International Society of Pharmacovigilance

*Committed to safer use of medicines worldwide*

# Intelligent Automation in Pharmacovigilance 2020
## 4th ISoP Seminar
10-11 December 2020

GLOBAL ONLINE WEBINAR

*AGENDA Version 0.14*

| Dates | Sessions | Time (UTC/GMT) | Time (EST) |
|---|---|---|---|
| 10 December 2020 | Welcome & Introduction | 13:30-13:45 | 08:30-08:45 |
| 10 December 2020 | Session 1: Natural language processing in support of pharmacovigilance activities | 13:45-15:00 | 08:45-10:00 |
| 10 December 2020 | Session 2: Regulatory advances in pharmacovigilance intelligent automation | 15:00-16:45 | 10:00-11:45 |
| 11 December 2020 | Session 3: Using automation in pharmacovigilance data analysis | 13:30-15:00 | 08:30-10:00 |
| 11 December 2020 | Session 4: Strategy for Future PV | 15:00-16.30 | 10:00-11.30 |

### Virtual meeting format

This virtual seminar will be conducted online using the ISoP Zoom platform. Live Q&A and panel discussions will follow presentations and sessions as per the agenda.

ISoP seminars must be free of commercial biases, and a strict conflict of interest policy is enforced. We create an international forum for all those with an interest in the clinical, scientific, and regulatory aspects of patient safety when using medicines. ISoP includes members from governmental, research and academic organisations as well as industry.

Participants will get access to recorded presentations to view on-line after the event. Additional resources for participants will also be made available online.

## Programme | Seminar Day 1

### Thursday, December 10, 2020

*The below timing is indicated in Universal Time Coordinated UTC (GMT) – Please adjust to your own time zone*

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| UTC 13:30 – 13:45<br>15' | **Welcome & Introduction**<br>**Jan Petracek** (ISoP Advisory Board) |
| **Session 1: Natural language processing in support of pharmacovigilance activities**<br>*Chair: Douglas Clark (Head of GSRS Technology, Analytics & Data Insights, Biogen)* | |
| UTC 13:45 – 14:05<br>15'+ 5' | **Sameen Desai** (Senior Director, Pharmacovigilance Innovation Lead, BMS)<br>**Establishing a Foundation of Natural Language Processing within Pharmacovigilance** |
| | *Abstract:*<br>*As the adoption of digital technologies has been accelerated by COVID-19, businesses require a common language to function effectively. This commonality may be achieved through the use of Natural Language Processing (NLP) specific to a particular function, product portfolio and ways of working. We have created an NLP model capable of extracting key information and identifying multiple data elements specific to pharmacovigilance (PV). As designed, the associated algorithm structures facilitate periodic algorithm updates and the inclusion of business logic and safety-relevant library updates. This language may permit PV to reduce data entry for case processing and enable downstream processes as well. Along with the model, we aim to create awareness and governance of algorithms, not only to ensure broad algorithm usage, but also ownership within the business of the 'language of PV'. Pharma will not be able to 'outsource' algorithms that need business expertise to build, optimize and maintain. Algorithm governance is a skill needed now for PV to have a digital future.* |
| UTC 14:05 – 14:25<br>15'+ 5' | **Sameer Thapar** (Director, Global PV, Oracle)<br>**Use of Natural Language Processing in high-volume case intake PV operations** |
| | *Abstract:*<br>*Natural Language Processing (NLP) is a collection of toolkits that assist with text parsing, sentiment analysis, and much more. Depending on the group and the resources available to them, construction of a toolkit can range from basic to extensive. Why does it matter? Because utilization of NLP in high volume PV intake can be either a smooth transition from manual to digital or one riddled with bottlenecks and process issues. A clear understanding of what entails will be presented to both educate and demonstrate the benefits of NLP in high volume case processing.* |
| UTC 14:25 – 14:45<br>15'+ 5' | **Brian Dreyfus** (Group Director, Oncology and Safety Analytics, BMS)<br>**Social Media Listening for Drug Abuse or Misuse with Prescription Drugs** |

