Ethics, regulatory and pharmacovigilance

PO - (8254) - LESSONS LEARNT FROM SCALING UP OF AN ONLINE SYSTEM FOR REVIEW AND MANAGEMENT OF PROTOCOLS IN SUB-SAHARAN AFRICA

Ngongo, Prince Bahati (Kenya); Kombe, Francis (Kenya); Kamali, Anatoli (Kenya); Ijsselmuiden, Carel (Switzerland)

1 - International AIDS Vaccine Initiative; 2 - Council on Health Research and Development

Background: The transition from paper-based to online ethic submission of health research protocols using the RHinnO Ethics (RE) platform has been shown to improve efficiency and quality of reviews. However, despite these documented benefits, there are only a total of 40 installations in 12 out of the 54 countries in Africa. We analyzed facilitators and barriers to adoption of RE.

Methodologies: We used a retrospective analysis to identify determinants of adoption or rejection of RE by grouping feedback from users into key emerging themes identified through three stages of RE adoption: 1) contractual 2) Trial 3) Full implementation.

Results: A total of 3947 protocols have been managed through RE by March 2018. Of those reached, twenty-five percent (25%) adopted and continue to use RE. Of those that rejected, fourteen percent (14%) rejected after the trial. At the contractual stage, the key determinants of adoption were the guarantee of sustainable funding, pre-existing good IT infrastructure, and the assurance of technical assistance from the providers. The key determinants of rejection were concerns of cyber security, limited control and ownership by RECs and cost of the annual subscription. At the trial stage, the determinants of continued adoption and use were continued IT support from providers and a proven comparative advantage over the paper-based system. The key determinant of rejection was limited support from organization leadership. Those who have continued through the implementation stage emphasized financial sustainability and continuous improvement of the RE as key determinants.

Conclusion and Recommendations:

Accelerated adoption of RE will require increased adaptability of the platform, decrease in cost of annual subscription, improved confidence in security and ownership of data. Developers, RECs and sponsors of RE need to develop a cost-effective funding strategy in order to increase efficiency, economies of scale and benefits related to harmonized and standardized digital platforms.