COVID-19 Update

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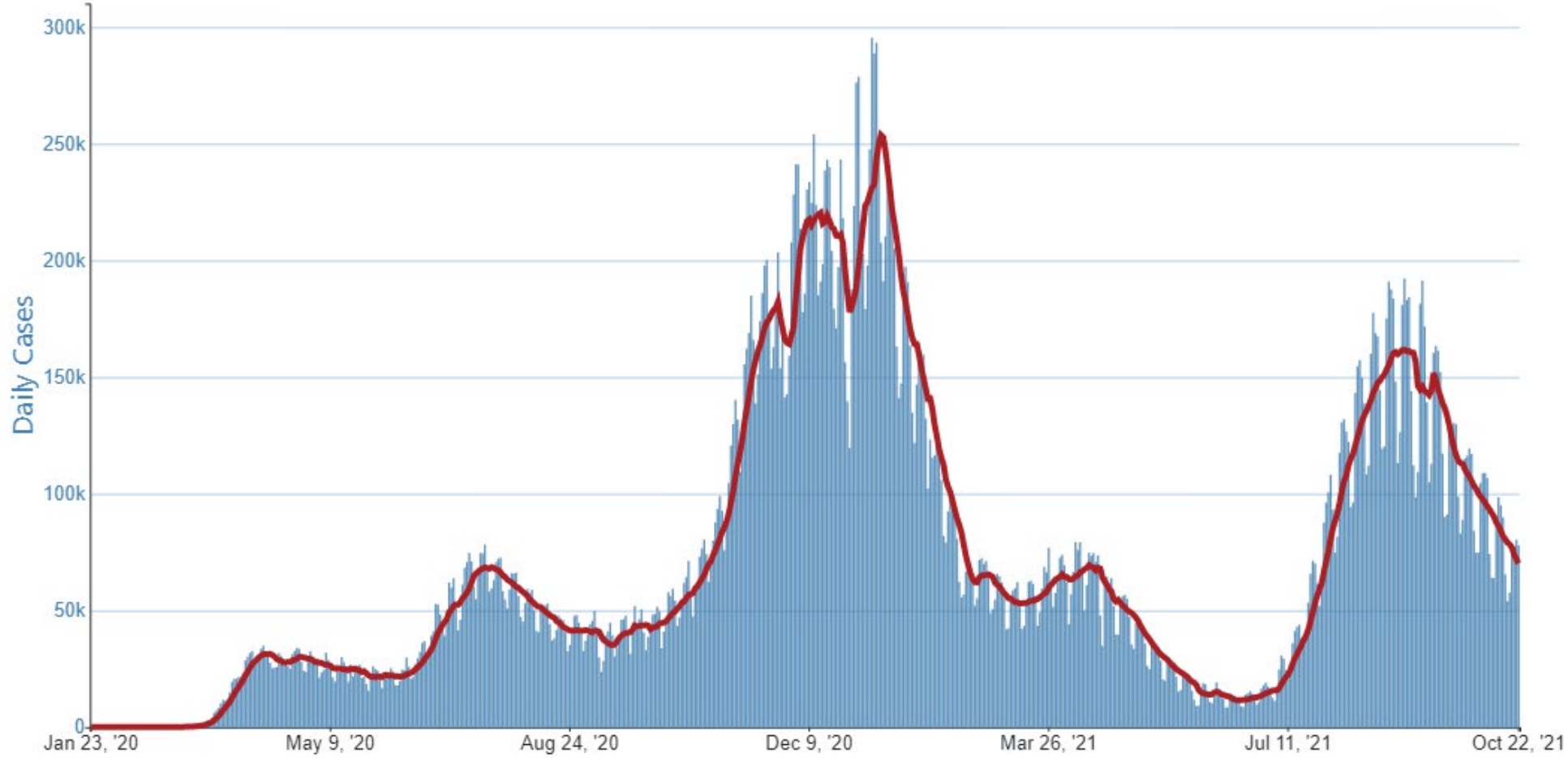
NIH Tribal Advisory Committee
October 26, 2021

