

COVID-19 Update

Emily Erbelding, M.D., M.P.H.

Director, Division of Microbiology and Infectious Diseases

National Institute of Allergy and Infectious Diseases

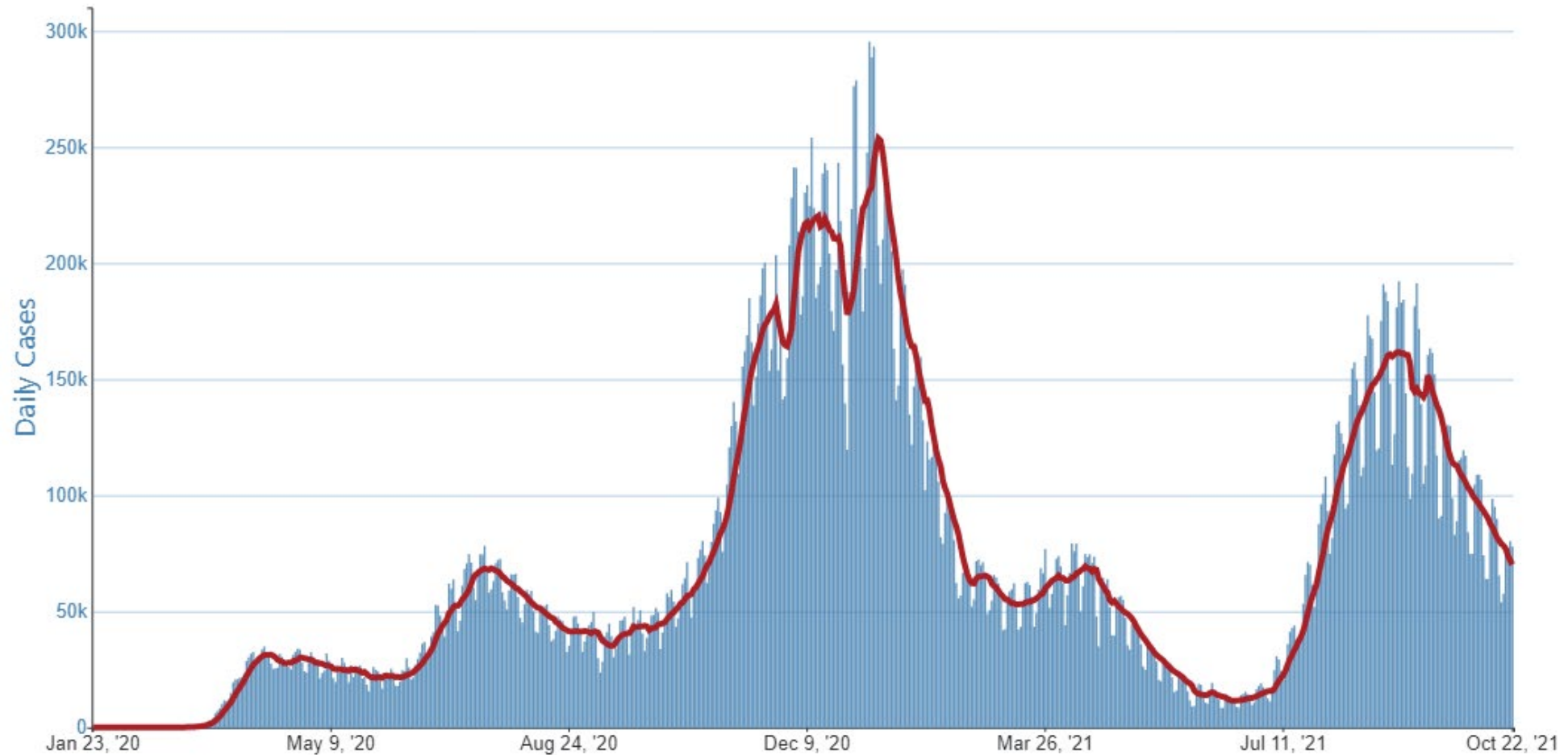
National Institutes of Health

NIH Tribal Advisory Committee

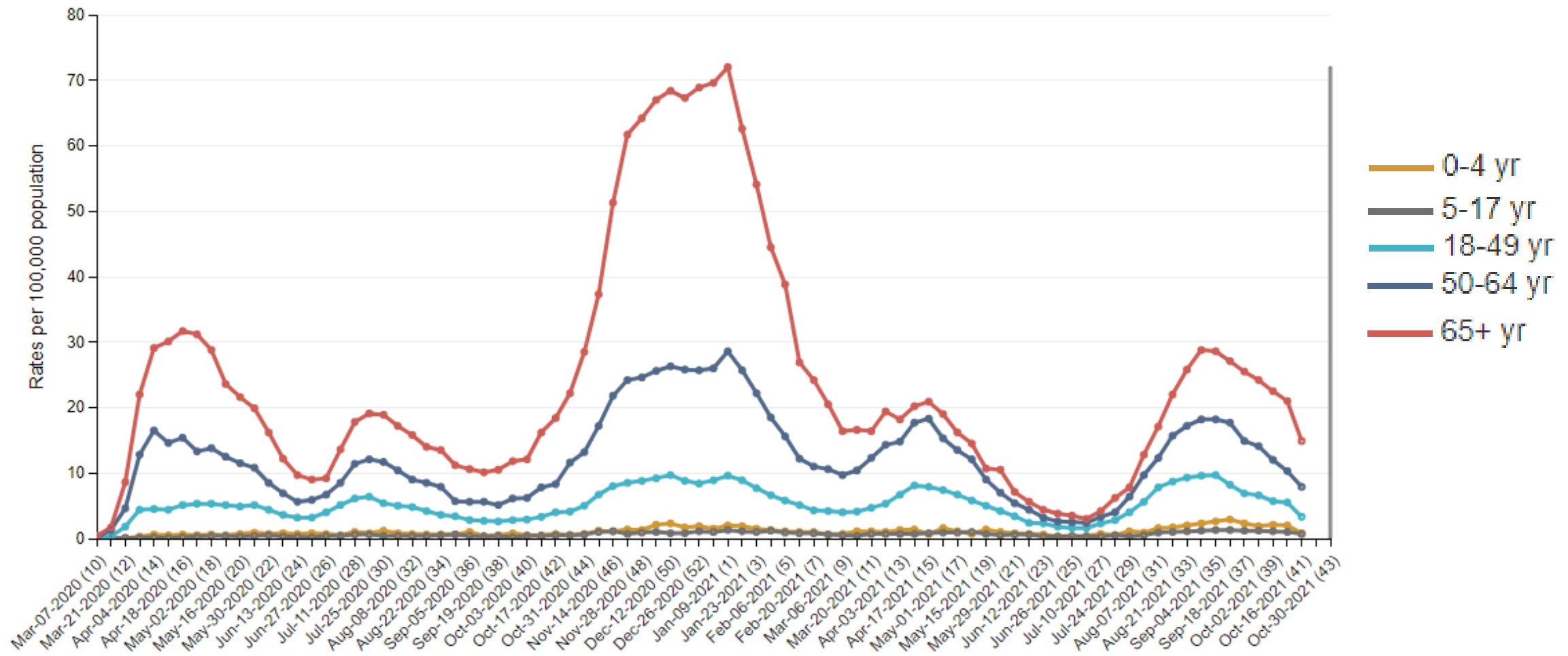
