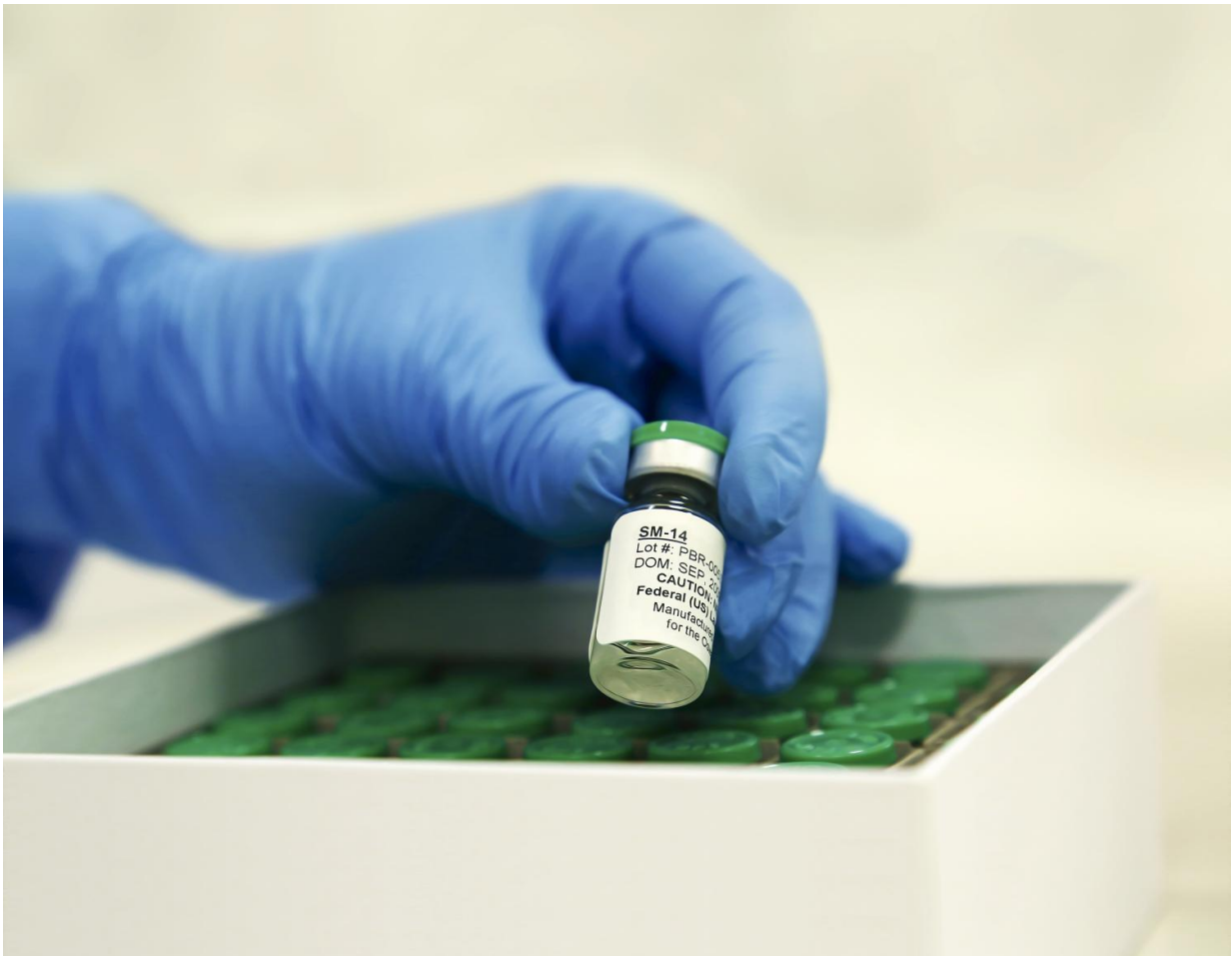


Novel schistosomiasis vaccine: New phase of clinical studies

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The schistosomiasis vaccine was developed by Fiocruz, Brazil. Credit: Gutemberg Brito/IOC/Fiocruz

The Oswaldo Cruz Foundation (Fiocruz) at Rio de Janeiro, Brazil, will start the phase II clinical trials of a vaccine for schistosomiasis, called 'Sm14 Vaccine'. The initiative is one of the health research and development projects prioritized by the World Health Organization (WHO), aiming to ensure the access of populations from developing countries to public health tools based on cutting edge technologies. The phase II clinical studies will be carried out in a partnership involving Fiocruz, public foundation attached to the Brazilian Ministry of Health, and the Brazilian biotechnology company Orygen Biotecnologia S.A..

One of the most socioeconomically devastating parasitic diseases, second only to malaria, schistosomiasis, also known as snail fever, infects more than 200 million people worldwide, according to WHO, mainly in developing countries. Related to precarious sanitary conditions, the disease is endemic in more than 70 countries, where 800 million people live at risk of infection, especially in Africa.

Novel vaccine

Developed and patented by the Oswaldo Cruz Institute (IOC/Fiocruz), the vaccine was produced from a single antigen, that stimulates the production of antibodies and prevents the parasite that causes the disease to install in the patient's organism and cause damage. The Sm14 protein, synthesized from the *Schistosoma mansoni* worm that causes schistosomiasis in Latin America and Africa, was the basis of the vaccine.

