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Questionable recruitment practices in Zydus Cadila's COVID-19 vaccine trial

CHAHAT RANA AND AATHIRA KONIKKARA

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A doctor in Guwahati holds a bottle with a COVID-19 vaccine on 28 November 2020. Prime Minister Narendra Modi visited Zydus Biotech Park in Ahmedabad to review coronavirus vaccine development work at facilities. DAVID TALUKDAR/ NURPHOTO/ GETTY IMAGES

In February, messages circulating on Whatsapp announced recruitments for a clinical trial of a COVID-19 vaccine, being conducted at hospitals in Bangalore and Mumbai. The messages did not mention the pharmaceutical company that was conducting the trials, but mentioned a fee that each participant would get and phone numbers of the people to contact. *The Caravan* has found that the texts were intended to recruit people into Indian pharmaceutical company Zydus Cadila's ongoing trial. The contacts listed in the messages were those of recruiting agents who are not part of the company or of the clinical-investigation teams.

Zydus Cadila is conducting a phase-three human trial for its COVID-19 vaccine candidate. The first and second phases of a vaccine clinical trial establish basic safety and immunogenicity—ability to elicit and immune response— in a small, often homogenous group of participants. A phase-

three trial tests the vaccine in a large, more diverse group of volunteers for efficacy. In the case of the vaccine, efficacy is by how much can it reduce transmission or severity of an infection. Zydus Cadila, which began recruitment in mid-January

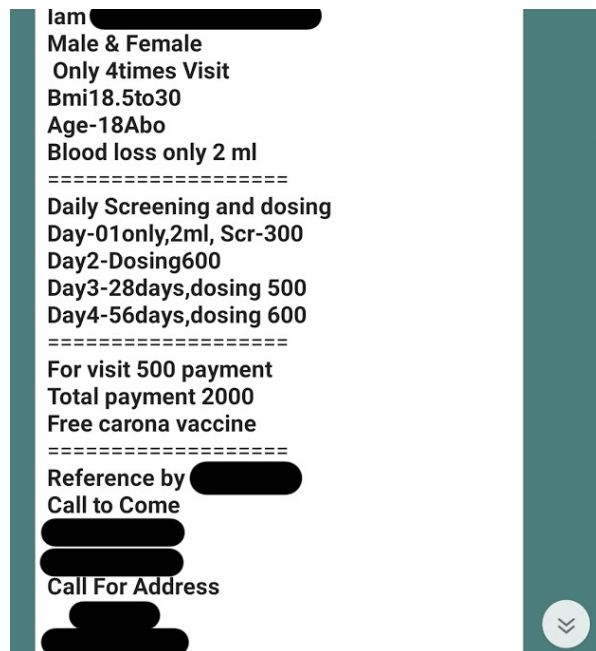
(<https://www.livemint.com/companies/news/zydus-cadila-starts-enrolment-for-phase-3-trial-of-covid-19-vaccine-11611130944188.html>), has said

(https://zyduscadila.com/public/pdf/pressrelease/Zydus_Cadila_receives_approvals_

it aims to recruit 30,000 volunteers for the trial across 45 sites across the country. The trial is randomised, double-blinded and placebo-controlled. The trial protocol uploaded on the Clinical Trial Registry of India said that it is being conducted to test the safety, immunogenicity and efficacy of the vaccine. Zydus Cadila wrote in an email to me that it has not commissioned third parties to conduct recruitments. I contacted the numbers listed on the Whatsapp messages and spoke to middlemen who said they had been commissioned by the company.

A Whatsapp message for recruitment at NRR Hospital promised “Free, Corona vaccine trials” to volunteers from across the country. NRR Hospital is listed as a site for the Zydus Cadila trial in the CTRI. The message said each volunteer would get Rs 500 per visit over four visits—a total of Rs 2,000. It added that a volunteer needed to be older than 18 and to have a body mass index between 18 and 30. The message had contact details of two persons named BK Reddy and Murali Putla. The latter said that he was getting paid by the Zydus Cadila to recruit participants. “We get a commission from the sponsors, we take no money directly from the participants,” he said.

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The WhatsApp message calling for volunteers for Zydus Cadila's COVID-19 vaccine trial at NRR Hospital in Bangalore.

Dr Ravindra Mittal, the principal investigator of the trial and the senior vice president of Cadila Healthcare Limited, told me that he could not comment on the validity of the Whatsapp message without consulting with a central team at Zydus Cadila responsible for trial conduct and recruitment procedures. Mittal said he oversaw the scientific aspects of the study but not recruitment and management. “Until then I am not sure whether we are involved in commissioning in this message,” Mittal said. Later, in an email response, a spokesperson for the company denied commissioning any independent agent or approving of the recruitment message for the trial at NRR hospital. “As a Sponsor, Zydus has not commissioned any agent to recruit the volunteers at any site. We have neither approved any whatsapp message nor submitted any whatsapp message for Ethics Committee approval at any site,” the email said.

