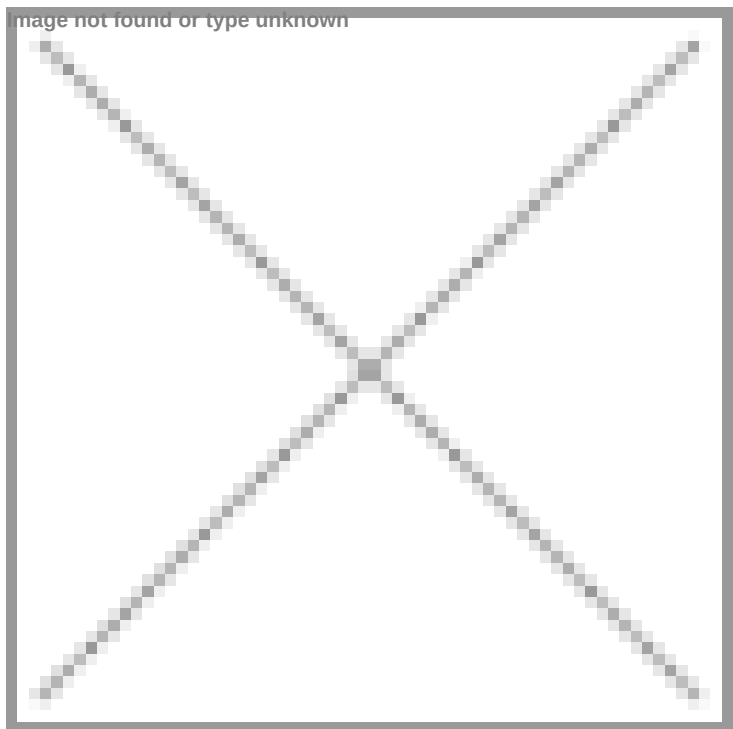


New project in Australia to support faster approvals of vaccines

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First-of-its-kind initiative will work with immunologists, vaccine developers and regulators



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 \$3 million funding from global health organisations- Coalition for Epidemic Preparedness Innovations (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.

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.

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.