they will be securely stored for later use, is flexible, scalable, and tested. This system ensures maintenance of "cold chain", which is essential to vaccine effectiveness. Each year, CDC distributes over 75 million doses of vaccines from every vaccine manufacturer to health departments and private health providers across the country. From these sites, vaccine may be transported in small quantities to clinical sites for immediate use, while maintaining cold chain. During an emergency, this proven system can be scaled up and expedited to manage and distribute almost 900 million doses of vaccine. It is the only existing vaccine distribution system with the capacity and flexibility to reach the entire nation to support the needs of a pandemic.

### Distribution of pandemic vaccine and supplies



\* <https://www.cdc.gov/vaccines/imz/immunization/vtr/index.html>  
† The Vaccine Tracking System (VTRAS) is CDC's management and ordering system for publicly-funded vaccines.  
‡ Immunization Information System (IIS)

Influenza pandemic distribution plan, 04/20/20

[www.cdc.gov/flu/pandemic-resources/](http://www.cdc.gov/flu/pandemic-resources/)

## Contacts for more information

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