Clinical trial evaluating mixed COVID-19 vaccine schedules begins

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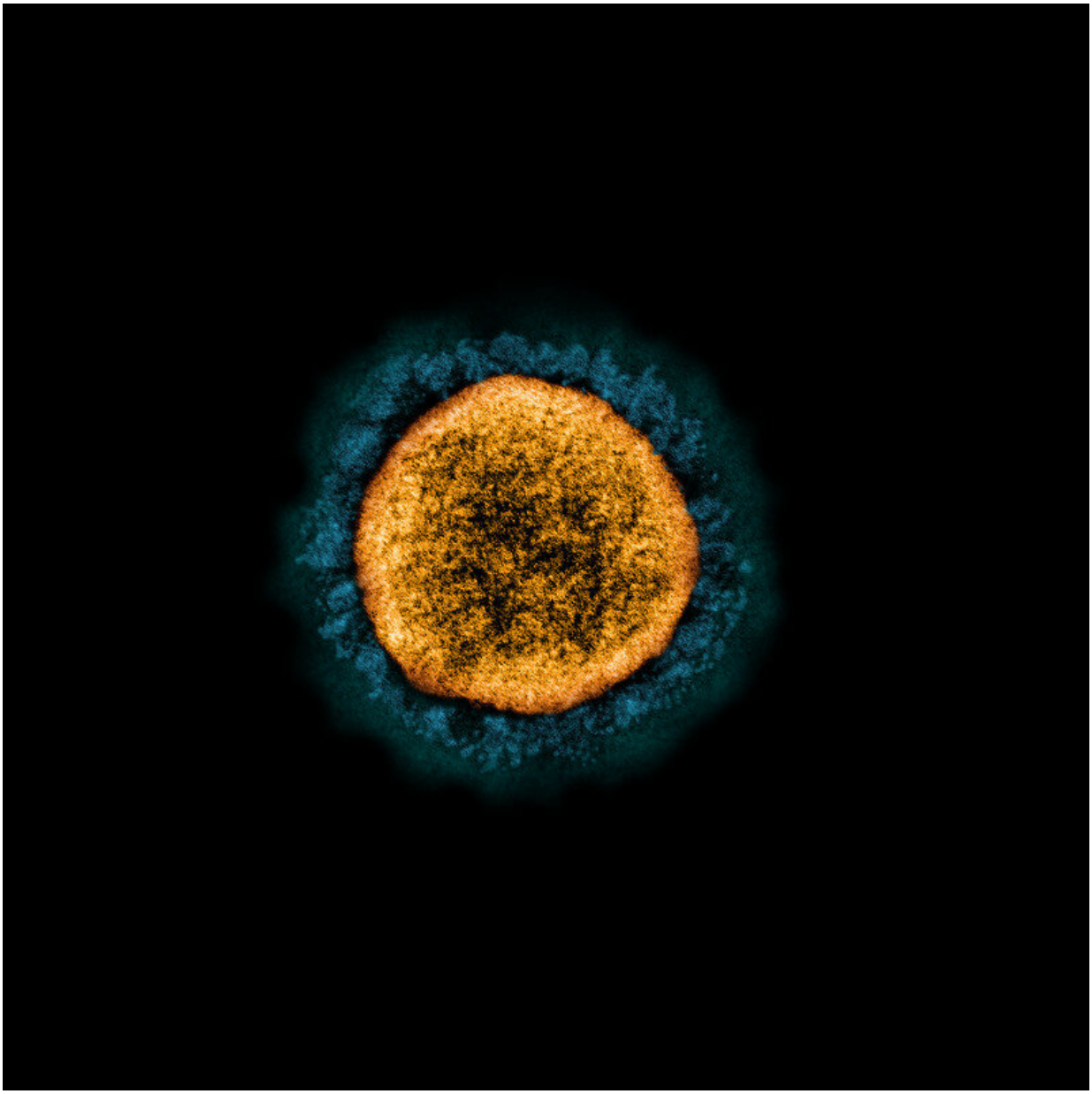

Transmission electron micrograph of a SARS-CoV-2 virus particle (UK B.1.1.7 variant), isolated from a patient sample and cultivated in cell culture. Image captured at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. Credit: NIAID

The National Institutes of Health has started a Phase 1/2 clinical trial in which adult volunteers who have been fully vaccinated against COVID-19 will receive booster doses of different COVID-19 vaccines to determine the safety and immunogenicity of mixed boosted regimens. The National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, is leading and funding the study through the Infectious Diseases Clinical Research Consortium, a clinical trials network that encompasses the Institute's long-standing Vaccine and Treatment Evaluation Units (VTEUs).

"Although the vaccines currently authorized by the U.S. Food and Drug Administration offer strong protection against COVID-19, we need to prepare for the possibility of needing booster shots to counter waning immunity and to keep pace with an evolving virus," said NIAID Director Anthony S. Fauci, M.D. "The results of this trial are intended to inform public health policy decisions on the potential use of mixed vaccine schedules should booster doses be indicated."

The trial is led by principal investigators Robert L. Atmar, M.D., at Baylor College of Medicine, Houston, and Kirsten E. Lyke, M.D., at the University of Maryland, College Park. It will include approximately 150 individuals who already have received one of the three COVID-19 vaccine regimens currently available under FDA Emergency Use Authorization in the United States: the Janssen COVID-19 vaccine (also referred to as the Johnson & Johnson vaccine, or Ad26.COV2-S), the Moderna COVID-19 vaccine (also known as mRNA-1273), and the

Pfizer-BioNTech COVID-19 vaccine (also known as (BNT162b2). Each vaccine group will enroll about 25 people ages 18 through 55 years and approximately 25 people age 56 years and older. Twelve to 20 weeks following their initial vaccination regimen, participants will receive a single booster dose of the Moderna COVID-19 vaccine as part of the trial.

People who have not yet received an FDA authorized COVID-19 vaccine are also eligible to enroll in the trial in a separate cohort. Initially, these volunteers will receive the two-dose Moderna COVID-19 vaccine regimen and will be assigned to receive a booster dose of a vaccine about 12 to 20 weeks later.

The trial has an adaptive design and may add arms as vaccines are awarded EUA and/or variant lineage vaccines become available for evaluation.

All trial participants will be followed for one year after receiving their last vaccination as part of the study. They will be asked to complete telephone check-ins and various in-person follow up visits. Trial investigators will evaluate participants for safety and any side effects post-vaccination. Participants also will be asked to provide blood samples periodically so that trial investigators can evaluate immune responses against current circulating strains of SARS-CoV-2, as well as emerging variants. If trial participants develop laboratory-confirmed symptomatic COVID-19, investigators will perform genetic sequence analyses on the participant samples to see if a variant strain of SARS-CoV-2 caused the infection.

Initial trial results are expected in late summer 2021. For more information about the trial, including a list of enrollment locations, please visit clinicaltrials.gov and search identifier NCT04889209.

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