CAN AUTOMATED REVIEW PLATFORMS IMPROVE THE EFFICIENCY OF AFRICAN RECS

In 2012, COHRED developed a cloud-based online ethics review platform, known as the Research for Health Innovation Organiser (*RHInnO Ethics* — www.rhinno.net), with initial funding from the Mapping African Research Ethics Review and Medicines Regulatory Capacity (MARC) project, provided by the European and Developing Countries clinical Trials Partnership (EDCTP). *RHInnO Ethics* was developed based on feedback from REC's and is intended to replace the current, complex paper based review system, and to improve the REC's efficiency and quality of reviews.

RHInnO Ethics is designed to facilitate, manage and track research applications throughout the research projects' life cycle. It allows online submission of research protocols to RECs, distribution of protocols to reviewers, communication between the REC and researchers, follow-up including amendments, reporting of severe adverse events and renewal of annual ethics clearance. *RHInnO Ethics* has been adopted by 8 countries through a combination of government financial mechanisms and support from international institutions such as COHRED, EDCTP and the International AIDS Vaccine Initiative (IAVI).
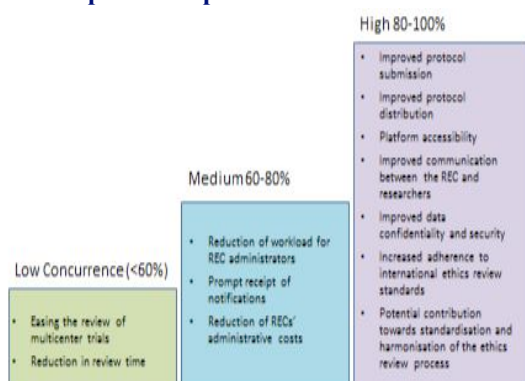
IMPACT OF RHINNO ETHICS

COHRED and IAVI evaluated its initial impact on REC efficiency in terms of improving the ethics review timelines, data security and REC operational costs. The evaluation used an online questionnaire administered to REC administrators/chairpersons. Both quantitative and qualitative data were collected. The REC's interviewed were diverse. They included membership of 9-46 members that reviewed between 50 – 2000 protocols annually, including observational, investigational new drugs and diagnostics. 100% of REC's queried responded. However the majority of those (80%) had used *RHInnO Ethics* for 1 year or less. Reported areas of impact were classified as having high- (81%-100%), medium- (60%-80%) and low-concurrence (<60%) of respondents.

WORK-STREAM EFFICIENCY

The vast majority of REC's reported that *RHInnO Ethics* had a positive influence on work stream efficiency, even after a relatively short period of use. More than 80% of users reported that both protocol submission and protocol distribution were made easier as a result of the elimination of multiple paper copies. 60-80% of REC's reported a reduction in both administrative workloads and administrative costs. The platform accessibility and usability, for both reviewers and submitters, helped contribute to these findings. One respondent commented that these work-stream efficiencies would be bolstered with expanded usage, "it will be a plus if more committees in other African countries are to see the benefit of this platform and the added value with simultaneous submission and review of multicenter trials".
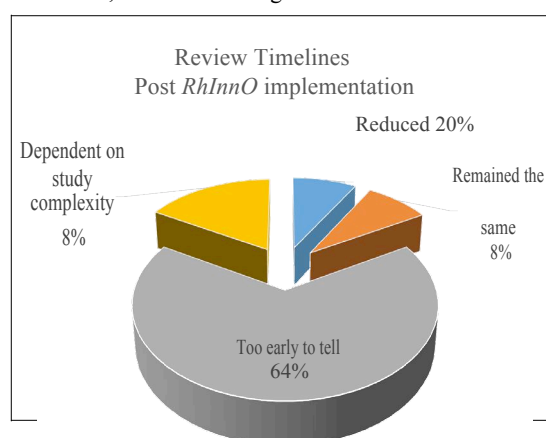
Areas of reported Impact

STANDARDIZATION

RHInnO Ethics was positively reported to impacting adherence to international ethics review standards and had a potential contribution towards standardisation and harmonisation of the ethics review process. One respondent commented: "Our country has multiple national and institutional REC's and each of these committees have different operating procedures and submission requirements. By using *RHInnO Ethics*, we can move towards harmonization of the ethics review process."

REVIEW TIMELINES

One of the areas where we anticipated *RHInnO Ethics* would have a significant short-term impact was with review timelines. However, given that 80% of REC's interviewed had used the platform for a year or less, most (64%) reported that it was too early to see any impact on review timelines. Nevertheless, 5 REC's who had used the platform for > 2 years, indicated a reduction in review timelines of approximately 56% of all studies, both low and high risk.

Review Timelines Post *RhInnO* implementation — Reduced 20%; Remained the same 8%; Too early to tell 64%; Dependent on study complexity 8%

KEY RECOMMENDATIONS

1. For policy makers - Facilitate policies and efficient approvals to move from paper-based to automated technology based review platforms.
2. For Ethics and Regulatory Bodies – ensure standardization of automated review platforms and cross-functionality between Research Ethics Committees (RECs) and National Regulatory Authorities (NRAs) to optimize efficiency.
3. For researchers - Ensure compliance to inbuilt quality assurance and control mechanisms to international standards.
4. For research sponsors and funders - Ensure sustainable support It should read: Ensure optimal pricing for annual maintenance fees which remain a key barrier to *RHInnO Ethics* adoption.
5. For *RHInnO Ethics* developers: Optimize functionality of *RHInnO Ethics* to generate administrative reports, relevant statistics and M&E indicators to RECs and NRAs, develop mechanisms for country capacity and transition to country ownership of databases.

REFERENCES

1. Maïga D, Akanmori BD, Chocarro L. Regulatory Oversight of Clinical Trials in Africa: Progress Over the Past 5 Years. *Vaccine.* 2009; 27: 7249–7252.
2. Benator SR. Towards progress in resolving dilemmas in international research ethics. Journal of law, medicine and ethics. 2004; 32:574-582.
3. Mokgatla B, IJsselmuiden CB, Marais D, Wassenaar DR. Mapping African ethical review committee activity onto capacity needs: The MARC Initiative and HRWeb's interactive database of RECs in Africa. Developing World Bioethics. 2012; 12: 74–82