India’s clinical trial rules

(https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-

documents/NewDrugs_CTRules_2019.pdf) of 2019 mandate that a trial centre should make all documentation available for the Drug Controller General of India's scrutiny before approval, including those pertaining to procedures to screen and recruit volunteers. The Director General of Health Services' guidelines on good clinical practice (<https://www.cmch-vellore.edu/sites/research/Files/Good%20Clinical%20Practices%20For%20Clinical%20Sponsor%20and%20Investigator%20Guidelines.pdf>) sponsor and / or investigator should seek the opinion of an independent Ethics Committee regarding suitability of the Protocol, methods and documents to be used in recruitment of Subjects and obtaining their Informed Consent including adequacy of the information being provided to the Subjects." Anant Bhan, a bioethics and global-health policy researcher, also said, "All recruitment strategies, including advertisements, should be approved by the ethics committee of the institution."

Reddy, the other contact mentioned in the message for NRR hospital, refused to comment. He referred me to Kiran Rajeeva, a member of Trial Guna, a clinical-research organisation in Bengaluru. Trial Guna offers support for clinical-trial monitoring and site management and according to its website, promises that its "data mining services and analytics approach provides customers with innovative solutions to access patient populations and reduce R&D costs." Rajeeva told me, "Neither I, nor any member of my team here, had anything to do with the message being circulated on Whatsapp. We do not recruit people via such Whatsapp messages. This seems to be the work of illegal and private agents who have no affiliation with our organisation." He said his team recruits trials participants through "word of mouth" and through healthcare workers at the trial site.

I spoke with Dr Ramesh Revanna, the on-site principal investigator and pulmonologist at NRR Hospital. He told me the hospital had nothing to do with the Whatsapp message. He said that, until now, his team had recruited 600 participants through "word of mouth." According to him, many participants were from the nursing school attached to the hospital.

“We give classes to our own healthcare workers explaining the trial and what it entails and all ethical procedures are followed in recruitment,” he said. “These healthcare workers then spread the word amidst family and friends who also come forward.”

Another Whatsapp message for participants for a COVID-19 vaccine trial at Sir Jamshedjee Jeejeebhoy Hospital, or JJ Hospital, in Mumbai provided a contact for Rajesh Rajgor. He told me that the trial was for the Zydus Cadila vaccine candidate and that he was not associated with the company, the hospital, or any clinical-research organisation. He said he had volunteered to recruit participants. Dr Akash Khobragade, an assistant professor at JJ Hospital and the principal investigator for the trial at this site, confirmed that this Whatsapp message had been approved by the hospital’s ethics committee. “This man is a volunteer for the trial and said he can help spread the word through a Whatsapp message and get more volunteers for us. He is not getting any money from us, apart from the travel reimbursement offered to each participant,” Khobragade said.



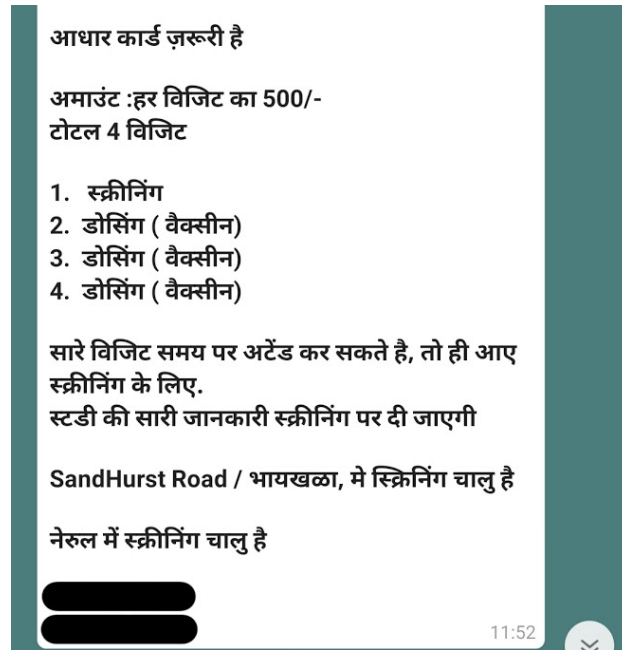
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A WhatsApp message for recruitment in Mumbai into Zydus Cadila's COVID-19 vaccine trial .

