



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

1st Newsletter (March 2018 to May 2019)

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PROFORMA (<https://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 systems in Ethiopia, Kenya, Tanzania, and Rwanda. The PROFORMA model aims to establish collaboration between National Medicine Regulatory Authorities (NMRAs), Public Health Programs (PHPs) and local Medical Universities to work together for sustainable public medicine safety monitoring.

The PROFORMA consortium constitutes:

Five Medical Universities: Karolinska Institute, Muhimbili University of Health and Allied Sciences, University of Rwanda, Addis Ababa University, University of Nairobi

Four National Medicines Regulatory Agencies (NMRAs): Tanzania Medicines and Medical devices Authority, Kenya Pharmacy and Poisons Board, Food, Ethiopian Food and Drug Administration and Rwanda FDA, and WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting - Lareb.

PROFORMA kick-off meeting was done in collaboration with another EDCTP2 funded project called Pharmacovigilance Africa (PAVIA) on 30th April 2018 in Dar es Salaam, Tanzania.



PROFORMA and PAVIA consortia members

Since the kick-off meeting, PROFORMA has done various activities during Period 1.

In country PROFORMA launch

The PROFORMA project started on 1st March 2018. The project was launched in all the four participating East African countries; Tanzania, Ethiopia, Kenya and Rwanda. The aim of the in-country PROFORMA launch was to introduce project objectives and initiate activities. The PROFORMA in country launch was well attended by relevant stakeholders including the Minister of Health, Vice Chancellor of local partner Universities, director of PHPs, Director General of the regulatory authorities and many others across the different medical and pharmaceutical disciplines. The in-country launch was followed by the baseline assessment of National Pharmacovigilance systems and infrastructure (Work Package 2: Baseline survey of the pharmacovigilance situation in each of the four countries).



PROFORMA & PAVIA launch in Tanzania, July 2018



PROFORMA & PAVIA launch in Ethiopia, August 2018



PROFORMA launch in Kenya, October 2018



PROFORMA launch in Rwanda, December 2018

National Pharmacovigilance Baseline Assessment (Work package 2)

The baseline assessment of the Pharmacovigilance systems and infrastructure in all the four participating African countries was completed in 2018. Aims of the assessment was to identify the strengths, gaps and pharmacovigilance capacity building priorities at a national level as well as to define the elements of a sustainable pharmacovigilance strategy and skills required to support the regulatory functions. The baseline assessment included NMRAs, PHPs, Health Facilities and Marketing Authorization Holders. Assessment reports were submitted to the respective NMRAs. Based on the identified gaps, national PV roadmaps have been developed that include comprehensive interventional measures aligned with the local needs and priorities for implementation.

Assessment of the current Pharmacovigilance teaching practice was done in each PROFORMA participating medical universit in East Africa. The aim was to identify gaps for improvement and needs for the development of undergraduate and postgraduate PV curriculum for future adoption into medical institutions.

Active surveillance of mass drug administration / immunization (Work package 4)

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.

Country	MDA (NTD) surveillance	Vaccine surveillance
Tanzania	Ivermectin & Albendazole (Lymphatic Filariasis)	HPV Vaccine
Ethiopia	Praziquantel & Albendazole (Schistosomiasis)	HPV Vaccine
Kenya	Diethylcarbamazine citrate & Albendazole Vs. Ivermectin, Diethylcarbamazine citrate & Albendazole (Lymphatic Filariasis)	Measles & Rubella Vaccine
Rwanda	Praziquantel & Albendazole (Schistosomiasis)	Measles & Rubella Vaccine

Active Cohort Event Monitoring

Safety surveillance following MDA in about 10,000 people, and drug efficacy, pharmacokinetics and pharmacogenetics studies in infected individuals were done in Kenya, Tanzania, Ethiopia and Rwanda.

For the vaccine pharmacovigilance, about 10, 000 vaccinees will be followed actively for up to one-month post vaccination.

Five PhD students, registered at Karolinska Institutet, are working on this project.

Two MSc students are also registered at University of Nairobi and Addis Ababa University.



Training of data collectors in Jomvu, Kenya (November, 2018)



Informing the School children about the study. (Rwanda, 2018)



Laboratory technicians screening for Schistosomiasis in Rwanda (February 2019)



Night blood screening for Lymphatic Filariasis microfilaria in Tanga, Tanzania (November, 2018)



ToT training - HPV vaccine surveillance. (Ethiopia, 2018)



Community sensitization in Tanga, Tanzania (November, 2018)

Tanzania and Kenya have completed the data collection for the safety monitoring in 10,000 and 20,000 respectively. Data collection for the safety of the HPV vaccine (1st dose) and MDA is currently on-going in Ethiopia. The active surveillance for the MDA in Rwanda is planned to start in March 2019, this is because that is when the MDA for Schistosomiasis is scheduled.

Completed events/activities in Period II

- Annual meeting is from 13th – 17th May 2019 in Kigali, Rwanda
- PV training course I: 20th – 24th May 2019 in Kigali, Rwanda



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

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