



COVID-19 Vaccines – New Data on Booster of Janssen Vaccine

- On September 21, 2021 the [Janssen \(Johnson & Johnson\) announced new data](#) on their COVID-19 vaccine showing that protection against COVID-19 increases when a booster shot of the vaccine is administered following the initial 1-dose regimen. The safety profile of the vaccine remained consistent and was generally well-tolerated when administered as a booster.
- The Phase 3 ENSEMBLE 2 study showed that a second dose of the Janssen COVID-19 vaccine given 56 days after the first dose provided:
 - 100% protection (CI: 33%-100%) against severe/critical COVID-19 – at least 14 days post-final vaccination.
 - 75% protection against symptomatic (moderate to severe/critical) COVID-19 globally (CI: 55%-87%).
 - 94% protection against symptomatic (moderate to severe/critical) COVID-19 in the U.S. (CI: 58%-100%).
 - When a booster of the Janssen COVID-19 vaccine was given two months after the first shot, antibody levels rose to four to six times higher than observed after the single shot.
 - Booster shot at six months provided 12-fold increase in antibodies.
- The data has been shared with the FDA for review and may ultimately inform a revision of the EUA for the Janssen COVID-19 vaccine. Timing for an EUA change has not been shared. Typically, the FDA will issue an approval/authorization decision, then the CDC's ACIP will review the data and issue recommendations for clinical practice.



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