

# ISoP 2021 Annual Meeting

*Coordinating key stakeholders of national Pharmacovigilance*

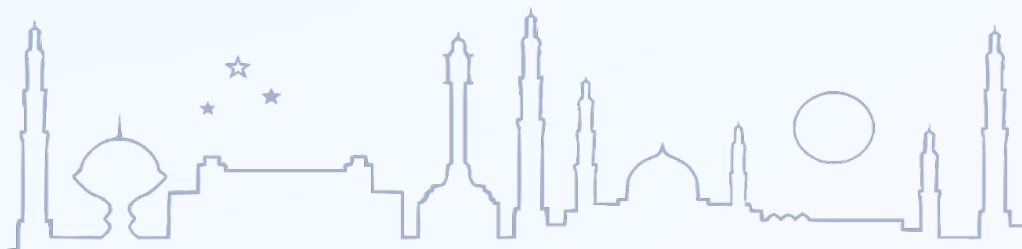
## **Supporting Coordinated Pharmacovigilance in Regulatory, Academic and Public Health sectors - the PROFORMA project**

**Professor Eleni Aklillu, PhD**

PROFORMA Project coordinator

Karolinska Institutet

Stockholm, Sweden



International Society of Pharmacovigilance

November 8

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# Disclaimer and declaration of conflict of interest

## Presenter's name:

Professor Eleni Aklillu, PhD  
PROFORMA project coordinator  
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## Declaration of Conflicts of Interest

- No conflict of interest to declare

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# Supporting coordinated pharmacovigilance in Regulatory, Academic and Public Health sectors

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1	Baseline PV assessment & interventions
2	Active Cohort Event Monitoring of MDA & Vaccines
3	Short & long term PV training



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# PROFORMA: Project Background & Rationale



Increased access to medicine

- Vaccine
- Drugs
- Diagnostics
- Interventions

Increased number of clinical trials



Increased Mass drug administration & Vaccination

Limited stockholder coordination to monitor safety



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# The PROFORMA - Partnership

Training-of-the-  
trainers for  
sustainability

Academia

NMRAS

Training to change  
policy into practice



RCOREs + WHO-cc, PHP  
Stakeholders



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# The PROFORMA - Consortium

ACADEMIA	NMRA	RCORE, WHO-CC
Karolinska Institutet		WHO CC in Pharmacovigilance Centre-Lareb
Addis Ababa University	Ethiopian-FDA	
University of Nairobi	Pharmacy and Poisons Board, Kenya	RCORE in PV
Muhimbili University	Tanzania Medicines & Medical Devices Authority	RCOREC in Medicines Evaluation and registration
University of Rwanda	Rwanda - FDA	



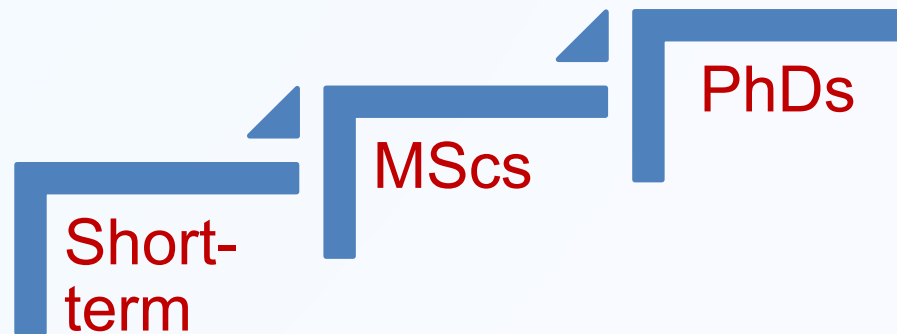
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# Coordinating key stakeholders of national pharmacovigilance

- Baseline assessment at NMRA, Universities, PHP (NTD & Immunization programs) (WP-2)
- Interventions to strengthening national PV & post-marketing surveillance (WP-3)
- Active cohort surveillance involving mass drug administration and immunization (WP-4)
- Generate PV trained cohort (WP-5)
  - Training of the trainers



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# Findings from the baseline assessment

Drug Safety (2020) 43:339–350

<https://doi.org/10.1007/s40264-019-00898-z>

## ORIGINAL RESEARCH ARTICLE



### Comparative Assessment of the National Pharmacovigilance Systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania

Abbie Barry<sup>1</sup> · Sten Olsson<sup>1</sup> · Omary Minzi<sup>2</sup> · Emile Bienvenu<sup>3</sup> · Eyasu Makonnen<sup>4,8</sup> · Appolinary Kamuhabwa<sup>2</sup> · Margaret Oluka<sup>5</sup> · Anastasia Guantai<sup>5</sup> · Ulf Bergman<sup>1</sup> · Eugène van Puijenbroek<sup>6</sup> · Parthasarathi Gurumurthy<sup>7</sup> · Eleni Aklillu<sup>1</sup>



