



ISoP 2021 Annual Meeting - Pre-Conference Course II - 02 & 04 November

Managing safety signals in daily practice

A challenge for License Holders and Health Authorities – pre-conference course

Introduction

Pharmacovigilance activities generate new signals of possible drug related problems from many different sources and of varying quality and strength. The phase between raising a safety concern and taking adequate steps to mitigate the safety issue is a challenge for both marketing authorisation holder and regulatory authority. This course will discuss how to validate and confirm safety signals and how to decide what actions to take and when. Representatives from regulators and industry will give perspectives of their respective roles and responsibilities in informing healthcare professionals and patients about new safety information.

Learning goals

1. Understand the needs and responsibilities from a regulatory and industry perspectives
2. Understand the process from signal detection to validation and confirmation of safety signals
3. Understand why and how to substantiate a signal with biologic and epidemiologic evidence.
4. Develop risk minimization strategy for managing safety information
5. Make the right choice for follow-up studies (From signal to regulatory action)
6. Informing healthcare professionals and patients timely and effectively

Date:

Tuesday 02 November and Thursday 04 November 2021.

Location:

Online – ISoP Zoom platform

Target audience:

PV experts working in regulatory and industry setting, with less than 5 years of experience or pharmacovigilance officers having little experience on signal management and risk communication.

Chairs:

- Eugène van Puijenbroek, MD, PhD, clinical pharmacologist. Head Science and Research Pharmacovigilance Centre Lareb, Professor of Pharmacovigilance, University of Groningen, the Netherlands.
- Mulugeta Russom. Pharmacist, Pharmacoepidemiologist and Pharmacovigilance Specialist. Head, Eritrean Pharmacovigilance Centre, National Medicines and Food Administration, Eritrea.

Training II	GMT	CET	Oman
Tuesday 02 November	UTC	UTC+1	UTC+4
Session A start	08:00	09:00	12:00
Session A end	10:00	11:00	14:00
<i>Intermission 30'</i>			
Session B start	10:30	11.30	14.30
Session B end	12:30	13.30	16.30
Thursday 04 November			
Session C start	08:00	09:00	12:00
Session C end	10:00	11:00	14:00
<i>Intermission 30'</i>			
Session D start	10:30	11.30	14.30
Session D end	12:30	13.30	16.30

Training II: Managing Safety Signals in Daily Practice (all sessions are planned from 9:00 -13:30 CET)			
Session A: November 2, 2021; Topic: Risk Management Chairs: Eugène van Puijenbroek – the Netherlands and Mulugeta Russom – Eritrea			
	<i>Session Title</i>	<i>Suggested Presenter</i>	<i>Timing</i>
II-A1	General Introduction signal management & Signal detection	Eugène van Puijenbroek, MD, PhD, Clinical pharmacologist	45'
II-A2	Workshop signal detection		45'
	Workshop	Plenary presentations	30'
			2h
COFFEE BREAK 30'			
Session B: November 2, 2021; Topic: Signal Assessment Chairs: Eugène van Puijenbroek – the Netherlands and Mulugeta Russom – Eritrea			
	<i>Session Title</i>	<i>Presenter</i>	<i>Timing</i>
II-B1	Signal prioritisation, validation and substantiation	Eugène van Puijenbroek, MD, PhD, Clinical pharmacologist	45'
II-B3	Workshop	Signal validation	45'
	Workshop	Plenary presentations	30'

			2h
Session C: November 4, 2021; Topic: From Signal to Regulatory Action Chairs: Eugène van Puijenbroek – the Netherlands and Mulugeta Russom – Eritrea			
	<i>Session Title</i>	<i>Presenter</i>	<i>Timing</i>
II-C1	From Signal to regulatory action: perspectives from LMICs	Mulugeta Russom, Pharmacist, Pharmacoepidemiologist & Pharmacovigilance Specialist	30'
II-C2	Signal management – a perspective from the pharmaceutical industry	Dr David J Lewis, EU & UK QPPV Head QPPV Office, Novartis	30'
	Workshop regulatory actions		30'
	Workshop	Plenary presentations	30'
			2h
COFFEE BREAK 30'			
Session D: November 4, 2021; Topic: Communication of safety signals Chairs: Eugène van Puijenbroek – the Netherlands and Mulugeta Russom – Eritrea			
	<i>Session Title</i>	<i>Presenter</i>	<i>Timing</i>
II-D1	Communication of safety signals: what, when and where	Priya Bahri, PhD	30'
II-D2	Workshop communication		60'
	Plenary sessions	Participants	30'
			2h