

SARS-CoV-2 Vaccines General Information

A Review of Pertinent Drug Information for SARS-CoV-2

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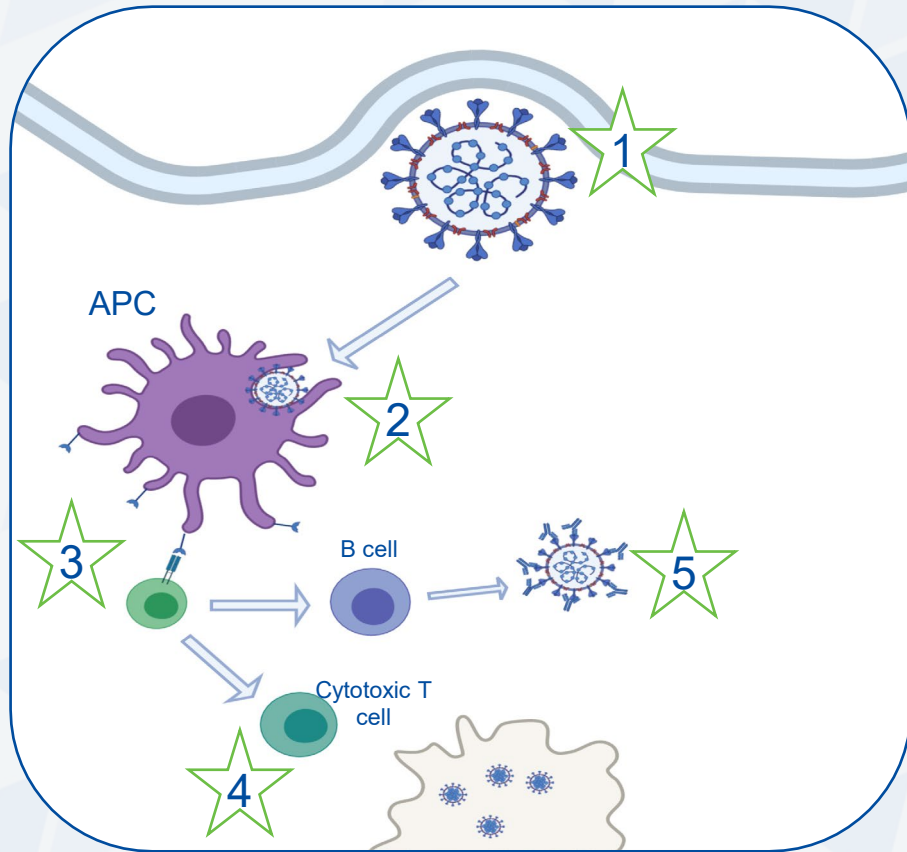
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February 16, 2020



Immunology Refresher



1

Virus released from cell after assembly

2

Antigen-presenting cells engulf virus

3

T-helper cells are activated by viral peptides displayed on antigen-presenting cells

