



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Intelligent Automation in Pharmacovigilance

Seminar– preliminary programme

4th – 5th December 2017

Cambridge, MA (USA)

Biogen Auditorium
12 Cambridge Center

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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.

ISO P offers a unique, highly focused, and scientific two-day seminar which will explore the emerging tools in process automation and the challenges their implementation brings to pharmacovigilance activities.

At the end of the seminar, pharmacovigilance leaders should be able to make better decisions and be prepared for this potentially disruptive innovation.

This seminar is aimed to engage all interested pharmacovigilance professionals in an industry, regulatory, or university setting.

[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 4th December 2017

08:00 – 08:45 **Registration**

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

Session 1: Case Intake Automation

Moderators: TBC

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: TBC

10:30 – 11:00 **Coffee break**

Session 2: ICSR Processing Automation

Moderators: TBC

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: TBC

12:30 – 13:30 **Lunch break**

Session 3: Signal Management Support Tools

Moderator: TBC

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: TBC

15:00– 15:30 Coffee break

Session 4: Risk Management Support Tools

Moderators: TBC

15:30 – 17:00 What are the tools used for delivering risk minimization and measuring its effectiveness?

What are the opportunities for automation in safety communication practice?

Simulation and testing support in designing risk management system(s).

Speakers: TBC

Day 2: Tuesday 5th December 2017

Session 5: New Skillset for Career in Pharmacovigilance

Moderators: TBC

- 09:00 – 10:30** 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: TBC

- 10:30 – 11:00** **Coffee break**

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

Moderators: TBC

- 11:00 – 12:30** 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: TBC

- 12:30 – 13:30** **Lunch break**

Session 7: Pharmacovigilance Insourcing and Outsourcing Model for Industry 4.0

Moderators: TBC

- 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: TBC

- 15:00– 15:15** **Closing remarks**