National Institute of Allergy and Infectious Diseases

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



https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

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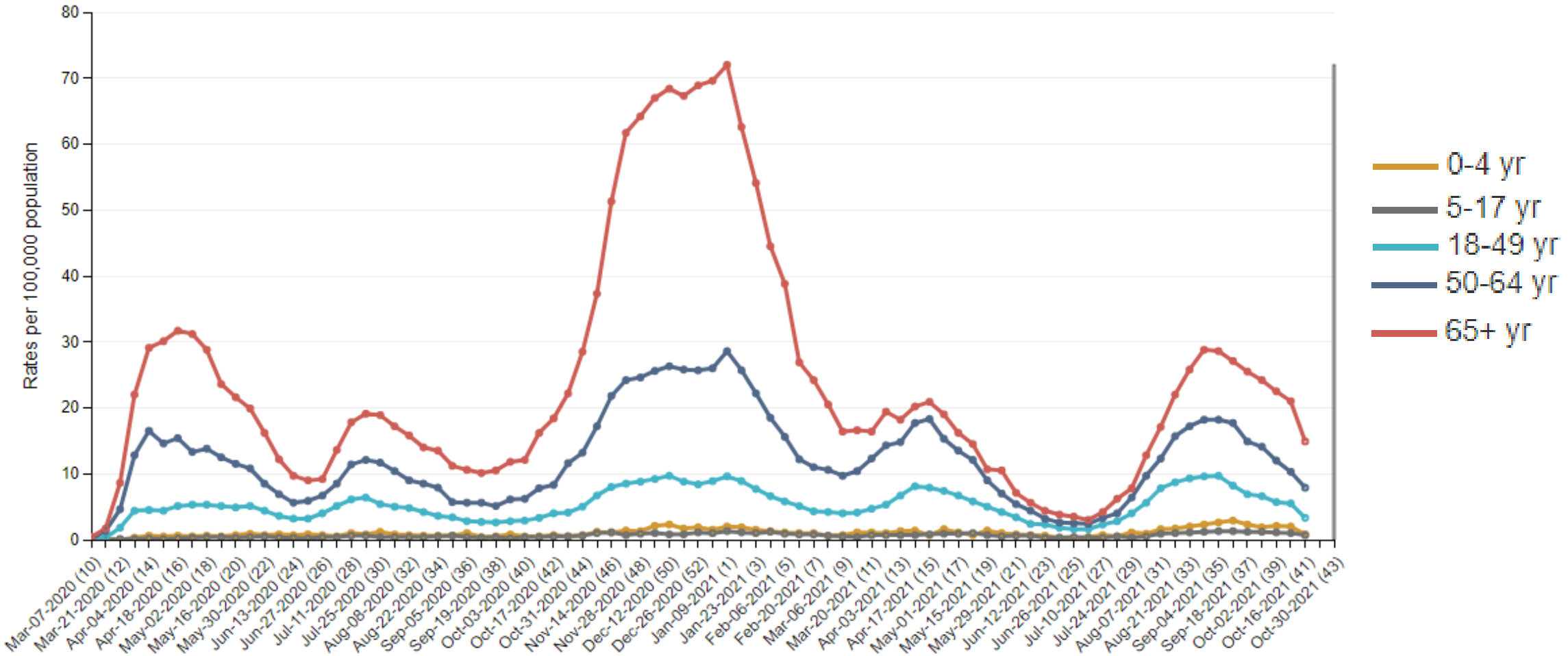
Rates of COVID-19 Associated Hospitalization



