Intelligent Automation in Pharmacovigilance

ISoP Seminar
4th – 5th December 2017
Boston/Cambridge, MA (USA)

Venue: Biogen Building 8, 812 Auditorium (Floor 1)
Enterance and security via Biogen Building 9 (300 Binney Street, Cambridge, MA 02142)

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www.isoponline.org or administration@isoponline.org

Day 1: Monday 4th December 2017

08:00 – 08:45 Registration

08:45 – 09:00 Welcome and Introduction
Priya Singhal, SVP and Global Head, SABR (Biogen)

09:00 – 10:30 Session 1: Case Intake Automation
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.
Moderator: Douglas W Clark, Senior Director DSA (Biogen)

09:00 – 09:30 AI + dynamic intake + business process = VALUE
April Davis, Industry Principal Director (Accenture) and Andrew Rut, CEO (MyMeds&Me)

09:30 - 10.00 Automatic Follow-Up - a case study from AstraZeneca
Andrew Finlay, EU Medical Information & Patient Safety Manager (AstraZeneca)

10.00 - 10.30 Can advanced methods improve post-market safety surveillance?
Taxiarchis Botsis, Medical Informatician, Center for Biologics Evaluation and Research (US FDA)
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<tr>
<th>Time</th>
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<tr>
<td>10:30 – 11:00</td>
<td>Coffee break</td>
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<td>11:00 – 12:30</td>
<td><strong>Session 2: ICSR Processing Automation</strong> &lt;br&gt;How can the existing tools meet the needs of both industry and regulators? &lt;br&gt;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? &lt;br&gt;<em>Moderator: Wayne Jack Wallis, Executive Director and Pharmacovigilance Research Fellow (Celgene)</em></td>
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<td>11:00 – 11:20</td>
<td>Autonarratives – what is the state of the art? &lt;br&gt;<em>Alexander Kluczka, Global Head ICSR Processing Oncology (Bayer)</em></td>
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<td>11:20 – 11:40</td>
<td>QC for Machine Learning and AE/ICSR Identification: Will the Real Ground Truth Please Stand Up? &lt;br&gt;<em>Shaun Comfort, Associate Director and Sr. Safety Science Leader (Genentech)</em></td>
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<td>11:40 - 12:00</td>
<td>Achieving PV Processing Automation with Technology Optimization &lt;br&gt;<em>Sameer Thapar, Director, Global Pharmacovigilance (Oracle)</em></td>
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<td>12.00 - 12:20</td>
<td>Streamlining Data Entry and Case Review (QC) through Cognitive Automation &lt;br&gt;<em>Aman Wasan, Vice President – Automation Strategy and Partnerships (ARIS Global)</em></td>
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<td>12.20 - 12.30</td>
<td>Panel discussion</td>
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<td>12:30 – 13:30</td>
<td>Lunch break</td>
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<td>13:30 – 15:00</td>
<td><strong>Session 3: Signal Management Support Tools</strong> &lt;br&gt;Where are the opportunities for automation in the signal management process? &lt;br&gt;How much do the existing tools help the actual signal management process? &lt;br&gt;What are the tools used by influential regulators and international organizations – WHO, FDA, EMA? &lt;br&gt;<em>Moderator: Phil Tregunno, Signal Management Unit Manager, and IMI WEB-RADR project lead (MHRA, ISoP Board member)</em></td>
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<td>13:30 – 14:00</td>
<td>Opportunities for signal automation at various steps of the signal management process &lt;br&gt;<em>Cvijeta Bielen, Medical Director (PrimeVigilance)</em></td>
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<td>14.00 - 14.30</td>
<td>Computational methods to enhance signal detection: the Uppsala Monitoring Centre experience &lt;br&gt;<em>Lucie Gattepaille, Data Scientist (Uppsala Monitoring Centre)</em></td>
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<td>14.30- 15.00</td>
<td>Signal Management Automation Opportunities &lt;br&gt;<em>Bill Blackwell, VP Safety Solutions (Commonwealth Informatics)</em></td>
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<td>15:00– 15:30</td>
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*Final version 3, November 24*
Session 4: Robotic Process Automation

Panel discussion:
Robotic process automation has currently three 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.

**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)*
- Deloitte speaker invited
Day 2: Tuesday 5th December 2017

09:00 – 10:30  Session 5: New Skillset for Careers in Pharmacovigilance

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.
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/ round table:
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?
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

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?
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 outsourcing 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 (Alnylam)

15:00– 15:15  Closing remarks