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Korea's IVI to develop adaptive Ph 1b/2a schistosomiasis vaccine trial

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The grant is a Trial Planning Grant, part of the Gates Foundation's Design, Analyze, Communicate (DAC) programme



The International Vaccine Institute (IVI) in South Korea has announced that the Bill & Melinda Gates Foundation has awarded a grant to IVI to develop an adaptive trial design protocol for a Phase 1b/2a clinical trial of schistosomiasis vaccine.

The grant is a Trial Planning Grant, part of the Gates Foundation's Design, Analyze, Communicate (DAC) programme which supports grantees in optimising clinical studies for informativeness and impact. The goal of IVI's schistosomiasis vaccine project is to advance the development of a safe, effective, and affordable vaccine to reduce morbidity and mortality from schistosomiasis in moderate- to high-transmission settings.

Dr Florian Marks, Deputy Director-General of Epidemiology, Public Health, and Impact at IVI, said, "We are grateful to the Gates Foundation for their support and guidance in planning an adaptive Phase 1b/2a clinical trial for a schistosomiasis vaccine candidate which would accelerate the clinical development timeline as well as licensure and pre-qualification processes."

Dr Thea Norman, Leader of the Design, Analyze, Communicate programme, said, "IVI is an exemplar of the type of partner that DAC Program looks for. IVI was an early adopter of our trial planning grants, is operating out in the field in low-resource settings, and now adds an approach to answer more questions during a trial."

IVI's schistosomiasis vaccine project has successfully sourced funding from the National Institute of Allergy and Infectious Diseases (NIH) and EU Horizon 2020 to support Phase 1 clinical trials of the SchistoShieldÒ vaccine. These trials include a first-in-human safety study in healthy American adults at an NIH Vaccine and Treatment Evaluation Unit followed by a Phase 1b safety and immunogenicity placebo-controlled study in healthy adults in Burkina Faso and Madagascar. With this Trial Planning Grant from the Gates Foundation, the IVI team will be able to adapt the Phase 1b study design, which could help speed up the clinical