



# Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional medicine regulatory harmonization in East Africa (PROFORMA)

2<sup>nd</sup> Newsletter (March 2019 to February 2021)

## PROFORMA coordinating team



Project coordinator



Financial coordinator



Project manager

PROFORMA ([www.proforma.ki.se](http://www.proforma.ki.se)) is a five-year project funded by EDCTP2 (<http://www.edctp.org/>). The aim is to strengthen the National pharmacovigilance infrastructure and post-marketing surveillance system in Ethiopia, Kenya, Tanzania, and Rwanda. The PROFORMA model aims to establish collaboration between National Medicine Regulatory Authorities, Public Health Programs, and local Medical universities for sustainable pharmacovigilance systems capacity building to monitor medicine safety.

### The 4<sup>th</sup> Annual PROFORMA consortium meeting

The 4<sup>th</sup> Annual PROFORMA consortium meeting was held virtually between 3<sup>rd</sup> & 5<sup>th</sup> February 2021, hosted by Karolinska Institutet. During the three-day event, PROFORMA project progress report and activities conducted under the six project work packages in Ethiopia, Kenya, Tanzania, and Rwanda was presented and discussed. In total 45 project members participated in the online event.

The National pharmacovigilance plan developed based on the findings from the baseline assessments, and the strategic interventions introduced so far in each country was presented and discussed. Results from the active safety and efficacy surveillance of mass drug administration for the prevention and control of schistosomiasis and soil-transmitted helminths (in Ethiopia and Rwanda), and lymphatics filariasis (in Kenya and Tanzania) were presented by the PROFORMA PhD students and discussed.

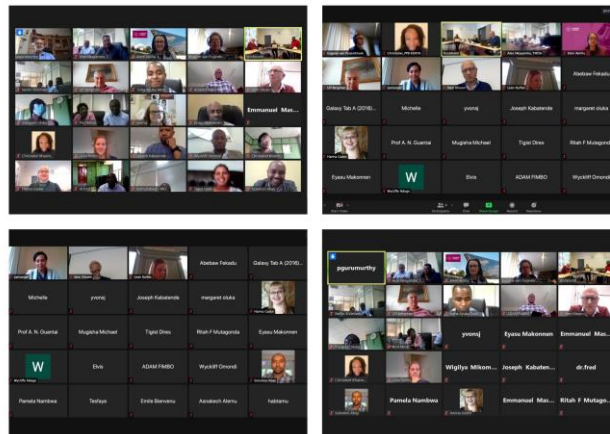


Figure 1. Online participants on the 4<sup>th</sup> Annual PROFORMA consortium meeting

### Pharmacovigilance capacity building

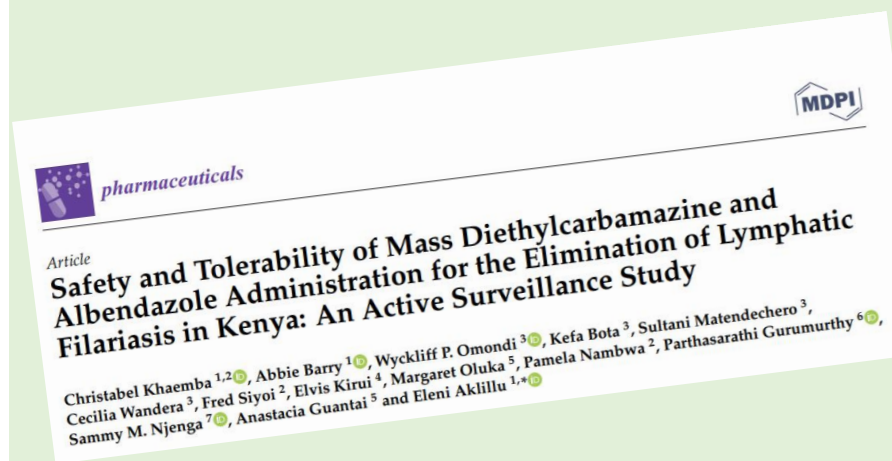
To generate a cohort of pharmacovigilance trained human resources, PROFORMA project is providing short- and long-term training in pharmacovigilance to healthcare providers and regulatory staffs. Currently a total of 12 post graduate students (7 PhDs + 5 MScs) are being trained in pharmacovigilance, clinical trials regulation and post-marketing surveillance.

