



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Pharmacovigilance in Africa beyond Spontaneous Report

Symposium & Training – Preliminary Programme
6-7-8 May, 2019, Nairobi, Kenya

(Venue: Sarova PanAfrica Hotel, Nairobi, Kenya)

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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 ISoP 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.

2019 ISoP/ASoP Symposium & Training, Nairobi

Monday May 6th | Day 1 | Symposium: Serving Africa's needs in Pharmacovigilance

08:00 - 09:00		<i>Registration</i>
09:00 - 09:30		Introducing the perspective of the 2019 ISoP/ASoP Symposium & Training, <i>by the chairpersons of the event.</i>
AM Session: Place of Africa in Global Pharmacovigilance		
09:30 - 10:15		Current trends in global pharmacovigilance
10:15 - 11:00		Pharmacovigilance in Africa: current status and trends
11:00 - 11:30		<i>Coffee break & Networking</i>
11:30 - 12:15		What is Africa missing in pharmacovigilance?
12:15 -13:00		Key drivers of the change in pharmacovigilance in Africa
13:00 -14:00		<i>Lunch break and networking</i>
PM Session: Building the African Medicines Agency (AMA)		
14:00 - 14:45		African Medicines Regulatory Harmonisation: NEPAD/AMRH/AMA
14:45 - 15:30		Creating a GVP for Africa: principles and milestones
15:30 - 16:00		<i>Coffee break & Networking</i>
16:00 -17:00		Supporting creating the African Medicines Agency (AMA): Panel discussion with the Presenters of the morning and afternoon sessions.
17:00		<i>End of Day 1</i>

Tuesday May 7 th Day 2 Course session 1: Africa's changing safety-regulatory landscape		
08:50 - 09:00		Introducing the session Africa's changing safety-regulatory landscape
09:00 - 09:40		Post-approval safety regulatory systems in Africa including inspections.
09:40 - 10:20		Implementing Qualified Persons for Pharmacovigilance (QPPV) in Africa
10:20 - 10:40		<i>Coffee break & Networking</i>
10:40 - 11:20		Solutions for improving ICSR collection.
11:20 -12:00		Focusing pharmacovigilance resources on activities the most value-adding for the safety of patients: License holders' point of view.
12:00 -13:00		Focusing resources on activities the most value-adding for the safety of African patients: Panel discussion with the Presenters of the session.
13:00 -13:50		Lunch break and networking

Tuesday May 7 th Day 2 Course session 2: Access to medicines to meet Africa's needs		
13:50 - 14:00		Introducing the session Access to medicines to meet Africa's needs
14:00 - 14:40		Vaccines for Africa: Current issues and perspective for the future. New mechanisms for vaccines.
14:40 - 15:20		Performing clinical trials in Africa: Pre-approval safety regulatory systems, achievements, challenges and trends
15:20 - 15:40		<i>Coffee break & networking</i>
15:40 - 16:20		Advances in Safety Technology for Africa.
16:20 - 17:00		3S, Proforma, and PAVIA: Three initiatives aimed at making new medicines available in a safer way in Africa
17:00		End of Day 2

Wednesday May 8 th Day 3 Course session 3: Pragmatic Active Methodologies for Africa		
08:50 - 09:00		Introducing the session Pragmatic Active Methodologies for Africa
09:00 - 09:40		Pharmacovigilance methods to address Africa's unique challenges.
09:40 - 10:20		Pharmacoepidemiology techniques for PV and database research for pharmacovigilance.
10:20 - 10:40		Coffee break & Networking
10:40 - 11:20		Measuring the burden of drug related harm in Africa.
11:20 - 12:00		Safety communication in Africa: Challenges and opportunities: NRA and MAH perspectives.
12:00 -13:00		Pharmacovigilance and epidemiological methods suitable for Africa: Panel discussion with the presenters of the session chaired by Ian Wong.
13:00 - 13:50		Lunch break and networking

Wednesday May 8 th Day 3 Course session 4: Benefit vs Risk and Risk minimisation		
13:50 - 14:00		Introducing Benefit vs Risk and Risk minimisation
14:00 - 14:40		Safety specifications and Benefit vs Risk evaluation
14:40 - 15:30		Risk management planning and risk minimisation methods
15:30 - 15:50		Coffee break & Networking
15:50 – 16:50		Hand-on group Exercise: Implementing a risk minimisation decision in the context of African Health Care Systems.
16:50 – 17:00		Concluding remarks of the meeting
17:00		End of the training course

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