



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

## Intelligent Automation in Pharmacovigilance ISoP Seminar

4<sup>th</sup> – 5<sup>th</sup> 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 4<sup>th</sup> December 2017

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| <b>08:00 – 08:45</b> | <b>Registration</b>  |
| <b>08:45 – 09:00</b> | <b>Welcome and Introduction</b><br><i>Priya Singhal, SVP and Global Head, SABR (Biogen)</i>  |
| <b>09:00 – 10:30</b> | <b>Session 1: Case Intake Automation</b><br><i>Moderator: Douglas W Clark, Senior Director DSA (Biogen)</i>  |
| <b>09:00 – 09:30</b> | <b>AI + dynamic intake + business process = VALUE</b><br><i>April Davis, Industry Principal Director (Accenture)<br/>and Andrew Rut, CEO (MyMeds&amp;Me)</i>                       |
| <b>09.30 - 10.00</b> | <b>Automatic Follow-Up - a case study from AstraZeneca</b><br><i>Andrew Finlay, EU Medical Information &amp; Patient Safety<br/>Manager (AstraZeneca)</i>                          |
| <b>10.00 - 10.30</b> | <b>Can advanced methods improve post-market safety surveillance?</b><br><i>Taxiarchis Botsis, Medical Informatician, Center for Biologics<br/>Evaluation and Research (US FDA)</i> |
| <b>10:30 – 11:00</b> | <b>Coffee break</b>  |
| <b>11:00 – 12:30</b> | <b>Session 2: ICSR Processing Automation</b><br><i>Moderator: Wayne Jack Wallis, Executive Director<br/>and Pharmacovigilance Research Fellow (Celgene)</i>                        |
| <b>11:00 – 11:20</b> | <b>Autonarratives – what is the state of the art?</b><br><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 5<sup>th</sup> 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**