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| | *Abstract:*<br><br>*Social media represents an opportunity to directly link with the patient to understand firsthand their experiences with medication. In this study, we analysed social media posts from Twitter, Facebook, and online chat forums to create an algorithm to automatically mine social posts for abuse or misuse related to 7 medications. Each post was assessed across 10 behavioural indicators of drug abuse or misuse. We show that posts identified by the algorithm as containing a higher number of the targeted behaviors were later identified by manual review as being more likely to capture actual references to abuse of these medications. Automated identification of social media posts potentially containing safety-related information makes feasible and scalable the inclusion of this novel data source.* |
| UTC 14:45 – 14:50<br>5' | **Wrap-up session** |
| *UTC 14:50 – 15:00*<br>*10'* | *Coffee break* |
| **Session 2: Regulatory advances in pharmacovigilance intelligent automation and big data**<br><br>*Chair: Jean-Christophe Delumeau (ISoP Executive Committee, Head of Policy Strategy, Bayer)* | |
| UTC 15:00 – 15:30<br>25'+ 5' | **Robert Ball** (Deputy Director, Office of Surveillance and Epidemiology, CDER, FDA)<br><br>**Lessons Learned applying AI to Pharmacovigilance at the FDA** |
| | *Abstract:*<br><br>*Popular models of innovation suggest that artificial intelligence approaches can help "disrupt" how data is used and in the process revolutionize healthcare, including the evaluation and monitoring of drug safety. This talk will review 10 years of experience applying natural language processing, machine learning, and novel visualizations to adverse event report data at the US Food and Drug Administration. The experience will be analyzed through the lens of innovation models, with focus on innovation in regulated industries. A summary of lessons learned from this experience will be presented.* |
| UTC 15:30 – 15:50<br>15'+ 5' | **Luis Pinheiro** (Data Analyst, European Medicines Agency -EMA)<br><br>**AI and EMA Current Thinking** |
| UTC 15:50 – 16:10<br>15'+ 5' | **Gianmario Candore** (Data Scientist, European Medicines Agency-EMA)<br><br>**Data Analysis and Real World Interrogation Network in EU (DARWIN EU)** |

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| | *Abstract:*<br><br>*One of the main recommendations of the HMA-EMA Joint Big Data Task Force report is the establishment of a secure European platform for timely access and analysis of healthcare data named Data Analysis and Real-World Interrogation Network (DARWIN EU). This and the other recommendations were adopted by the Heads of Medicines Agencies and the EMA Management Board in 2019. The presentation will summarise the HMA-EMA Big Data Task Force main recommendations and will focus on DARWIN EU describing the reasons to establish it, how it will work and its interface with the European Health Data Space.* |
| UTC 16:10 – 16:30<br>15'+ 5' | **Phil Tregunno** (Group Manager, Vigilance, Intelligence and Research, MHRA)<br><br>**AI and MHRA Current Thinking** |
| | *Abstract:*<br>*The presentation will cover the MHRA's outreach program in relation to cross sector use of AI, insights from MHRA discussions with vendors and the pharmaceutical industry, and an overview of how the MHRA anticipates use of AI over the next 12 months.* |
| UTC 16:30 – 17:00<br>30' | **Panel Discussion followed by closing remarks** |
| | **End of Day 1** |

