



WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop

Enhancing Preparedness for Pharmacovigilance

20 – 22 Sept 2021

Conducted via Zoom

**WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop: Enhancing Preparedness for
Pharmacovigilance | 20 – 22 September 2021**

**The Programme is accurate as of 14 July 2021 and may be subjected to further refinement if necessary before the actual workshop.*

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Enhancing Preparedness for Pharmacovigilance

20 – 22 September 2021

Day 1 – 20 September, Mon

	Topic
Day 1	Pharmacovigilance in the COVID-19 Vaccine-era
8.45am SGT 2.45am CEST	Registration and Briefing on use of Zoom
9.00am SGT 3.00am CEST	Welcome
9.15am SGT 3.15am CEST	Opening remarks
9.30am SGT 3.30am CEST	Global report on COVID-19 vaccines <ul style="list-style-type: none"> • WHO - Update on vaccine safety and key safety issues to date • Descriptive Analysis of COVID-19 Vaccines reporting in VigiBase
10.15am SGT 4.15am CEST	Break
10.30am SGT 4.30am CEST	COVID-19 vaccination landscape in ASEAN Sharing by ASEAN regulators
11.15am SGT 4.15am CEST	Challenges in monitoring safety of COVID-19 vaccines – Industry perspective
12.00pm SGT 6.00am CEST	Lunch
1.00pm SGT 7.00am CEST	Panel Discussion Current areas for urgent intervention towards effective pharmacovigilance
2.00pm SGT 8.00am CEST	CIOMS guide to active vaccine safety surveillance – Practical framework for implementation
2.45pm SGT 8.45am CEST	WHO Listed Authorities (WLA) and Global Benchmarking Tool (GBT) for pharmacovigilance Adapting for COVID-19 situation
3.30pm SGT 9.30am CEST	Break
4.00pm SGT 10.00am CEST	Group Discussion <ul style="list-style-type: none"> • Regulators' session: Applying GBT on local pharmacovigilance systems • Industry session: Identifying strengths and opportunities for strengthening the ASEAN pharmacovigilance system
5.30pm SGT 11.30am CEST	End

Day 2 – 21 September, Tue

Topic	
Day 2	
Enhancing effective in PV	
8.45am SGT 2.45am CEST	Registration
9.00am SGT 3.00am CEST	Risk Management Plan throughout the Product Lifecycle <ul style="list-style-type: none"> • Objective and Principles of Risk Management • Key Components of a Risk Management Plan • HSA's RMP Requirements and Experiences
10.30am SGT 4.30am CEST	Break
11.00am SGT 5.00am CEST	Group Discussion <ul style="list-style-type: none"> • Regulators' session: Reviewing RMP for local population • Industry session: Developing a RMP for the local NRA
12.30pm SGT 6.30am CEST	Lunch
2.00pm SGT 8.00am CEST	UMC's ecosystem of tools for National Pharmacovigilance Centres <ul style="list-style-type: none"> • VigiFlow • VigiBase
2.45pm SGT 8.45am CEST	Reliance in Pharmacovigilance <ul style="list-style-type: none"> • Data sharing for decision support
3.30pm SGT 9.30am CEST	Break
4.00pm SGT 10.00am CEST	Group Discussion <ul style="list-style-type: none"> • Regulators' session: VigiLyze training • Industry session: Facilitating reliance in PV – Challenges and Solutions from Industry
5.30pm SGT 11.30am CEST	End

Day 3 – 22 September, Wed

Topic	
Day 3	Pharmacovigilance in promoting public health
8.45am SGT 2.45am CEST	Registration
9.00am SGT 3.00am CEST	Leveraging digital innovations for early detection of Vaccine Related Events (VRE) <ul style="list-style-type: none"> • Inform COVID-19 vaccine safety communications and interventions
9.30am SGT 3.30am CEST	Patients' role in developing proper pharmacovigilance communications
10.00am SGT 4.00am CEST	Harnessing social media to reduce misinformation
10.30am SGT 4.30am CEST	Break
11.00am SGT 5.00am CEST	Role of pharmacovigilance in digital health
11.30am SGT 5.30am CEST	Artificial intelligence in pharmacovigilance
12.00pm SGT 6.00am CEST	Closing remarks
12.15pm SGT 6.15am CEST	End of Workshop