ICMR clarifies on timeline for completion of clinical trials for COVID-19 vaccine 'Covaxin'

Shardul Nautiyal, Mumbai
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The Indian Council of Medical Research (ICMR) has clarified that timeline for completion of all clinical trials for the COVID-19 vaccine 'Covaxin' and its deadline for public launch is not August 15 this year. Instead, the new vaccine will be launched as per the timeline from Clinical Trials Registry of India (CTRI) and Bharat Biotech International Limited (BBIL) which is a year and three months. The premier research agency further stated that currently clinical trial subjects are being enrolled with oversight from empanelled hospitals of the clinical trials based on ICMR directive.

According to an ICMR spokesperson, "August 15, 2020 timeline should not be talked about as it was meant to prompt and motivate principal investigators at all clinical trial sites to expedite clinical trial process as per global regulatory norms to come out with a vaccine as soon as possible."

"It was meant to tighten the entire process of multi-stakeholder engagement involving accountability from hospitals ethics committees and the sponsor company conducting clinical trials which is Bharat Biotech international Limited. ICMR has played its role as a regulator to bring about clinical research in the country in an efficient and timely manner," he further added.

In a statement earlier, ICMR had stated, "It has been envisaged to launch the Covaxin vaccine for public health use latest by August 15, 2020 after completion of all clinical trials." In fact, ICMR director general Dr Balram Bhargava on July 2 had written to all 12 trial sites for the COVID-19 vaccine candidate, Covaxin, that all clinical trials had to be completed by August 15, in time for a public launch. As per CTRI, the expected duration of the trial for Covaxin vaccine is one year and three months.

BBIL successfully developed Covaxin, India's first vaccine candidate for COVID-19, in collaboration with ICMR-National Institute of Virology (NIV). The SARS-CoV-2 strain was isolated in NIV, Pune and transferred to BBIL. The indigenous, inactivated vaccine candidate was developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) High Containment facility located in Genome Valley, Hyderabad, India.

Commenting on the development, Dr Chirag Shah, senior director, business strategy, Cliantha Research Limited, a leading global clinical research company, said, "ICMR clarification is very much aligned to the global vaccine research norms and as per the clinical trial design for a pandemic like COVID-19, it might take around one month for the phase I human trial, which will do the safety assessment and 4 to 6 months in phase –II, which will assess both safety and immunogenicity of the vaccine."

"Phase –II human trials will help us know how many antibodies have been generated in the trial subject to understand proper efficacy of the vaccine," Dr Shah further explained.

Medical fraternity had raised an alarm over the issue with reference to the vaccine development for safety and efficacy stating that all three phases of clinical trials for a vaccine candidate in a month's time is totally uncalled for and defies scientific rationale. A vaccine usually goes through three phases of human trials. DCGI has given approvals for phase I and II trials so far.

Moreover, regulatory experts have also raised concern that Covaxin is an attenuated vaccine and not a recombinant vaccine which again requires high level of testing and protocols and hence will take longer time than prescribed.

Attenuated vaccine is a vaccine created by reducing the virulence of a pathogen, but still keeping it viable (or live). A recombinant vaccine is a vaccine produced through recombinant DNA technology. This involves inserting the DNA encoding an antigen (such as a bacterial surface protein) that stimulates an immune response into bacterial or mammalian cells, expressing the antigen in these cells and then purifying it from them.

"Announcing a timeline without calculations has already raised unrealistic hope and expectations amongst Indian patients. Immune response observations in human testing for a vaccine need to follow a prescribed time span without compromising scientific standards. However, on July 04, 2020, ICMR had revised their statement highlighting vaccine process will be fast-tracked but without bypassing necessary protocols," remarked Ahmedabad based pharma expert Dr Sanjay Agrawal.

DCGI granted permission to BBIL to initiate phase I and II human clinical trials after the company submitted results generated from preclinical studies, demonstrating safety and immune response.

Announcing the vaccine development milestone, Dr. Krishna Ella, chairman and managing director, BBIL had said, "We are proud to announce Covaxin, India's first indigenous vaccine against COVID-19.The collaboration with ICMR and NIV was instrumental in the development of this vaccine. The proactive support and guidance from DCGI has enabled approvals to this project. Our R&D and manufacturing teams worked tirelessly to deploy our proprietary technologies towards this platform. Expedited through national regulatory protocols, the company accelerated its objective in completing the comprehensive pre-clinical studies. Results from these studies have been promising and show extensive safety and effective immune responses."

Speaking about BBIL expertise, Suchitra Ella, joint managing director had said, "Our ongoing research and expertise in forecasting epidemics has enabled us to successfully manufacture a vaccine for the H1N1 pandemic. Continuing our focus on creating the only BSL-3 containment facilities for manufacturing and testing in India, BBIL is committed to advancing vaccine development as a matter of national importance to demonstrate India's strength in handling future pandemics."