

## Pfizer Vaccine Project Links

Pfizer Emergency Authorization Update August 23, 2021 - Footnote 8 gives information regarding the two products. Footnote 9 gives the reason the approved vaccine isn't available yet, and that's the reason for the FDA to continue using the EUA experimental version of the vaccine. Section III.Y states that the FDA did not give approval for the "Pfizer-BioNTech COVID-19 Vaccine."

<https://www.fda.gov/media/150386/download>

Pfizer trial data showing 84% efficacy instead of the 91% cited by the FDA. Take note at the top of page 7 where it states that from 4 month to data cutoff Vaccine Efficacy was 83.7%. - <https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf#page=7>

Pfizer & BioNTech vaccine drug fact sheet which lists both products on one page - <https://www.fda.gov/media/144414/download>

COMIRNATY Drug Insert Sheet - <https://www.fda.gov/media/151707/download>

FDA Approval letter for the Comirnaty vaccine - <https://www.fda.gov/media/151710/download>

Industry peers petition the FDA to forgo approval of the vaccine until full trials were completed. Take note of the download link of the petition and their concerns - <https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/>

This is the Defense Department Memorandum for the mandatory vaccination program. Please take note of this phrase, "Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA)" - <https://news.usni.org/2021/08/25/secdef-austin-memo-on-mandatory-service-member-covid-19-vaccinations>

Israeli study demonstrating that, "SARS-CoV-2-naïve vaccinees had a 13.06-

fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection with the Delta variant compared to those previously infected." (Massive Study) - <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf>

Pfizer Press Release regarding the FDA approval - <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full>

'FDA set to grant full approval to Pfizer vaccine without public discussion of data' - <https://www.bmj.com/content/374/bmj.n2086>

August 23rd article by BMJ - 'Does the FDA think these data justify the first full approval of a covid-19 vaccine?' - <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/>

Article questioning the efficacy of the trial data which led to the first EUA for the BioNTech Vaccine - <https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/>

UK study of many showing covid case rates for all variants. Pay attention to the bottom of page 17 about deaths showing that more people fully vaccinated were dying than those not vaccinated - [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1001358/Variants\\_of\\_Concern\\_VOC\\_Technical\\_Briefing\\_18.pdf#page=17](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variants_of_Concern_VOC_Technical_Briefing_18.pdf#page=17)

FDA statements regarding the use of advisory committees for future approval of vaccines - <https://www.healthaffairs.org/doi/10.1377/hblog20200814.996612/full/>

FDA Adverse Dashboard - <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard>

EudraVigilance adverse reporting system - [https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F\\_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22](https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22)

[Substance%20High%20Level%20Code%22&P3=1+42325700](#)

Pro-vaccine industry peers petition FDA to hold off approving the Pfizer vaccine - [formal "Citizen Petition"](#)

'FDA QUANDARY' article - <https://therepublicjournal.com/state-attorney-general-fda-quandary/>

Average hospital stay for non-icu covid patients was 2 days - <https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-021-06371-6>