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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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INTRODUCTION:

The HTAi Vortal is a product of the HTAi Information Retrieval Group (IRG) which has collected resources in the field of Health Technology Assessment (HTA) since 2005.

In 2011, a new technical platform was set up and the legacy Vortal content was split in three sections: HTA producers and networks, Selected references and Career development (including trainings). The same year, a fourth section was created to host a new product of the IRG: SuRe.info.

In 2014, the Vortal added a new service to other Interest sub groups of HTAi: the hosting of "Custom bibliographies". But while the Vortal was probably quite unique in 2005, other Websites have been developed since then to offer quite similar functionalities.

The present communication aims at evaluating how the Vortal compares with similar tools existing on the Web.

METHODS:

Vortal competitors have been identified using a quick empirical search of the Web.

Functionalities have been identified by testing the website or their archive; maintainers have been sometimes contacted to ask for complementary information. A grid listing all functionalities has been established and filled in with the collected information.

RESULTS:

Several competitors have been identified. The Vortal presents functionalities similar to online tools, but detailing level is different. Also, the Vortal provides a better integration resulting in more efficiency. And, the Vortal is the only Web platform to offer a service of publication of custom bibliographies to the different HTAi Interest Sub Groups.

CONCLUSIONS:

After 12 years of existence, the HTAi Vortal is still a recognized online resource about HTA. While some existing functionalities are to be found in other online tools, some remain unique to the Vortal. Further research is needed to evaluate the preferences of people with interest in HTA.

PP125 Evidence-based Policy Making – Bottom-Up Heuristic Engagement Process

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INTRODUCTION:

Solid organ and hematopoietic cell transplantation are some of the more expensive procedures universally paid by the public Brazilian Unified Healthcare System (SUS). Transplanted patients depend on maintenance immunosuppression to prevent death or graft loss. A bottom-up heuristic process proposed new immunosuppression drugs for incorporation into the SUS.

METHODS:

Systematic evidence synthesis and Brazilian transplantation registries base-cases, Kaplan-Myer survival and economic assessments were presented in specialized national congresses with open public Delphi sessions to build professional Clinical and Therapeutic Protocols (PCDT) by consensus. Five consensus transplantation PCDTs with a SUS perspective budget impact and sensitivity analysis were submitted to the Health Ministry SUS Technology Incorporation National Commission (CONITEC) plenary for a decision. PCDTs were publicized in CONITEC Internet and *Diário Oficial da União, an,* official periodic publication, as well as undergoing widespread dissemination through mailings for Public Consultation. Public contributions were added to PCDTs to support Health Ministry policy making.

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