# Programme | Seminar Day 2

## Friday, December 11, 2020

**Session 3: Using automation in pharmacovigilance data analysis**

*Chair: Andrew Bate (Head, Safety Innovation & Analytics, GSK)*

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| UTC 13:30 – 13:50<br>15'+ 5' | **Eva-Lisa Meldau** (Data Scientist, Uppsala Monitoring Centre)<br>**Automated drug coding using AI: an evaluation of WHODrug Koda on adverse event reports** |
| | *Abstract:*<br>*WHODrug Koda is an AI solution that has been developed with the aim of automatically coding concomitant drugs in clinical trials. Now we evaluate the same algorithm on adverse event reports from VigiBase. We illustrate the possibilities and limitations of automated drug coding with WHODrug Koda.* |
| UTC 13:50 – 14:10<br>15'+ 5' | **Danielle Abatemarco** (Scientific Publications Lead, WorldWide Patient Safety, Bristol-Myers Squibb) and **Oeystein Kjoersvik** (Product Owner, MSD – Czech Republic) on behalf of TransCelerate<br>**Validation of Intelligent Automation Technologies in Pharmacovigilance: Emerging Use Cases and Best Practices** |
| | *Abstract:*<br>*In recognizing the need for aligned language in describing and validating various intelligent automation technology in PV, TransCelerate has proposed a classification system of AI-based systems for use by our industry in validating systems with health authorities. After evaluating the existing regulation for each class of system, we propose an extension of existing guidance to ensure appropriate validation of AI-based static systems in PV utilizing ISPE's GAMP® 5 methodology. In doing so, we can begin to articulate best practices for health authorities to use when validating these systems to ensure they are fit for purpose. We will discuss our recent investigations into the various components of AI-based validation and assurance, including: planning, requirements and specifications, data selection, model development, acceptance testing, and modification (re-training) triggers.* |
| UTC 14:10 – 14:30<br>15'+ 5' | **Nils Erlanson** (Data Scientist, Uppsala Monitoring Centre)<br>**A data-driven approach to cluster reports with similar adverse event profiles** |

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| | *Abstract:*<br><br>*By using the reporting patterns of MedDRA terms in ICSR reports from a single substance our method can cluster reports with similar adverse event profiles together. This presentation will cover how the clusters are created by using a probabilistic model, and how the algorithm can be used for exploring and creating case series as well as identifying adverse event profiles.* |
| UTC 14:30 – 14:45<br>15' | **Panel Discussion** |
| *UTC 14:45 – 15:00*<br>15' | *Coffee Break* |

| Session 4: Strategy for Future PV<br><br>*Chair: Deirdre McCarthy (ISoP Executive Committee, Senior Director, AlloVir)* | |
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| UTC 15:00 – 15:30<br>25'+ 5' | **Andrew Bate** (Head, Safety Innovation & Analytics, GSK)<br>**Overcoming barriers for widespread adoption of automation in PV** |
| | *Abstract:*<br>*Despite huge technological advances in the capabilities to capture, store, link and analyse data electronically, there has been some but limited impact on routine pharmacovigilance. We discuss emerging research in the use of artificial intelligence, machine learning and automation across the pharmacovigilance lifecycle including pre-licensure. Reasons are provided on why adoption is challenging and we also provide a perspective on changes needed to accelerate adoption, and thereby improve patient safety. Last, we make clear that while technologies could be superimposed on existing pharmacovigilance processes for incremental improvements, these great societal advances in data and technology also provide us with a timely opportunity to reconsider everything we do in pharmacovigilance operations to maximise the benefit of these advances.* |
| UTC 15:30 – 15:50<br>15'+ 5' | **Sean Darcy** (Executive Director Global Patient Safety, Regeneron)<br>**Reality check - considerations for evaluating AI tools in the business** |
| UTC 15:50 – 16:05<br>15'+ 5' | **Jeff Philip** (Director, TADI Safety Analytics & Data Science, Biogen)<br>**Being Intelligent about Automation - Biogen's Use of New and Existing Technologies to Deliver Business Value** |
| UTC 16:05 – 16:15<br>10' | **Jan Petracek** (ISoP Advisory Board)<br>**Your career in future pharmacovigilance – ISoP framework to make your job future proof** |
| | *Abstract:*<br>*ISoP has made significant progress in building global qualification framework for pharmacovigilance professionals. This scheme is already considering the foreseeable needs of pharmacovigilance community to address advent of new technologies, including advanced analytics and machine learning. Get ready for the likely future needs for knowledge, skills and attitudes to ensure your desirable career progression.* |
| UTC 16:15 – 16:25 | **Panel Discussion** |
| *UTC 16:25 – 16:30* | *Closing remarks* |