



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Intelligent Automation in Pharmacovigilance ISoP Seminar

4th – 5th December 2017

Boston/Cambridge, MA (USA)

Venue: Biogen Building 8, 812 Auditorium (Floor 1)

Entrance and security via Biogen Building 9 (300 Binney Street, Cambridge, MA 02142)

Day 1: Monday 4th December 2017

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| 08:00 – 08:45 | Registration |
| 08:45 – 09:00 | Welcome and Introduction
<i>Priya Singhal, SVP and Global Head, SABR (Biogen)</i> |
| 09:00 – 10:30 | Session 1: Case Intake Automation
<i>Moderator: Douglas W Clark, Senior Director DSA (Biogen)</i> |
| 09:00 – 09:30 | AI + dynamic intake + business process = VALUE
<i>April Davis, Industry Principal Director (Accenture)</i>
<i>and Andrew Rut, CEO (MyMeds&Me)</i> |
| 09.30 - 10.00 | Automatic Follow-Up - a case study from AstraZeneca
<i>Andrew Finlay, EU Medical Information & Patient Safety
Manager (AstraZeneca)</i> |
| 10.00 - 10.30 | Can advanced methods improve post-market safety surveillance?
<i>Taxiarchis Botsis, Medical Informatician, Center for Biologics
Evaluation and Research (US FDA)</i> |
| 10:30 – 11:00 | Coffee break |
| 11:00 – 12:30 | Session 2: ICSR Processing Automation
<i>Moderator: Wayne Jack Wallis, Executive Director
and Pharmacovigilance Research Fellow (Celgene)</i> |
| 11:00 – 11:20 | Autonarratives – what is the state of the art?
<i>Alexander Kluczka, Global Head ICSR Processing Oncology (Bayer)</i> |

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



- 11:20 – 11:40** **QC for Machine Learning and AE/ICSR Identification: Will the Real Ground Truth Please Stand Up?**
Shaun Comfort, Associate Director and Sr. Safety Science Leader (Genentech)
- 11.40 - 12.00** **Achieving PV Processing Automation with Technology Optimization**
Sameer Thapar, Director, Global Pharmacovigilance (Oracle)
- 12.00 - 12.20** **Streamlining Data Entry and Case Review (QC) through Cognitive Automation**
Aman Wasan, Vice President – Automation Strategy and Partnerships (ARIS Global)
- 12.20 - 12.30** **Discussion**
- 12:30 – 13:30** **Lunch break**
- 13:30 – 15:00** **Session 3: Signal Management Support Tools**
Moderator: Phil Tregunno, Signal Management Unit Manager, and IMI WEB-RADR project lead (MHRA, ISoP Board member)
- 13:30 – 14:00** **Opportunities for signal automation at various steps of the signal management process**
Cvijeta Bielen, Medical Director (PrimeVigilance)
- 14.00 - 14.30** **Computational methods to enhance signal detection: the Uppsala Monitoring Centre experience**
Lucie Gattepaille, Data Scientist (Uppsala Monitoring Centre)
- 14.30- 15.00** **Signal Management Automation Opportunities**
Bill Blackwell, VP Safety Solutions (Commonwealth Informatics)
- 15:00– 15:30** **Coffee break**
- 15:30 – 17:00** **Session 4: Robotic Process Automation**
- Panel discussion:**
Moderator: Darren Tang, Chief Technology Officer (PrimeVigilance and PharmInvent)
- Speakers:**
- *Mark Fletcher, EVP Global Sales (Automation Anywhere)*
 - *Mark Mannion, Managing Director (Extra Technology)*
 - *Eric Sandor, Pharmacovigilance Artificial Intelligence (PVAI) Business Leader (Genpact)*



Day 2: Tuesday 5th December 2017

09:00 – 10:30

Session 5: New Skillset for Careers in Pharmacovigilance

Panel discussion:

Moderator: Jan Petracek, CEO (PrimeVigilance, ISoP Board member)

Speakers:

- *Diane Beck, VP, Head of Pharmacovigilance Services (Takeda International Inc.)*
- *Taxiarchis Botsis, Medical Informatician, Center for Biologics Evaluation and Research (US FDA)*
- *Alexander Kluczka, Global Head ICSR Processing Oncology (Bayer)*
- *Phil Tregunno, Signal Management Unit Manager, and IMI WEB-RADR project lead (MHRA, ISoP Board member)*
- *Shui Ki Henry Seto, VP, Global Patient Safety (Vertex)*

10:30 – 11:00

Coffee break

11:00 – 12:30

Session 6: Pharmacovigilance Automation – Are you in danger of disruption?

Panel discussion:

Moderators: Tauqeer Karim, VP, Drug Device Safety Officer – Fresenius Medical Care (FMCNA) and Phil Tregunno (Signal Management Unit Manager, and IMI WEB-RADR project lead (MHRA, ISoP Board member)

Speakers:

- *Mark Mannion, Managing Director (Extra Technology)*
- *Tarak Thakker, Pharmacovigilance Leader (IBM Watson)*
- *Hershell Thompson, Senior Managing Consultant (Navitas Life Sciences)*

12:30 – 13:30

Lunch break

13:30 – 15:00

Session 7: Pharmacovigilance Insourcing and Outsourcing Model for Industry 4.0

Moderators: Monica Mehta, Seasoned PV Operations Leader (Biogen) and Deirdre McCarthy, Senior Director, Pharmacovigilance (IQVIA, ISoP Board member)

13.30 - 14.00

The optimal service mix for 2020

Jan Petracek, CEO (PrimeVigilance, ISoP Board member)



- 14.00 - 14.30** **Opportunities for innovation and automation to influence the PV out sourcing model**
Brian Wellins, Senior Director PV (PPD)
- 14.30 - 15.00** **The decisions to be made by Heads of PV Ops for Industry 4.0**
Sean Darcy, Senior Director (Alynlam)
- 15:00– 15:15** **Closing remarks**