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of Maternal Immunization on Foetal Outcomes
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Title: Strengthening quality assurance in clinical research in resource-constrained settings: The ethical imperative to develop, implement, and evaluate ancillary care policies

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Background PregInPoxVac is a Phase 3, open-label trial evaluating the safety and immunogenicity of subcutaneous MVA-BN vaccination in pregnant women in Boende, DR Congo. To assess maternal, foetal and neonatal outcomes (including miscarriage, stillbirth, and congenital infection), 362 pregnant women aged 16–35 years were enrolled and randomised 3:2 to receive two MVA-BN doses 28 days apart, either before 32 weeks' gestation or within 72 hours postpartum. Given access to care constraints in the study setting, an ancillary care (AC) framework was developed and incorporated into trial design to address unmet healthcare needs beyond trial procedures, and to strengthen the study's quality assurance through enhanced adverse event collection and monitoring.

Methods Between 27 June 2025 and 16 April 2026, 477 adverse events were reported during 430 unscheduled visits by 212 participants (58.6%). The most frequent events were influenza like illness (n=122), urogenital infections (n=109), mild preterm labour threat (n=73), malaria (n=44), and gastrointestinal illness (n=33). Most events were mild (n=439), six were severe, none leading to withdrawal. No event was assessed as vaccine related. AC interventions included direct medical care and provision of 917 concomitant medications.

Conclusion These findings demonstrate a high burden of maternal morbidity and highlight the ethical and scientific value of integrating AC in settings with access to care constraints. AC provisions not only contribute to participant retention and wellbeing, but also improve adverse event reporting, timely clinical management, and data completeness, thereby strengthening the validity of safety assessments in maternal immunization trials in resource-constrained settings.