

Discover & Deliver: Vaccine & Variants Update

As the U.S. marks the tragic milestone of 500,000 deaths from coronavirus, here is the latest we know about vaccine effectiveness against virus variants.

What's new: On Monday, the FDA [released new guidance](#) on the approval process for updating the vaccines to combat emerging coronavirus variants. Rather than conduct a new, large-scale clinical trial, [companies can submit data](#) from immunogenicity studies to illustrate that the antibody levels produced against the new strain are as effective as those produced by the authorized vaccine. The FDA did not specify the size of trial required but noted the study would only have to be conducted in one age group for the updated vaccine to receive authorization.

What's next: On February 4, [Johnson & Johnson filed](#) an emergency use authorization (EUA) application for their one-shot COVID-19 vaccine, which was found to be 72% effective at preventing infection in the U.S. This Friday, the FDA's Vaccines and Related Biological Products Advisory Committee will meet to discuss the application. If the FDA accepts the recommendation of the Advisory Committee – which they frequently do – Johnson & Johnson could receive the EUA in [early March](#), with vaccines administered shortly thereafter. At a House Energy & Commerce hearing this morning, [Johnson & Johnson](#) stated that 4 million doses will be available immediately after authorization, with 20 million doses will be available in the U.S. by the end of March.

Bottom line: As [over 1,000 clinical trials](#) continue across the United States, this week's developments illustrate why clinical research remains critical. Even as case numbers decline across the U.S., the science must keep pace with the evolving virus threats.

By early next week, we may have three FDA authorized COVID-19 vaccines, with innovative scientific community at the ready to combat the new virus variants that may endanger our return to normal.

—Kelly Anderson, Senior Director, Health and Drug Policy, Global Innovation Policy Center

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