SCRECU

Scaling up of Capacity of Research Ethics Committees in Uganda

EDCTP
European & Developing Countries
Clinical Trials Partnership

European Union

project partners

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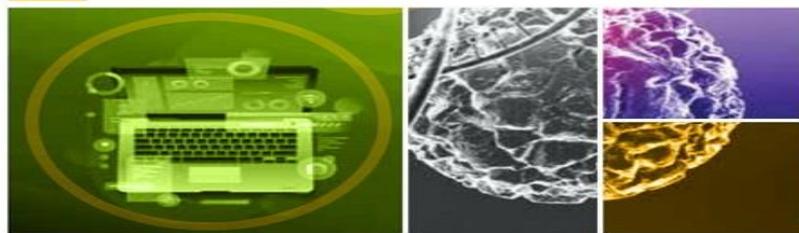
Policy brief No. 2

Policy brief on the rollout and implementation of a National Research and Information Management System (NRIMS) in Uganda

Executive Summary

The Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) project [EDCTP; CSA2015ERC-863], which preceded the Scaling Up of Capacity of Research Ethics Committees in Uganda (SCRECU), developed a protoype of a clinical trials information management system (CRIMS) which was upgraded to National Research Information Management System (NRIMS) under the EDTCP supported successor Scaling Up of Capacity of Research Ethics Committees in Uganda (SCRECU).

The SCRECU project trained and equipped 26 RECs with IT facilities and made regular follow-ups to support them. Feedback from the RECs was gathered regularly through virtual meetings and the embedded chat platform. The feedback was then used as the basis for system updates, patches, and continuous improvement of the platform.

All the REC chairpersons, administrators and IT personnel who have been trained in the use of NRIMS for management of submissions, review and feedback processes, approvals, and post-approval processes are now using NRIMS. The NRIMS have registered over 10,000 researchers, received over 6,000 with over 2,500 approvals granted online. The NRIMs, which is currently hosting over twelve thousand local and international researchers provides a one-stop center for research management in Uganda.

Regional regulatory agencies such as Mathari in Kenya and College of Medicine REC-University of Malawi have already adopted NRIMS.

The UNCST is on the path to becoming a national and regional Centre of Excellence (CoE) status on Research Regulations and Management. However, the national regulatory agencies (NRAs), and policy makers need to leverage the real-time data generated through NRIMS to carry out analytics and generate evidence that inform policy.

1.0   Introduction

The Uganda National Council for Science and Technology and partners implemented the Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) project funded in 2017 by the European & Developing Countries Clinical Trials Partnership (EDCTP). The project that was concluded in June 2019 developed a Clinical Trials Information Management System (CRIMS) meant to improve clinical trial management in the country. CRIMS aimed at harmonizing standards of the in-country approval across all regulatory agencies as well set up an online and sustainable platform for review and approval of a clinical trial. The initiative to build the CRIMS with the ability to address the needs of the regulatory agencies was to enable integration and harnessing of the research potential whilst protecting the safety, rights, and welfare of the individual study participants, community, researcher, sponsor, and the country at large.

In order to encompass all research, Social Sciences, Agricultural Sciences, Physical Sciences, Engineering and Technology, and the Medical and Health Sciences; the CRIMS, which was developed under the CREDU, was upgraded to a National Research Information Management System (NRIMS) in November 2019. However, an outstanding challenge was that after the system was fully developed the Research Ethics Committees (RECs) were not able to tap into and use it for the purposes and good intentions it was built to accomplish.

In a bid to address this shortcoming, the Uganda National Council for Science and Technology (UNCST) in collaboration with Mbale Regional Referral Hospital and Busitema University has been implementing a two-year project funded by the European Developing Countries Clinical Trials Partnerships (EDCTP) titled, Scaling Up of Capacity of Research Ethics Committees in Uganda (SCRECU).

The main objective of the project is to build sustainable capacity for the NRIMS framework for all the RECs in Uganda with capabilities of facilitating multi-REC ethical review of research, national registration of research, and subsequent monitoring of approved studies by research ethics committees in Uganda.

