



Day 1 – 22nd July 2024

08:00 - 09:00 **Registration**

09:00 – 10:30 **Opening Ceremony**

- *Uganda Ministry of Health*
- *Helen Ndagije, Director Product Safety, Uganda National Drug Authority*
- *Angela Caro Rojas President, International Society of Pharmacovigilance*
- *Chairman NDA (TBC)*

10:30 – 11:00 **Coffee Break and Photographs**

Session 1: Advancing PV Data-Driven Decision Making in Africa

11:00 – 11:05 **Chairpersons**

- *Comfort Ogar, Senior Pharmacovigilance Manager, United States Pharmacopeia (USP)*
- *Jayesh Pandit, QPPV, Bayer East Africa Ltd*

11:05 - 11:25 **Data Collection to Data-Driven Decision-Making for Patient Safety in Africa: A case of the AU-3S pilot during COVID-19 pandemic in promoting patient safety**

- *Kenneth Onu, Principal Program Officer, AUDA-NEPAD*

11:25 - 11:45 **Spontaneous reporting data analysis using VigiLyze for signal detection and regulatory decision making - Experiences and lessons from Eritrea**

- *Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre*

11:45 - 12:05 **Envisioning database networks for safety surveillance in Africa - opportunities and challenges**

- *Kimberly Gutu, Project Manager, VIDA*

12:05 - 12:25 **Use of RWD for PV data-driven decision: Experience from Botswana**

- *Lebogang Koitsiwe, Pharmacovigilance Manager, BoMRA*

12:25 - 12:35 **Oral Presentation: Impact of serious adverse drug reactions on the quality of life of patients on highly active antiretroviral therapy**

- *Peter Bassi, Associate Professor of clinical Pharmacology and Therapeutic, University of Abuja, Nigeria*

12:35 – 12:45 **Oral Presentation: Omeprazole and risk of hypertension: analysis of existing literature and the WHO global pharmacovigilance database**

- *Merhawi Bahta, National Medicines and Food Administration, Ministry of Health, Asmara, Eritrea*

12:45 – 12:50 **Diamond Sponsor Presentation**

- *Symerre Grey-Johnson, Director Human Capital & Institutional Development, AUDA-NEPAD*



12:50 – 13:50 **Lunch**

Session 2: Signal Management and Risk Communication

13:50 – 13:55 **Chairpersons**

- *Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre*
- *Peter Bassi, Associate Professor of clinical Pharmacology and Therapeutic, University of Abuja, Nigeria*

13:55 – 14:15 **The Role of Patient Reporting in Strengthening Signal Detection in PV Databases**

- *Ronald Kiguba, Senior Lecturer, Makerere University*

14:15 – 14:35 **Eritrea experience in signal management and risk communication: success stories, challenges and lessons learned**

- *Yodit Fitsum Ghebregabhier, PV Officer, Eritrean Pharmacovigilance Centre*

14:35 – 14:55 **The Journey from Safety Signals to Risk Factors to Product Label - A Case of Efavirenz Signal Management and Risk Communication**

- *Mukonzo Jackson - Uganda*

14:55 – 15:15 **Utilization and impact of the WHO Global Surveillance and Monitoring System database**

- *Babatunde Jayeola - WHO AFRO*

15:15 – 15:25 **Oral Presentation: An investigation of tenofovir induced renal toxicity reports received by Botswana Medicines Regulatory Authority**

- *Pono Pono, Botswana Medicines Regulatory Authority*

15:25 – 15:35 **Oral Presentation: Patient experiences of sexual dysfunction after transition to dolutegravir-based HIV treatment in Western Uganda**

- *Henry Zakumumpa, Makerere University, Uganda*

15:35 – 15:45 **Oral Presentation: Signal Management and Risk Communication in Pharmacovigilance: Exploring Dynamics, Challenges, and Strategies in Uganda**

- *Christopher Cox, Makerere University College of Health Sciences, Uganda*

15:45 – 15:50 **Sponsor Presentation**

- TBC

15:50 – 16:15 **Coffee Break and Poster Session**

Session 3: Vaccine Safety Monitoring in Africa

16:15 - 16:20 **Chairpersons**

- *Peter Bassi, Associate Professor of clinical Pharmacology and Therapeutic, University of Abuja, Nigeria*
- *Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre*