The use of agents reduces transparency and accountability in recruitment for a clinical trial. “Use of agents for recruitment purposes is unusual and should be frowned upon, given that they are probably functioning on enhancing the number of participants recruited to get their commission,” Bhan pointed out. Agents may not be aware of legal requirements and ethical practices in recruiting for a trial. While speaking to me, Putla, who has no scientific or medical credentials, claimed that there was no harm in taking part in the trial and participants would only benefit by receiving the free vaccine. His claim has no basis since the aim of the trial is to find out whether the vaccine candidate is safe and whether it works.

In mid-January, Zydus Hospital in Ahmedabad released a recruitment advertisement

(<https://twitter.com/AnantBhan/status/1351582141209956352>) that was circulated on Whatsapp, which called for participants for the trial of an “Ahmedabad based Made in India Vaccine with high efficacy and safety.”

In fact, the trial was to test its efficacy and safety. “No claims about a vaccine’s safety can be made before the trial is completed,” Sandhya Srinivasan, a bioethicist and a contributing editor for the *Indian Journal of Medical Ethics*, said.

Public-health activists also pointed out that using the word “free” in a vaccine trial recruitment message was problematic—that it implied that the vaccine was an approved product that volunteers would have otherwise have to pay for. “The way this message is constructed, the word trial just gets lost and it seems like this is a free vaccine, when it is not,” Amulya Nidhi, a member of the Jan Swasthya Abhiyaan or the People’s Health Movement, said. Bhan said that the recruitment process for a trial should not overplay any particular aspect of the study, such as compensation. “The recruitment should not misconstrue any information with regard to the trial,” he said.

The DGHS’s guidelines on [good clinical practice](https://www.cmch-vellore.edu/sites/research/Files/Good%20Clinical%20Practices%20For%20Clinical%20Trials%20in%20India.pdf) (<https://www.cmch-vellore.edu/sites/research/Files/Good%20Clinical%20Practices%20For%20Clinical%20Trials%20in%20India.pdf>) offering compensation to participants for time spent and expenses incurred, like that for travel to the trial site. However, participants cannot be induced to take part in a trial with large sums of money. The document says, “payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgement.” In *The Caravan’s* January [report](https://caravanmagazine.in/health/in-bhopal-covaxin-trial-volunteers-allege-irregularities-in-recruitment-and-treatment) (<https://caravanmagazine.in/health/in-bhopal-covaxin-trial-volunteers-allege-irregularities-in-recruitment-and-treatment>) about allegations of irregularities in a Covaxin trial in Bhopal, the activist Rachna Dhingra pointed out that the promised Rs 750 was a large inducement for poor families. Similarly, the promise of Rs 2,000 can be an inducement. “What amounts to a large amount is subjective,” Srinivasan said. “But more than that is the language of the message, which seems to advertise money as an incentive, when an official message for recruitment should not

explicitly mention the monetary compensation. Furthermore the fact that the message makes it appear like the participant will receive a free vaccine in the bargain adds to the illegitimacy of it all.”

Further confusion has surfaced in the procedures being followed in the trial. Revanna, the on-site investigator at NRR, told me that a team from Zydus Cadila had audited trial proceedings at NRR Hospital on 17 February. “They found everything to be going as per norms,” he said. However, the Zydus Cadila spokesperson denied that such an audit took place. “The trial has never been halted at NRR Hospital at any stage. There was no audit on 17 Feb 2021 at NRR hospital for this study. Our trials are being conducted as per GCP guidelines in compliance with all the regulatory and ethical norms,” the spokesperson wrote in the email.

The Zydus Cadila vaccine trial has run into other kinds of trouble. On 17 February, five people in Noida were arrested (<https://www.hindustantimes.com/cities/noida-news/five-of-private-lab-in-greater-noida-detained-for-administering-unauthorised-covid-vaccine-to-18-people-101613499298195.html>) for illegally administering the vaccine to 18 people in a lab which was approved to conduct the trial. According to a news report (<https://timesofindia.indiatimes.com/city/noida/up-seven-booked-for-vaccine-trials-at-lab-that-wasnt-registered/articleshow/81081214.cms>), these volunteers were recruited by Nari Raksha Dal, a group in Ghaziabad, who offered a free-vaccine camp to the participants.

Nidhi from the Jan Swathya Abhiyan said that unethical recruitment for trials was common. “This is not a new practice. There is a whole nexus of illegal agents who get commissioned to recruit people. It doesn’t matter what false knowledge they propagate or how much danger this puts potential participants in,” he said.

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