New NDCT Rules offer clarity in guidelines for Indian clinical trial subjects to actively participate in new COVID-19 vaccine trials

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Monday, July 20, 2020, 08:00 Hrs [IST]

India is poised to become a major hub for clinical research as new New Drug and Clinical Trial (NDCT) Rules, 2019 has been able to offer clarity in guidelines for Indian clinical trial subjects to actively participate in new COVID-19 vaccine trials, according to experts. Experts also attribute development of clinical research in India to diverse patient population pool as compared to global patient population.

Clinical trials protocol has today become more streamlined with the coming up of NDCT Rules, 2019 involving a lot of regulatory, economic, skill and subject enrollment interventions and protocols. NDCT Rules 2019 are being fruitful in providing guidance on running clinical trials smoothly in accordance with approved protocol from ethics review boards and regulatory authorities.

According to Dr Sujay Shivaji Patil, clinical researcher, Medical Affairs and Pharmacovigilance Consultant, "Every subject participating in a clinical trial demands safety and confidentiality. As per the new NDCT Rules, 2019, complete information on need for conducting a particular clinical trial in patients is justified and is provided to participants in a subject information sheet. The subject has every right to ask for more information until he or she is satisfied for participation in the trial. Once subject is satisfied, legal confirmation on his enrolment in clinical trial is done by signing the informed consent form (ICF). An audio-video recording of the informed consent process in case of vulnerable subject's participation in clinical trials is required during testing of new chemical entities or new molecular entities."

For HIV and Leprosy trial, only audio recording of the informed consent process would suffice. NDCT rules mentions every subject participating in a clinical trial, the investigator needs to provide adequate medical care to the trial participant for any adverse event occurrence, clinical trial related injury or death. Only one caveat being medical compensation to be provided is based on investigator's judgment in relation to product being tested.

"Compared to other countries, clinical trials are 50 per cent cheaper in India. India has all potential to contribute for the global drug development where nearly 60 per cent are done by pharma companies and rest 40 per cent by the clinical research organisations (CROs). There is a pickup of the clinical trial numbers due to easy regulatory approvals, large patient population and huge market access," explained Dr. Lakshmi Sravanthi M, Assistant Professor, Department of Pharmacology, Sri Satya Sai Medical Hospital And Research Institute, Chennai.

"It generally takes nearly a decade or more for a drug to come to market but in view of health emergency, development of COVID-19 vaccine has entered phase 1 and phase 2 in countries like Russia, US and India," Dr Lakshmi added.

Time required to review clinical trial application for new drugs developed outside is being reduced to 90 days from 180 days and to 30 days for drugs discovered in India. In case, if any Indian discovered drug does not receive approval for clinical trial within 30 days, it is considered an auto-confirmatory approval.

Dr Patil explained, "Every trial needs to be conducted as per International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines and as per approved protocol by the regulatory authority keeping in mind subject safety, confidentiality and rights. There should be minimal to no protocol deviations which would be one of the benchmarks for clinical trial result acceptance."

In India, there are two potential candidates that are about to enter human trials this month. India's Covaxin produced by the Indian Council of Medical Research (ICMR), Bharat Biotech and National Institute of Virology, Pune have started its human trials for the country's first indigenous COVID Coronavirus vaccine. Oxford COVID-19 vaccine began phase III trials on July 1, 2020 and exciting results are expected soon. Moderna vaccine development group also published their interim results from phase I trials last week which revealed sufficient titres of neutralizing antibodies on a 2 dose vaccination schedule 28 days apart.

COVID-19 vaccine called AZD 1222 developed by researchers at Oxford University Jenner's Institute has generated an immune response against the disease in phase-1 trial. These trials began in April 2020 and results are expected to be rolled out soon. Phase 2 and phase 3 trials are still in process.

"This vaccine is one of the leading candidates about to hit market early but as per Astrazeneca CEO the vaccine is likely to provide protection for 1 year. About 2 billion doses are expected to be produced by the company this year end. Other vaccines which are in phase 3 trials which include inactivated vaccine by Sinovac and RNA vaccine by Moderna. A total of more than 130 different vaccine candidates are currently being tested for COVID-19 infection," Dr Patil informed.

"There is a race going on to find a suitable vaccine but it s too early to predict when a vaccine will arrive. Oxford University has conducted a trial on 1,000 patients and confirmed that they have cleared phase IV trial. But still it is hypothetical until and unless it is available in Indian market. As the Indian conditions are different the human trial must be conducted in India to find its efficacy which will take additional time. At present, I can see only convalescent plasma transfusion as an empirical treatment with promising results," Pharma consultant Dr Sanjay Agrawal said.

"In Indian scenario, virus is not similar to what we find in Britain or other parts of the world. This virus is mutating its genome and is different in India. If Oxford University or any other institution is able to develop vaccine, it is great news but first we have to protect those who are already infected and are in serious condition through therapies like convalescent plasma transfusion," Pharma consultant Anshu Yadav said.