International Journal of  
*Environmental Research  
and Public Health*



Article

### Comparative Assessment of the Pharmacovigilance Systems within the Neglected Tropical Diseases Programs in East Africa—Ethiopia, Kenya, Rwanda, and Tanzania

Abbie Barry<sup>1</sup> , Sten Olsson<sup>1</sup> , Christabel Khaemba<sup>2</sup> , Joseph Kabatende<sup>3</sup> , Tigist Dires<sup>4</sup>, Adam Fimbo<sup>5</sup>, Omary Minzi<sup>6</sup>, Emile Bienvenu<sup>7</sup>, Eyasu Makonnen<sup>8,9</sup> , Appolinary Kamuhabwa<sup>6</sup>, Margaret Oluka<sup>10</sup>, Anastasia Guantai<sup>10</sup>, Eugène van Puijenbroek<sup>11</sup>, Ulf Bergman<sup>1</sup>, Alex Nkayamba<sup>5</sup>, Michael Mugisha<sup>7</sup>, Parthasarathi Gurumurthy<sup>12</sup> and Eleni Aklillu<sup>1,\*</sup>



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# Active Cohort Event Monitoring of MDA & Vaccines



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



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# Activities

- Ethics approval, Stakeholder meetings.
- Develop work plan, protocols, and SOPs, CRFs , Database
- Training for data collectors including schoolteachers, PHP staff, health extension workers, nurses, lab technicians and data management team.
- Field work



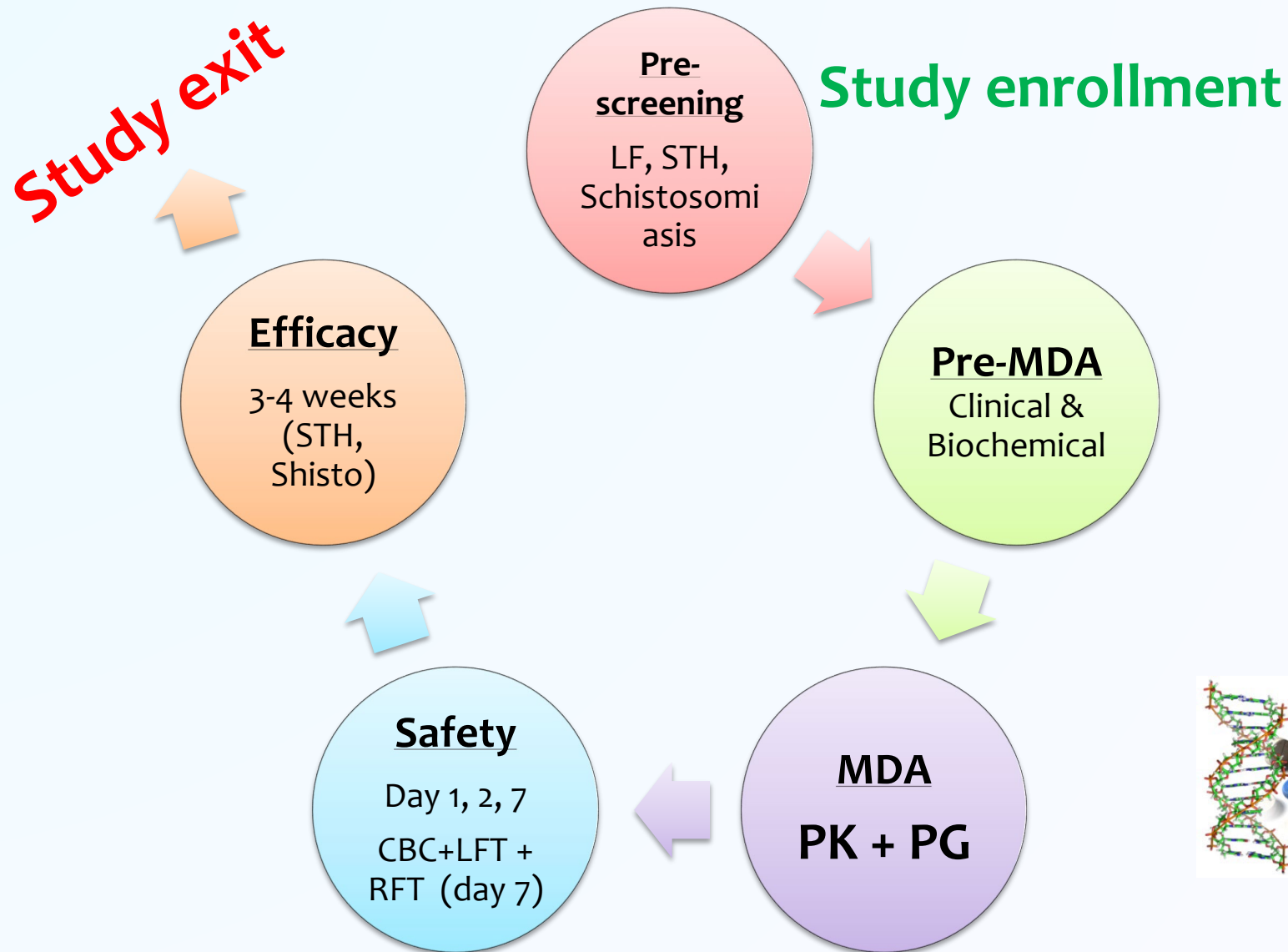
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# Study flow chart – ACM in MDA





