

Intelligent Automation in Pharmacovigilance 2024

8th ISoP Seminar

Draft Agenda, version 4

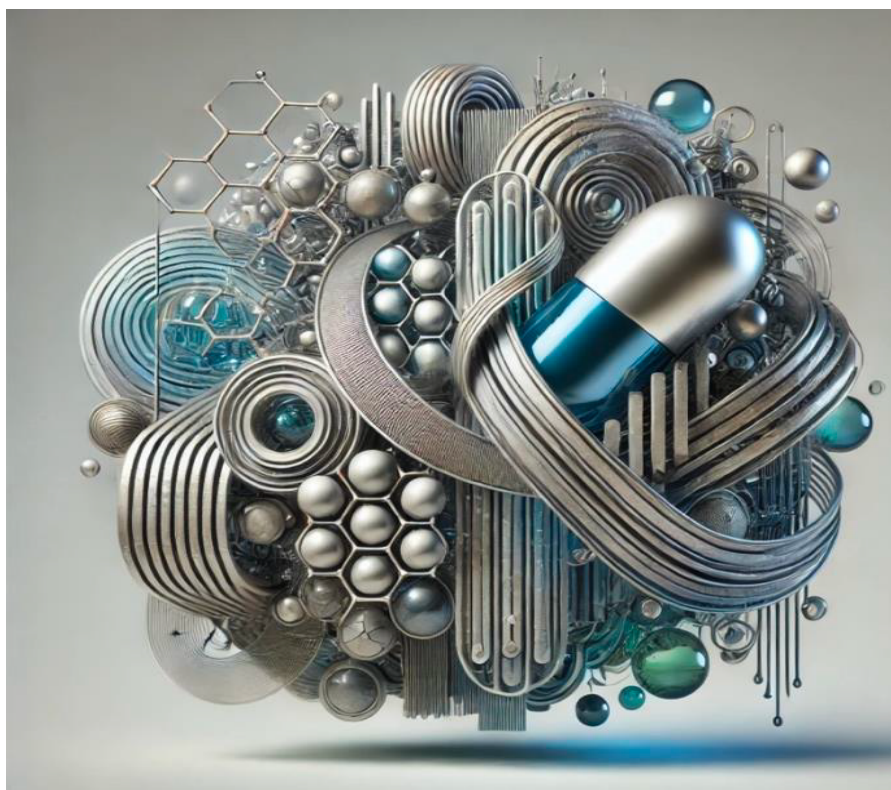
5-6 December 2024
Boston, Cambridge, U.S.

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International Society of Pharmacovigilance

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ISoP seminars must be free of commercial biases, and a strict conflict of interest policy is enforced. We create an international forum for all those with an interest in the clinical, scientific, and regulatory aspects of patient safety when using medicines. ISoP includes members from governmental, research and academic organizations as well as industry.

ISoP would like to extend its gratitude to Biogen for hosting the meeting at its premises, and to iVigee for their organizational support.

Agenda | Seminar Day 1: Foundations and Key Updates

Thursday, December 5, 2024

8:30 – 8:45	Welcome & Introduction Monica Mehta (<i>Vice President, Global Pharmacovigilance, Biogen</i>) Jan Petracek (<i>Course Coordinator, ISO P, CEO@iVigee</i>)
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Session 1: Intelligent Automation in Pharmacovigilance – Status Update

Chair: TBC

8:45 – 9:30 30' + 15'	Jim Barrett (Uppsala Monitoring Centre) Critical evaluation of AI solutions for PV
9:30 – 10:15 30' + 15'	Speaker invited
10:15 – 10:45 30'	<i>Networking Coffee Break</i>

Session 2: Regulatory Perspectives on AI in Pharmacovigilance

Chair: TBC

10:45 – 11:15 20' + 10'	Oanh Dang (<i>Regulatory Science & Applied Research Lead in Pharmacovigilance, FDA/CDER/OSE/RSS</i>) An update on FDA scientific and regulatory activities related to AI in pharmacovigilance
11:15 – 11:45 20' + 10'	Mohammed Fouda (Signal Management Lead, SFDA, Chair, ISO P SIG on AI in PV) Using AI in Saudi FDA – case study
11:45 – 12:15 20' + 10'	EMA and SwissMedic speakers invited
12:15 – 13:15 60'	<i>Lunch break</i>

Session 3: AI-driven Case Intake and Processing

Chair: **Douglas Clark** (*Head of Technology, Analytics & Data Insights (TADI), Biogen*)

13:15 – 13:45 20' + 10'	Andrew Mitchell (CEO @ YEZA.AI) AI Agents in Pharmacovigilance
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13:45– 14:15 20'+ 10'	Maurizio Sessa (University of Copenhagen) Large Language Models for Causality Assessment
14:15 – 14:45 20'+ 10'	Speaker invited
14:45 – 15:15 30'	<i>Networking Coffee Break</i>
Session 4: Lessons Learned from AI Projects	
Chair: TBC	
15:15 – 15:45 20'+ 10'	Anjali Snah (Bristol Myers Squibb) BMS Experience with AI projects
15:45– 16:15 20'+ 10'	Andrew Rut (Former Head of Safety, GSK) Overcoming The Seven Deadly Sins of AI - A Journey to Personalised Benefit-Risk
16:15– 16:45 20'+ 10'	Hua Carroll (Biogen)
End of Day 1	

Agenda | Seminar Day 2: Advanced Applications and Strategic Implementation

Friday, December 6, 2024

Session 5: AI in Data Analysis and Signal Detection

Chair: TBC

8:30 – 9:00	Welcome Back and Recap of Day 1
9:00 – 9:30 20'+ 10'	Eva- Lisa Meldau (Uppsala Monitoring Centre) Beyond precision and recall: rethinking evaluation metrics in PV
9:30 – 10:00 20'+ 10'	Jun Ren (Biogen) Leveraging AI for Enhanced Causality Assessment
10:00 – 10:30 20'+ 10'	Nicole Baker (CEO@Biologit) Use cases of ML and NLP, while complying with regulatory aspects of AI
10:30 -11:00 30'	<i>Coffee break</i>

Session 6: Building Trust in Artificial Intelligence

Chair: TBC

11:00 – 11:30 20'+ 10'	Jan Petracek (CEO @ iVigee, Director @ Institute of Pharmacovigilance, ISoP SIG Vicechair of AI in PV) Deepfakes and Their Impact on Data Integrity
11:30 – 12:00 20'+ 10'	Sameer Thapar (invited) (Oracle Health Sciences)
12:00 – 12:30 20'+ 10'	Speaker invited
12:30 – 13:30 60'	<i>Lunch break</i>

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Session 7: Research, implementation, and future trends of intelligent automation in PV

Chair: TBC

13:30 – 14:00 20'+ 10'	Andrew Bate (Invited, remote) Intelligent Automation in Pharmacovigilance – major research trends
14:00 – 14:30 20+10'	Robert Scheiner (CIO @ iVigee) Strategic Roadmaps for Implementing AI in PV
14:30 – 15:00 20+10'	Speaker invited
15:00 – 15:30 30'	Audience Q&A and Closing Remarks
End of the seminar	