4

Cytotoxic T cells enabled to identify and destroy infected cells

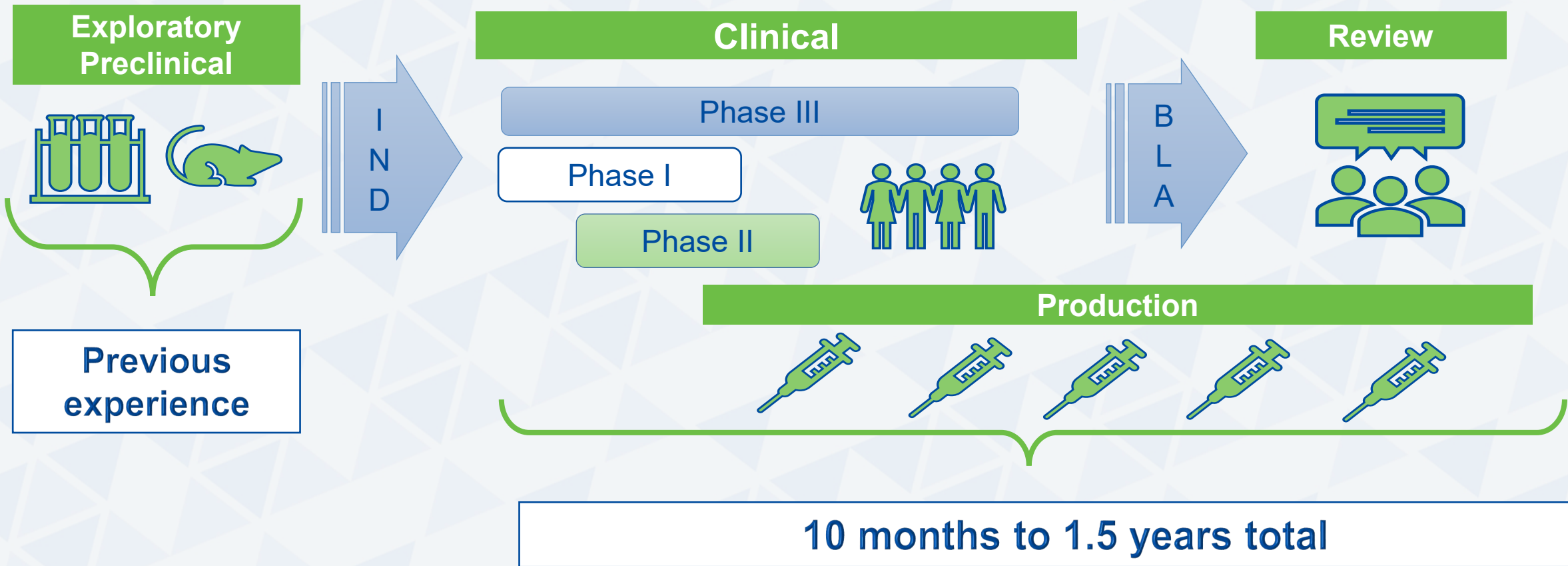
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B cells enabled to create antibodies that block virus from infecting cells

Previous Vaccine Timeline



SARS-CoV-2 Vaccine Timeline



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IND: Investigational new drug
BLA: biologics license application



SARS-CoV-2 Vaccine Development



Global Vaccine Outlook



>170 in preclinical development
>60 in clinical trials on humans
2 Currently approved via EUA pathway in the US

*2 EUA approved in US



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Updated as of February 14, 2021
The New York Times. Coronavirus Vaccine Tracker
<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> Accessed Feb 4, 2021
Funk CD, et al. Front Pharmacol. 2020. 11:937

