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Pfizer and BioNTech invitro vaccine study shows efficient neutralization of SARS-CoV-2 U.K. strain

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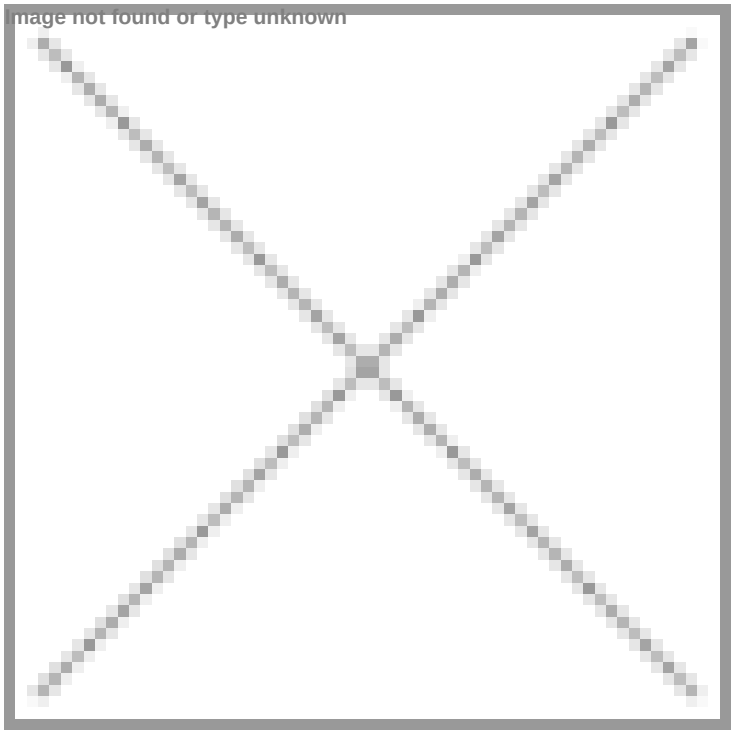
Study showing COVID-19 vaccine elicits antibodies that neutralize pseudovirus bearing the SARS-CoV-2 U.K. strain spike protein in cell culture



Pfizer Inc and BioNTech SE on Jan 20, 2021 announced results from an *in vitro* study that provides additional data on the capability of sera from individuals immunized with the Pfizer-BioNTech COVID-19 vaccine BNT162b2 to neutralize the SARS-CoV-2 U.K. strain, also known as B.1.1.7 lineage or VOC 202012/01. The results were published on the preprint server bioRxiv and submitted to a peer-reviewed journal.

The B.1.1.7 lineage is a rapidly spreading variant of SARS-CoV-2 initially detected in the United Kingdom that carries a larger than usual number of genetic changes with 10 mutations located in the spike protein. BioNTech and Pfizer have previously published data from an *in vitro* study that evaluated one of the key mutations (N501Y) in the U.K. strain, which is also shared by the South African strain. That study showed efficient neutralization of the N501Y mutated spike bearing virus by sera of individuals who had received the Pfizer-BioNTech COVID-19 vaccine.

The current *in-vitro* study investigated the full set of UK strain spike mutations. To this aim, a pseudovirus featuring the UK strain spike protein was generated.

The pseudovirus recapitulates SARS-CoV-2 virus binding and cell entry. Sera of participants from the previously reported German Phase 1/2 trial inhibited pseudovirus bearing the U.K. strain SARS-CoV-2 spike in a neutralization range that is regarded as biologically equivalent to the unmutated Wuhan SARS-CoV-2 spike.

While the pseudovirus system used is a surrogate for authentic SARS-CoV-2, previous studies have shown excellent concordance between pseudotype neutralization and SARS-CoV-2 neutralization assays. The preserved neutralization of the pseudovirus bearing the U.K. strain spike by BNT162b2-immune sera makes it likely that COVID-19 caused by the UK virus variant will also be prevented by immunization with BNT162b2.

Pfizer and BioNTech are encouraged by these early *in vitro* study findings. Further data are needed to monitor the Pfizer-BioNTech COVID-19 vaccine's effectiveness in preventing COVID-19 caused by new virus variants. So far, for COVID-19 vaccines it has not been established what reduction in neutralization might indicate the need for a vaccine strain change. Should a vaccine strain change be required to address virus variants in the future, the Companies believe that the flexibility of BioNTech's proprietary mRNA vaccine platform is well suited to enable such adjustment.