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Quest Life Sciences receives WHO notice: Reports

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Singapore: According to reports, Quest Life Sciences has received a 'notice of concern', or NoC from the World Health Organisation (WHO) for 'critical' lapses and deviations from standards in its clinical trials of HIV drugs.

The WHO's prequalification team had visited the Chennai-based Contract Research Organisation (CRO) Quest's facilities in October 2014 and inspected the clinical trial of Lamivudine, Zidovudine and Nevirapine, a combination of drugs for treating HIV patients.

Reportedly, the team observed lack of data integrity in clinical trial records, failures in protection of subject safety, inadequate quality assurance. The team further said thatÃ?Â 67 percent of the subject pre-study electrocardiograms (ECGs) were duplicates, with the details of the patients and dates having been changed to make the ECGs appear as if they were from different subjects who had participated in the study.

"This means that ECGs may not have been performed or were unreliable and therefore ineligible/unfit subjects could have been used in the study and protocol requirements may not have been met," the WHO said in a statement.

The company has said it will conduct the entire clinical study again at its own cost, to ensure the lifting of the NoC.

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