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Consortium set to further establish vaccine safety evidence-generation network in Africa

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Establishing vaccine safety benchmarking in Africa for African vaccines



A research consortium is set to further establish a vaccine safety evidence-generation network in Africa, seeking to understand the general prevalence of anticipated adverse events specifically relevant to African populations.

Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) is providing up to $9.9 million for the *Background Rates of Adverse Events for Vaccine Evaluation in Africa* project led by the Global Vaccine Data Network (GVDN)—based at Auckland UniServices Limited in the University of Auckland—in partnership with the University of the Witwatersrand in South Africa, Navrongo Health Research Center in Ghana, International Foundation Against Infectious Diseases in Nigeria, Eagle Research Center in Rwanda, and Health Research Operations Kenya (operating as KEMRI-Wellcome Trust Research Programme) in Kenya.

CEPI funds will support local researchers across these research sites to understand incidence rates of naturally occurring clinical events, such as Guillain-Barré Syndrome, sensorineural hearing loss, and others, that typically occur in African populations (i.e., without any medical interventions).

With this baseline data, or background rates, researchers in Africa will then be able to evaluate whether an adverse event reported in a vaccine trial may be associated with the vaccine—an adverse event of special interest (AESI)—or is coincidental and occurs at a rate within expected background levels in the general population.

This comprehensive monitoring—specific to African populations—helps set expectations for what might be expected when the vaccine is rolled out more widely, minimising the risk of trials being halted or public confidence in the vaccines being undermined. Crucially, this data enables regulatory authorities to make informed decisions about vaccine safety on its path to approval and roll-out.