PROFORMA project developed pharmacovigilance curriculum for undergraduate students. The undergraduate curriculum received accreditation by local medical universities and integrated as a one-week standalone examinable course for final year students at the University of Rwanda, University of Nairobi, and University of Rwanda.

The PROFORMA pharmacovigilance E-learning developed for healthcare professional is adopted by local medical universities and is being used for pre-service and in service teaching.

## Active surveillance of mass drug administration / immunization

In each of the four participating east African countries, PROFORMA is conducting active safety surveillance of one targeted mass drug administration (MDA) for treatment and prevention Neglected Tropical Diseases (NTDs) and one newly introduced vaccine. Active safety surveillance was done in more than 40,000 individuals who received MDA for the prevention and control of NTDs in Ethiopia, Kenya, Tanzania, and Rwanda.



PROFORMA conducted a large-scale prospective active safety surveillance study to identify the incidence, type, severity, and risk factors for adverse events following MDA of single dose diethylcarbamazine and albendazole in 10,010 participants from Kilifi County, Kenya.

Results of the active safety surveillance of dual therapy for the prevention and control of lymphatic filariasis conducted in Kenya is published (*Pharmaceuticals* 2021: Mar 15;14(3):264. doi. 10.3390/ph14030264).

Data analysis from the active surveillance of triple therapy with ivermectin, diethylcarbamazine and albendazole in Kenya is ongoing. Likewise, data analysis for the safety surveillance of ivermectin and albendazole for control of lymphatic filariasis in Tanzania, and safety surveillance of praziquantel and albendazole for prevention of schistosomiasis and soil-transmitted helminths in Ethiopia and Rwanda are ongoing.

## COVID-19 vaccine safety surveillance

The PROFORMA project is engaged in supporting the national medicine regulatory authorities in Ethiopia, Kenya and Rwanda to conduct active and passive safety surveillance of COVID-19 vaccine.

## The 3rd PROFORMA Annual PV training

The 3rd PROFORMA pharmacovigilance training on “Signal Detection and Management” was held online over a period of five days between 27th January to 12th February 2021. The training was given by Professor Eugene van Puijenbroek and Dr Lean Rolfes from The Netherlands Pharmacovigilance Centre Lareb. The training was delivered through lectures, group assignments and scientific papers discussion, in which the two main methods of signal detection were applied: ‘case series analysis’ and ‘statistical signal detection’.

A total of 48 individuals working at the national medicine regulatory authorities, medical universities, the neglected tropical diseases programs and immunization programs, healthcare professionals and pharmacists from Ethiopia, Kenya, Tanzania, and Rwanda participated in this training. A certificate of attendance was issued to participants after completion of the training.

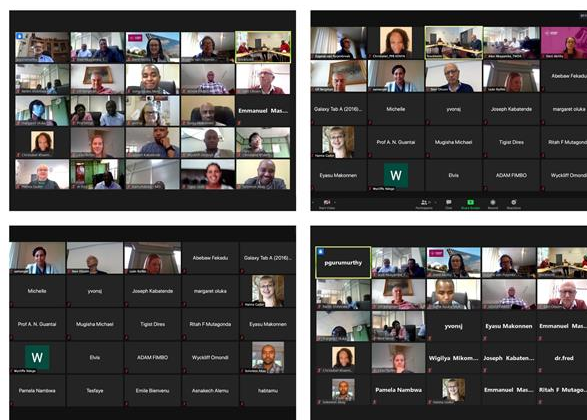


Figure 2: Online participants on the 3rd PROFORMA Annual Pharmacovigilance training

