Background There remains an urgent need for a prophylactic HIV vaccine to control generalised epidemics. PeP has demonstrated effectiveness of 86% and is recommended by WHO; uptake is generally high, but retention is disappointing in some settings. The EDCTP2 project PePvacc will assess the efficacy of two combination prophylactic vaccine regimens (DNA, MVA and Env protein/adjuvant) each compared to placebo and the proportion of infections averted by F/TAF in comparison to TDF/FTC. A Registration Cohort, recruiting HIV negative volunteers at risk of HIV will precede the trial.

Methods The PePvacc partnership agreed that 70% vaccine efficacy had public health relevance. The trial uses available. This innovative adaptive trial design uses validated software to determine vaccine efficacy and a novel methodological approach to uncertain-