4th Romanian Pharmacovigilance Workshop

Introduction to HL7, the ISOICSR (E2B(R3)), the ISO IDMP standards, EudraVigilance changes – direct reporting, access policy, ICSR downloads, EVDAS and MAH signal detection

Bucharest, 11 – 13 December 2017

2017 is one of the most challenging years for pharmacovigilance in the EU, as technical changes as well as legislative changes are implemented with far reaching implications for both regulators and industry. This 4th pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance.

Calin Lungu, MD
DDCS S.A., Luxembourg

Calin is the Chief Executive Officer of Drug Development Consulting Services (DDCS), established in 1999, a pharmacovigilance quality assurance consulting firm located Luxembourg. He has worked for 15 years in drug development, clinical research, pharmacovigilance and quality assurance. He is a medical doctor. Calin has conducted more than 140 pharmacovigilance systems audits for various pharmaceutical companies, has audited transfer of safety databases and MedDRA recoding, PSUR processes, CCSI processes, signal detection, has participated in the preparation, conduct and follow-up of various regulatory inspections in the area of pharmacovigilance in Europe, has advised several EU and non-EU pharmaceutical companies in establishing/improving a pharmacovigilance system in conformity with current regulatory requirements.
Calin has been a Eudraviglance Trainer since 2004 and has trained more than 250 Eudravigilance and XEVMPD courses and has been a professional trainer in the use of the EudraVigilance Data Analysis System for European National Competent Authorities and the European Medicines Agency between 2008 and 2013.

Julie James
Blue Wave Informatics LLP, United Kingdom

Julie has almost 20 years of experience in the description and management of the information about medicines, for both patient care and clinical research. Originally a pharmacist, Julie brings that first-hand experience of working with medicines and needing information about them to all her subsequent work. As well as having supported the development of several national medicines terminologies and medicines management initiatives, in regulated research, Julie is a primary author of the IDMP suite of standards and continues to support their implementation. She was also a major contributor to the development of the ICSR standard for pharmacovigilance. Julie has significant experience in design, development and implementation of systems for managing regulatory information, clinical study information, pharmacovigilance, study data capture and supply management as well as teaching the principles, methodologies and practices for this. Julie is consultant and partner in Blue Wave Informatics LLP, based in the UK.

Rene Spronk
Ringholm bv, The Netherlands

René Spronk has studied Informatics at the Twente University of Technology in the Netherlands. He has provided systems integration consultancy in healthcare to hundreds of healthcare provider organisations and application vendors since 1996, using a variety of interoperability standards. He has provided numerous HL7, DICOM and IHE training courses in various European countries. He is involved as a volunteer in the activities of HL7, at the international level as well as within various European HL7 country organizations, and in IHE Europe. He was awarded with an HL7 "Volunteer of the Year" award in 2008, and was made a "HL7 Fellow" in 2011. René is a Trainer/Senior Consultant with Ringholm bv in the Netherlands.

Agenda

Day 1

Monday 11th December 2017

Morning

08:30 – 09:00
Welcome and registration

9:00 – 09:15
Introduction and overview of the agenda

09:15 – 10:00
Introduction to HL7, HL7 version 3 Foundation: Reference Information Model (RIM)

10:15 – 10:40
Coffee break

10:40 – 11:20
HL7 version 3 Foundation: Data Types, Vocabularies and Terminologies

11:20 – 12:00
Use of ISO OIDs, example domain & exercise: patient demographics

12:00 – 12:30
HL7 Questions and Answers

12:30 – 13:30
Lunch Break

Afternoon

13:30 – 14:15
Introducing the ICSR: the vision and value proposition on from E2B

14:15 – 15:00
Looking at the ICSR Part 1: The Report, the Reporter, the Patient/Subject

15:00 – 15:40
Coffee break

15:40 – 16:15
Looking at the ICSR Part 2: The Product, the Assessment, the Study

16:15 – 16:45
Using the ICSR, now and in the future

16:45 – 17:00
ICSR Questions and Answers

17:00
End of Day 1

Agenda

Day 2

Tuesday 12th December 2017

Morning

9:00 – 10:00
Introduction to IDMP: the vision and value proposition; overview of the suite of standards

10:00 – 10:15
Questions and Answers

10:15 – 10:40
Coffee break

10:40 – 11:20
ISO 11615: the MPID and PCID, and implementation using the Structured Product Label (HL7 SPL)

11:20 – 12:00
Practical considerations for implementing IDMP for the EU and globally, including RMS and OMS

12:00 – 12:30
IDMP Questions and Answers

12:30 – 13:30
Lunch Break

Afternoon

13:30 – 15:00
MAH access to EudraVigilance Data Analysis System (e-RMRs, active substance groupings and line listings)

15:00 – 15:40
Coffee break

15:40 – 16:15
EudraVigilance Data Access Policy: what access is granted and how to access data for each stakeholder group

16:15 – 16:45
Screening EudraVigilance and ICSR Export Manager

16:45 – 17:00
Questions and Answers

17:00
End of Day 2

Agenda

Day 3

Wednesday 13th December 2017

09:00 – 09:45
EVWEB 8.0 – features and functionalities

09:45 – 10:30
EMA Medical Literature Monitoring Services

10:30 – 11:10
Coffee Break

11:10 – 12:00
EV direct reporting: changes and foreseen challenges

12:00 – 12:30
Questions and Answers

12:30 – 13:00
Knowledge evaluation

13:00
End of Day 3

Please note that the order in which the sessions are presented may change according to the faculty's availability at this event.

The workshop will be held at:

Novotel Hotel, Calea Victoriei 37B, sector 1, Bucharest, Romania

The registration form will be available in due course.

Please contact Madalina Nedelciu (madalina.nedelciu@businesstravel.ro) for any questions regarding this course and if you like to register