



COVID-19 Vaccine Update Webinar Series

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Pictured: a representation of a coronavirus

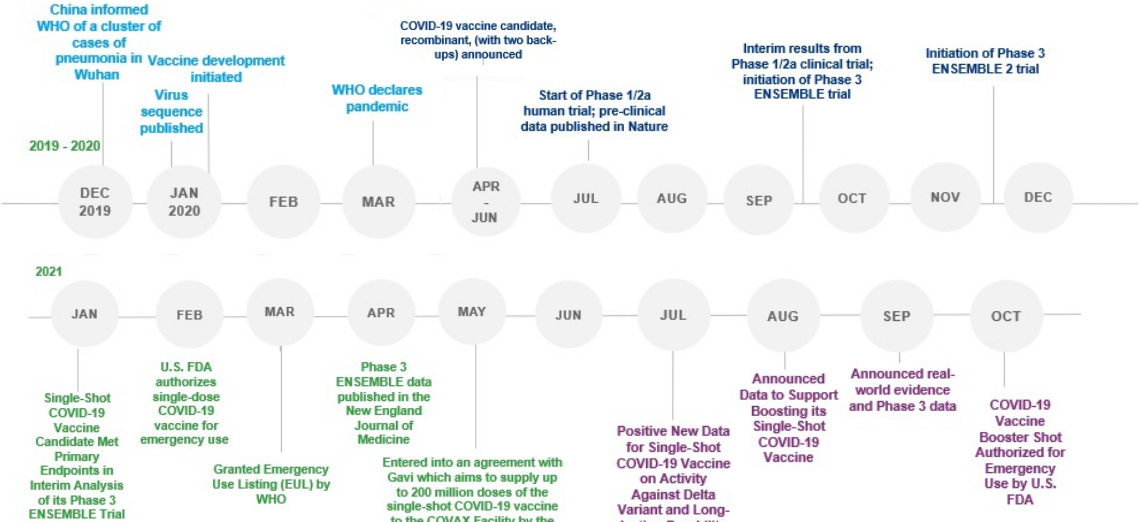


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Janssen's Quest for a COVID-19 Vaccine





2019 - 2020

- DEC 2019: China informed WHO of a cluster of cases of pneumonia in Wuhan
- JAN 2020: Virus sequence published
- FEB: Vaccine development initiated
- MAR: WHO declares pandemic
- APR - JUN: COVID-19 vaccine candidate, recombinant, (with two back-ups) announced
- JUL: Start of Phase 1/2a human trial; pre-clinical data published in Nature
- SEP: Interim results from Phase 1/2a clinical trial; initiation of Phase 3 ENSEMBLE 2 trial
- NOV: Initiation of Phase 3 ENSEMBLE 2 trial
- DEC: Initiation of Phase 3 ENSEMBLE 2 trial

2021

- JAN: Single-Shot COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial
- FEB: U.S. FDA authorizes single-dose COVID-19 vaccine for emergency use
- MAR: Granted Emergency Use Listing (EUL) by WHO
- APR: Phase 3 ENSEMBLE data published in the New England Journal of Medicine
- MAY: Entered into an agreement with Gavi which aims to supply up to 200 million doses of the single-shot COVID-19 vaccine to the COVAX Facility by the end of 2021.
- JUL: Positive New Data for Single-Shot COVID-19 Vaccine on Activity Against Delta Variant and Long-lasting Durability of Response
- AUG: Announced Data to Support Boosting its Single-Shot COVID-19 Vaccine
- SEP: Announced real-world evidence and Phase 3 data
- OCT: COVID-19 Vaccine Booster Shot Authorized for Emergency Use by U.S. FDA



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Booster Emergency Use Authorization & Recommendations



VRBPAC voted unanimously in support of a booster dose amendment to the EUA for individuals 18 and older at least two months after primary vaccination.



FDA issued EUA for a booster dose following Johnson & Johnson primary vaccination.¹

FDA issued EUA for the Johnson & Johnson COVID-19 Vaccine to boost **other authorized COVID-19 vaccines.**



ACIP unanimously recommended a booster dose.

¹ Commissioner, Office of the "Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for Covid-19 Vaccines." U.S. Food and Drug Administration, FDA. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>

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What's Next: A Look Ahead to Upcoming Milestones

Data Readouts and Clinical Trials

Variant COV2007 Study
COV-Boost and
COV2008 Studies

Regulatory Milestones

Biologics License
Application (BLA)
Submission

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