



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

## Intelligent Automation in Pharmacovigilance

**Seminar– preliminary programme**

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

**Boston/Cambridge, MA (USA)**

Biogen Auditorium  
12 Cambridge Center

Enquiries: ISoP Phone and Fax +44 (0)20 3256 0027

[www.isoonline.org](http://www.isoonline.org) or [administration@isoonline.org](mailto:administration@isoonline.org)

Can process automation help us to cope with the ever-increasing demands in pharmacovigilance?

The increasing volume of regulated data management and data analysis activities in pharmacovigilance are very time consuming and costly, and process automation has potential to provide much higher efficiency and heavily reduced costs. However, process automation is a complex strategic decision, and needs to be evaluated correctly.

ISoP offers a unique, highly focused, and scientific seminar which explores the emerging tools in process automation and the challenges their implementation brings to our pharmacovigilance activities. This enables pharmacovigilance leaders to make better informed decisions while being ready for innovation that is already on its way to our industry.

There will be ample opportunity to exchange views and ideas in discussions both following individual presentations, after the panel discussion at the end of the seminar, and during coffee breaks.

The faculty will consist of international experts in pharmacovigilance, representing government, academia, and industry.

Training certificates of attendance will be provided to those who complete the seminar.

This seminar is organized in Boston (USA) Massachusetts' capital. It is the first time that such an ISoP meeting has been undertaken in North America.

The International Society of Pharmacovigilance would like to extend its gratitude to Biogen for hosting the meeting at its premises, and to PrimeVigilance for their organizational support.

## Day 1: Monday 4<sup>th</sup> December 2017

**08:00 – 08:45**      **Registration**

**08:45 – 09:00**      **Introduction to the course**

### **Session 1: Case Intake Automation**

*Moderator: Monica Mehta (Biogen)*

**09:00 – 10:30**      Examining the current progress with the existing pilot programs focusing on case intake automation  
Discovering the tools under development  
Understanding and defining the main challenges of stakeholders

***Speakers (15 mm + 5 mm Q/A x 4):***

*Andrew Finlay (AstraZeneca)*

*Celgene speaker invited*

*US FDA (speaker invited)*

*April Davis (Accenture)*

**10:30 – 11:00**      **Coffee break**

### **Session 2: ICSR Processing Automation**

*Moderator: Wayne Jack Wallis (Celgene) invited*

**11:00 – 12:30**      How can the existing tools meet the needs of both industry and regulators?  
What are the tools under development?  
Will the QC and medical review steps in case processing someday become fully automated or will aspects of this workflow continue to be handled by humans?

***Speakers (15 mm + 5 mm Q/A x 4):***

*Alexander Kluczka (Bayer)*

*Shaun Comfort (Genentech)*

*Sameer Thapar (Oracle)*

*ARIS Global (speaker invited)*

**12:30 – 13:30**      **Lunch break**

### **Session 3: Signal Management Support Tools**

*Moderator: Phil Tregunno (ISoP Board)*

**13:30 – 15:00**      Where are the opportunities for automation in the signal management process?  
How much do the existing tools help the actual signal management process?  
What are the tools used by influential regulators and international organizations – WHO, FDA, EMA?

***Speakers (15 mm + 5 mm Q/A x 4):***

*Lucie Gattepaille (Uppsala Monitoring Centre/WHO)*

*Phil Tregunno (ISoP Board)*

*Cvijeta Bielen (PrimeVigilance)*

*Bill Blackwell (Commonwealth Informatics)*

**15:00– 15:30**      **Coffee break**

### **Session 4: Robotic Process Automation Technology Platforms**

*Moderators: Darren Tang (PrimeVigilance and PharmInvent)*

**15:30 – 17:00**      *Robotic process automation has currently four recognised leading technology platform providers, used by most of the process automation projects and consultancy companies. First-hand understanding of what these platform technology providers can offer to pharmacovigilance will be invaluable for decision makers in pharmacovigilance.*

***Speakers invited:***

- *Automation Anywhere (IBM Watson)*
- *UI Path*
- *Blue Prism*
- *Thoughtonomy*

## Day 2: Tuesday 5<sup>th</sup> December 2017

### Session 5: New Skillset for Careers in Pharmacovigilance

*Moderator: Jan Petracek (ISoP Board)*

**09:00 – 10:30**

**Panel discussion:**

What are the new areas of competence required for modern pharmacovigilance?

Lost jobs due to automation – what retraining options are there in PV?

Emerging types of jobs and services in pharmacovigilance

**Speakers:**

*Alexander Kluczka (Bayer)*

*Achint Kumar (Biogen)*

*Phil Tregunno (ISoP Board)*

*Veronique F. Kugener (Takeda)*

*Henry Seto (Vertex)*

*FDA representative invited*

**10:30 – 11:00**

**Coffee break**

### Session 6: Pharmacovigilance Automation – Are You in Danger of Disruption?

*Moderator: Tauqeer Karim (FMCNA) and Phil Tregunno (ISoP Board)*

**11:00 – 12:30**

**Panel discussion:**

How the new pharmacovigilance departments might look after a full implementation of intelligent automation?

What are the jobs/roles in PV that are most likely to be replaced by automation?

What changes an automated process may bring to geographical location(s) of pharmacovigilance services?

**Speakers:**

*Mark Mannion (Extra Technology)*

*MIT speaker invited*

*Harvard speaker invited*

*Round table with Heads of Safety*

**12:30 – 13:30**

**Lunch break**

## **Session 7: Pharmacovigilance Insourcing and Outsourcing Model for Industry 4.0**

*Moderators: Monica Mehta (Biogen) and Deirdre McCarthy (ISoP Board)*

**13:30 – 15:00**      What services will PV departments likely insource and outsource?  
What service mix will be available under Industry 4.0?  
How will the cooperation between government, academia and industry  
be influenced by automation?

*Speakers (3 x 30 mm):*

*Sean Darcy (Alnylam)*

*Jan Petracek (ISoP Board)*

*Lisa Hornick (PPD) invited*

**15:00– 15:15**      **Closing remarks**