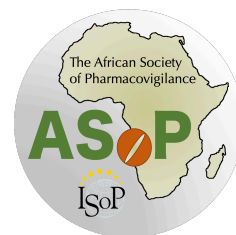




# ISO P and the African Society of Pharmacovigilance

The African Chapter of the  
International Society of Pharmacovigilance  
(ASoP)



Symposium  
& Training

## Pharmacovigilance in Africa beyond Spontaneous Reports

Nairobi, Kenya 6-7-8 May, 2019

SAROVA PANAFRIC HOTEL  
Kenyatta Avenue, Valley Road  
00100 Nairobi, Kenya  
**Meeting room:** Simba Hall / Mezzanine

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This Symposium and Training event, the first of this kind organised in Africa, will be addressing the specific needs and interests of people working in the field of pharmacovigilance either in regulatory agencies, pharmaceutical companies, in academia, hospitals or community settings.

Despite efforts for improving the spontaneous reporting of adverse events in Africa, the reporting behaviour remains sub-optimal to the extent of urging to develop new approaches for collecting safety data e.g. by involving consumers and patients directly. On the other hand, risk minimisation methods that suit African health care systems need to be developed and implemented. In such a context, and moreover in the perspective of the upcoming constitution of the African Medicinal Agency, this mid-year Symposium & Training Course is aimed to be a milestone for sharing ideas on how to improve the different components of safety regulatory systems and practices.

This ISO P Symposium & Training Course is intended for an audience including representatives from National Regulatory Authorities, Universities, Hospitals and industry professionals. At the term of this event the participants are expected to have an overall understanding of pharmacovigilance systems, practices and issues in Africa and beyond, and be capable of promoting practices according to international standards.

The faculty contributing to this course consists of international and national experts in pharmacovigilance, representing government, academia, and industry.

## Monday May 6<sup>th</sup> | Day 1 | Symposium: Serving Africa's needs in Pharmacovigilance

08:00 - 08:30	30'	<i>Registration.</i>
08:30 - 09:00	30'	Introducing the perspective of the 2019 ISoP/ASoP Symposium & Training, <i>by the chairpersons of the event.</i>
<b>AM Session: Place of Africa in Global Pharmacovigilance.</b> <i>Session chair: Hilda Ampadu, The African Collaborating Centre for Pharmacovigilance (ACC), Ghana.</i>		
09:00 - 09:45	45'	Current trends in global pharmacovigilance <i>Presenter: Sten Olsson, President of ISoP, Sweden.</i>
09:45 - 10:30	45'	Pharmacovigilance in Africa: current status and trends <i>Presenter: Hilda Ampadu.</i>
10:30 - 11:00	30'	<i>Coffee break &amp; Networking.</i>
11:00 - 12:45	45'	What is Africa missing in pharmacovigilance? <i>Presenters: Comfort Ogar, Management Sciences for Health (MSH), Nigeria and Sten Olsson - on behalf of Ambrose Isah, University of Benin, Nigeria.</i>
11:45 -12:30	45'	Key drivers of the change in pharmacovigilance in Africa. <i>Presenter: Christabel Khaemba, Pharmacy and Poisons Board, Kenya.</i>
12:30 -13:30	60'	<i>Lunch break and networking.</i>

### **PM Session: Building the African Medicines Agency (AMA).**

*Session chair: Margareth Ndomondo-Sigonda, New partnership for Africa's development (African Union-NEPAD), Tanzania and South Africa.*

13:30 - 14:15	45'	African Medicines Regulatory Harmonisation: NEPAD/AMRH/AMA <i>Presenter: Margareth Ndomondo-Sigonda.</i>
14:15 - 15:00	45'	Creating a GVP for Africa: Principles and milestones. <i>Presenter: Paul Tanui, New Partnership for Africa's Development (NEPAD), South Africa.</i>
15:00 - 15:30	30'	<i>Coffee break &amp; Networking.</i>
15:30 -16:30	60'	Supporting creating the African Medicines Agency (AMA): <b>Panel discussion</b> with the Presenters of the morning and afternoon sessions.
16:30 – 17:00	30'	Conclusion of the Symposium <i>by the chairpersons of the event</i>
17:00		<i>End of Day 1.</i>