October 26, 2021



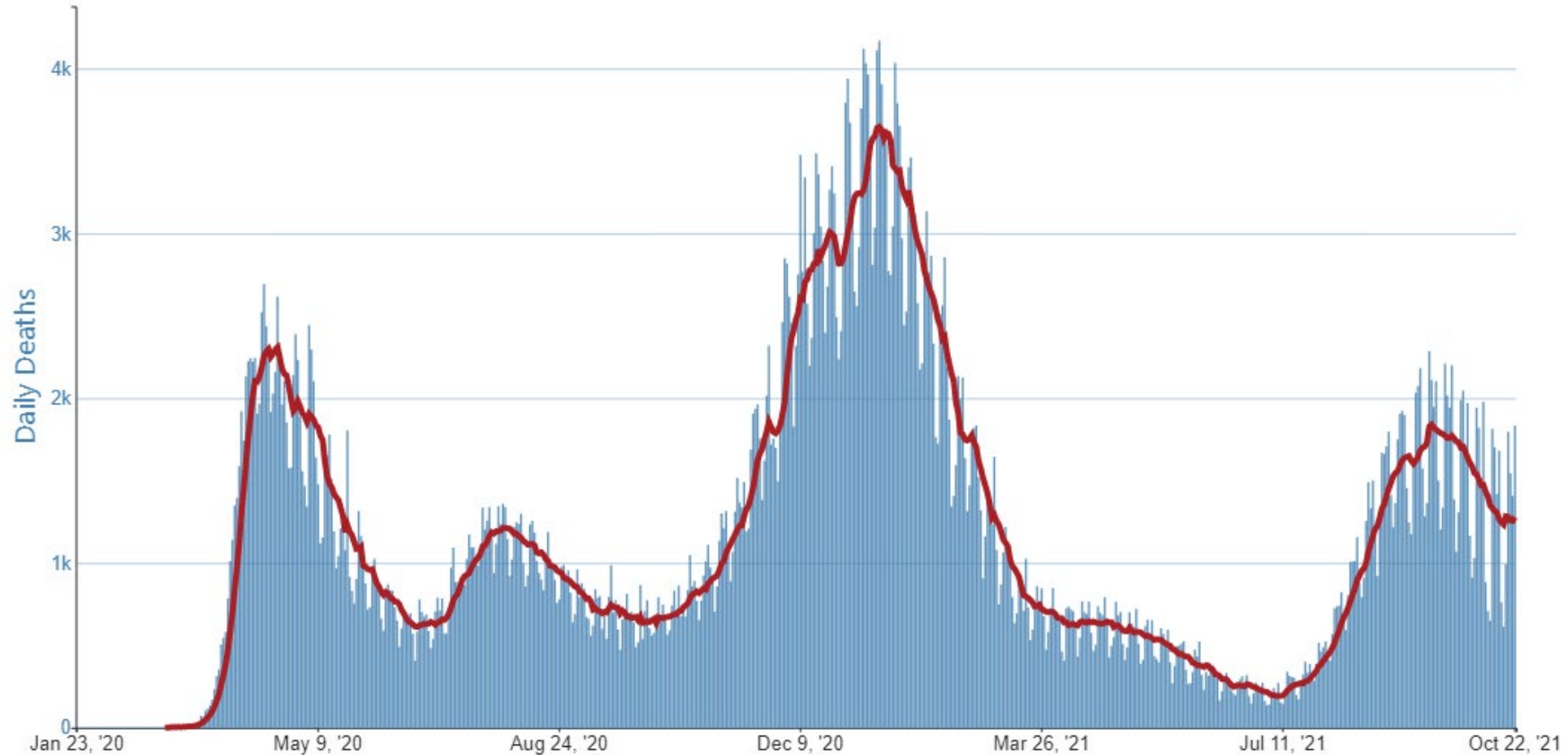
Daily Trends in COVID-19 Cases in the U.S. Reported to the CDC



