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PP122 Strengthening Ethics Compliance In A Large Research Program: Uganda

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INTRODUCTION:

The infectious Diseases Institute (IDI) is a research institute at the College of Health Sciences, Makerere University. Over the years, the number of research studies has greatly increased with an average of fifty active studies per year**.** Because of the voluminous study activities, investigators were faced with inadvertences of ethical approval deadlines (1). In 2015, a centralized electronic Regulatory Affairs Information System (RAIS) was developed and piloted to track the regulatory process of the entire research projects. RAIS is a web-based system, developed using a Net framework and runs on any operating system using a web browser such as "Google Chrome" and "Mozilla Firefox".

METHODS:

A signed approval letter from an accredited Research Ethics Committee, National Drug Authority and Uganda National Council of Science and Technology, the reviewed protocol, consent forms and data collection tools are uploaded electronically into the RAIS with study staff contact information, CVs and Good Clinical Practice (GCP) certificates. RAIS sends automatic "no reply" emails to the investigators and research administration notifying for the need of annual renewal 56, 28 and 14 days before the expiry date of the approvals. The investigator or designated person prepares the application package which is then forwarded to the Research Regulatory Officer for review and submission to the regulatory authority.

RESULTS:

From January 2015 to November 2016, fourty-three ongoing studies were uploaded to the RAIS of which eleven were clinical trials, twenty-one observational studies, seven diagnostic and four implementation studies. Studies that obtained their annual approvals before the expiry date was 90.7 percent, compared to 29 percent that had reported early submission for annual renewal between January 2013 and December 2014. RAIS has enabled continuity of study activities with timely annual renewed approvals, supported the tracking of staff GCP certificates and populated timely notifications to investigators, resulting in submission of annual application packages on time.

CONCLUSIONS:

RAIS has strengthened ethical regulatory compliance and provided an effective platform for tracking regulatory processes, thus enabled continuity of study activities with timely annual renewal approvals and greatly supported the tracking of staff GCP certificates.

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PP124 The HTAi Vortal: A Comparative Analysis

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