CONTEXT AND IMPORTANCE OF THE PROBLEM

Key issues

In line with the above objective, SCRECU trained REC Administrators and IT personnel and equipped them with tablet computers.

There was need to follow-up the RECs to ascertain the impact the intervention and the adoption of NRIMS was making and to evaluate the adoption and the effectiveness of CRIMS nationally. This is meant to enable the generalization and potential adoption of the system in the east African region.

METHODOLOGY

The project team made regular follow-ups to support the 26 research ethics committees. Feedback is gathered regularly gathered through virtual

meetings and the embedded chat platform. The feedback is then used as the basis for system updates, patches, and continuous improvement of the platform.

2.0   Findings

In the course of the follow-up visits, the team found out the following:

i. All the 26 accredited Research Ethics Committees (RECS) were using the NRIMS and that all the REC administrators and IT support had been trained in the use of NRIMS for management of submissions, review and feedback processes, approvals, and post-approval processes.

ii. The NRIMS had registered over 10,000 researchers (UNCST and 26 RECs).

iii. Over 6,000 applications had been received through the NRIMS.

iv. Over 2,500 approvals had been granted online.

v. Regional regulatory agencies such as Mathari in Kenya and College of Medicine REC-University of Malawi have already adopted NRIMS

2.1   Challenges

The following challenges that need to be addressed for the better rollout and implementation of a National Research and Information Management System (NRIMS) were identified.

i. Weak capacity among the national regulatory agencies and policy makers to leverage real-time access data generated through NRIMS to perform prompt and quick data analyses for decision-making.

ii. Inadequate ability to leverage the outputs from the NRIMS to inform policy

iii. The NRAs do not involve Policy Analysts in the research clearance and management processes. ⌜L⌟⌜SEP⌟

2.2   Lessons Learnt and outcomes

i. There is increased efficiency in the institutional workflows such as facilitation of working remotely for staff and stakeholders within the regulatory system.

ii. Increased growth of the UNCST Internet presence.

iii. Increased demand for UNCST services has positioned UNCST on a path to a Center of Excellence for service provision in research and grant management in the region.

iv. Improved efficiency and reduction of response times to clients and stakeholders with at least 50 percent reduction of approvals turnaround time.

v. Reduction of paperwork by over 95 percent. Before the project, Principle Investigators (PIs) were previously required to submit as many copies of their research proposal as the number of members of a REC. This has reduced cost in printing and courier for both researchers and UNCST.

vi. RECs Quorum has improved with over 90 percent of the RECs recording 100 percent quorum for meetings in the last 1 year.

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vii. PIs now respond to comments in a period of 1-4 days compared to the average was 4 weeks before the project.

POLICY RECOMMENDATIONS

The following recommendations have been provided for maximizing the benefits of the NRIMS

i. The national regulatory agencies (NRAs) need to support the NRIMS in order to facilitate continuity of research regulation workflows amidst the pandemic thereby guaranteeing the safety of the regulatory officers while allowing research activities to continue.

ii. The NRAs and policy makers need to leverage NRIMS, which now provides Real-time access to data so that they can perform prompt and quick analyses and make inferences for reporting and decision-making.

iii. Regulator and individual institutions should utilize the NRIMS for Data Analytics

iv. UNCST should support the roll out of NRIMs within the region as other Regional regulatory agencies such as Mathari in Kenya and the College of Medicine REC-University of Malawi have already adopted it.

3.0   Conclusions

The NRIMS is providing a one-stop center for research management in Uganda. It supports online research submissions, reviews, approvals, and post-approval processes. NRIMs is currently hosting over Twelve thousand local and international researchers.

Regional regulatory agencies such as Mathari in Kenya and College of Medicine REC-University of Malawi have adopted NRIMS.

The fact that other regional regulatory agencies are now benchmarking with the UNCST on NRIMs with the aim of adopting it as a platform for research management in their respective jurisdictions underscores importance of NRIMS and the success of the SCRECU project. This places UNCST on the path to a national and regional Centre of Excellence (CoE) status on Research Regulations and Management.

References

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