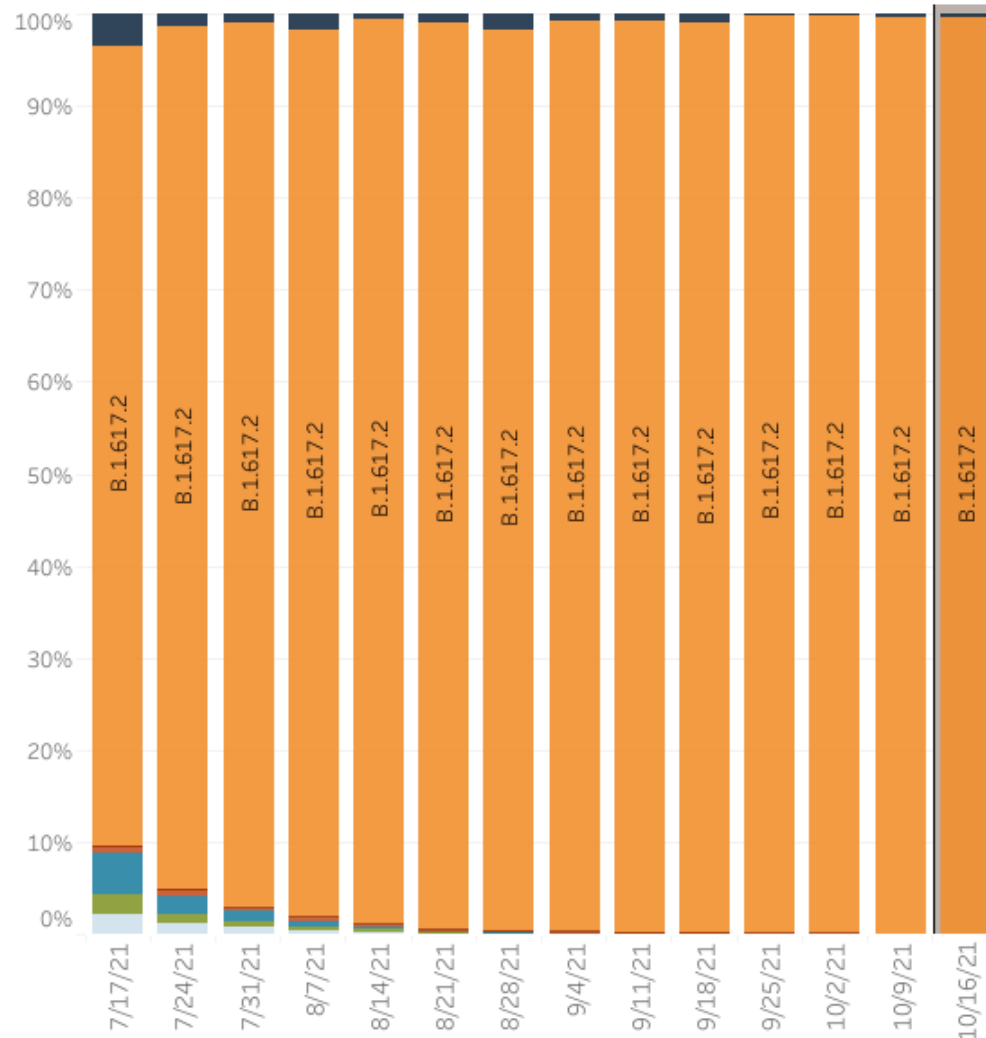
Rates of COVID-19 Associated Hospitalization



Daily Trends in COVID-19 Deaths in the U.S. Reported to the CDC



Circulating Variants in the U.S.



USA					
WHO label	Lineage #	US Class	%Total	95%PI	
Alpha	B.1.1.7	VBM	0.0%	0.0-0.0%	
Gamma	P.1	VBM	0.0%	0.0-0.0%	
Delta	B.1.617.2	VOC	99.6%	99.3-99.7%	
	AY.1	VOC	0.1%	0.0-0.1%	
	AY.2	VOC	0.0%	0.0-0.0%	
N/A	B.1.621	VBM	0.0%	0.0-0.0%	
Other	Other*		0.3%	0.2-0.6%	