The agenda is subject to change



- 16:20 - 16:30 **Enhancing Vaccine Pharmacovigilance and vaccine safety database: The role of National immunization Programme**
- *Uchenna Elemuwa, Director Pharmacovigilance, NAFDAC, Nigeria*
- 16:30 – 16:40 **Vaccine safety and pharmacovigilance within the context of CEPI’s 100 days mission**
- *Rebecca Chandler, Vaccine Safety Lead, CEPI*
- 16:40 – 16:50 **Vaccine hesitancy and the importance of safety monitoring in enhancing coverage for new vaccines**
- *Ombeva Malande, Director, East Africa Centre for Vaccines and Immunization*
- 16:50 – 17:30 **Panel Discussion: Vaccine Safety and Mitigating Vaccine Hesitancy**
- Chair:** *Hannelie Meyer, Head of the South African Vaccination and Immunisation Centre*
- Panelists:**
- *Uchenna Elemuwa, Director Pharmacovigilance, NAFDAC*
 - *Rebecca Chandler, Vaccine Safety Lead, CEPI*
 - *Ombeva Malande, Director, East Africa Centre for Vaccines and Immunization*
- 17:30 - 17:40 **Oral presentation: Strengthening the Adverse Events Following Immunization Surveillance System for COVID-19 Vaccine Safety Monitoring and beyond: a case of Tanzania**
- *Damas Matiko, Tanzanian Medicines and Medical Device Authority/TMDA*
- 17:40 - 17:50 **Oral presentation: Patient Reported Outcomes of Adverse Events After COVID-19 Vaccination in Nigeria: A Mixed Methods Study**
- *Comfort Ogar, Senior Pharmacovigilance Manager, United States Pharmacopeia (USP)*
- 17:50 - 17:55 **Sponsor Presentation**
- TBC
- 18:00 - 20:00 **Drinks Reception**



Day 2 – 23rd July 2024

Session 4: Regulatory Harmonization for PV

09:00 – 09:05 Chairpersons

- *Kate Kikule, Senior Principal Technical Advisor, USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program*
- *Victoria Prudence Nambasa, Senior Program Officer, AUDA-NEPAD*

09:05 – 09:25 The role of ISO P in the African Medicines Agency (AMA) Pharmacovigilance Framework

- *Helen Ndajige, Director Product Safety, Uganda National Drug Authority*

09:25 – 09:45 ISO P Strategic Vision and How to Support Africa

- *Angela Caro Rojas President, International Society of Pharmacovigilance*

09:45 – 10:05 Updates on Regional PV Harmonization in Africa

- *Chimwemwe Chamdimba, Head AMRH -AUDA-NEPAD*

10:05 – 10:15 Oral Presentation: Assessing the maternal vaccine pharmacovigilance landscape in Uganda

- *Victoria Prudence Nambasa, Senior Program Officer, AUDA-NEPAD*

10:15 – 10:25 Oral Presentation: Pharmacovigilance Guideline Harmonisation in Africa

- *Thuli Makhene, Bayer, South Africa*

10:25 – 10:30 Sponsor Presentation

- *TBC*

10:30 - 11:00 Coffee Break and Poster Session

Session 5: Pharmacovigilance in Africa: A Local Perspective

11:00 – 11:05 Chairpersons

- *Nimisha Kotecha, Managing Director, IntuVigilance*
- *Dorothy Aywak, Head of Pharmacovigilance, Kenyatta National Hospital*

11:00 - 11:20 Why is Pharmacovigilance important to Africa?

- *Jayesh Pandit*

11:20 - 11:40 PV from Local Manufacturers' Perspective

- *Nelson Wamakuyu, QPPV, Quality Chemical Ltd*

11:40 - 12:00 PV from Local Distributors' Perspective

- *Uthuman Kiryowa*

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- 12:00 – 12:10 **Oral Presentation: Discovering the potential of local pharmaceutical manufacturers in Africa through effective pharmacovigilance**
- *Blessed Kitentera, National Drug Authority, Uganda*
- 12:10 – 12:20 **Oral Presentation: A cost-effectiveness analysis of active and passive vaccinovigilance of adverse events following Measles-Rubella Immunization for Children in Eastern Uganda**
- *Michael Muhoozi, Makerere University Center for Health and Population Research, Uganda*
- 12:20 – 12:25 **Sponsor Presentation**
- *TBC*
- 12:25 - 13:25 **Lunch**

Session 6: Active Monitoring of Medicines/Vaccines

- 13:25 – 13:30 **Chairpersons**
- *Comfort Ogar, Senior Pharmacovigilance Manager, United States Pharmacopeia (USP)*
 - *TBC*
- 13:30 – 13:50 **Navigating Challenges and Successes: Leveraging New Technologies in Adverse Event Reporting in the context of active surveillance**
- *Omar Aimer, ISoP EC member and Treasurer, NASoP President, Medical Device SIG lead*
- 13:50 – 14:10 **The role of active safety monitoring of COVID-19 vaccines in maximizing reporting and enhancing the quality of immunization campaigns – experiences from Africa**
- *Edinam Amavi Agbenu, Vaccine Safety Officer, WHO Regional Office for Africa*
- 14:10 – 14:30 **Combining data from clinical trials and post-introduction active safety monitoring studies to enhance safety decision-making**
- *Berhnards Ogutu, Senior Clinical Scientist, KEMRI*
- 14:30 – 14:40 **Oral Presentation: Leveraging COVID-19 Vaccine Safety Monitoring in Ethiopia and Pakistan to Enhance System-Wide Safety Surveillance**
- *Aida Hagos, Ethiopia*
- 14:40 – 14:50 **Oral Presentation: Active sentinel site surveillance of novel Oral Polio Vaccine2 (nOPV2) in Ethiopia**
- *Tigist Gebreyesus, Ethiopian Food and Drug Authority*
- 14:50 – 15:00 **Oral Presentation: Safety Outcomes of COVID-19 Vaccines in People Living with HIV: A Prospective Cohort Study in Uganda**
- *Kato Sengendo, Infectious Diseases Institute, Uganda*



