reported collateral effects, such as gastroesophageal reflux, headaches and dizziness. One study evaluated the effect of nifedipine on LESP and one on esophageal emptying. Nifedipine decreased LESP, but there was no effect on esophageal emptying.

CONCLUSIONS:

The available evidence shows isosorbide is effective in the management of gastrointestinal symptoms. Frequently health care of Chagas disease patients is delivered by primary care physicians. So, information on effectiveness of interventions can be aggregated to clinical guidelines, having an important value to inform general practitioners on the decision-making process regarding treatment of this group of patients, avoiding referencing to a specialized care.

REFERENCES:

1. WHO (2016) *Chagas disease (American trypanosomiasis)*. Available at: http://www.who.int/mediacentre/factsheets/fs340/en/ (Accessed: 13 January 2017).

2. Matsuda NM, Miller SM, Evora PBR. (2009) The chronic gastrointestinal manifestations of Chagas disease, Clinics (Sao Paulo), 64(12):1219–1224.

PP120 Health Technology Assessment Framework To Capture The Full Value Of Value Added Medicines

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INTRODUCTION:

Value added medicines (VAM) are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers through drug repositioning, drug reformulation or drug combination (1-3). Recently, the European Commission, through the Safe and Timely Access to Medicines for Patients (STAMP) program, considered the issue of VAM development and regulatory process. Current Health Technology Assessment (HTA) tools may not fully capture the benefits of VAM, which could lead to obstacles for patient access to VAM in several European countries (1). The study objective was to identify how HTA frameworks should evolve to reflect VAM value.

METHODS:

HTA expert interviews were performed as a preparatory step to an advisory board meeting. The following topics were addressed: (i) Eligibility for HTA and early HTA dialogues; (ii) Attributes that should be considered in HTA; (iii) HTA methodology; and (iv) Involvement of stakeholders in HTA.

RESULTS:

VAMs bring additional benefit to patients and society. Therefore, the possibility for VAM assessment on a voluntary basis and within the appropriate assessment patterns/tools should be, in principle, included into HTA frameworks, as well as into early HTA dialogues. HTA should be patient-centric, and attributes such as patient preference, adherence, and patient reported outcomes should be considered where relevant. Unmet patient needs and disease burden should be used in a transparent and reproducible deliberative process. All these attributes should be used as explicitly and meaningfully weighted appraisal modifiers. HTA methodology should be comprehensive and should integrate societal perspectives. Patient representatives should take part in the decision-making process.

CONCLUSIONS:

Current HTA frameworks should evolve to enhance VAM value recognition and encourage industry investment in medicines with high potential value for society.

REFERENCES:

1. Toumi M, Rémuzat C. Value added medicines: What value repurposed medicines might bring to society? *J Mark Access Health Policy.* 2017;5(1):1264717.

https://doi.org/10.1017/S026646231700277X Published online by Cambridge University Press

2. Murteira S, Ghezaiel Z, Karray S, Lamure M. Drug reformulations and repositioning in pharmaceutical industry and its impact on market access: reassessment of nomenclature. *J Mark Access Health Policy*. 2013 Aug 6;1. doi: 10.3402/jmahp.v1i0.21131.

3. Dudley J, Berliocchi L. *Drug Repositioning: Approaches and Applications for Neurotherapeutics*. Boca Raton, FL: CRC Press, Taylor & Francis Group; 2017.

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.

REFERENCES:

1. Ochieng J, Ecuru J, Nakwagala F, Kutyabami P. Research site monitoring for compliance with ethics regulatory standards: review of experience from Uganda. *BMC Med Ethics.* 2013;14:23. doi: 10.1186/1472-6939-14-23.

PP124 The HTAi Vortal: A Comparative Analysis

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