New Hospitalization of Patients with COVID-19, ages 0-17 years

United States | 0 - 17 Years

66,419

Total Admissions

Aug 01, 2020 - Oct 22, 2021

157

Current 7-Day Average

Oct 16, 2021 - Oct 22, 2021

184

Prior 7-Day Average

Oct 09, 2021 - Oct 15, 2021

371

Peak 7-Day Average

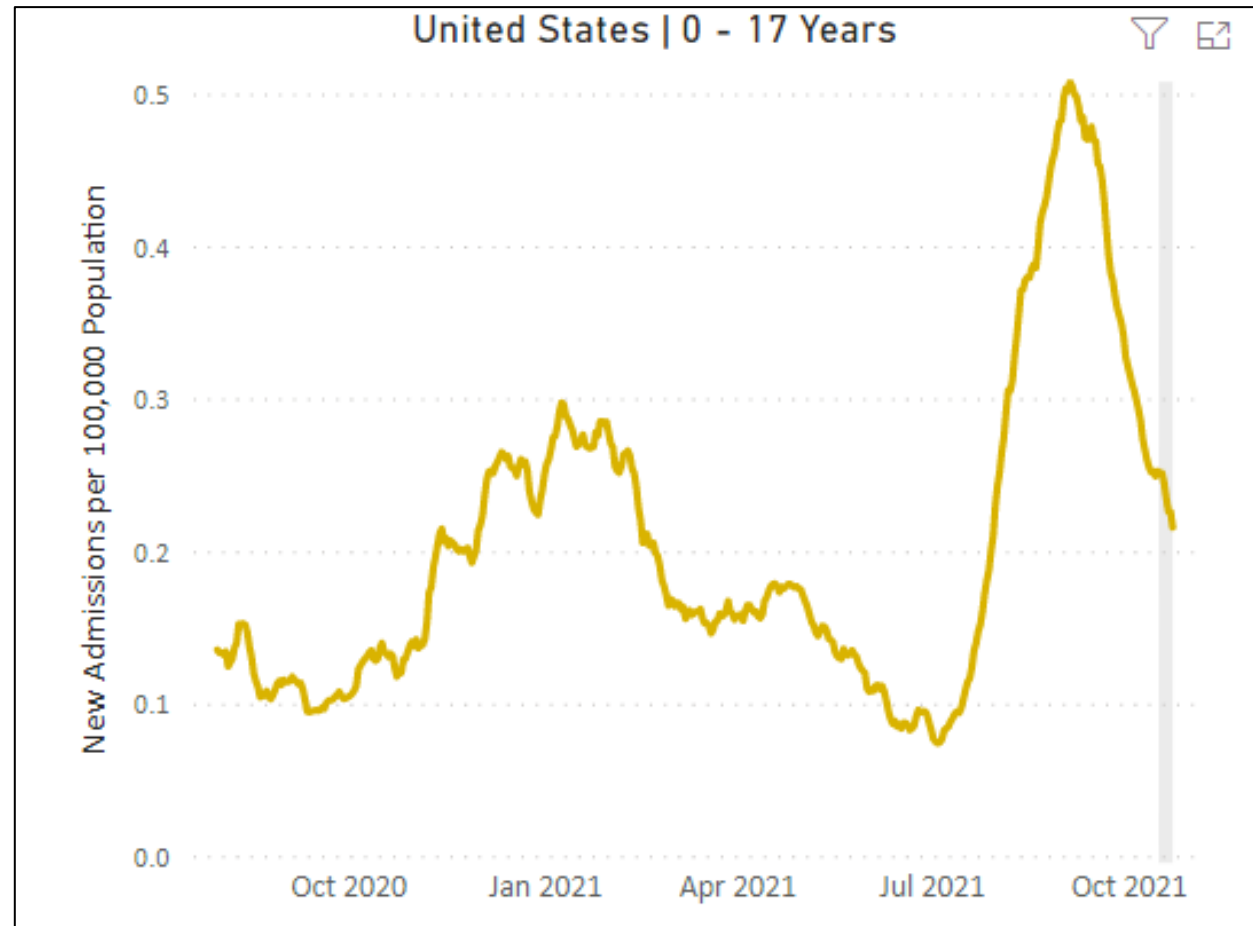
Aug 29, 2021 - Sep 04, 2021

-14.6%

Percent change from prior 7-day
avg. of Oct 09, 2021 - Oct 15, 2021

-57.6%

Percent change from peak 7-day
avg. of Aug 29, 2021 - Sep 04, 2021

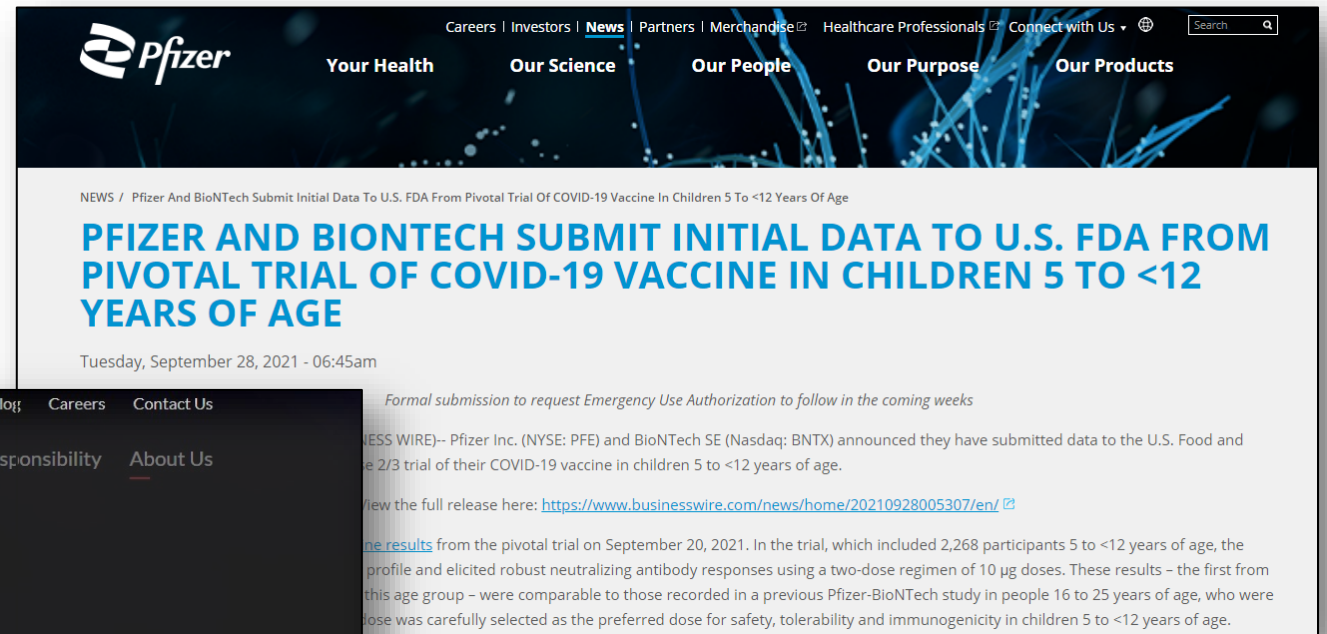


<https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions>



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Pediatric Data



The image shows the Pfizer website header with navigation links: Careers, Investors, News, Partners, Merchandise, Healthcare Professionals, Connect with Us, and a search bar. Below the header is a navigation bar with links: Your Health, Our Science, Our People, Our Purpose, and Our Products. The main content area features a news article titled "PFIZER AND BIONTECH SUBMIT INITIAL DATA TO U.S. FDA FROM PIVOTAL TRIAL OF COVID-19 VACCINE IN CHILDREN 5 TO <12 YEARS OF AGE" dated Tuesday, September 28, 2021 - 06:45am. The article text is partially visible, mentioning a formal submission to request Emergency Use Authorization and a press release from Business Wire.

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Your Health | Our Science | Our People | Our Purpose | Our Products

NEWS / Pfizer And BioNTech Submit Initial Data To U.S. FDA From Pivotal Trial Of COVID-19 Vaccine In Children 5 To <12 Years Of Age

PFIZER AND BIONTECH SUBMIT INITIAL DATA TO U.S. FDA FROM PIVOTAL TRIAL OF COVID-19 VACCINE IN CHILDREN 5 TO <12 YEARS OF AGE

