

Paris, October 1, 2020

## Press information

### COVID-19 Vaccines: 25,000 Volunteers Needed for Large-Scale Clinical Trials in France - Registration Now Open



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 Ministry of Solidarity and Health and the Ministry of Higher Education and Research, 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. Driven by Inserm, COVIREIVAC federates 24 Clinical Investigation Centers (CICs) located in university hospitals across France, in close collaboration with the College of Teachers in General Practice. The clinical operational aspects of the various university hospitals are coordinated by the Paris Hospital Group AP-HP. Today, COVIREIVAC opens the registration process for volunteers to participate in the first large-scale clinical trials in France.

To make these trials possible, COVIREIVAC is looking for 25,000 volunteers aged 18 or over and **has launched the registration and information website** [www.covireivac.fr](http://www.covireivac.fr). Developed with the support of Public Health France and the Medicines Agency (ANSM), it aims to provide the most accurate information possible on vaccine development so that potential volunteers can make an informed decision.

### **Join the fight**

Volunteers in COVID-19 vaccine trials have a role to play in fighting the pandemic, moving research forward and thus contributing in the medium term to their own protection and that of their fellow citizens - particularly the most vulnerable. Becoming a volunteer also means participating in a scientific challenge alongside the scientific and medical community.

If you are interested in volunteering, simply pre-register at [www.covireivac.fr](http://www.covireivac.fr) and complete a preliminary health questionnaire. Volunteers will then be contacted according to the needs of the various trial protocols (age, pre-existing conditions, geographical location), following which they can either confirm or withdraw their agreement to participate in the specific trial for which they have been called. It is also possible that they may never be called.

### **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 in 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 trial 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.

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.

*"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.

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.

### **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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