



International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

Intelligent Automation in Pharmacovigilance 2021

Fifth ISO P Seminar

6-7 December 2021



GLOBAL ONLINE WEBINAR

Dates	Sessions	Time (UTC/GMT)	Time (EST)
6 December 2021	Welcome & Introduction	13:30-13:45	08:30-08:45
6 December 2021	Session 1: State of the Art – Academia and Innovative Pharma	13:45-15:15	08:45-10:15
6 December 2021	Session 2: New Views from Regulatory Agencies	15:30-17:00	10:30-12:00
7 December 2021	Session 3: Updates from Industry Consortia and Technology Providers	13:30-15:00	08:30-10:00
7 December 2021	Session 4: New experience with methodology, science and technology	15:15-16.45	10:15-11.45



Virtual meeting format

This virtual seminar will be conducted online using the ISO P Zoom platform. Live Q&A and panel discussions will follow presentations and sessions as per the agenda.

Preliminary Programme | Seminar Day 1

Monday, December 6, 2021

	13:30 – 13:45 UTC <i>15'</i>	Welcome & Introduction Jan Petracek (<i>ISoP Advisory Board, Director of the Institute of Pharmacovigilance, Board Director of iVigee</i>)
Session 1: State of the Art – Academia and Innovative Pharma <i>Chair: Jean-Christophe Delumeau (ISoP Executive Committee, Head of Policy Strategy, Bayer)</i>		
1A	13:45-14:10 UTC <i>20' + 5'</i>	Machine Learning in Healthcare and lessons for Pharmacovigilance (<i>Title to be confirmed</i>) Yuan Luo (Associate Professor, Chief AI Officer, Northwestern University Feinberg School of Medicine)
1B	14:10-14:35 UTC <i>20' + 5'</i>	Pharmacovigilance State of the Art for AI toolbox (<i>Title to be confirmed</i>) Antoine Pariente (Professor, Pharmacology and Pharmacoepidemiology, University of Bordeaux)
1C	14:35-15:00 UTC <i>20' + 5'</i>	Intelligent automation in PV projects by Transcelerate Consortium (<i>Title to be confirmed</i>) Ray Kassekert (Senior Director, Global Head, Safety Data Services, GSK)
1D	15:00-15:15 UTC <i>15'</i>	Panel Discussion Panelists: Andrew Bate, Jean-Christophe Delumeau, Yuan Luo, Ray Kassekert, Antoine Pariente, Jan Petracek
	15:15 – 15:30 UTC	Coffee Break
Session 2: New Views from Regulatory Agencies <i>Chair: Jan Petracek (ISoP Advisory Board, Director of the Institute of Pharmacovigilance, Board Director of iVigee)</i>		
2A	15:30-15:50 UTC <i>15' + 5'</i>	US FDA Update Robert Ball (Deputy Director, Office of Surveillance and Epidemiology, CDER, US FDA)
2B	15:50-16:10 UTC <i>15' + 5'</i>	MHRA Update Phil Tregunno (Group Manager, Vigilance, Intelligence and Research, MHRA)
2C	16:10-16:30 UTC <i>15' + 5'</i>	EMA Update on use of PV Automation Luis Pinheiro (Signal Management Lead, European Medicines Agency)
2D	16:30-17:00 UTC <i>30'</i>	Panel Discussion followed by closing remarks Panelists: Andrew Bate, Robert Ball, Jean-Christophe Delumeau, Luis Pinheiro, Jan Petracek, Phil Tregunno
End of Day 1		

Preliminary Programme | Seminar Day 2

Tuesday, December 7, 2021

Session 3: Updates from Technology Providers

Chair: Amie Serpico (Senior Director, Global Patient Safety, Vertex Pharmaceuticals)

3A	13:30-14:00 UTC <i>20' + 10'</i>	AI for unstructured healthcare data: application to coding of patient reporting of ADRs, Medication Shield Technology Louis Letinier (Medical Director & Co-Founder, Synapse Medicine) and Francesco Salvo (Associate Professor, Coordinator of EU2P, University of Bordeaux)
3B	14:00-14:15 UTC <i>10' + 5'</i>	Fully automated management of incoming E2B cases plus demonstration Sameer Thapar (Senior Director, Global PV, Oracle)
3C	14:15-14:30 UTC <i>10' + 5'</i>	AI in pharmacovigilance and clinical safety – medical literature monitoring Nicole Duarte Vigar Baker (CEO and Co-Founder, Biologit)
3D	14:30-14:45 UTC <i>10' + 5'</i>	AI Capabilities of ReTrans Enterprise for literature monitoring Raghu Chikkamuniyappa (Director, Alwis Group) and Abdul Rahim (Technical Director, Alwis Group)
3E	14:45-15:00 UTC <i>10' + 5'</i>	Application of AI in literature monitoring for PV using a rule-based NLP approach Sunil Jain (Founder, LiterAltire)
15:00-15:15 UTC		Coffee Break
<h3>Session 4: New experience with methodology, science and technology</h3> <p>Chair: Deirdre McCarthy (ISoP Executive Committee, Senior Director, AlloVir)</p>		
4A	15:00-15:30 UTC <i>20' + 10'</i>	Machine Learning in PV – The need for end to end thinking Andrew Bate (Vice President, Head, Safety Innovation & Analytics, GSK)
4B	15:30-15:50 UTC <i>15' + 5'</i>	Financial industry automation journey and its applicability to pharmacovigilance Robert Scheiner (CIO, iVigee)
4C	15:50-16:10 UTC <i>15' + 5'</i>	Automation initiatives, including NLP, machine learning projects and robotics use cases (Title to be confirmed) Uwe Langermann (Vice President, Head of Quality, Technology & Analytics, Bayer)
4D	16:10-16:30 UTC <i>20'</i>	Panel Discussion Panelists: Andrew Bate, Deirdre McCarthy, Uwe Langermann, Jan Petracek, Phil Tregunno, Robert Scheiner
	16:30-16:45 UTC <i>15'</i>	Closing remarks
End of the webinar		