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CEPI

Fighting outbreaks with FEEVA: New project could support faster approvals of infectious disease vaccines

MELBOURNE/SYDNEY/OSLO, 23 JULY 2025—Australian scientists will kickstart research into how early vaccine studies can safely support faster approvals of vaccines in response to infectious disease outbreaks.

FEEVA (a Framework for Evidence Evaluation in Vaccine Assessment) is a new collaborative project led by the Kirby Institute at UNSW Sydney and the Australian Living Evidence Collaboration (ALEC) at Monash University supported by up to US $3m funding from global health organisations CEPI and Wellcome.

The first-of-its-kind initiative will work with immunologists, vaccine developers and regulators to explore how early evidence on a vaccine's efficacy could be reviewed by regulators alongside robust safety data to support potential early deployment in an outbreak.

Typically, late-stage trials involving thousands of participants are used to assess the efficacy of a vaccine and guide regulatory approvals. However, with the world looking to respond more rapidly and equitably to outbreaks in as little as 100 days, large-scale efficacy trials may not be possible in the first few months after an outbreak emerges as there may be too few confirmed cases. Early efficacy data can instead be gathered from research in cells, tissues and preclinical models, as well as human challenge trials and observational studies that track the natural course of a disease.

Hon Professor Jane Halton, Chair of the CEPI Board, says: "During a deadly disease outbreak, every day without a vaccine costs lives. This innovative partnership aims to speed up vaccine development and approval when each day counts, accelerating access to vaccines during future epidemics and pandemics."

"Data from early preclinical and clinical studies could help move away from efficacy trials to the pre-agreed use of early immune markers for accelerated development and approvals of vaccines", explains **Dr Adam Hacker, Director and Global Head of Regulatory Affairs and Quality at CEPI**. "However, there are currently no harmonised guidelines on how to determine the importance of different and often complex sources of evidence that get produced from these early vaccine explorations, consequently limiting the intended use of these studies to fasttrack authorisation of an outbreak vaccine to 100 days."

The FEEVA Team will develop a voluntary toolkit that researchers, vaccine developers, regulators and policymakers can use as a standardised way to both grade the evidence for vaccine effectiveness arising from these non-traditional trial designs and plan how studies can run ahead of an outbreak to get the right data. In an outbreak, regulators and health officials can use the tools to review early available vaccine data and, depending on the outbreak's size, severity and impact, guide potential emergency approvals of a vaccine based on benefit-risk scenarios.

"The response to an infection outbreak involves teams working across the research spectrum, from developing laboratory tests to studying immunity to running clinical trials. However, the process for

assessing and integrating the results of these studies is not always clear. The FEEVA project aims to ensure we can make the best use of all of the available evidence to inform the development and use of vaccines" says **Professor Miles Davenport, Head of the Infection Analytics Program at the Kirby Institute, UNSW Sydney**.

"COVID-19 showed how exposed a globalised world is to infectious diseases, and the lifesaving importance of vaccines and pandemic preparedness. This critical work will help regulators and researchers to assess the quality of non-clinical research as part of the body of evidence of vaccine effectiveness. In doing so, it will help deliver effective vaccines to people faster", says **Professor Tari Turner, ALEC Academic Director, Monash University**.

In addition to outbreak diseases, FEEVA will provide a critical tool to evaluate evidence from studies of endemic diseases, such as paratyphi A, for which large-scale efficacy studies may also be unfeasible due to their size, complexity or duration.

Debbie King, Research Lead in the Infectious Disease team at Wellcome, says: "Bringing more safe and effective vaccines to the market is vital for managing and preventing infectious disease outbreaks. Currently there is a bottleneck in the vaccine pipeline, with later-stage trials requiring large numbers of participants and long periods of follow-up resulting in high costs. Testing if these vaccine candidates work and are safe in humans is a step that cannot be by-passed, but by enabling early-stage data to be consistently evaluated, we are increasing the chance of developing and delivering potentially life-saving vaccines to the people most in need. Without this innovation, these vaccines may not get made, resulting in otherwise preventable deaths."

The development of the framework will also be supported by the FEEVA researchers reviewing previous examples of vaccine approvals in the absence of human efficacy data, such as the approval of Janssen's Ebola Zaire vaccine based on preclinical and immunogenicity findings.

The guidelines will be made available online and open-access so that all experts around the world can follow the same vaccine assessment framework.

FEEVA will run for four years. The work will be reviewed and guided by external expert and consultation panels and overseen by a Steering Committee.

ENDS

Notes to Editors

- CEPI will provide up to $1.9 million funding to FEEVA. Wellcome will provide up to $1.1 million.
- Both CEPI and Wellcome will sit on the FEEVA Project Steering Committee and will be actively involved in broader project discussions.
- Researchers, vaccine developers, regulators and policymakers who would like more information about the project are invited to contact the FEEVA team via email: feeva@kirby.unsw.edu.au

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 60 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.

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