https://gis.cdc.gov/grasp/covidnet/covid19_3.html

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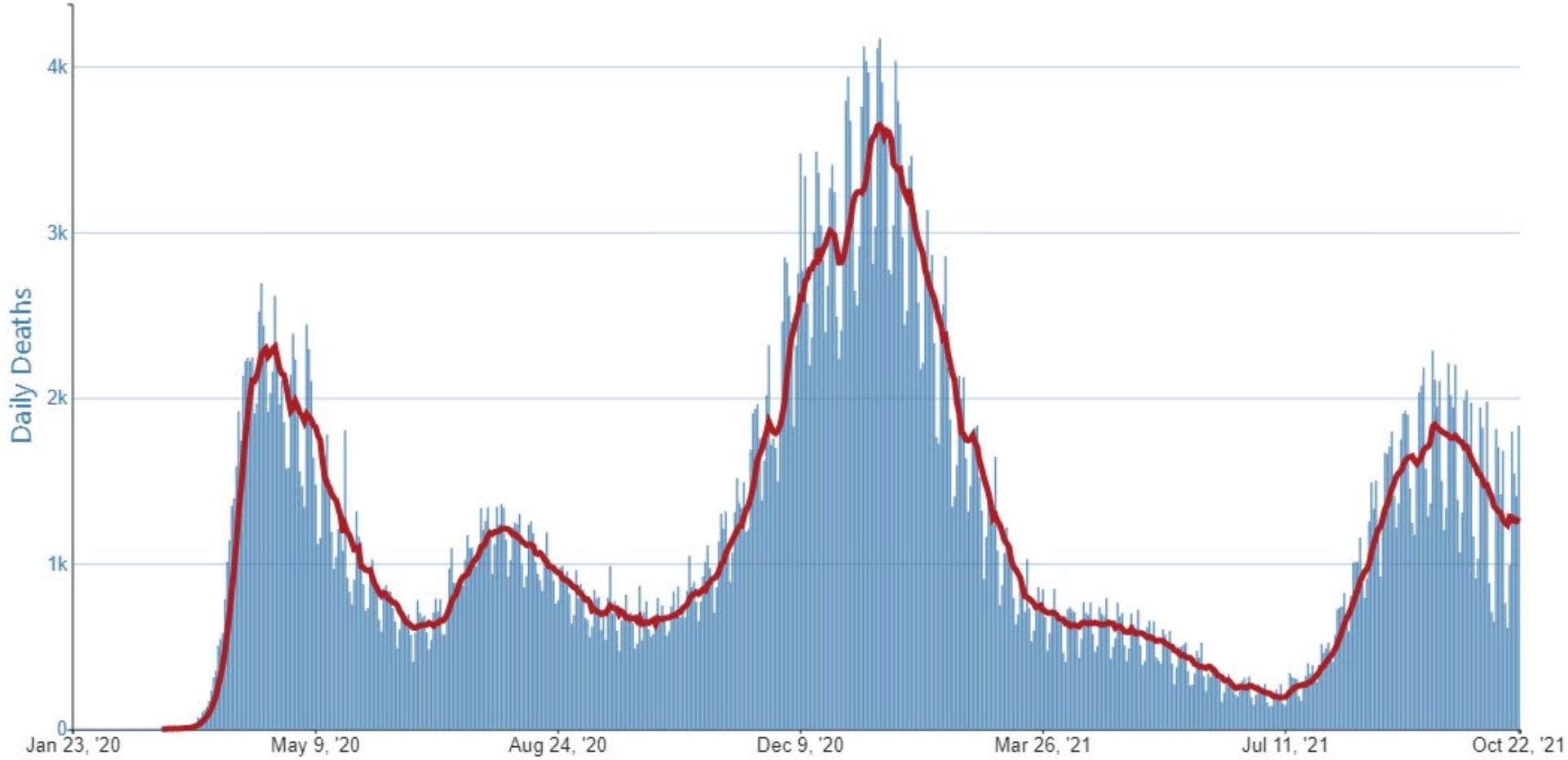
Daily Trends in COVID-19 Deaths in the U.S. Reported to the CDC



