

Day 1 - 22nd July 2024

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

09:00 – 09:05 Welcome Remarks / house keeping

Julius Mayengo, Manager Pharmacovigilance NDA

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

09:05 – 09:10 **Chairpersons**

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

09:10 – 09:30 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
- 09:30 09:50 Role of VigiLyze for signal detection and regulatory decision making Experiences and lessons from Eritrea
 - Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre
- 09:50 10:10 Envisioning database networks for safety surveillance in Africa opportunities and challenges
 - Kimberly Gutu, Project Manager, VIDA
- 10:10 10:30 Use of RWD for PV data-driven decision: Experience from Botswana
 - Lebogang Koitsiwe, Pharmacovigilance Manager, BoMRA
- 10:30 10:40 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

10:40 – 10:45 **Sponsor Presentation**

 Deirdre McCarthy, Senior Program Officer, Integrated Development, Bill & Melinda Gates Foundation

10:45 – 11:15 Coffee Break and Poster Session

Session 2: Signal Management and Risk Communication

11:15 – 11:20 **Chairpersons**

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

11:20 – 11:40 The Role of Patient Reporting in Strengthening Signal Detection in PV Databases



- Ronald Kiguba, Senior Lecturer, Makerere University
- 11:40 12:00 Eritrea experience in signal management and risk communication: success stories, challenges and lessons learned
 - Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre
- 12:00 12:20 The Journey from Safety Signals to Risk Factors to Product Label A Case of Efavirenz Signal Management and Risk Communication
 - Mukonzo Jackson, Associate Professor and Chair Department of Pharmacology and Therapeutics, Makerere University
- 12:20 12:40 Utilization and impact of the WHO Global Surveillance and Monitoring System database
 - Edith Andrews Annan, Technical Officer, Medicines and Health Technologies, WHO
- 12:40 12:50 Oral Presentation: Patient experiences of sexual dysfunction after transition to dolutegravir-based HIV treatment in Western Uganda
 - Henry Zakumumpa, Makerere University, Uganda
- 12:50 13:00 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
- 13:00 13:05 **Sponsor Presentation**
 - USP
- 13:05 14:00 Lunch

Session 3: Vaccine Safety Monitoring in Africa

- 14:00 14:05 **Chairpersons**
 - Peter Bassi, Associate Professor of clinical Pharmacology and Therapeutic, University of Abuja, Nigeria
 - Mulugeta Russom, Head of Eritrean Pharmacovigilance Centre
- 14:05 14:15 Enhancing Vaccine Pharmacovigilance and vaccine safety database: The role of National immunization Program
 - Uchenna Elemuwa, Director Pharmacovigilance, NAFDAC, Nigeria
- 14:15 14:25 Vaccine safety and pharmacovigilance within the context of CEPI's 100 days mission
 - Rebecca Chandler, Vaccine Safety Lead, CEPI
- 14:25 14:35 Vaccine hesitancy and the importance of safety monitoring in enhancing coverage for new vaccines
 - Ombeva Malande, Director, East Africa Centre for Vaccines and Immunization
- 14:35 15:15 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
- 15:15 15:25 **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
- 15:25 15:35 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)
- 15:35 15:40 **Sponsor Presentation**
 - IntuVigilance
- 15:40 16:00 Coffee Break and Poster Session

Conference Opening Ceremony

- 16:00 16:10 Remarks from the President of The ISoP Africa Chapter
 - Dr Helen Byomiire Ndagije, President ISoP Africa Chapter,
- 16:10 16:20 Remarks from the President of ISoP Global
 - Angela Caro Rojas President, International Society of Pharmacovigilance
- 16:20 16:30 Remarks from the Secretary to the Authority
 - David Nahamya, Secretary to the Authority
- 16:30 16:40 Remarks from the Chairperson of the Board NDA
 - Dr Medard Bitekyerezo, Chairperson Board NDA
- 16:40 16:50 Remarks from AUDA-NEPAD
 - Symerre Grey- Johnson, Director Human capital and institutional development
- 16:50 17:00 Speech from Country representative WHO
 - Dr Yonas Tegegn Woldemariam, Country Representative WHO
- 17:00 17:15 Opening remarks/ Speech from the minister of Health
 - Dr Jane Ruth Aceng Ocero, Minister of Health, Uganda
- 17:15 17:30 **Photographs**
- 18:00 20:00 **Drinks Reception**

The agenda is subject to change



Day 2 - 23rd July 2024

Session 4: Regulatory Harmonization for PV

08:45 - 08.50 **Chairpersons**

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

08:50 - 09:10 The role of ISoP in the African Medicines Agency (AMA) Pharmacovigilance Framework

• Helen Ndajige, Director Product Safety, Uganda National Drug Authority

• Angela Caro Rojas President, International Society of Pharmacovigilance

09:30 – 09:50 Updates on Regional PV Harmonization in Africa

Vanessa Msengezi, AMRH Programme AUDA-NEPAD

09:50 – 10:00 Oral Presentation: Assessing the maternal vaccine pharmacovigilance landscape in Uganda

Victoria Prudence Nambasa, Senior Program Officer, AUDA-NEPAD

10:00 – 10:10 Oral Presentation: Pharmacovigilance Guideline Harmonisation in Africa

Thuli Makhene, Bayer, South Africa

10:10 – 10:15 Sponsor Presentation

• Rene Industries

10:15 – 10:30 Coffee Break and Poster Session

Session 5: Pharmacovigilance in Africa: A Local Perspective

10:30 – 10:35 **Chairpersons**

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

10:35 – 10:55 Why is Pharmacovigilance important to Africa?

