



Webinar
on
“Utilization of Vigiflow
&
VigiLyze-Ensuring quality of
ICSRs and Signal Detection”

September 22, 2022
14:00 - 17:00 (IST)

Targeted Participants

- ◎ **SEARO Countries**
- ◎ **Regional PV Centres**
- ◎ **National PV Centres of WHO-PIDM**

Organized by:

Indian Pharmacopoeia Commission

National Coordination Centre- Pharmacovigilance Programme of India (NCC-PvPI)
WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services
Ministry of Health & Family Welfare, Govt. of India, Sector-23, Rajnagar, Ghaziabad-201002

BACKGROUND

The Indian Pharmacopoeia Commission (IPC) is working as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) under the aegis of Ministry of Health & Family Welfare, Government of India. The NCC-PvPI, IPC is collecting, collating and analyzing Individual Case Safety Reports (ICSRs) and sending recommendations for the confirmed Signal, Prescribing Information Leaflet (PIL) changes to the National Regulatory Authority (Central Drugs Standards Control Organization) for taking appropriate regulatory action in the country.

The NCC-PvPI, IPC is also designated as a WHO-Collaborative Centre for the Pharmacovigilance in Public Health Programmes (PHPs) and Regulatory Services. The NCC-PvPI, IPC being a WHO-CC is regularly providing support to the WHO capacity building activities in SEARO countries by conducting trainings, workshops, webinars and also sharing the drug safety information like drug safety alerts, PvPI newsletter etc. through emails.

OBJECTIVE

1. To provide a practical training in the context of recent update of VigiFlow.
2. To build up the national capacity building on Pharmacovigilance in SEARO countries. To provide the training on Utilization of VigiFlow & VigiLyze in;
 - i. Ensuring quality of ICSRs
 - ii. Signal detection
3. To provide the training on WHO-Drug Standardized Drug Grouping (SDG)
4. To provide the training on Signal detection by using VigiLyze

NUMBER OF ATTENDEES

- About 200 participants from the WHO-Member States, National PV Centres of WHO-PIDM and Regional PV Centres (AMCs) may be expected to join this webinar.

REGISTRATION LINK

- **To join webinar, please register through the following link:-**
https://docs.google.com/forms/d/e/1FAIpQLSf8vYNli5-Xg2nAawtw4qzMi8lba57DC8v_iCeceiZNRU4tiA/viewform
- **Meeting link, User ID and Access Code to join Webinar through Webex will be provided after confirmation of registration.**

AGENDA

[Date: September 22, 2022 | Time: 14:00 - 17:00 (IST)]

INAUGURAL SESSION

Address by:-

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|----------------------|--|
| 14:00 – 14:10 | Dr. V. Kalaiselvan
Senior Principal Scientific Officer, IPC, Ghaziabad, India |
| 14:10 – 14:20 | Dr. Jai Prakash
Senior Principal Scientific Officer, IPC, Ghaziabad, India |
| 14:20 – 14:30 | Dr. Adrien Inoubli
Regional Adviser for Medical Products Quality & Regulation, WHO-SEARO Office,
New Delhi, India |

TECHNICAL SESSIONS

- | | |
|----------------------|--|
| 14:30 – 15:00 | Topic
An overview of updated Vigiflow
Speakers/Facilitators
<i>Representative from WHO-Uppsala Monitoring Centre, Sweden</i> |
| 15:00 – 15:30 | Topic
WHO-Drug Standardized Drug Grouping (SDG) by Vigilyze
Speakers/Facilitators
<i>Representative from WHO-Uppsala Monitoring Centre, Sweden</i> |
| 15:30 – 16:30 | Topic
Signal detection by using Vigilyze
Speakers/Facilitators
<i>Member of Signal Review Panel, NCC-PvPI, IPC</i> |
| 16:30 – 17:00 | Topic
Questions & Answers/ Concluding Session
Panel Members <ul style="list-style-type: none">• Dr. Adrien Inoubli
Regional Adviser for Medical Products Quality & Regulation, WHO-SEARO Office,
New Delhi, India• Dr. Noha Ilesan
Technical Officer, WHO Headquarter, Geneva, Switzerland• Dr. V. Kalaiselvan
Senior Principal Scientific Officer, IPC, Ghaziabad, India• Representatives from WHO-UMC, Sweden |