# Active safety surveillance of MDA in Ethiopia



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# Ethiopia - ToT for data collectors



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# Training for data collectors - Kenya



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# Field work in Tanga - Tanzania



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# Field work - Tanzania



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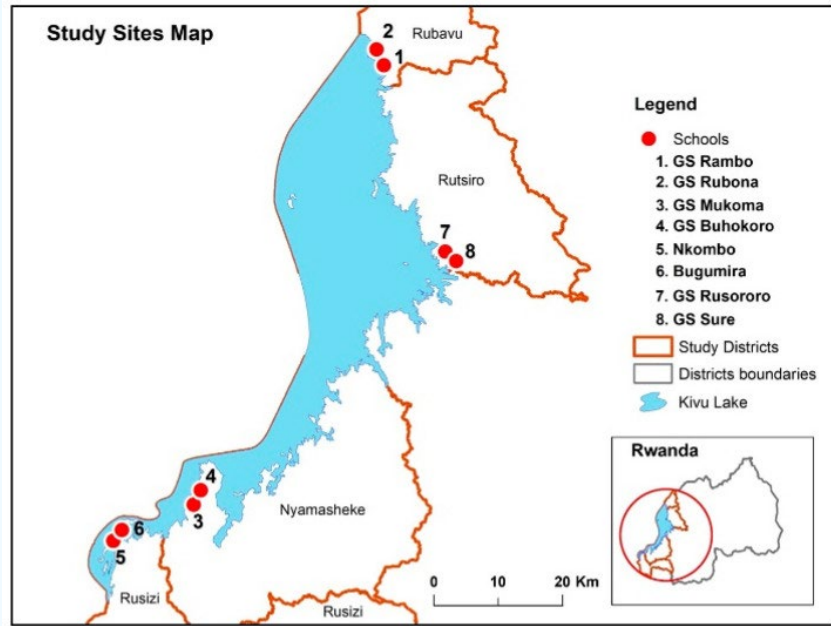
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# Field work - Rwanda



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# WP 5. Short and long-term training

Country specific  
training



Existing  
PV courses



PhD students



MSc students



PV curricula



E-learning  
for HCPs



**Lead: Short courses: Lareb, PPB**  
**MSc training: Uni Nairobi**  
**PhD training : KI**



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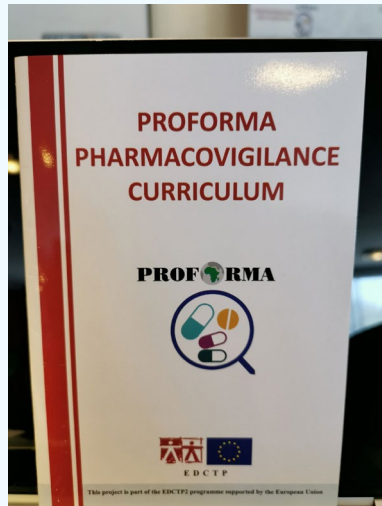


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# PV – curriculum & E-learning module

- Postgraduate & Undergraduate PV curriculum



- PV e-learning module developed



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# PROFORMA – PV sort courses

- **1<sup>st</sup> PROFORMA- Pharmacovigilance training course**  
(20 – 24 May 2019, Kigali, Rwanda)
- **2<sup>nd</sup> PROFORMA- Pharmacovigilance course**  
**Training of Trainers** - (Nairobi 17-21 February)
- **3<sup>rd</sup> PROFORMA- Pharmacovigilance course**  
**Signal detection and management** –  
(virtual 27<sup>th</sup> Jan - 12<sup>th</sup> February 2021)



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# PROFORMA -PhD students (KI)



Tanzania



Sweden



Rwanda



Kenya



Ethiopia



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# Students ongoing Activities



- *Postgraduate courses*
- *PK/PG lab analysis*
- *Data analysis, manuscript writing and publications...*



