



COVID-19 vaccines development: How close are we?

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EDITORIAL

Public perception of the review of medications and vaccines for coronavirus disease 2019 (COVID-19) has become enmeshed in politics. COVID-19 vaccine has whipped up unrealistic expectations that one is just around the corner. More than 100 possible vaccines are in various stages of development around the world, according to the World Health Organization. Some are even in late-stage human clinical trials. But certain things can't be rushed, like how long it takes a person's immune system to respond to a vaccine or the wait to check for side effects. A large number of companies started piloting vaccine candidate. Data safety monitoring is crucial and under scanner. Underlining the critical role that independent scrutiny plays in one of the greatest global crises. Without a specific cure, the vaccine quest has become more than just a search along the pathway that research and pharma companies have traditionally taken. There are demands that probable vaccines be put into a pipeline for accelerated approval to yield political dividends too.

Before any vaccine can be used widely, it must go through development and testing to make sure that it's effective against the virus or bacteria and that it doesn't cause other problems. The stages of development generally follow this timeline:

Exploratory stage:

This is the start of lab research to find something that can treat or prevent a disease. It often lasts 2 to 4 years.

Pre-clinical stage:

Scientists use lab tests and testing in animals, such as mice or monkeys, to learn whether a vaccine might work. This stage usually lasts 1 to 2 years. Many potential vaccines don't make it past this point. But if the tests are successful and the FDA signs off, it's on to clinical testing.

KEYWORDS

COVID-19, development, phase, trials, vaccine

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Clinical development:

This is a three-phase process of testing in humans. Phase I usually lasts 1 to 2 years and involves fewer than 100 people. Phase II takes at least 2 years and includes several hundred people. Phase III lasts 3 or 4 years and involves thousands of people. Overall, the clinical trial process may stretch to 15 years or more. About a third of vaccines make it from phase I to final approval.

Cerebral Regulatory review and approval:

Scientists with the FDA and CDC go over the data from the clinical trials and sign off.

Manufacturing:

The vaccine goes into production. The FDA inspects the factory and approves drug labels.

Quality control:

Scientists and government agencies keep tabs on the drug-making process and on people who get the vaccine. They want to make sure it keeps working safely.

U.S. is on the way to prepare the vaccine before November. India had its moment of vaccine controversy when the ICMR harried trialists to expedite testing of Bharat Biotech's Covaxin by August 15. Overall, the road to a vaccine has become an arena for marketing and jingoism. AZD1222 has already been tested in Phase-1 and Phase-2 trials, where the data on its safety and ability to induce a relevant response by the immune system were evaluated and independent peer-review had deemed it fit to be tested in larger populations. A Phase-3 trial is the most daunting one. In the case of a vaccine, there is the additional burden of proof that it cannot sicken the healthy and the odds of adverse reactions greatly increase when a piece of virus is injected into thousands of volunteers. Vaccine trials take years of development precisely because of the chances of unexpected complications and to expect a vaccine, which has cleared accelerated Phase-1/2 trials, to inexorably clear Phase-3, flies in the face of evidence from the history of vaccine development. Developed at Oxford, AZD1222 was evolved on an adenovirus platform not used in a commercially approved vaccine in humans.

So million dollar question is when will we have a coronavirus vaccine?

- A vaccine would normally take years, if not decades, to develop. Researchers hope to achieve the same amount of work in only a few months.
- Most experts think a vaccine is likely to become widely available by mid-2021, about 12-18

months after the new virus, known officially as Sars-CoV-2, first emerged.

- That would be a huge scientific feat, and there are no guarantees it will work.
- But scientists are optimistic that, if trials are successful, then a small number of people - such as healthcare workers - may be vaccinated before the end of this year.
- It is worth noting that four coronaviruses already circulate in human beings. They cause common cold symptoms, and we don't have vaccines for any of them.

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AVAILABILITY OF DATA AND MATERIALS

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ETHICS APPROVAL AND CONSENT TO PARTICIPATE

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COMPETING INTERESTS

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