"This is the first time that a parasite vaccine produced with cutting edge Brazilian technology reaches phase II clinical studies. We are working to contribute to face a public health problem that affects poor populations in various parts of the world "says Miriam Tendler, researcher at the Laboratory of Experimental Schistosomiasis of the IOC, who leads the study.

Based on a breakthrough technology, the Sm14 Vaccine has patents deposited in Brazil, Europe, United States, Australia, Japan, New Zealand, South Africa, Canada, Cuba, Egypt and India, in addition to the African intellectual property organizations ARIPO and OAPI.

"This vaccine represents a combination of significant values. It brings together scientific expertise and transforming capacity, leading to a process of innovation aimed at solving a neglected disease, with very significant global impact. It is the first for the disease in the world, being the result of an initiative with deep roots in Fiocruz, lead by researcher Miriam Tendler. It is also a result of exemplary public-private partnerships, "says Paulo Gadelha, President of Fiocruz.

The final step of the development of the Sm14 Vaccine is the target of a public-private partnership (PPP) between Fiocruz and Orygen Biotecnologia S.A., now a partner in the development and production of the human vaccine.

"This research may bring a huge social and scientific impact for Brazil, which is the main mission of Orygen since its creation. Sm14 is one of the initiatives that show the ability of Brazilian innovation and we are proud to participate actively in this project, "says Andrew Simpson, Scientific Director of Orygen Biotecnologia S.A..

Prioritization by the World Health Organization

The contrast between developed and developing countries in health technological inputs is a major concern of WHO. In 2010, the World Health Assembly announced the creation of a working group with expert advisors in funding and coordination of scientific research and development, called CEWG. In May 2013, the CEWG released a strategic plan of action in order to give developing countries access to platforms for the solution of chronic [public health](#) issues specific to

those countries. A few months later, the Group made public a preliminary list with 22 candidate projects and in December 2013 it announced the 7 + 1 innovation projects, selected to be supported politically and strategically by the Cooperative Fund managed by WHO - among them, the Sm14 Vaccine.



This image shows a snail that transmits schistosomiasis. Credit: Gutemberg Brito/IOC/Fiocruz

A particularity related to the Sm14 Vaccine is the fact that it shifts the paradigm of technology transfer that traditionally follows a vertical logic where the northern hemisphere 'provides' knowledge to the [southern hemisphere](#). Sm14 inaugurates a horizontal premise, where the southern

hemisphere develops a technology for the southern hemisphere, starting with the Brazil-Africa collaboration in phase II clinical trials of the schistosomiasis vaccine.

Phase II Clinical Studies

Phase II A clinical studies will be conducted in adults living in the schistosomiasis endemic region in Senegal, Africa, an area that is hit simultaneously by two species of the parasite *Schistosoma*. This feature, which does not exist in any Brazilian region, is very important to evaluate the safety of the Sm14 Vaccine in an expanded scope comprising these two agents. The chosen area is hyperendemic, i.e. has high prevalence rate of the disease, which affects the population continuously. In this step of the research, the safety of the product will be evaluated, as well as its ability to induce immunity in vaccinated people. It is planned the participation of 350 volunteers, initiating with adults and including children during the three planned stages of phase II.

While the phase I clinical studies have been conducted with healthy volunteers in non-endemic areas, in the phase II studies the volunteers will be residents of endemic areas, who have already had contact with the disease, which reflects the actual situation where the [vaccine](#) will be used. The Sm14 Vaccine will be administered in three doses, with intervals of one month between each one.

The phase II A clinical study will be carried out in partnership with the non-governmental organization of Senegal Espoir pour La Santé, being coordinated in the field by Gilles Riveau, from the Pasteur Institute of Lille, in France, and General Director of the Centre de Recherche Biomedicale Espoir pour La Santé.

"This phase will be conducted by an internationally respected institution, in a modern laboratory, staffed by highly qualified professionals," says

Tendler.

Independent audits by local institutions are planned, following the international rules of research with humans. These audits will also include monitoring by an Advisory Council composed of experts from several countries. The clinical tests will take place between September and December 2016, which corresponds to the period of highest endemicity of the disease in the African territory. Both the research protocol and the regulatory documentation were submitted to Senegalese authorities. The results of the study are expected in 2017.

"We are proud of the important contribution that the Sm14 Vaccine represents, not only for its innovative scientific characteristics, but also for its innovation in the creative flow, since it shows that a country with an endemic disease is able to generate a technology that responds to a challenge, at the same time, local and global. This is, in fact, performing science for society," says Wilson Savino, Director of the IOC.

Expectations

In the phase I [clinical studies](#), which had the results published in January 2016 on the international scientific journal "Vaccine", the researchers had already demonstrated the specific mechanisms of the immune response elicited by the Sm14 Vaccine: activation of antibody response and of the Interferon-gamma cytokine, which is produced by the body in response to the infectious agent. Now the experts will map the mechanisms that confer protection from the disease.

Cases of schistosomiasis occur in environments where there is no proper sanitation services: feces of people infected with the Schistosoma worm, when dumped inappropriately in rivers and other fresh water courses, can infect snails of the genus Biomphalaria. In turn, the snails release larvae of the worm in the water, potentially infecting people through

skin contact, restarting the cycle of the disease.

"Vaccination has the potential to disrupt the cycle of transmission of schistosomiasis. The Sm14 Vaccine was developed to induce a long lasting immunity", says Tandler.

Provided by Oswaldo Cruz Institute

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