## Tuesday May 7<sup>th</sup> | Day 2 | Course 1: Africa's changing safety-regulatory landscape

08:45 - 09:00	15'	Introducing <b>Africa's changing safety-regulatory landscape</b> . <i>Session chair: Christabel Khaemba</i>
09:00 - 09:40	40'	Post-approval safety regulatory systems and Inspections in Africa. <i>Presenter: Helen Byomire, National Drug Authority, Uganda.</i>
09:40 - 10:20	40'	Implementing Qualified Persons for Pharmacovigilance (QPPV) in Africa. <i>Presenter: George Sabblah, Ghana FDA.</i>
10:20 - 10:40	20'	<i>Coffee break &amp; Networking.</i>
10:40 - 11:15	35'	Solutions for improving the collection of individual safety reports. <i>Presenter: Victoria Nambasa, National Drug Authority, Uganda.</i>
11:15 - 11:25	10'	Patterns, practices and determinants detecting and reporting of ADRs. <i>By Peter Nuwagira, Mbarara Univ. of Science &amp; Technology, Uganda</i>
11:25 - 12:00	35'	Focusing pharmacovigilance resources on activities the most value-adding for the safety of patients: License holders' point of view. <i>Presenters: Jean-Christophe Delumeau and Jayesh Pandit</i>
12:00 - 13:00	60'	Focusing resources on activities most value-adding for the safety of African patients: <b>Panel discussion</b> with the Presenters of the session.
13:00 - 13:50		<i>Lunch break and networking.</i>

## Tuesday May 7<sup>th</sup> | Day 2 | Course 2: Access to medicines to meet Africa's needs

13:50 - 14:00	10'	Introducing the session <b>Access to medicines to meet Africa's needs</b> . <i>Session chair: Sten Olsson.</i>
14:00 - 14:40	40'	Vaccines for Africa: Current issues and perspective for the future. New mechanisms for vaccines. <i>Presenter: Houda Langar, Director and Regional Advisor for Vaccines, WHO-EMRO, Egypt.</i>
14:40 - 15:20	40'	Performing clinical trials in Africa: Pre-approval safety regulatory systems, achievements, challenges and trends. <i>Presenter: Edward Abwao, Pharmacy and Poisons Board, Kenya.</i>
15:20 - 15:40	20'	<i>Coffee break &amp; networking.</i>
15:40 - 16:20	40'	Advances in Safety Technology for Africa. <i>Presenter: Deirdre McCarthy, IQVIA, USA.</i>
16:20 - 17:00	40'	3S, Proforma, and PAVIA: Three initiatives aimed at making new medicines available in a safer way in Africa   <i>Presenter: Sten Olsson.</i>
17:00 - 18:00	60'	ASoP Assembly.
18:00		<i>End of Day 2.</i>

**Wednesday May 8<sup>th</sup> | Day 3 | Course 3: Pragmatic Active Methodologies for Africa**

08:45 - 09:00	15'	Introducing the session <b>Methodologies for Africa</b> . <i>Session chair: Monica Plöen, Uppsala Monitoring Centre, Sweden.</i>
09:00 - 09:40	40'	<i>Benefit vs Risk Evaluation: principles and methods.</i> <i>Presenter: Jean-Christophe Delumeau</i>
09:40 - 10:20	40'	Pharmacovigilance methods to address Africa's unique challenges. <i>Presenter: George Sabblah, Ghana FDA.</i>
10:20 - 11:00	40'	PV Systems at Regulatory Authorities and Market Authorization Holders. <i>Presenter: Jayesh Pandit, KAPI and Bayer Kenya.</i>
11:00 - 11:20	20'	<i>Coffee break &amp; Networking.</i>
11:20 - 12:20	60'	VigiFlow and VigiLyze as a national, regional and global Pharmacovigilance platform. <i>Presenters: Monica Plöen and Helena Sköld, Uppsala Monitoring Centre.</i>
12:20 - 13:00	40'	VigiLyze practicum. <i>Facilitators: Monica Plöen and Helena Sköld, Uppsala Monitoring Centre.</i>
13:00 - 13:50	50'	<i>Lunch break and networking.</i>

**Wednesday May 8<sup>th</sup> | Day 3 | Course 4: Benefit vs Risk and Risk minimisation**

13:50 - 14:00	10'	Introducing <b>Benefit vs Risk and Risk minimisation</b> . <i>Session chair: Jean-Christophe Delumeau, ISOPEC member, Bayer South East Asia, Singapore.</i>
14:00 - 14:40	45'	Risk Management planning and Risk Minimisation. Principles and methods. <i>Presenter : Jean-Christophe Delumeau</i>
14:40 - 15:30	45'	Communicating on Risk Minimisation in Africa <i>Presenters: Christabel Khaemba and Jayesh Pandit</i>
15:30 - 15:50	20'	<i>Coffee break &amp; Networking.</i>
15:50 - 16:50	60'	<b>Hand-on group Exercise:</b> Implementing a risk minimisation decision in the context of African Health Care Systems. <i>Facilitators: Christabel Khaemba, Jayesh Pandit and Jean-Christophe Delumeau.</i>
16:50 - 17:00	10'	Concluding remarks of the meeting.
17:00		<i>End of the training course.</i>