



La science pour la santé
From science to health

COVIREIVAC, the French platform for testing vaccine candidates A one-stop access to the French expertise in vaccinology and to a pool of 25,000 Volunteers for Large-Scale Clinical Trials



COVIREIVAC has now opened the registration process for volunteers to participate in the first large-scale clinical trials in France.

International research is being mobilized in order to develop safe and effective vaccines for COVID-19. Around thirty vaccine candidates are at the clinical evaluation stage, with some undergoing Phase 3 trials to demonstrate their efficacy.

At the request of the French government, France – drawing on the excellence of its clinical research in vaccination – has taken steps to help evaluate the most promising vaccine candidates with the deployment of the COVIREIVAC platform.

Managed by Inserm with the operational help of F-CRIN, COVIREIVAC federates 24 Clinical Investigation Centers (CICs) located in university hospitals across France, in close collaboration with the College of Teachers in General Practice (j'avais traduit dans un document General Practitioners Teaching Association) and its 11 000 members. It also involves a network of clinical immunological research labs to ensure immunomonitoring capabilities throughout the trials. The clinical operational aspects of the various university hospitals are coordinated by the Paris Hospital Group AP-HP.

To make these trials possible, COVIREIVAC is setting up a pool of 25,000 volunteers aged 18 or over and **has launched the registration and information website www.covireivac.fr**. Developed with the support of Public Health France and the National Agency for Medicines Safety (ANSM), it aims to provide the most accurate information possible on vaccine development so that potential volunteers can make an informed decision. The registration process involves filling up a short health and life habit questionnaire that will allow the Covireivac team to quickly identify relevant volunteers for a given research protocol (age, location, preexisting conditions that are Covid-1ç risk factors, professions that are in contact with the general public, etc.)

French research, a key player in developing safe and effective vaccines

Two vaccine clinical trials are currently ongoing in France: a Phase 1 trial in healthy subjects for a vaccine developed by Institut Pasteur in collaboration with CEPI, Themis and MSD which has begun at Cochin Hospital (Paris Hospital Group AP-HP), and a trial targeting healthcare workers on the contribution of the BCG vaccine to boosting systemic immunity and protection against COVID-19, which is coordinated by AP-HP.

Two types of large-scale clinical trials are envisaged in France. The first is Phase 2 trials to closely study the ability of vaccines to produce an immune response (immunogenicity) in elderly people, whose immune system is generally weakened despite being most at risk of developing severe forms of the disease. The second is Phase 3 trials for the large-scale study of the efficacy and safety of promising vaccine candidates, depending on the intensity of the virus' circulation in France in the months to come. The phase 2 immunogenicity trials can be conducted separately or as ancillary studies in phase 3 trials.

The platform is scaled to conduct up to 3 phase 3 trials and up to 5 phase 2 trials.

These clinical trials could start between October and the end of the year, depending on the evolution of the epidemic and the ongoing discussions with industry.

In addition to the follow-up and monitoring of the volunteers during the trials, a specific system for monitoring participants will be set up by the platform at the end of the trials, in conjunction with primary care doctors and ANSM. This monitoring will therefore make it possible to track the safety of the vaccines over the long term.

"Good clinical trials are crucial for the development of safe and effective vaccines. As researchers and doctors, we are all committed to rigorous evaluation that will provide the health authorities with the essential data to guarantee the quality of the vaccines developed. What we now need is volunteers to mobilize alongside us," emphasizes Odile Launay, Professor of Infectious and Tropical Diseases at Université de Paris, coordinator of Cochin-Pasteur CIC at Cochin Hospital (AP-HP), and coordinator of COVIREIVAC.

On 1st October, COVIREIVAC opened the registration process for volunteers to participate in large-scale clinical trials in France.

Within 48 hours, more than 20 000 volunteers had started the registration process and more than 15 000 volunteers had already completed it.

Targeted communications will continue in the next few days and weeks to make sure the pool can meet the criteria of various research protocols for several trials conducted in parallel

COVIREIVAC, a "one-stop shop" for France

The COVIREIVAC platform is working in close collaboration with the Scientific Committee for COVID-19 Vaccines, chaired by Inserm Research Director and CARE Committee member Marie-Paule Kieny. The clinical trials conducted will focus on the most promising vaccines, selected by the Scientific Committee.

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