https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths

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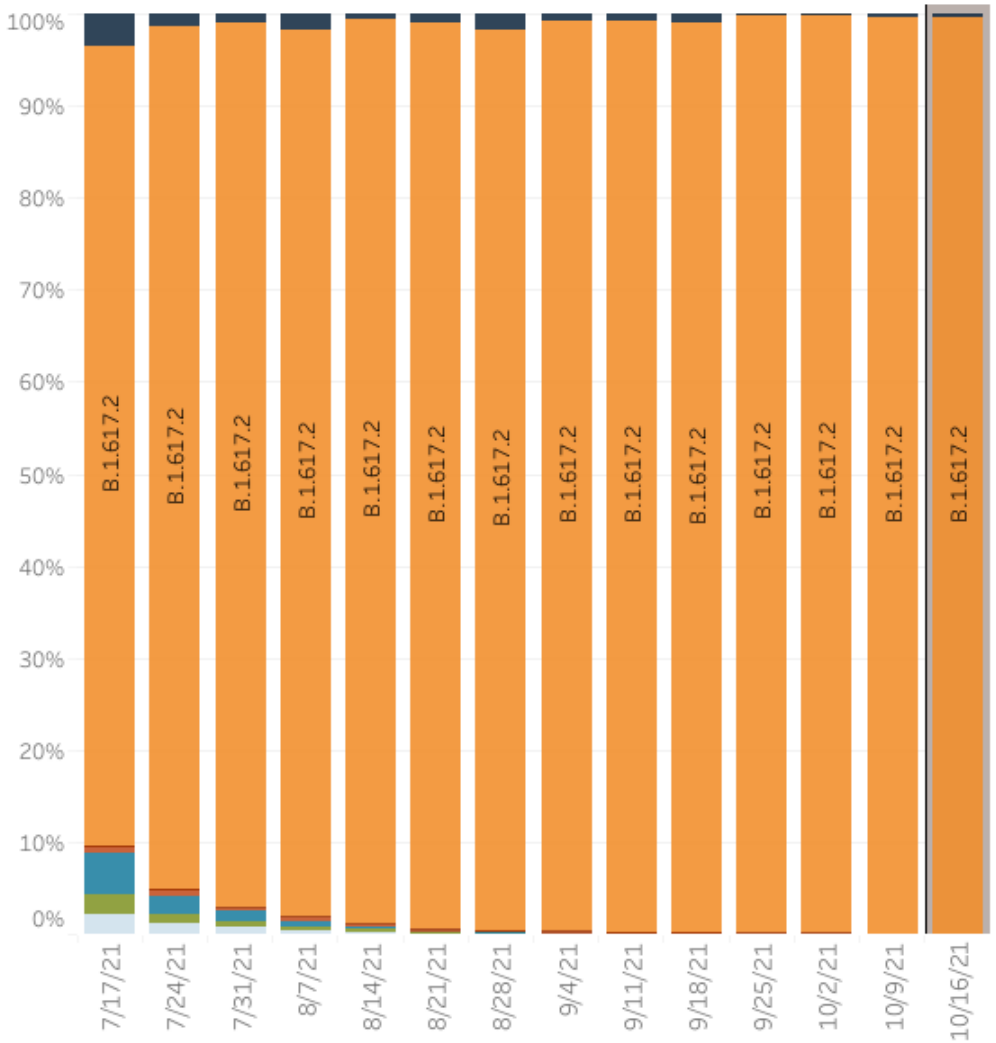
Circulating Variants in the U.S.



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%	

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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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

