

## Phase III Clinical Trials with Soberana 02 in Havana

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The polyclinics 19 de Abril, in Vedado, Plaza and Héroes del Moncada, were chosen as clinical sites for the third phase of the trials for the vaccine candidate Soberana 02, in the municipality of Plaza de la Revolución, which will begin in coming days.

Thus was reported this Monday by Dr. Mayra García Carmenate to the Defense Council of that territory. She is the leading researcher of these clinical studies in Havana, who announced that the universe to be examined is made up of 5,375 volunteers with ages ranging 19-80 years old.

She explained that all participants will undergo rigorous medical examinations, which include a PCR test, and, after vaccination, they will remain for an hour under observation by a staff certified in medical emergencies.

The research subjects will also have in their possession a diary to record these events, so that when they go home they can write down if they ran a fever, felt any pain in the arm, or another of the most frequent symptoms when the population receive any vaccine.

"Today we can be sure that our vaccine candidate is very safe. The adverse events that have been reported are mild pain at the injection site, in the first 24 hours after administration, and in some subjects they feel a little under the weather, but nothing serious. Nor have there been systemic events, such as high fever or sickness that limits the activities of the person, much less hospitalized because of the vaccine," she assured.

Also a meticulous selection process was carried out for the health personnel who will carry out the study to guarantee the standard demanded by the regulatory authority that carries out this procedure.

At the meeting, it was also announced that a group of students from the CUJAE and six professors from the University of Havana will guarantee the storage and management of the data. They will be helped by other 16 students from the Medical School, as support personnel.

The Municipal Defense Council of Plaza de la Revolución will accompany the entire process to guarantee the logistics and anything else they need.

The expert also confirmed that phase III clinical studies will be extended this month to the municipalities of Playa, Centro Habana, Old Havana, Cerro, Marianao, La Lisa, and Diez de Octubre.

Plaza de la Revolución is considered the starting territory of the pandemic, because it was the first in the Cuban capital to report a confirmed case, hence in April 2020 it was chosen for the intervention trial with the VA-MENGOC-BC vaccine, which stimulates the population's natural immunity, and later for the studies of phases I and II of Sovereign 02.

Finally, Dr. García Carmente called to raise awareness because at the moment the most effective "vaccine" is sanitary measures: correct use of the mask, physical distancing, disinfection with chlorinated solution, hygiene of hands and surfaces, and sanitizing shoe mats.

**Translated by: Amikal Labañino Valdés/ Cubasi Translation Staff**