



## **7<sup>th</sup> Romanian Pharmacovigilance Workshop**

**EudraVigilance news, Signal detection, Covid-19 pharmacovigilance, MedDRA 23.1, inspections and audits, risk management plans and more...**

**Bucharest, 21 – 23 September 2020**

Since 22 November 2017, we have witnessed a year of many changes, regulatory as well as technical. This 7<sup>th</sup> pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance. Unprecedented changes have also occurred to pharmacovigilance activities due the Covid-19 pandemic.

**Due to possible travel or meeting restrictions that might be in place, this workshop may be held online with the same agenda.**

### **Faculty**

- Calin LUNGU, MD, DDCS S.A., Luxembourg



**Monday 21 September  
2020**

## **Morning**

08:30 – 09:00

Welcome and registration

9:30 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

EudraVigilance news, EVWEB evolutions

10:15 – 10:40

Coffee break

10:40 – 11:20

EVDAS main concepts and tools for MAHs, experience from the pilot phase, 2020 changes in EVDAS

11:20 – 12:00

User interaction with the EMA service desk, overview and examples

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

## **Afternoon**

13:30 – 14:15

MedDRA 23.1, focus on Covid-19

14:15 – 15:00

Covid-19 Pharmacovigilance

15:00 – 15:40

Coffee break

15:40 – 16:15

XEVMPD refresher, changes, issues and solutions

16:15 – 16:45

PSUSA outcomes, examples

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



## Tuesday 22 September 2020

### Morning

9:00 – 10:15

Pharmacovigilance inspections – common findings and metrics, recent experiences

10:15 – 10:40

Coffee break

10:40 – 11:20

Educational materials

11:20 – 12:00

Referral procedures

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

### Afternoon

13:30 – 14:15

The road to ISO IDMP standards implementation

14:15 – 15:00

The handling of safety signals from a regulatory perspective

15:00 – 15:40

Coffee break

15:40 – 16:15

Pharmacovigilance audits of pharmacovigilance databases validation, transfers

16:15 – 16:45

Pharmacovigilance audits of the signal detection process

16:45 – 17:00

Questions and Answers

17:00

End of Day 2



# Agenda

Day 3

## Wednesday 23 September 2020

09:00 – 09:45

SPOR and the interface with the EMA unique account and EudraVigilance registration, changes to XCOMP registration

09:45 – 10:30

Case study: registration of a new QPPV with EudraVigilance in the new EMA unique account and SPOR and merging an affiliate with the headquarter profile

10:30 – 11:10

Coffee Break

11:10 – 11:50

Safety communication, DHCP communications

11:50 – 12:15

Questions and Answers

13:00

End of the workshop

The workshop will be held at:

**Crowne Plaza Hotel,  
Bulevardul Poligrafiei 1,  
sector 1, Bucharest,  
Romania**

The registration form will be available in due course.

Please contact Alexandru Popescu ([alexandru.popescu@businesstravel.ro](mailto:alexandru.popescu@businesstravel.ro)) for any questions regarding this course and if you like to register.