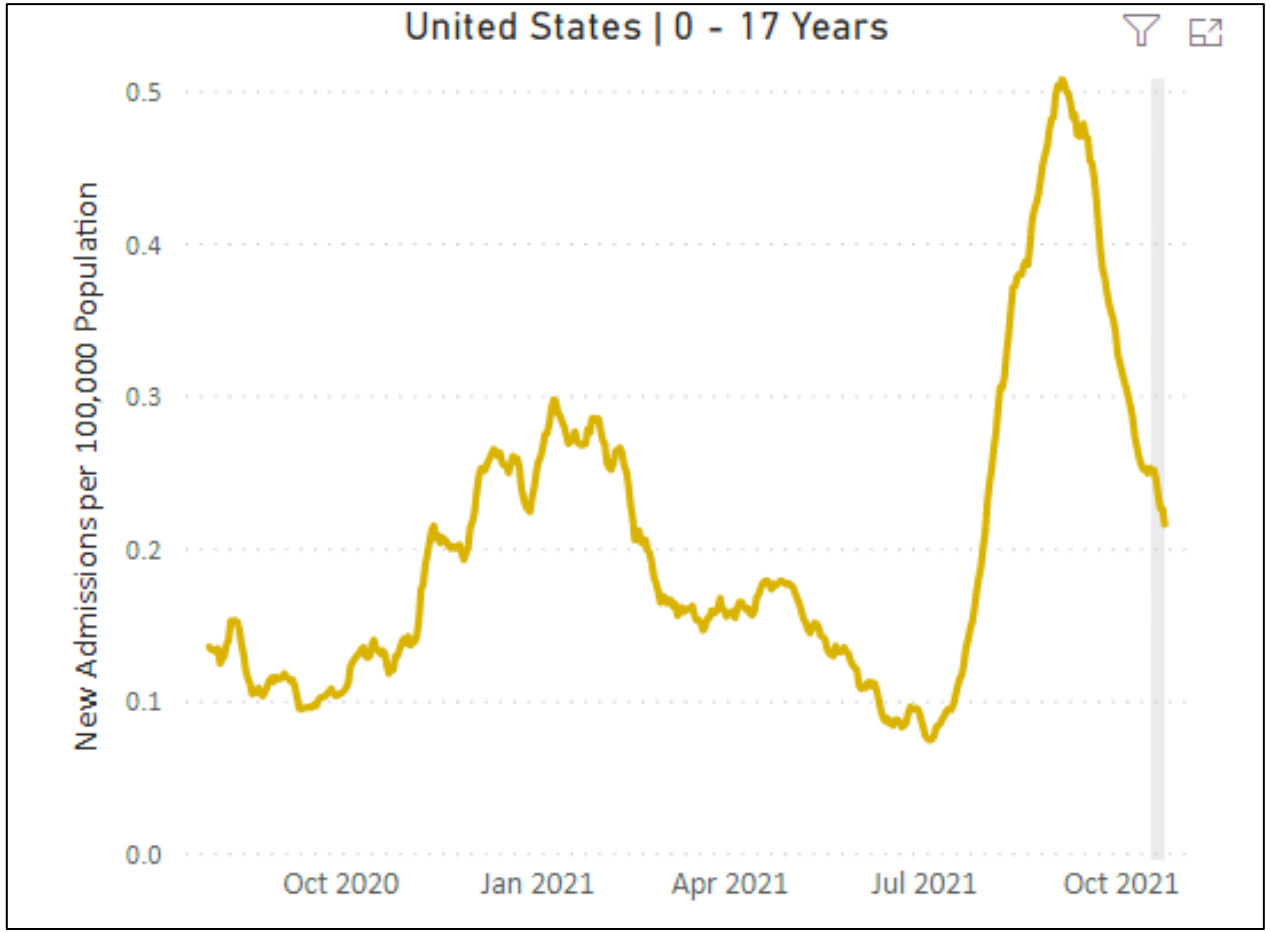
Aug 29, 2021 - Sep 04, 2021

-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