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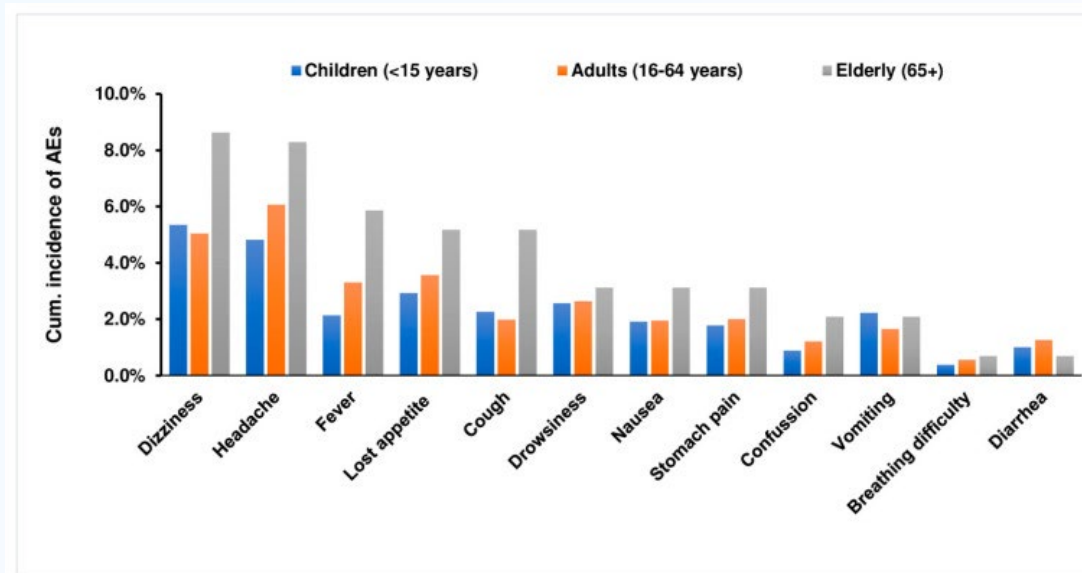


## Article

# Safety and Tolerability of Mass Diethylcarbamazine and Albendazole Administration for the Elimination of Lymphatic Filariasis in Kenya: An Active Surveillance Study

Christabel Khaemba <sup>1,2</sup> , Abbie Barry <sup>1</sup> , Wyckliff P. Omondi <sup>3</sup> , Kefa Bota <sup>3</sup>, Sultani Matendechero <sup>3</sup>, Cecilia Wandera <sup>3</sup>, Fred Siyoi <sup>2</sup>, Elvis Kirui <sup>4</sup>, Margaret Oluka <sup>5</sup>, Pamela Nambwa <sup>2</sup>, Parthasarathi Gurumurthy <sup>6</sup> , Sammy M. Njenga <sup>7</sup> , Anastacia Guantai <sup>5</sup> and Eleni Aklillu <sup>1,\*</sup>

Pharmaceuticals 2021, 14, 264.  
<https://doi.org/10.3390/ph14030264>



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# PROFORMA project - Expected outcomes

- ✓ Pharmacovigilance trained human resources from all stockholders
  - 12 postgraduates (7 PhDs + 5 MScs)
  - 1888 HCPs, schoolteachers, HCPs, PHP staffs, etc., trained
- ✓ Improved undergraduate and post graduate pharmacovigilance teaching practices
- ✓ Improved PV infrastructure and regulatory capacity for post-marketing surveillance in PHPs
- ✓ Tools and competencies for data collection, management, communication and feed-back developed
- ✓ ***Sustained pharmacovigilance stockholder coordination between NMRA, Academia and Public Health sectors!!!***



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## Acknowledgment

شكرا لك على انتباهك

Thank you for your attention

спасибо за Ваше внимание

Σας ευχαριστώ για την προσοχή σας

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תודה לך על תשומת הלב

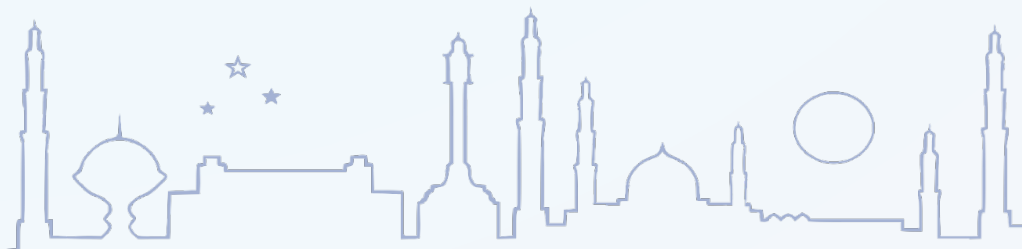
This project is part of the EDCTP2 programme supported by the European Union



EDCTP



Sida



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