

Phase III clinical trials of the Cuban vaccine Soberana 02 underway

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Clinical trials of Cuban vaccine underway

Havana, March 11 (RHC)-- Cuba's Center for State Control of Medicines, Equipment and Medical Devices (Cecmed) has begun an inspection of the Phase III clinical trial of the anti-COVID-19 vaccine candidate Soberana 02.

The verification will make it possible to know if the good clinical practices demanded by a study of this complexity are being complied with, as an essential step towards mass vaccination of the population of the Caribbean nation, according to a local TV report.

The Cecmed authorities visited this Wednesday the Clinical Trials Coordination Center, which is in charge of the integral management of the research.

They reviewed the management of information and vital issues such as the functioning of the coordination room and the computer center, where they work with the results in real time of what is happening in the eight municipalities of the capital that are taking part in the trial.

The specialists involved in the investigation stated that they will review all the documentation generated by the study, as well as the activity of the ethics committees and the data monitoring committee and will interview the volunteers who will receive the immunogen dose, to know if they obtained informed consent.

Soberana 02 started its Phase III clinical trial on Monday this week, in which 48 clinical sites in Havana are involved, where the vaccination will be produced, which should reach more than 40 thousand people.

This is the most advanced of the five candidates created by the Cuban biotechnology industry to face COVID-19, all of which are at different stages of their tests in humans to check the immune response and adverse reactions.

<https://www.radiohc.cu/index.php/en/noticias/nacionales/250295-phase-iii-clinical-trials-of-the-cuban-vaccine-soberana-02-underway>



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