

Intelligent Automation in Pharmacovigilance 2023

7th ISO P Boston Seminar

4-5 December 2023

Biogen Building 6, Auditorium 6, 115 Broadway, Cambridge, MA 02142



ISO P 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. ISO P includes members from governmental, research and academic organizations as well as industry.

All registered participants will get access to recorded presentations to view on-line after the event. Additional resources for participants will also be made available online.

Agenda | Seminar Day 1

Monday, December 4, 2023

8:30 – 8:45

Welcome & Introduction

Monica Mehta (*Vice President, Global Pharmacovigilance, Biogen*)
Jan Petracek (*Course Coordinator, ISO P, CEO, iVigee*)

Session 1: Large Language Models and Generative AI - new 2023 disruptor for PV industry

Chair: Neal Grabowski (*Head Signal Management - Global Pharmacovigilance, Sanofi*)

8:45 – 9:30
30' + 15'

Yuan Luo (*Chief AI Officer & Prof. at Northwestern University*)

Large Language Models for Pharmacovigilance

9:30 – 10:00
20' + 10'

Andrew Semmes (*Sr. Project Manager, Moderna*)

A Framework for Assessing Opportunities & Risks of Leveraging Large Language Models in Pharmacovigilance

30'	<i>Coffee break</i>
Session 2: Updates from the Regulatory Authorities	
Chair: Andrew Bate (<i>VP, Head of Safety Innovation & Analytics, Global Safety, GSK</i>)	
10:30 – 11:00 20' + 10'	Luis Pinheiro (<i>Scientific Administrator, EMA</i>) - virtual presentation EMA AI Roadmap
11:00 – 11:30 20' + 10'	Phil Tregunno (<i>Deputy Director, Patient Safety Monitoring, Safety and Surveillance, MHRA</i>) AI and Digitalisation – a Regulatory Perspective
11:30 – 12:00 20' + 10'	Robert Ball (<i>Deputy Director, Office of Surveillance and Epidemiology, CDER, FDA</i>) - virtual presentation Artificial Intelligence for Pharmacovigilance at FDA: Where are we now?
12:00 – 13:00 60'	<i>Lunch break</i>
Keynote Lecture	
Chair: Douglas Clark (<i>Head of Technology, Analytics & Data Insights (TADI), Biogen</i>)	
13:00 – 13:45 30' + 15'	Andrew Beam (<i>Assistant Professor, Department of Epidemiology, Harvard T.H. Chan School of Public Health, Founding Deputy Editor of NEJM AI</i>) The present and future of AI in healthcare and medicine
Session 3: AI-driven Case Intake and Processing	
Chair: Solange Hebert (<i>Director, Global Case Management, Apellis Pharmaceuticals</i>)	
13:45 – 14:15 20' + 10'	Hua Carroll (<i>Senior Director, Head ICSR Medical Evaluation/Global Safety Officer, Biogen</i>) ICSR causality assessment ML project
14:15 – 14:45 20' + 10'	Jan Hejtmanek (<i>Partner, Deloitte CE</i>) AI in Medical Information Call Centre
30'	<i>Coffee break</i>
Session 4: AI in Data Analysis and Signal Detection	
Chair: Robert Scheiner (<i>CIO, iVigee</i>)	
15:15 – 15:45 20' + 10'	Neal Grabowski (<i>Head Signal Management - Global Pharmacovigilance, Sanofi</i>) Intelligent Automation Opportunities in Signal Detection & Management: Map data is not available
15:45 – 16:30 30' + 15'	Maurizio Sessa (<i>Associate Professor, University of Copenhagen</i>) Revolutionize Signal Management with AI

16:30	<i>Q&A, End of Day 1</i>
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Agenda | Seminar Day 2

Tuesday, December 5, 2023

Session 5: Current and Future AI Tools for PV Operations

Chair: Hua Carroll (*Senior Director, Head ICSR Medical Evaluation/Global Safety Officer, Biogen*)

8:30 – 9:00 20' + 10'	Sameer Thapar (<i>Senior Director, Oracle</i>) What if...Rebuilding PV Using Today's Tech
9:00 – 9:30 20' + 10'	Nicole Baker (<i>CEO, Biologit</i>) Beyond Traditional Methods: AI-Driven Safety and Efficacy Identification in Pharmacovigilance
9:30 – 10:00 20' + 10'	Robert Scheiner (<i>CIO, iVigee</i>) Building an AI Agent for Regulatory Intelligence in Pharmacovigilance
30'	<i>Coffee break</i>

Session 6: AI in Pharmacovigilance Science

Chair: Phil Tregunno (*Deputy Director, Patient Safety Monitoring, Safety and Surveillance, MHRA*)

10:30 – 11:00 20' + 10'	Andrew Bate (<i>VP, Head of Safety Innovation & Analytics, Global Safety, GSK</i>) Generative AI and unrequited trust
11:00 – 11:30 20' + 10'	Walter Strauss (<i>VP, Safety & Pharmacovigilance, Moderna</i>) Update on CIOMS Group on AI in PV
11:30 – 12:00 20' + 10'	Jim Barrett (<i>Senior Data Scientist, Uppsala Monitoring Centre</i>) 20 years of machine learning for duplicate detection: adding new features to an old model
12:00 – 13:00 60'	<i>Lunch break</i>

Session 7: AI in Pharmacovigilance Practice

Chair: Nicole Baker (*CEO, Biologit*)

13:00 – 13:30 20'+ 10'	Aman Wasan (<i>CEO, ArisGlobal</i>) LLM and GenAI: Impact on PV
13:30 – 14:00 20+10'	John Cheevers (<i>CCO (Technology), Quinecsa Solutions</i>) The use of AI/ML technology in PV especially targeting the biotech and small Pharma market
14:00 – 14:30 20+10'	Sean Darcy (<i>Darcy Consulting Group</i>) Experience with the implementation of an AI-powered case intake system
30'	<i>Coffee break</i>

Session 8: Panel Discussion – Next Pharmacovigilance Frontiers

Chair: Shui Ki (Henry) Seto (*VP, Head of Global Patient Safety, Vertex Pharmaceuticals*)

15:00 – 15:30 30'	Jan Petracek (<i>CEO, iVigee</i>) State of the art overview - how much can AI help already and what is coming?
15:30 – 16:30 60'	Panel Discussion - include speakers and chairs of the seminar. All unanswered questions from the sessions and new questions will be addressed
16:30	<i>Closing Remarks</i>

End of the seminar