



## PROFORMA PROJECT

### BACKGROUND

PROFORMA project is a five (5) years project which was instigated in March, 2018 and will run until February 2023. It is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP), a funding mechanism under the EU's Horizon 2020 research program.

The PROFORMA project focuses on building functional and sustainable national pharmacovigilance systems in Ethiopia, Kenya, Rwanda and Tanzania, allowing safe introduction of new products for the treatment of Poverty-Related Diseases. The initial phase of the project will consist of thorough analysis of the current status, operation and outcome/impact of the pharmacovigilance programmes in the four countries. This will involve a consideration of the presence and status of pharmacovigilance in the legal and regulatory system, the healthcare service, the pharmaceutical supply chain, the Public Health Programmes, and by general media and by civil society and consumers.

### OBJECTIVE

The primary objective of PROFORMA is to build the local pharmacovigilance capacity and post-marketing surveillance of drugs deployed under mass drug administration (MDA) and immunization in public health programmes of the participating East African countries. This will be done through short and long-term training of staff of national medicines regulatory authorities (NMRAs). A comprehensive pharmacovigilance programme in mass treatment and immunization programmes will be developed to monitor the public safety and detect adverse events on time. Active cohort surveillance and cross-sectional observational studies to monitor the safety and efficacy of drugs selected by the NMRA's will be conducted as part of providing support to the respective national drug authorities.

Drugs to be monitored through PROFORMA project will be selected by the respective national public health programmes and NMRAs taking into consideration the national needs and priorities of each participating East African country.

### WORK PACKAGES

The project will be implemented under 6 work packages:

- Work Package 1:** Co-ordination and organizational aspects of PROFORMA to ensure delivery on time and adherence to budget.
- Work package 2:** Baseline survey of the pharmacovigilance situation in each of the four countries.
- Work package 3:** Strengthening national pharmacovigilance systems in the selected countries.

**Work package 4:** Post marketing surveillance of medicines and vaccines deployed by Public Health Programmes in mass administration campaigns.

**Work package 5:** Short and long term training in pharmacovigilance

**Work package 6:** Communication and Dissemination



*Members of PROFORMA and PAVIA projects posed for a group photo at Kunduchi Beach Hotel in Dar Es Salaam during Tanzania kick off meeting on 30<sup>th</sup> July, 2018*



*Director for Medical products (Mr. Adam M. Fimbo-left) explain the objectives of PROFORMA project and why kick-off meeting was held to signify the beginning of strengthening of pharmacovigilance system in Tanzania: Kunduchi Beach Hotel 30th July, 2018.*

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