



3rd Seminar

# Intelligent Automation in Pharmacovigilance 2019

Boston/Cambridge  
2-3 December, 2019

BIOGEN BUILDING 8

**Entrance and security via Biogen Building 9**

300 Binney Street, Cambridge, MA 02142 - USA

**Meeting room:** 812 Auditorium/Floor 1

International Society of Pharmacovigilance

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## Programme | Seminar Day 1

### Monday, December 2nd 2019

08:00 – 08:45	<b>Registration</b>
08:45 – 09:00	<b>Introduction to the course</b> Welcome from the hosting organisation (Biogen) Welcome from ISoP and NASoP
09:00 – 10:30	<b>Session 1: Approaches and Experience with Automation in PV</b> <i>Moderator: Jeffrey Philip, Director SABR DSA (Biogen)</i>
09:00 – 09:45	<b>MHRA approach to AI for safety monitoring</b> Phil Tregunno, Group Manager, Vigilance, Intelligence and Research Group (MHRA)
9:45 – 10:30	<b>Guidance for Validation of Automated Pharmacovigilance Systems</b> Elizabeth Savage, Johnson & Johnson Kristof Huysentruyt, UCB
10:30 – 11:00	<i>Coffee break</i>
11:00 – 12:30	<b>Session 2: Technology Providers – Reality Check</b> <i>Moderator: Douglas W Clark, Senior Director DSA (Biogen)</i>
11:00 – 11:30	<b>Case studies of applying AI to pharmacovigilance processes</b> TBD

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11:30 – 12:00	<b>From Hype to Practical Reality</b> Emmanuel Belabe, AVP, Global PV (ArisGlobal)
12:00 – 12:30	<b>Updates on AI in Pharmacovigilance</b> Sameer Thapar, Director of Global PV (Oracle)
<i>12:30 – 13:30</i>	<i>Lunch break</i>
13:30 – 15:00	<b>Session 3: Emerging Approaches to PV</b> <i>Moderator: Shui Ki (Henry) Seto, VP, Head of GPS (Vertex Pharmaceuticals)</i>
13:30 – 14:00	<b>Paradigm Shift in Exploring Relatedness</b> Lucie Gattepaille, Data Scientist, Research Department (Uppsala Monitoring Centre)
14:00 – 14:30	<b>Re-imagining PV Data Capture</b> Anton Rachmanov, Automation Business Lead (PrimeVigilance)
14:30 – 15:00	<b>Lessons from machine learning in signal detection for the automation of case report entry and management</b> Andrew Bate, Head of Safety Innovation and Analytics (GSK)
<i>15:00– 15:30</i>	<i>Coffee break</i>
15:30 – 17:00	<b>Session 4: Opportunities and Case Studies</b> <i>Moderator: Deirdre McCarthy (ISoP Secretary General)</i>
15:30 – 16:00	<b>Identifying and Assessing Opportunities for Automation and AI in the Pharmacovigilance Lifecycle</b> Kelly Traverso, VP, Safety Strategy and Consulting (Vault Safety, Veeva)
16:00 – 16:30	<b>PV Automation: Retrospective, Prospective, and Remediation Case Studies using AI/ML</b> Raj Kasuganti, Director, IQVIA Technology Solutions
16:30 – 17:00	<b>Road to Automation in PV of Biogen</b> Douglas W Clark, Senior Director DSA (Biogen)
17:00	Q&A, closing the day one

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## Programme | Seminar Day 2

Tuesday, December 3rd 2019

09:00 – 10:30	<b>Session 5: Experience, Approach and Expectations of Regulators</b> <i>Moderator: Jan Petracek (ISoP Board member)</i>
09:00 - 10:00	<b>Automation in US FDA pharmacovigilance systems</b> Robert Ball, Deputy Director of OSE, AI in PV Leader (US FDA)
10:00-10:30	<b>MHRA expectations for MAH's introducing automation features in their pharmacovigilance processes</b> Phil Tregunno, Group Manager, Vigilance, Intelligence and Research Group (MHRA)
<i>10:30 – 11:00</i>	<i>Coffee break</i>
11:00 – 12:30	<b>Session 6: Strategy for disruption in PV</b> <i>Moderator: Monica Mehta, Vice-President Global PV (Biogen)</i>
11:00 – 11:30	<b>Automation landscape and its impact on pharmacovigilance</b> Jan Petracek (ISoP Board member)
11:30-12:20	<b>Panel discussion chaired by Monica Mehta</b> Panelists: Robert Ball, Véronique Kugener, Jan Petracek Henry Seto, Phil Tregunno.
12:20 – 12:30	Closing remarks and end of the ISoP seminar
<i>12:30 – 13:30</i>	<i>Lunch break</i>
13:30 – 17:00	<b>North America Chapter of International Society of Pharmacovigilance Annual Meeting (NASoP)</b>

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