15:00 – 15:10 **Oral Presentation: Building Pharmacovigilance Capacity among Health Professionals in Uganda through Curriculum Intervention**

- *Jonans Tusiimire, Mbarara University of Science and Technology, Uganda*

15:10 – 15:15 **Sponsor Presentation**

- *TBC*

15:15 - 15:45 **Coffee Break and Poster Session**

Session 7: Digital Health and Patient Engagement in PV

15:45 – 15:50 **Chairpersons**

- *Kennedy Odokonyero*
- *Clarice Ambale, Centre for Health Solutions, Kenya*

15:50 – 16:10 **Using peer support to promote patient-led digital pharmacovigilance in limited-resource settings**

- *Ronald Kiguba, Senior Lecturer, Makerere University*

16:10 – 16:30 **Health Data Analytics for Pharmacovigilance in Africa**

- *Helena Sköld, Head of VigiBase and Regulatory Services, Uppsala Monitoring Centre*

16:30 – 16:50 **Artificial Intelligence in Pharmacovigilance**

- *Mohammed I. Fouda, Saudi Arabia FDA*

16:50 – 17:00 **Oral Presentation: Digital Transformation Approach for African Safety Surveillance: Insights from AU-3S Programme's Deployment Towards AfriVigilance**

- *Kudakwashe Dandajena, AUDA-NEPAD*

17:00 – 17:10 **Oral presentation: Pharmacovigilance Monitoring System PViMS (OpenRIMS-PV) – A Digital Tool to Enhance Decision-Making for Active and Passive Patient Safety Monitoring**

- *Deane Putzier, Management Sciences for Health/ Medicines Technologies and Pharmaceutical services program*

17:10 – 17:20 **Oral presentation: Assessing the background incidence rates of adverse events of special interest in obstetric and neonatal care using the GAIA in Uganda**

- *Dan Kajungu, Makerere University Centre for Health and Population Research (MUCHAP), Uganda*

17:20 – 17:25 **Sponsor Presentation**

- *TBC*

18:00 - 21:00 **Gala Dinner**



Day 3 – 24th July 2024

09:00 – 09:30 Poster Session

Session 8: Impact of the African genetic background on AE and future PV monitoring

09:30 - 09:35 **Chairpersons**

- *Victoria Prudence Nambasa, Senior Program Officer, AUDA-NEPAD*
- *TBC*

09:35 – 09:55 **Using data precision medicine solutions to address adverse drug reactions**

- *Janine Scholefield, Research Group Leader at Council for Scientific and Industrial Research (CSIR)*

09:55 – 10:15 **Use of local African datasets to infer and predict high-impact drug-gene pairs to monitor and minimize ADR**

- *Berhnards Ogutu, Senior Clinical Scientist, KEMRI*

10:15 - 10:25 **Oral Presentation: Transitioning Children to Optimized Regimens of Pediatric Dolutegravir (TORPEDO) Study: Pharmacovigilance Endline Results in Uganda, Nigeria and Benin**

- *Nuwagira Aston, Clinton Health Access Initiative, Uganda*

10:25 - 10:35 **Oral Presentation: Strengthening Pharmacovigilance using the COM-B Model at Facilities Starting Children on Dolutegravir-based Regimens in Uganda from January 2022 to December 2022**

- *Claudia Janice Latabu, Infectious Disease Institute, Uganda*

10:35 - 10:45 **Oral Presentation: Increasing the proportion of correctly documented adverse drugs (ADRs) at Mulago ISS Clinic, a high volume HIV care facility in Kampala Uganda**

- *Dorothy Nakanwagi, Makerere University Joint AIDS Program, Uganda*

10:45 – 10:50 **Sponsor Presentation**

- *TBC*

10:50 - 11:15 **Coffee Break**

ISO P Africa Chapter- Business Meeting

11:15 - 11:45 **The Structure of ISO P African Chapter: Constitution, bylaws, and governance structure and TW**

11:45 - 12:30 **Discussions and approval**

12:30 – 13:00 **Updates from Regional or Country Chapters**

13:00 – 13:45 **TWG Meetings**

The agenda is subject to change



Closing Ceremony

13:45 - 13:55 **Award for Best Poster**

13:55 – 14:05 **Induction of New Executives**

14:05 – 14:15 **Future for the African Chapter - Remarks by the incoming President**

14:15 – 14:20 **Final Comments, Farewells and Close of Meeting**

14:20 – 15:20 **Lunch**