SARS-CoV-2 Vaccine Platforms

Traditional approaches

Recently licensed approaches

Novel approaches

Live attenuated or whole inactivated vaccines



Genetic-code vaccines



Viral vector vaccines

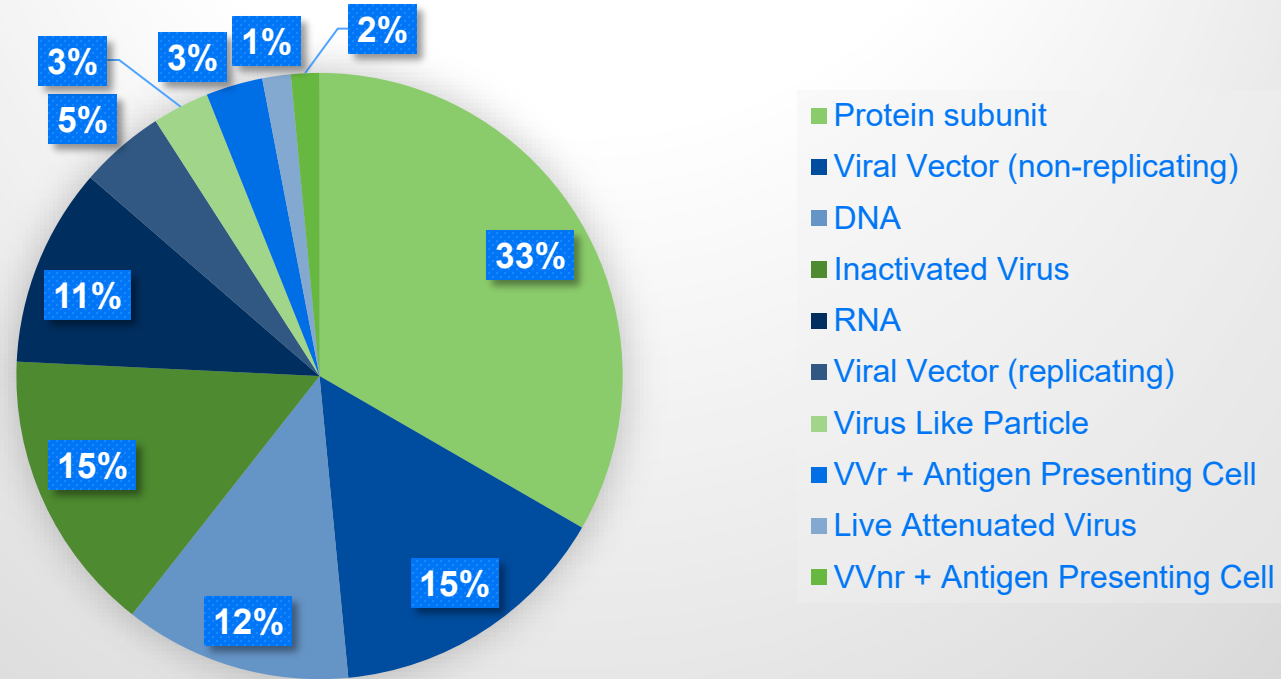


Protein-based vaccines



Current SARS-CoV-2 Vaccine Landscape By Platform

Candidate Vaccines as of February 12, 2021



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VVr: Viral Vector replicating
VVnr: Viral Vector non-replication



Vaccine Platform Overview

	Live Attenuated	Inactivated	Viral vector	Protein-subunit	Genetic-code
MOA	<ul style="list-style-type: none"> • Weakened version of virus that replicates to extent without causing disease 	<ul style="list-style-type: none"> • Inactivated version of actual virus grown and chemically inactivated 	<ul style="list-style-type: none"> • Based on another virus with spike protein which has been disabled from replication 	<ul style="list-style-type: none"> • Viral subunits expressed via various cell lines to stimulate immune response 	<ul style="list-style-type: none"> • Uses DNA or RNA to create antigens for immune system to target
Pros	<ul style="list-style-type: none"> • Immune response has broad target range • Given intranasally • Familiar, proven technology 	<ul style="list-style-type: none"> • Immune response has broad target range • Familiar, proven technology 	<ul style="list-style-type: none"> • Produced without handling live virus • Familiar, proven technology • Good immune response 	<ul style="list-style-type: none"> • Produced without handling live virus • Experience producing 	<ul style="list-style-type: none"> • Easy and quick to design • Large scale production
Cons	<ul style="list-style-type: none"> • Time-consuming to grow • Specific facilities for production • Safety concerns 	<ul style="list-style-type: none"> • Time-consuming to grow • Specific facilities for production 	<ul style="list-style-type: none"> • Partial neutralization by existing immunity • Prime-boost regimens 	<ul style="list-style-type: none"> • Spike protein hard to express • RBD-based prone to impact of antigenic drift 	<ul style="list-style-type: none"> • Relatively new technology • Stability issues
Vaccine Candidates	<ul style="list-style-type: none"> • Codagenix • Indian Immunologicals Ltd. 	<ul style="list-style-type: none"> • Sinovac • Sinopharm 	<ul style="list-style-type: none"> • AstraZeneca • CanSino Biologics • Johnson & Johnson 	<ul style="list-style-type: none"> • Novavax • AdaptVac 	<ul style="list-style-type: none"> • Moderna • Pfizer-BioNtech

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Pertinent SARS-CoV-2 Vaccine Candidates

Candidate Name	Vaccine Platform	Sponsor	Clinical Trial Phase	Dosing	Storage	Cost
BNT162b2	mRNA-based	Pfizer-BioNtech	EUA	2 doses (d0, d21)	-70°C	\$20/dose
mRNA-1273	mRNA-based	Moderna	EUA	2 doses (d0, d28)	-20°C	\$32-37/dose
AZD1222	Non-replicating viral vector	AstraZeneca	Phase 3	2 doses (d0, d28)	2-8°C	\$3-4/dose
Ad26.COV2.S	Non-replicating viral vector	Johnson&Johnson	Phase 3	1 dose	2-8°C	\$10/dose
NVX-CoV2373	Recombinant protein	Novavax	Phase 3	2 doses (d0, d21)	2-8°C	\$16/dose



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World Health Organization. Draft landscape of COVID-19 candidate vaccines. <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>. Accessed Dec. 15, 2020

The New York Times. Coronavirus Vaccine Tracker. <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> Accessed Dec. 15, 2020

Biospace. Comparing COVID-19 Vaccines: Timelines, Types and prices. <https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/> Accessed Dec 15, 2020

Current and Future Challenges

Under-represented populations

- Pregnant and breastfeeding women, immunocompromised, diverse race and ethnicities

Vaccine Hesitancy

- Willingness to get COVID-19 vaccination ~63%

Phase 3 enrollment and long-term outcomes

- Many frontline workers involved in phase 3 trials → impact long term outcomes

Equitable Administration

- On top of number of vaccines, storage requirements and cost will significantly impact certain areas of the world

EUA Vaccine FAQs

Persons with a History of SARS-CoV-2 Infection

- Vaccination regardless of prior infection

Persons with Known Current SARS-CoV-2 Infection

- Defer vaccination until recovery and isolation discontinued (

Persons Previously Received Passive Antibody Therapy

- No data
- Defer vaccination for at least 90 days to avoid vaccine interference

Immunocompromised Persons

- No Data
- Can receive vaccination unless otherwise contraindicated

Pregnant or Breastfeeding Persons

- No data
- May choose to be vaccinated
- Discussion with healthcare provider

Public Health Recommendations

- Protection not immediate or 100%
- Continue to follow current distancing and protection guidance

Contraindications

- Severe reaction after previous dose of vaccine
- Immediate reaction to previous dose of vaccine or any of its components
- Immediate allergic reaction to polysorbate



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Registries

- Registries for Vaccine and Breastfeeding

- Human Breastmilk Study

- Icahn School of Medicine at Mount Sinai
 - Investigator: Dr. Rebecca L.R. Powell
 - To sign up email: covid19humanmilkstudy@gmail.com

- Mommy's Milk Research Study

- University of California at San Diego
 - To sign up email: milkstudy@health.ucsd.edu

- Registries for Pregnancy

- C-VIPER

- <https://corona.pregistry.com/>
 - Registration open February 8, 2021 → register online (NCT NCT04705116)



V-Safe After Vaccination

- V-safe is a smartphone app that uses texts and surveys to provide check-ins following vaccination
 - Easiest way to tell the CDC of any side effects that are encountered following vaccination
 - It will also set a reminder for the 2nd vaccination in the series!
- You will need a smart phone and your SARS-CoV-2 vaccination information to register and use v-safe
- Instructions can be found at:
 - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

V-Safe After Vaccination

	Pfizer-BioNTech	Moderna	All COVID-19 vaccines
People receiving 1 or more doses in the United States*	12,153,536	9,689,497	21,843,033
Registrants completing at least 1 v-safe health check-in†	997,042	1,083,174	2,080,216
Pregnancies reported to v-safe	8,633	6,498	15,131

*Data as of 1/24/2021

†Data as of 1/20/2021

- Most frequently reported reactions following vaccination: pain, fatigue, headache, myalgia
 - Rates mostly consistent across both vaccines, numerically Moderna slightly higher reactions reported

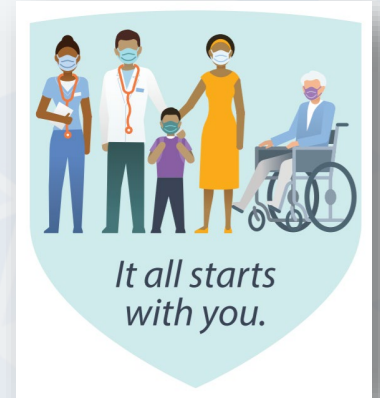


Safety Updates

- Reports of deaths following COVID-19 vaccination in community dwelling adults aged <65 years
 - **Expected sudden cardiac death count:** 168 deaths (based on estimated background rate of sudden cardiac death = 29.6/100,000 person-years)
 - **Reported VAERS sudden cardiac death count following COVID vaccination:** 18 deaths
- Reports of deaths following COVID-19 vaccination in LTCF residents to VAERS
 - Assessment after excluding residents with positive SARS-CoV-2 test within 20 days prior 7-day post vaccination window
 - Mortality lower among vaccinated vs unvaccinated within the same facilities
 - Short term mortality likely unrelated to COVID-19 vaccination in skilled nursing facility residents



Useful Links




- CDC Website
 - <https://www.cdc.gov/vaccines/covid-19/index.html>
- CDC Vaccine Communication Toolkit
 - <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>
- CDC Guidance for Infection Prevention Considerations Post Vaccination
 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html>
- COVID-19 Real-Time Learning Network (CDC and IDSA)
 - <https://www.idsociety.org/covid-19-real-time-learning-network/>

1. Get Vaccinated
2. Tell Others Why
3. Build the Confidence



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