

Moderna hails diversity of COVID trial participants

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Biotech firm Moderna said Thursday that it had successfully recruited ethnic minorities, older people and those with underlying health issues for its COVID-19 vaccines trial, after it pushed to enrol groups most vulnerable to the virus.

Moderna said it had now signed up all 30,000 participants for the phase-3 trial, and more than 25,000 of them had already received a second dose of the vaccine, four weeks after the first.

The firm said it was working "to develop a vaccine for everyone, including communities that have historically been under-represented in <u>clinical research</u> and are disproportionately impacted by COVID-19."

More than 7,000 people taking part in the trial are over 65, and more than 5,000 under 65 have high-risk diseases such as diabetes, severe obesity and cardiac disease.

The firm said more than 11,000 are "from communities of color, representing 37 percent of the study population and similar to the diversity of the US at large"—6,000 are Hispanic or Latino, and more than 3,000 are African-American.

Massachusetts-based Moderna is one of the few companies to have launched a large-scale clinical trial less than 10 months after the genetic sequencing of the novel <u>coronavirus</u> was established.



Some Chinese, Russian and other Western projects are also in advanced tests, including US firm Pfizer.

Moderna hopes to have sufficient results by the end of November and to then file an emergency authorization request with the US Food and Drug Administration (FDA).

The company has already said it was aiming to file for authorization soon after November 25, with Pfizer at the third week of November.

The US government says it will distribute the first doses immediately after authorization free of charge.

Health Secretary Alex Azar said Wednesday there would be enough doses to vaccinate the "most vulnerable" Americans before the end of the year, then the elderly and <u>health workers</u> in January, and all Americans by early April.

In the <u>trials</u>, half of the volunteers receive a placebo, and the other half get the vaccine.

Initial FDA guidance stipulated that if the number of participants in the vaccinated group naturally contracting the virus and falling ill with COVID-19 was at least 50 percent lower than in the placebo group, the vaccine would be declared effective.

But on Thursday, a National Institutes of Health official said during a meeting of the FDA's advisory committee on vaccines that they would require a 60 percent efficacy for emergency use.

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