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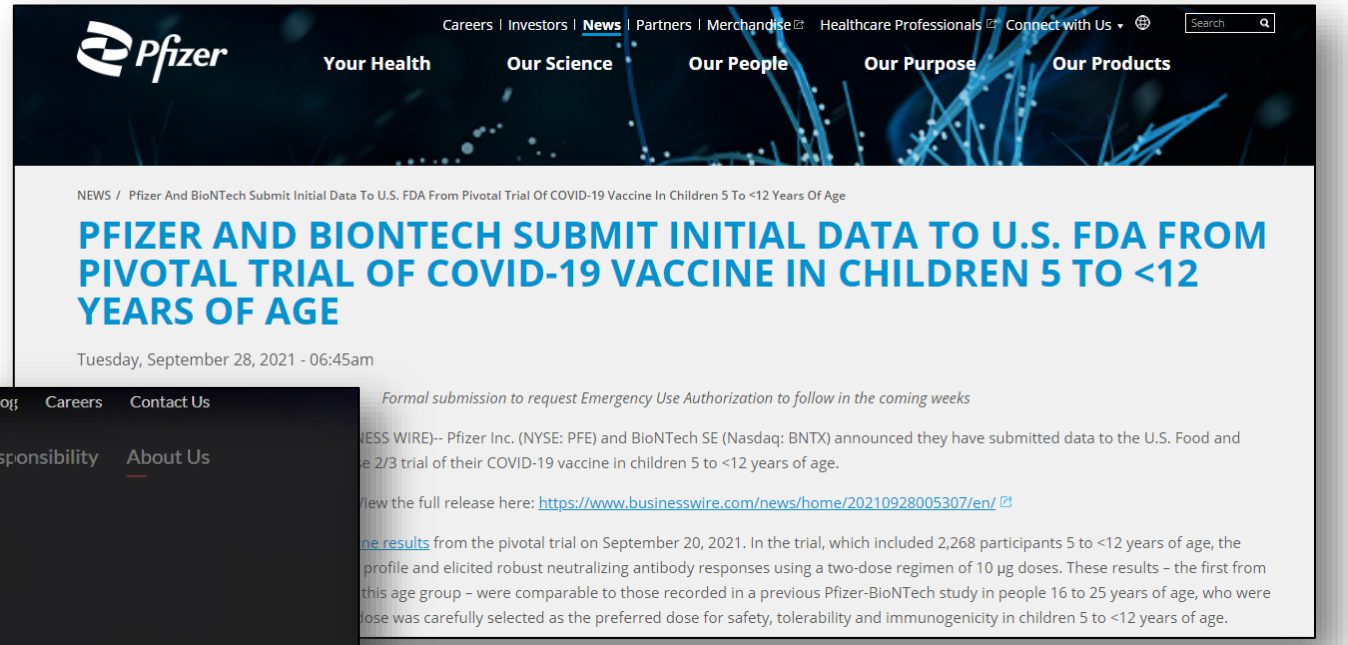
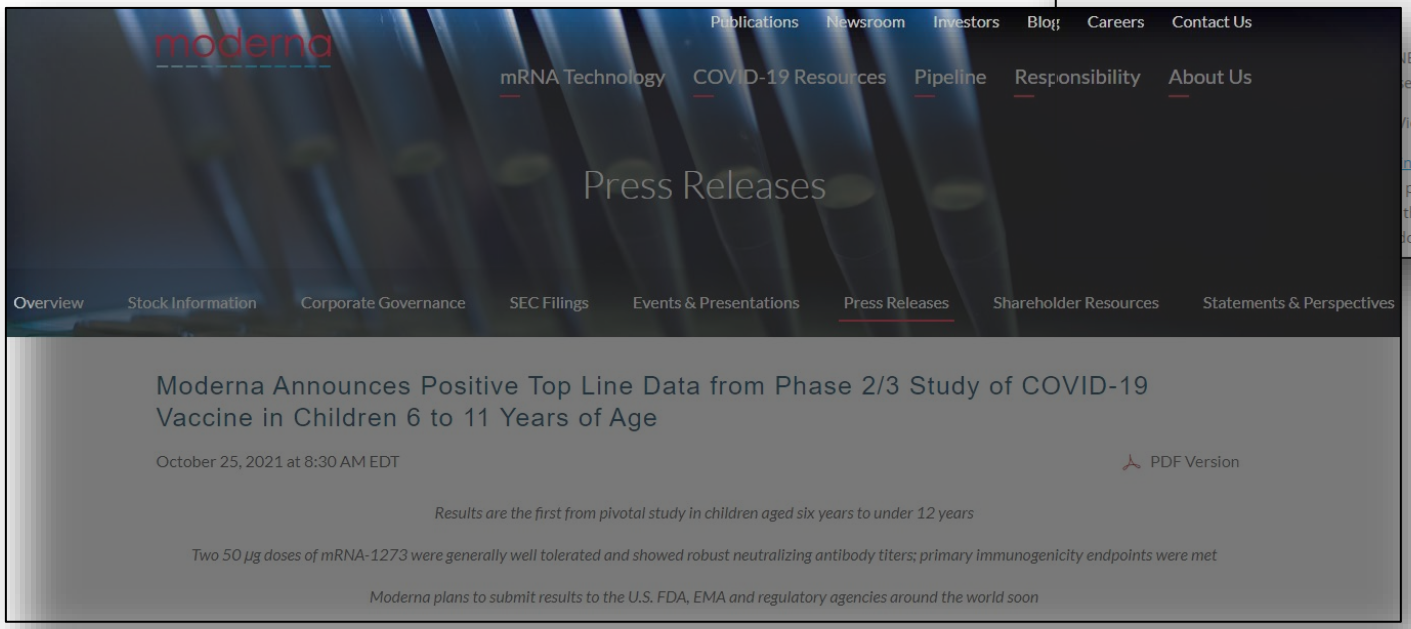
Pediatric Data