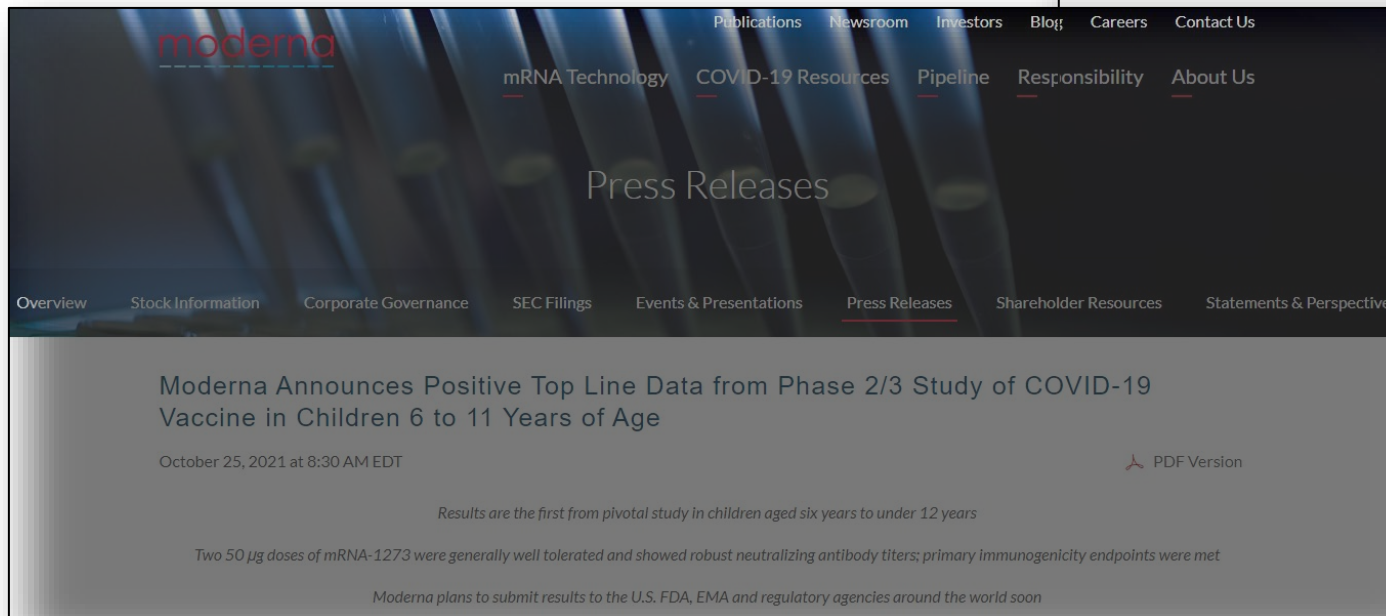
Tuesday, September 28, 2021 - 06:45am

Formal submission to request Emergency Use Authorization to follow in the coming weeks

BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced they have submitted data to the U.S. Food and Drug Administration (FDA) for a Phase 2/3 trial of their COVID-19 vaccine in children 5 to <12 years of age.

View the full release here: <https://www.businesswire.com/news/home/20210928005307/en/>

[View the full release here](#) from the pivotal trial on September 20, 2021. In the trial, which included 2,268 participants 5 to <12 years of age, the vaccine profile and elicited robust neutralizing antibody responses using a two-dose regimen of 10 µg doses. These results – the first from this age group – were comparable to those recorded in a previous Pfizer-BioNTech study in people 16 to 25 years of age, who were carefully selected as the preferred dose for safety, tolerability and immunogenicity in children 5 to <12 years of age.



The image shows the Moderna website header with navigation links: Publications, Newsroom, Investors, Blog, Careers, and Contact Us. Below the header is a navigation bar with links: mRNA Technology, COVID-19 Resources, Pipeline, Responsibility, and About Us. The main content area features a press release titled "Moderna Announces Positive Top Line Data from Phase 2/3 Study of COVID-19 Vaccine in Children 6 to 11 Years of Age" dated October 25, 2021 at 8:30 AM EDT. The article text is partially visible, mentioning results from a pivotal study in children aged six years to under 12 years.

moderna

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Press Releases

Overview | Stock Information | Corporate Governance | SEC Filings | Events & Presentations | **Press Releases** | Shareholder Resources | Statements & Perspectives

Moderna Announces Positive Top Line Data from Phase 2/3 Study of COVID-19 Vaccine in Children 6 to 11 Years of Age

October 25, 2021 at 8:30 AM EDT

[PDF Version](#)

Results are the first from pivotal study in children aged six years to under 12 years

Two 50 µg doses of mRNA-1273 were generally well tolerated and showed robust neutralizing antibody titers; primary immunogenicity endpoints were met

Moderna plans to submit results to the U.S. FDA, EMA and regulatory agencies around the world soon

VRBPAC Meeting on Pfizer's Pediatric Data



ADVISORY COMMITTEE MEETING

Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement

OCTOBER 26, 2021

Scheduled

The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will meet in open session to discuss Pfizer Inc.'s request to amend its Emergency Use Authorization (EUA) to allow for the use of the Pfizer-BioNTech COVID-19 vaccine in children 5 through 11 years of age.



