



PRESS RELEASE
For immediate release

IVI and Mozambique's INS launch mix-and-match COVID-19 vaccine study

- Study will assess the safety and immunogenicity of a heterologous regimen of two approved COVID-19 vaccines in adults
- Aims to mitigate vaccine shortages and support flexible immunization programs

December 20, 2021, SEOUL, Republic of Korea; MAPUTO, Mozambique; OSLO, Norway – The International Vaccine Institute (IVI), Mozambique's Instituto Nacional de Saúde (INS), and the Coalition for Epidemic Preparedness Innovations (CEPI) announced today the start of a Phase II mix-and-match trial in Mozambique to investigate a prime-boost regimen using two different COVID-19 vaccines. Vaccination schedules where the second dose is not necessarily the same as the first would allow for more flexible immunization programs in the event of vaccine shortages and may potentially elicit broader protective immune responses.

The study, led by INS with support from trial sponsor IVI and funded by CEPI, will assess the safety and immunogenicity of a two-dose schedule using Sinopharm's BBIBP-CorV and Johnson & Johnson's Ad26.COV2.S vaccines administered 28 days apart compared to a homologous prime-boost regimen. Both vaccines are approved and currently part of Mozambique's COVID-19 vaccine rollout program.

Dr. Florian Marks, Deputy Director General at IVI and IVI Principal Investigator, said: "Demonstrating the safety and efficacy of a mixed schedule of COVID-19 vaccines will have a significant impact on ensuring timely vaccinations and controlling the pandemic, particularly in the regions most affected by vaccine shortages. Amid an ongoing global pandemic with inequitable and interrupted access to vaccines, it is vital to make available a good, or potentially even better, alternative to the homologous dose schedules we have relied on so far."

Dr. Ilesh Jani, Director of the INS and Mozambique's Principal Investigator, said: "The Sinopharm and Johnson & Johnson vaccines are widely used in many African nations and assessing the safety and efficacy of this mix-and-match combination will facilitate a flexible and more efficient rollout of COVID-19 vaccines in Africa."

Dr Melanie Saville, Director of Vaccine Research & Development at CEPI, said: "This trial will generate valuable data about a mix-and-match combination of two vaccines which are being rolled out in many countries in Africa. It will support our efforts to expand access to vaccines by bringing greater flexibility to vaccination campaigns on the continent and beyond during periods of vaccine scarcity or uncertain supply."



This Phase II trial is a single-center, observer-blind, randomized study to assess the safety and immunogenicity of heterologous prime-boost regimens compared to homologous prime-boost using BBIBP-CorV and a single dose of Ad26.COVS COVID-19 vaccines given intramuscularly in adults 18-65 years old. A total of 360 eligible participants will be enrolled in the study with follow-ups until 48 weeks after the second vaccination.

This trial is part of the ECOVA project to expand access to COVID-19 vaccines in Africa, a \$12.7M USD CEPI-funded project led by IVI with consortium members: INS, the International Centre for Diarrhoeal Disease Research (icddr,b), the University of Heidelberg, Harvard Medical School, and the University of Antananarivo.

The ECOVA project is one of a series of programmes funded by CEPI which aim to address current gaps in clinical knowledge of vaccine performance both now and in the long term, in order to expand access to COVID-19 vaccines as part of the global vaccination rollout. This funding forms part of CEPI's next 5-year plan, published in March 2021, which aims to strengthen our defenses against COVID-19 and reduce or even eliminate the future risk of pandemics and epidemics.

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About the International Vaccine Institute (IVI)

The International Vaccine Institute (IVI) is a nonprofit inter-governmental organization established in 1997 at the initiative of the United Nations Development Programme (UNDP). IVI has 36 countries and the World Health Organization (WHO) on its treaty, including the Republic of Korea, Sweden, India, and Finland as state funders.

Our mandate is to make vaccines available and accessible for the world's most vulnerable people. We focus on infectious diseases of global health importance such as cholera, typhoid, shigella, salmonella, schistosomiasis, chikungunya, group A strep, Hepatitis A, HPV, TB, HIV, MERS, COVID-19, as well as antimicrobial resistance. For more information, please visit <https://www.ivi.int>

About Instituto Nacional de Saúde (INS)

The Instituto Nacional de Saúde is the National Public Health and Research Institute in Mozambique, an autonomous public entity that functions under the umbrella of the Ministry of Health.

The mission of the INS is to improve the well-being of the Mozambican people through the generation of scientific and technological solutions for public health problems in Mozambique. The INS implements programs and projects on endemic infectious diseases, emerging infectious diseases, non-communicable diseases and health systems. For more information, please visit www.ins.gov.mz. Follow us via Twitter: @instituto_ins and Facebook: facebook.com/ins.gov.mz.



CEPI

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19 CEPI's work focused on developing vaccines against Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus – it has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).

During the current pandemic, CEPI initiated multiple programmes to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale and access. These programmes leverage the rapid response platforms developed by CEPI's partners prior to the emergence of COVID-19 as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 candidates and to enable fair allocation to these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a \$3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a universal vaccine against COVID-19 and other *Betacoronaviruses*, and create a “library” of vaccine candidates for use against known and unknown pathogens. The plan is available at <http://www.endpandemics.cepi.net>.

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