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VRBPAC Meeting on Pfizer's Pediatric Data

FDA U.S. FOOD & DRUG ADMINISTRATION

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.

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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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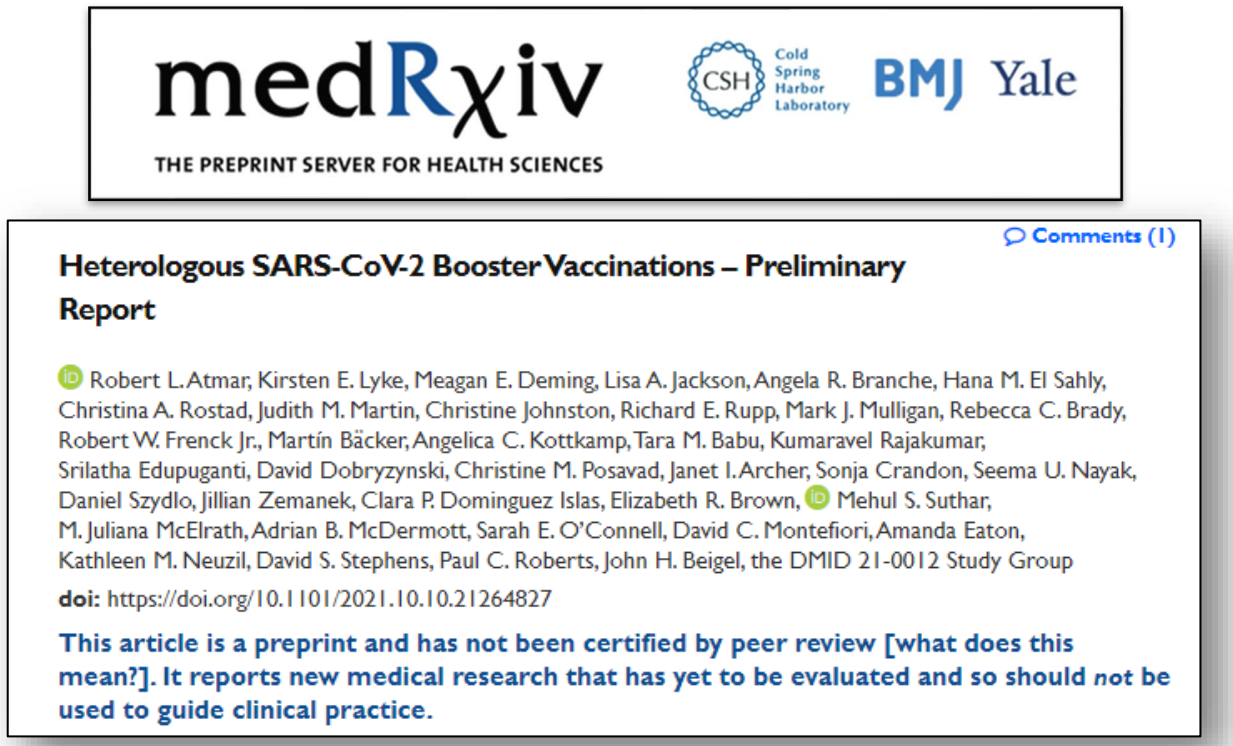
Mix and Match Trial



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.

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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.

https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html

THANK YOU!

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