Pfizer's Booster Dose



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NEWS / Pfizer And BioNTech Announce Phase 3 Trial Data Showing High Efficacy Of A Booster Dose Of Their COVID-19 Vaccine

PFIZER AND BIONTECH ANNOUNCE PHASE 3 TRIAL DATA SHOWING HIGH EFFICACY OF A BOOSTER DOSE OF THEIR COVID-19 VACCINE

Thursday, October 21, 2021 - 06:45am

- First results from any randomized, controlled COVID-19 vaccine booster trial demonstrate a relative vaccine efficacy of 95.6% against disease during a period when Delta was the prevalent strain
- In trial with more than 10,000 participants 16 years of age and older, COVID-19 booster was found to have a favorable safety profile
- Companies plan to submit these data to FDA, EMA and other regulatory agencies to further support licensure in the U.S. and other countries

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced topline results from a Phase 3 randomized, controlled trial evaluating the efficacy and safety of a 30-µg booster dose of the Pfizer-BioNTech COVID-19 Vaccine in more than 10,000 individuals 16 years of age and older. In the trial, a booster dose administered to individuals who previously received the Pfizer-BioNTech primary two-dose series restored vaccine protection against COVID-19 to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% when compared to those who did not receive a booster. These are the first efficacy results from any randomized, controlled COVID-19 vaccine booster trial.



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Mix and Match Trial



Heterologous SARS-CoV-2 Booster Vaccinations – Preliminary Report

[Comments \(1\)](#)

Robert L. Atmar, Kirsten E. Lyke, Meagan E. Deming, Lisa A. Jackson, Angela R. Branche, Hana M. El Sahly, Christina A. Rostad, Judith M. Martin, Christine Johnston, Richard E. Rupp, Mark J. Mulligan, Rebecca C. Brady, Robert W. Frencik Jr., Martin Bäcker, Angelica C. Kottkamp, Tara M. Babu, Kumaravel Rajakumar, Srilatha Edupuganti, David Dobryzynski, Christine M. Posavad, Janet I. Archer, Sonja Crandon, Seema U. Nayak, Daniel Szydlo, Jillian Zemanek, Clara P. Dominguez Islas, Elizabeth R. Brown, Mehul S. Suthar, M. Juliana McElrath, Adrian B. McDermott, Sarah E. O'Connell, David C. Montefiori, Amanda Eaton, Kathleen M. Neuzil, David S. Stephens, Paul C. Roberts, John H. Beigel, the DMID 21-0012 Study Group

doi: <https://doi.org/10.1101/2021.10.10.21264827>

This article is a preprint and has not been certified by peer review [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

Trial:

- Phase 1/2 clinical trial designed to assess the safety, reactogenicity and immunogenicity of heterologous or homologous booster vaccination in individuals who received an EUA COVID-19 vaccine primary regimen

Results:

- All combinations of booster vaccinations were well-tolerated and immunogenic.
- Booster vaccines may enhance waning immunity and expand the breadth of immunity against SARS-CoV-2 variants of concern.

Booster Eligibility

CDC Expands Eligibility for COVID-19 Booster Shots

Media Statement

For Immediate Release: Thursday, October 21, 2021

Contact: [Media Relations](#)

(404) 639-3286

For individuals who received a Pfizer-BioNTech or Moderna COVID-19 vaccine, the following groups are eligible for a booster shot at 6 months or more after their initial series:

- 65 years and older
- Age 18+ who live in [long-term care settings](#)
- Age 18+ who have [underlying medical conditions](#)
- Age 18+ who work or live in [high-risk settings](#)

For the nearly 15 million people who got the Johnson & Johnson COVID-19 vaccine, booster shots are also recommended for those who are 18 and older and who were vaccinated two or more months ago.

There are now booster recommendations for all three available COVID-19 vaccines in the United States. Eligible individuals may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received, and others may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.



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THANK YOU!