Jayesh Pandit, Bayer

10:55 – 11:15 PV from Local Manufacturers' Perspective

• Frances Namatovu, QPPV, Quality Chemical Ltd

11:15 – 11:35 PV from Local Distributors' Perspective

TBC



- 11:35 11:45 Oral Presentation: Discovering the potential of local pharmaceutical manufacturers in Africa through effective pharmacovigilance
 - Blessed Kitentera, National Drug Authority, Uganda
- 11:45 11:55 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 Centre for Health and Population Research, Uganda
- 11:55 12:00 **Sponsor Presentation**
 - Infectious Diseases Institute
- 12:00 12:50 Lunch

Session 6: Active Monitoring of Medicines / Vaccines

- 12:50 12:55 **Chairpersons**
 - Comfort Ogar, Senior Pharmacovigilance Manager, United States Pharmacopeia (USP)
 - Julius Mayengo, Manager Pharmacovigilance, National Drug Authority
- 12:55 13:15 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
- 13:15 13:35 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
- 13:35 13:55 Combining data from clinical trials and post-introduction active safety monitoring studies to enhance safety decision-making
 - Berhnards Ogutu, Senior Clinical Scientist, KEMRI
- 13:55 14:05 Oral Presentation: Leveraging COVID-19 Vaccine Safety Monitoring in Ethiopia and Pakistan to Enhance System-Wide Safety Surveillance
 - Aida Hagos, Ethiopia
- 14:05 14:15 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
- 14:15 14:25 Oral Presentation: Building Pharmacovigilance Capacity among Health Professionals in Uganda through Curriculum Intervention
 - Jonans Tusiimire, Mbarara University of Science and Technology, Uganda
- 14:25 14:30 Sponsor Presentation



• Uganda National Drug Authority

14:30 – 14:50 Coffee Break and Poster Session

	_		- -			_		
Session	7:	Digital	Health	and	Patient	Engagement	in	PV

14:50 - 14:55 **Chairpersons**

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

14:55 – 15:15 Using peer support to promote patient-led digital pharmacovigilance in limited-resource settings

• Ronald Kiguba, Senior Lecturer, Makerere University

15:15 – 15:35 Health Data Analytics for Pharmacovigilance in Africa

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

15:35 – 15:55 Artificial Intelligence in Pharmacovigilance

Mohammed I. Fouda, Head, Signal Detection Section, Saudi Food and Drug Authority

15:55 – 16:15 Using Technology for Better Data Collection in Pharmacovigilance

Mick Foy, Director of Delivery, MHRA

16:15 – 16:25 **Oral Presentation: Digital Transformation Approach for African Safety Surveillance: Insights from AU-3S Programme's Deployment Towards AfriVigilance**

Kudakwashe Dandajena, AUDA-NEPAD

16:25 – 16:35 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

16:35 – 16:40 **Sponsor Presentation**

Quality Chemicals Ltd

16:40 Transport to the Gala Dinner Venue

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
- Bisaso Kuteesa, NDA

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 10:35 The Implementation of Precision Medicine, an African Agenda from a Private Sector perspective
 - Eshara Chotoo, CEO, Antares Genomics
- 10:35 10:45 Oral Presentation: Digital Transformation Approach for African Safety Surveillance: Insights from AU-3S Programme's Deployment Towards AfriVigilance
 - Kudakwashe Dandajena, AUDA-NEPAD
- 10:45 10:55 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
- 10:55 11:05 Oral Presentation: Transitioning Children to Optimized Regimens of Pediatric Dolutegravir (
 TORPEDO) Study: Pharmacovigilance Endline Results in Uganda, Nigeria and Benin
 - Aston Nuwagira, Clinton Health Access Initiative, Uganda
- 11:05 11:15 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
- 11:15 11:25 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

11:25 – 11:30 Sponsor Presentation

Joint Medical Stores

11:30 - 11:50 Coffee Break

The agenda is subject to change



ISoP Africa Chapter- Business Meeting

11:50 – 12:20	The Structure of ISoP African Chapter: Constitution, bylaws, and governance structure and TW
12:20 – 12:50	Discussions and approval
12:50 – 13:05	Updates from Regional or Country Chapters
13:05 - 13:40	TWG Meetings

Closing Ceremony

13:40 – 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