

PPB Issues Guidance for Clinical Trials Impacted by COVID-19

Kenya's Pharmacy and Poisons Board (PPB) has issued [Guidance to Sponsors and Investigators for Conduct of Clinical Trials during the COVID-19 Pandemic in Kenya](#), which takes effect April 20, 2020. The guidance addresses the following topics:

- Management of and amendments to existing trials
- Restarting a trial that has been halted
- Providing the investigational medicinal product (IMP) to trial participants
- Reporting of serious adverse events (SAEs), and submission of annual safety reports (DSURs) and end of trial notifications
- Protocol deviations, serious breaches, and waivers
- Risks/benefits of conducting trials that may impact a participant's immune system
- Signatures and alternate methods of demonstrating approval

The guidance also discusses expedited review of new studies relating to COVID-19, including parallel ethics and regulatory review, which usually is not allowed.

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