DIA Learning

Best Practices for Data Supervisors in Pharmacovigilance

Virtual Live Training Course

20-22 June 2022 13:00-17:00 CEST

OVERVIEW

Advances and developments in data use in pharmacovigilance are driving new training needs and demands. The sheer volume of data, along with the enforcement of new ISO standards for Individual Case Safety Reports, have created a pressing need for industry best practices to cover numerous aspects of working the data. These include data entry conventions, management data, quality assurance and preparing to work with AI tools, all within the limitations imposed by the EU GDPR.

LEARNING OBJECTIVES

At the conclusion of this virtual live course, participants will be able to:

- Apply knowledge of the industry best practices at your supervisory/managerial job
- Understand most important impacts of the new regulatory requirements stemming from ISO/HL7 27953-2, ICH E2B(R3), and their implementation guides in the EU and US
- Orient yourself in the context of near future upcoming revisions of ICH E2D, and impact of US Sentinel and EU Darwin projects
- Acquire conflict resolution skills related to contradictory guidelines and legislation, data exchange partner practices, and legacy practices
- Improve your defensive skills for your data management practices in front of inspectors and auditors
- Get ready for upcoming AI tools in pharmacovigilance

KEY TOPICS

- Industry Best Practices in Data Entry and Data Management
- ISO ICSR implementation in EU, US, and UK
- Highlights of EU GVP Module VI and other influential regulatory guidelines all supervisors must know
- Considerations of ICH E2 series and CIOMS guidelines in terms of their influence on global data management practices
- Conflict resolutions – contradictory guidelines, partner practices, legacy practices, local versus global approaches
- Defence of your data management practices in front of inspectors and auditors
- Work with emerging AI tools

WHO WILL ATTEND

This course is intended for the professionals working within the pharmaceutical industry, academia, governmental institutions as well as IT solution providers in pharmacovigilance, drug safety, quality assurance/quality control, and IT and validation positions.
Level: Intermediate

FACULTY

Jan Petracek
Director
Institute of Pharmacovigilance
Czech Republic

Gro Laier
Principal Safety Lead
BASE life science
Denmark

Jan Kolouch
Executive Director
NextPV Services
Czech Republic

Robert Scheiner
CIO
iVigee
France

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

DATA FLOW IN THE PHARMACOVIGILANCE SYSTEM - BEST DESIGNS

Jan Petracek

Design of the pharmacovigilance data flow is one of the key decisions MAHs must ensure early on in the system setup. Author will share the best practices and examples of this setup and explore pros and cons for various approaches.

- Data Flow
- PSMF
- Conventions
- Interfaces

15:00 BREAK

15:30 SESSION 2

REVIEW OF DATA RECORDING CONVENTIONS EXAMPLES

Gro Laier

In this session different company approaches to data recording and grey zones of legislation will be presented including the decision three for PV process making and how to defend the processes for inspectors. Legal basis underpinning these decisions will be provided for practical use. Although conflicts with third country legislation is touched upon the focus is on the EU legislation. The topics will be covered via examples.

- Which PV data to record?
  - Definition of PV data
  - Unexpected therapeutical benefit
  - Invalid cases
- Coding conventions
  - Medical terms
  - Drug information
- Reference Safety Information
  - ICSR
  - SUSAR

17:00 Q&A

17:30 END OF DAY 1

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 10.5 credits.

DAY 2

13:00 SESSION 3

WORK WITH EUDRAVIGILANCE

Jan Kolouch

EudraVigilance rules represent a good example of the prominent detailed regulatory requirements for data structure and data quality in pharmacovigilance. As the EudraVigilance rules are not fully harmonised with globally applicable rules, advanced knowledge and tips for practical and compliant solutions will be shared by the expert speaker.

- EudraVigilance Business Rules
- Most typical conflicts between the EV rules and company rules
- Examples of the good data flow for Electronic Data Exchange with EV, or using EV
- Resolution of the conflicts between local and global approaches
- Case Examples

14:30 BREAK

15:00 SESSION 4

CONFLICT RESOLUTION EXERCISE

Gro Laier

Grey zones of regulations and standards leads to various conflicts between jurisdictions as well as between the EU QPPV and local QPPVs of affiliates and partners. Global pharmacovigilance system must deal with all requirements and expectations in an effective manner. Examples of conflict areas and their solutions will be presented. Furthermore, examples of the implementation of data privacy in PV will be discussed.

- Global involvement of local QPPVs
- Need for a SDEA?
  - Same product different country
  - Same country, different therapeutical area
- Update cases from partners?
- Data collection from NIS
- Data Privacy in PV

16:30 BREAK

17:00 SESSION 5

DATA QUALITY CHECK OF ICSRS ENTERED IN ISO ICSR STANDARD

Jan Kolouch

ISO ICSR standard becomes required reality globally. Issues of transition, migration, and implementation of the new standard in data management practices are growing. This session explores the typical challenges and their best solutions.

- ISO ICSR standard principles
- Applicable principles of QC and QA
- Transition
- Migration
- Links with IDMP
- Challenges and solutions

18:30 Q&A

19:00 END OF DAY 2

DAY 3

13:00 SESSION 6

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING TOPICS FOR PV DATA SUPERVISORS

Robert Scheiner

Pharmacovigilance System Experts and Data Supervisors need not be AI experts, but they should know enough about AI to explore the possibilities of collaboration with those who are. This session follows a guideline-based example-driven format to present in simple terms the most important topics to know about when using Artificial Intelligence in PV. We will:

- Demistify the AI/ML landscape
- Go through almost all AI PV use cases
- Shortly touch some of the AI PV implementation challenges
- See what happens to the results: measuring, improving, evaluating and interpreting
- Review the journey to take an AI capacity from books and labs to production
- See how to be community-awarene of what is going on (as this is one of the main driver for AI in PV)

14:30 BREAK

15:00 SESSION 7

DEFENCE OF YOUR DATA MANAGEMENT PRACTICE IN FRONT OF AN INSPECTOR/AUDITOR

Jan Petracek, Gro Laier and Jan Kolouch

Practical examples of defences you can use for your choices in data management practices. Exercises for the group.

- Tricky audit and inspection questions
- Defence of conventions
- Defence of validation
- Grey zones in data processing
- Examples and practical exercises

16:30 Q&A

17:00 END OF THE VIRTUAL LIVE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

System Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

REGISTRATION FORM Virtual Live Training Course

Best Practices for Data Supervisors in Pharmacovigilance # 22547
20-22 June 2022 13:00-17:00 CEST

DIA Learning

REGISTRATION FEES

Registration fee includes full admission to virtual course, and electronic access to course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 25 April 2022	MEMBER valid from 26 April 2022	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'305.00 ❑	€ 1'450.00 ❑	€ 1'635.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 725.00 ❑	€ 910.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CET. **Tel.** :+41 61 225 51 51

Email: Basel@DIAglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #22547 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature