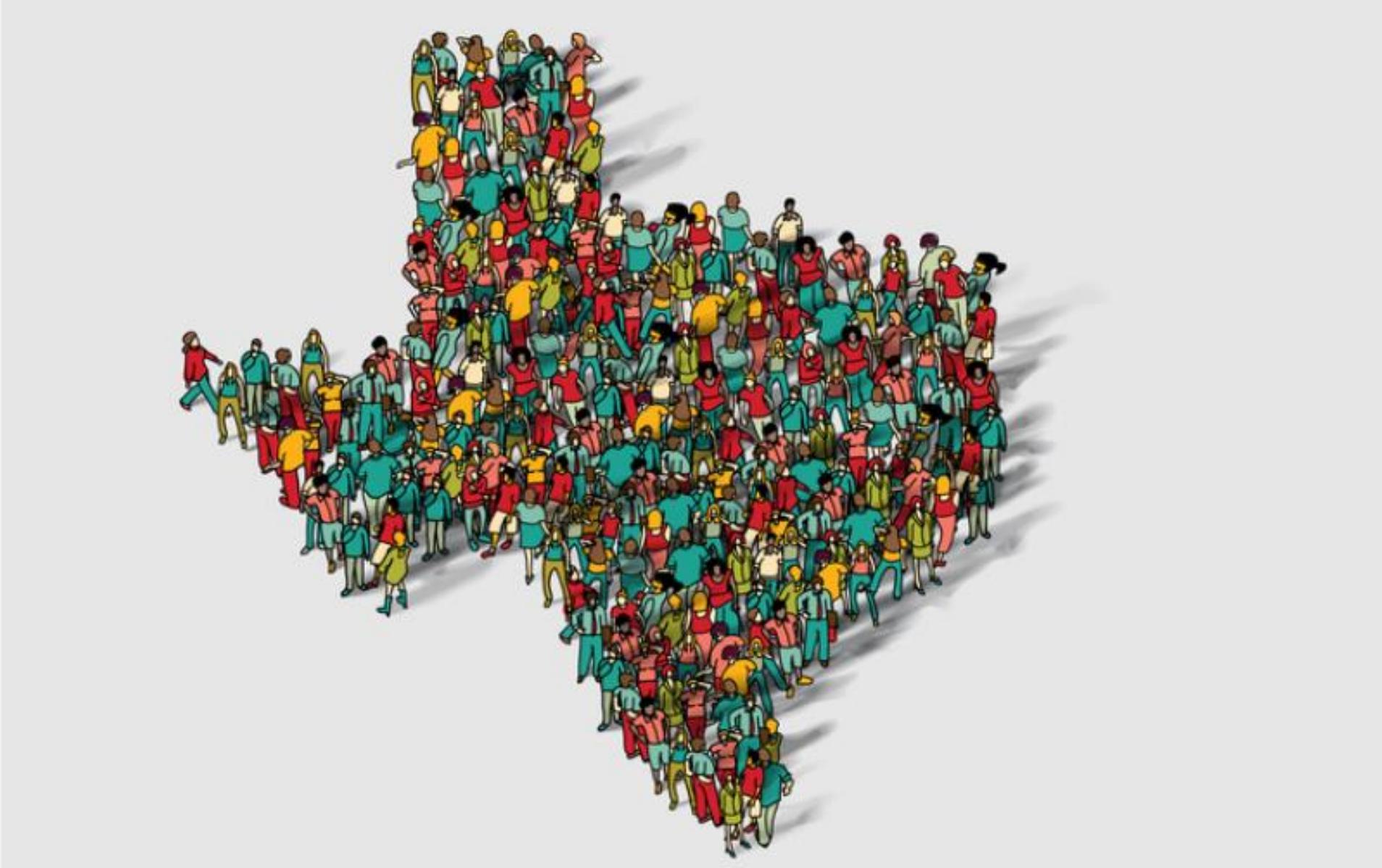

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April 13, 2021

COVID-19 Vaccine Updates

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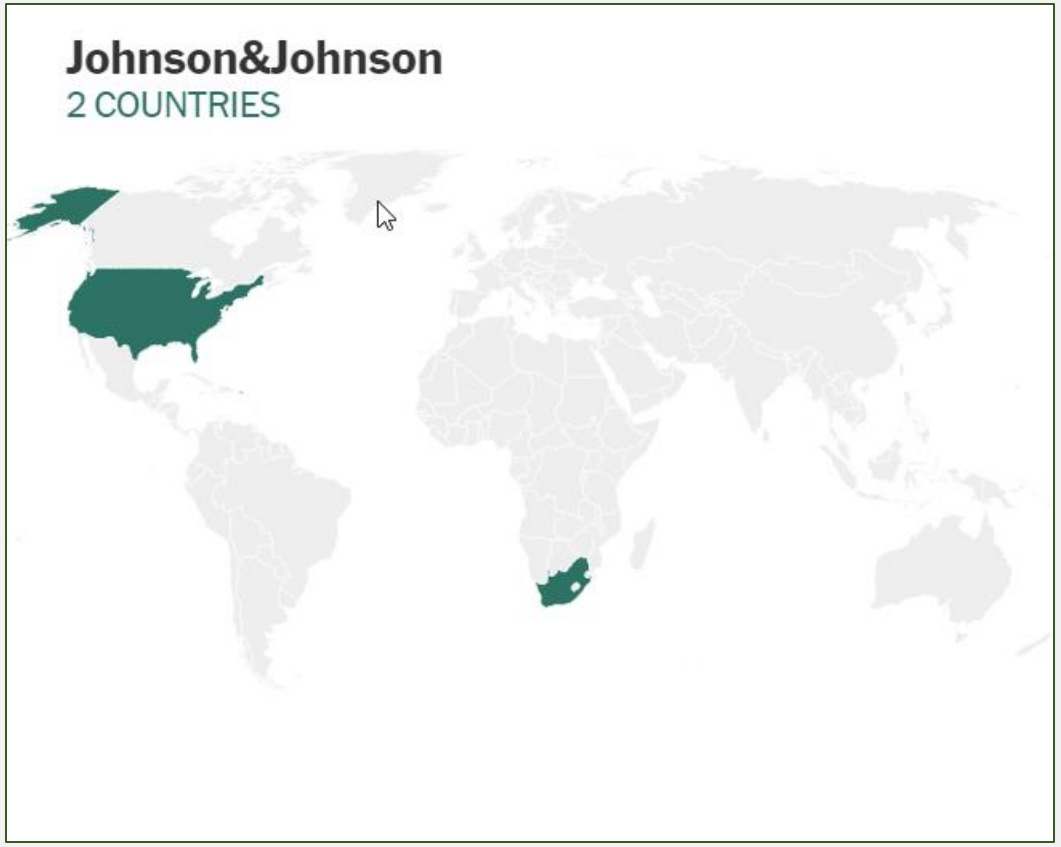
Senior Scientific Advisor
Texas Department of State Health Services

Vaccine Candidates	Technology Platform	Storage & Handling	Dose (Intramuscular Injection)	Status
Pfizer	m-RNA	Ultra-low frozen: 6mos Frozen: 2 weeks Refrigerated: 5 days	2 (0, 21 days)	EUA (≥16 yrs)
moderna	m-RNA	Frozen: 6mos Refrigerated: 30 days	2 (0, 28 days)	EUA (≥18 yrs)
janssen	Viral Vector (Non-Replicating)	Frozen: 2 years Refrigerated: 3mos	1	EUA (≥18 yrs)
AstraZeneca UNIVERSITY OF OXFORD	Viral Vector (Non-Replicating)	Refrigerated: 6mos	2 (0, 28 days)	Phase 3 (Tentative US EUA Filing in April)
NOVAVAX	Recombinant Subunit Adjuvant (Matrix M™)	Refrigerated: 3mos	2 (0, 21 days)	Phase 3 (Tentative US EUA Filing in April)

J&J COVID-19 Vaccine

- Six cases of unusual blood clots
- Preliminary reports of anxiety-related events following vaccination
- Manufacturing issues in the US delaying vaccine supply



https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html

TEXAS Health and Human Services

Texas Department of State Health Services

Novavax COVID-19 Vaccine

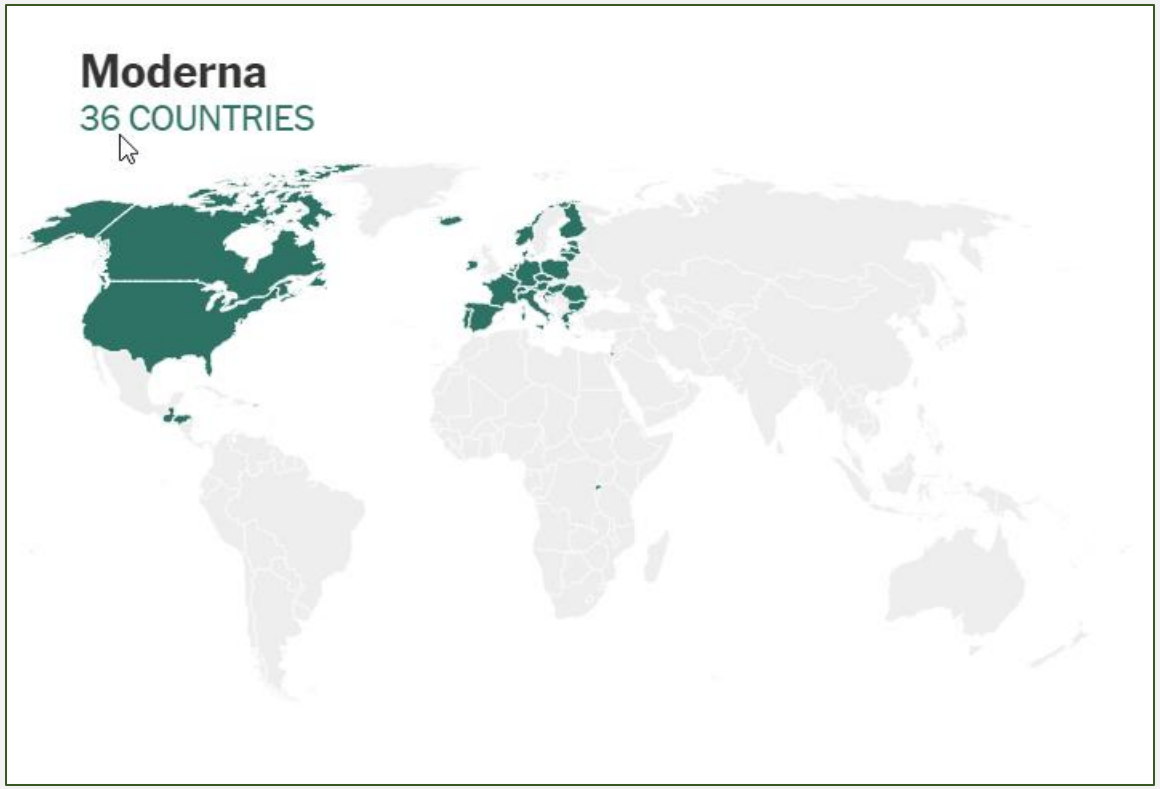
- Recombinant nanoparticle technology using proprietary saponin-based Matrix-M™ adjuvant
  - Purified protein is encoded by the genetic sequence of the SARS-CoV-2 spike (S) protein and is produced in insect cells
  - Stored under refrigerated temperatures
  - 2 – dose regimen (0 day and 21 days, IM)
  - SARS-CoV-2 rS (5 µg) + Matrix-M1 adjuvant (50 µg)
- 89.3% vaccine efficacy in an UK study
- 48.6% vaccine efficacy in a South Africa study
- Cross-over of study participants initiated in both UK and South Africa clinical trials

Novavax COVID-19 Vaccine
Phase 3 US & Mexico Study

- A randomized, placebo-controlled in 30,000 participants 18 years and older
  - Placebo (saline) versus [SARS-CoV-2 rS (5 µg) + Matrix-M1 adjuvant (50 µg)]
  - 2-dose regimen (0 day and 21 days, IM)
- Enrollment completed in February 2021
- Cross-over of study participants planned
- Target submission end of the month
- Manufacturing partnership with GSK

March 31, 2021, the FDA approved the following label updates for Moderna COVID-19 vaccine

- Two different vial presentations of their vaccine
  - Vial with 10-11 doses
  - Vial with 13-15 doses
- Storage and handling improved
  - Vaccine vials to remain at room temperature conditions for a longer period (total of 24 hours from previous 12 hours)
  - Additionally, a punctured vial is now useable for up to 12 hours, an increase from the previous 6 hours



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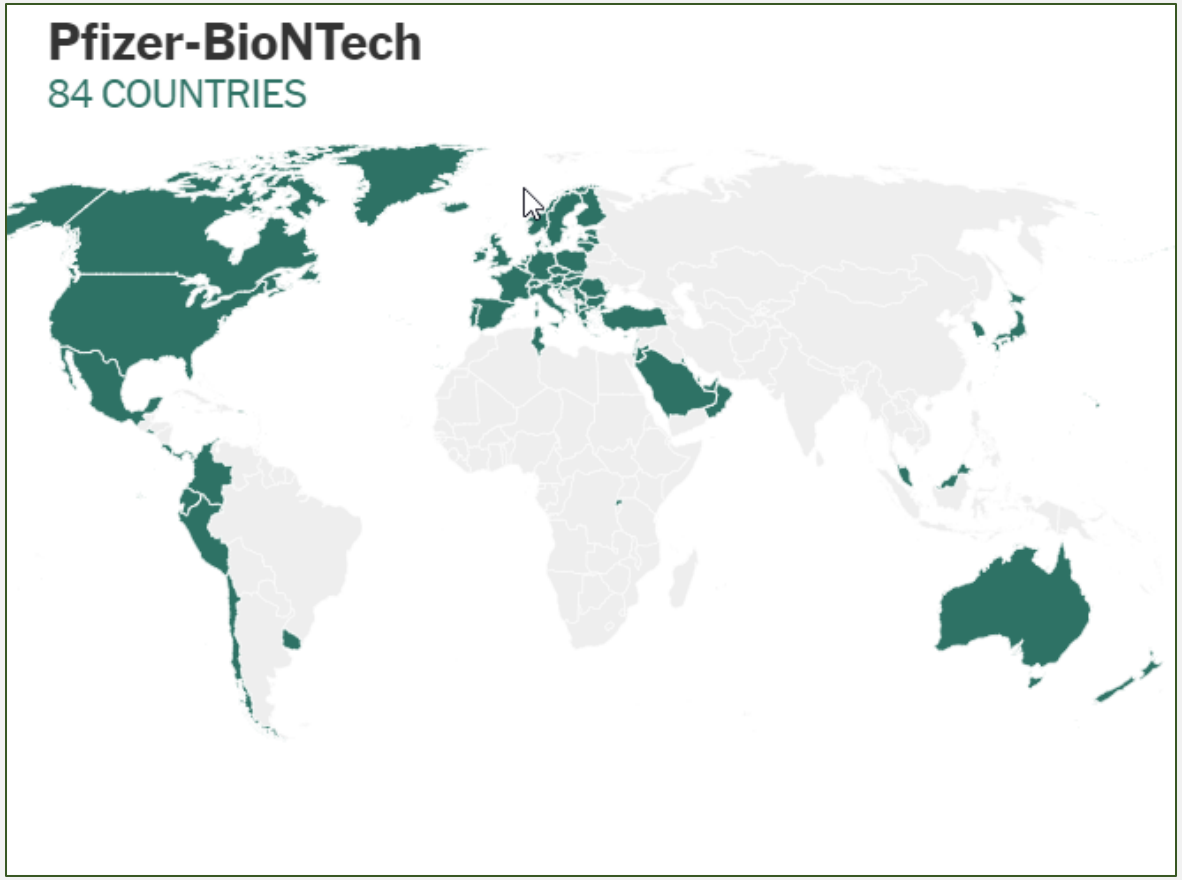
Pfizer COVID-19 Vaccine Updates

Phase 3 -Six months Follow-up

- Of the 44,000 participants 16 years of age and older in the Phase 3 study, >12,000 participants have at least six months follow-up after their second dose
- In the US, Pfizer reported 91.3% vaccine efficacy observed against COVID-19, measured seven days though up to six months after the second dose
- The vaccine was 100% effective in preventing severe disease
- In South Africa [B1.341], among 800 participants, 9 cases of COVID-19 were observed, all in the placebo group, indication vaccine efficacy of 100%
  - Six of the nine cases confirmed via sequencing to be the B.1.351 lineage

Pfizer COVID-19 Vaccine

- Pfizer stated with favorable efficacy and safety of the vaccine positions to submit a Biologics License Application to the US FDA



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COVID-19 Vaccine
B.1.351 variant (South Africa)

	Efficacy [B.1.351]	Booster	New Vaccine Construct
Pfizer	100% Vaccine Efficacy (Clinical Trial)	• Third dose of BNT162b2 to understand the effect of a booster on immunity • The study will draw upon participants from the Phase 1 study in the US - Booster dose of the current vaccine 6 to 12 months after receiving their initial 2-doses	• Ongoing discussions with regulatory authorities, regarding a clinical study to evaluate a variant-specific vaccine having a modified mRNA sequence. • This study would use a new construct of the vaccine based on the B.1.351 lineage
moderna	Neutralizing titers (6x fold reduction)	• An amendment to the Phase 2 study will enroll 60 participants previously vaccinated with mRNA-1273 to receive a single booster dose of either: 1. 20 µg of a variant-specific booster candidate, mRNA-1273.351, based on the B.1.351 variant (N=20) 2. 50 µg of mRNA-1273.351 (N=20) 3. 50 µg of a multivalent booster candidate (mRNA-1273.211), which combines mRNA-1273 and mRNA-1273.351 in a single vaccine (N=20)	
Janssen	57% Vaccine Efficacy (Clinical Trial)	• Ongoing two-dose study (Day 1 and Day 57) in Belgium, Colombia, France, Germany, the Philippines, South Africa, Spain, UK, and US • The study will assess efficacy of the investigational vaccine after both the first and second dose to evaluate protection against the virus and potential incremental benefits for duration of protection with a second dose	
AstraZeneca / University of Oxford	10.4% (Clinical Trial)	• Plans to start trials on next-generation vaccines that will work against all current SARS-CoV-2 variants	
NOVAVAX	48.6% Vaccine Efficacy (Clinical Trial)	• Initiated development of new constructs against the emerging strains as a booster and/or combination bivalent vaccine with plans to initiate clinical trials in 2Q21	

COVID-19 Vaccine Special Populations

Pfizer COVID-19 Vaccine

Study in Pregnant Women

- Pfizer has initiated a global clinical trial to evaluate COVID-19 vaccine in pregnant women.
  - Enroll ~4,000 healthy pregnant women 18 years of age or older vaccinated during 24 to 34 weeks of gestation
  - U.S., Canada, Argentina, Brazil, Chile, Mozambique, South Africa, U.K., and Spain
  - Two doses of the vaccine or placebo administered 21 days apart.
  - Enrollment began in late February
  - Will assess safety in infants of vaccinated pregnant women and the transfer of potentially protective antibody to their infants through ~ 6 months of age.
  - Infants will be monitored through approximately six months of age

Pfizer COVID-19 Vaccine Updates

Phase 3 Adolescent Study

- The study enrolled 2,260 adolescents 12 to 15 years of age in the US
  - 1,131 in the vaccine group and 1,129 in the placebo group
- 100% vaccine efficacy observed in this population
  - 18 cases of COVID-19 observed in the placebo group versus non
- April 9, 2021, the company submitted the results to the FDA and requested an amendment to the Emergency Use Authorization to expand use in the adolescents 12-15 years of age.

	Adolescents (12 – 17 years)	Pediatric (6 months – 11 years)
Pfizer	• Authorized for 16 years and older • Submitted for EUA expansion for 12 – 15 years	• Phase 1/2/3 Study • Three age cohorts 1. 5 to 11 years 2. 2 to 5 years 3. 6 months to 2 years • N=4,644 in the US and Europe • Two-dose schedule • Begun enrolling
moderna	• Phase 2/3 randomized, placebo-controlled study • N=3,000 • 2-dose schedule • Enrollment completed	• Phase 2/3 Study • N=6,750 in the US and Canada Part 1: 2 to 12 years (either 50ug or 100 ug) Part 1: 6 mos to < 2yrs (25ug, 50ug or 100ug) Part 2: Placebo controlled vs the selected dose • Begun enrolling
janssen	• Expansion of an ongoing Phase 2a study to include adolescents 12 – 17 years of age • Single dose and two-dose regimens • Vaccination schedules at one, two and three-months intervals in two-dose vaccine regimens	
AstraZeneca / University of Oxford	• Phase 2/3 • N=200 • Aged 6 to 17 years • On-hold	
NOVAVAX	None at this time	

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