## PROFORMA Publications

1. Barry, A., Olsson, S., Minzi, O. *et al.* Comparative Assessment of the National Pharmacovigilance Systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania. *Drug Saf* **2020**, 43, 339–350. <https://doi.org/10.1007/s40264-019-00898-z>
2. Fimbo, A.M.; Minzi, O.M.S.; Mmbando, B.P.; Barry, A.; Nkayamba, A.F.; Mwamwitwa, K.W.; Malishee, A.; Seth, M.D.; Makunde, W.H.; Gurumurthy, P.; Lusingu, J.P.A.; Kamuhabwa, A.A.R.; Aklillu, E. Prevalence and Correlates of Lymphatic Filariasis Infection and Its Morbidity Following Mass Ivermectin and Albendazole Administration in Mkinga District, North-Eastern Tanzania. *J. Clin. Med.* **2020**, 9, 1550. <https://doi.org/10.3390/jcm9051550>
3. Gebreyesus, T.D.; Tadele, T.; Mekete, K.; Barry, A.; Gashaw, H.; Degefe, W.; Tadesse, B.T.; Gerba, H.; Gurumurthy, P.; Makonnen, E.; Aklillu, E. Prevalence, Intensity, and Correlates of Schistosomiasis and Soil-Transmitted Helminth Infections after Five Rounds of Preventive Chemotherapy among School Children in Southern Ethiopia. *Pathogens* **2020**, 9, 920. <https://doi.org/10.3390/pathogens9110920>
4. Kabatende, J.; Mugisha, M.; Ntirenganya, L.; Barry, A.; Ruberanziza, E.; Mbonigaba, J.B.; Bergman, U.; Bienvenu, E.; Aklillu, E. Prevalence, Intensity, and Correlates of Soil-Transmitted Helminth Infections among School Children after a Decade of Preventive Chemotherapy in Western Rwanda. *Pathogens* **2020**, 9, 1076. <https://doi.org/10.3390/pathogens9121076>
5. Khaemba, C.; Barry, A.; Omondi, W.P.; Bota, K.; Matendehero, S.; Wandera, C.; Siyoi, F.; Kirui, E.; Oluka, M.; Nambwa, P.; Gurumurthy, P.; Njenga, S.M.; Guantai, A.; Aklillu, E. Safety and Tolerability of Mass Diethylcarbamazine and Albendazole Administration for the Elimination of Lymphatic Filariasis in Kenya: An Active Surveillance Study. *Pharmaceuticals* **2021**, 14, 264. <https://doi.org/10.3390/ph14030264>
6. Barry, A.; Olsson, S.; Khaemba, C.; Kabatende, J.; Dires, T.; Fimbo, A.; Minzi, O.; Bienvenu, E.; Makonnen, E.; Kamuhabwa, A.; Oluka, M.; Guantai, A.; van Puijenbroek, E.; Bergman, U.; Nkayamba, A.; Mugisha, M.; Gurumurthy, P.; Aklillu, E. Comparative Assessment of the Pharmacovigilance Systems within the Neglected Tropical Diseases Programs in East Africa—Ethiopia, Kenya, Rwanda, and Tanzania. *Int. J. Environ. Res. Public Health* **2021**, 18, 1941. <https://doi.org/10.3390/ijerph18041941>

### Upcoming events/activities

- 5<sup>th</sup> PROFORMA Annual consortium meeting: 7<sup>th</sup> – 11<sup>th</sup> February 2022 in Addis Ababa, Ethiopia
- 4<sup>th</sup> PROFORMA annual pharmacovigilance training: 2<sup>nd</sup> – 18<sup>th</sup> February 2022 in Addis Ababa, Ethiopia

For more information about the PROFORMA project, visit the project website.

<https://proforma.ki.se/>

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