DIA Learning

Benefit-Risk and Medical Writing Week

26-30 November 2018
Holiday Inn London Kensington Forum hotel, London, UK

OVERVIEW

This course will give you an overview on the essential principals for Benefit-Risk Management and RMP and PSUR writing.

In the first part of the course there will be tackled the legislation environment that allows the development of Benefit-Risk Management. Additionally, the theoretical material will be supported by various practical examples from which attendees will be able to extract the knowledge needed to be applied in different situations in their company. The second and third part of the module will present the facts and practical aspects of the RMP management, all explained based on the GVP module V, VII and XVI suggestions.

This course will also present the most up to date recommendations from EU and global agencies, aspects that each industry representative needs to understand in order to facilitate the medicine development life cycle.

It is possible to register for each part separately:

- Benefit-Risk Management
- EU-RMP Creation
- Medical Writing of Periodic Safety Update Reports (PSUR/PBRER)

LEARNING OBJECTIVES

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

- Describe safety, efficacy, and effectiveness profiles of drugs
- Plan safety and efficacy follow-up systems, including the best choice of study designs and available registries
- Present the Benefit-Risk documents to regulatory authorities and health technology assessment bodies
- Measure effectiveness of the planned actions – both risk minimisation and benefit optimisation
- Understand requirements of EU Good Pharmacovigilance Practice Module V and XVI
- Learn the best medical writing practices for EU-RMP and consistency check with other parts of the dossier
- Understand the project management challenges and budget implications of EU-RMP
- Understand interpretation and application of the ICH E2C (R2) guideline, associated Q&A, and EU GVP Module VII standards and templates
- Understand important legal and regulatory context of PBRER, including local regulatory intelligence tips

WHO WILL ATTEND

Professionals with experience in: pharmacovigilance, drug safety, regulatory affairs, quality assurance, risk management, medical affairs or similar positions within the pharmaceutical industry.

- Global Safety Physicians
- Drug Safety Specialists
- Experts in Pharmacovigilance
- Pharmacists
- Pharmacovigilance Scientists and Project Managers
- Medical Writers
- Regulatory Affairs & Product Safety Technicians
- Medical Safety Officers
- QPPVs

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

FACULTY

Michael Forstner
Senior VP - Head of Risk Management and Pharmacoepidemiology, PrimeVigilance, Switzerland

Steve Mayall
Principal Consultant, Huron, United Kingdom

Zuzana Vinterova
Director, Medical Writing
PrimeVigilance s.r.o., Czech Republic

LEARNING OBJECTIVES

- Exploring the new European benefit-risk management planning
- Legal possibilities for benefit optimisation and risk minimisation of products in the EU
- PSUR: regulations, format and content of the document
- PBRER: regulations, format and content of the document
- Practical aspects of planning and medical writing related to aggregate reports

Participants will be provided with preparatory material to facilitate their learning process at the group exercises onsite.

Participants are required to bring their laptops with them for this course.

Benefit-Risk Management

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

08:45 SESSION 1

INTRODUCTION TO BENEFIT-RISK MANAGEMENT
Michael Forstner

- Key concepts and terminology
- Essential principles for benefit-risk management
- Foreseeable developments

10:30 COFFEE BREAK

11:00 SESSION 2

INTRODUCTION TO BENEFIT-RISK METHODOLOGIES
Michael Forstner

- The concept of risk
- Overview of qualitative and quantitative methods
- Use of the methodology by US and EU regulators

11:45 SESSION 3

EXAMPLES OF APPLICATION OF BENEFIT-RISK METHODOLOGIES
Michael Forstner

- ZHA, FMEA, FTA
- BR frameworks, Conjoint analysis, MCDA
- QALYs, NNTH/NNTB

12:15 LUNCH

13:15 SESSION 4

DESIGNING RISK MANAGEMENT SYSTEMS
Michael Forstner

13:45 SESSION 5

DOS AND DON'TS IN SAFETY SPECIFICATION
Michael Forstner

14:00 SESSION 6

TOOLBOX FOR PHARMACOVIGILANCE PLANNING
Michael Forstner

- Pharmacovigilance toolbox
- Design of studies and registries used in pharmacovigilance planning
- Matching safety concerns with appropriate pharmacovigilance tools

14:45 COFFEE BREAK

15:15 SESSION 7

EFFICACY SPECIFICATION AND FOLLOW-UP PLAN
Jan Petracek

- Creation of efficacy specification and relevant regulatory discussions in EU-RMPs and PSURs(PADERs)
- Design of studies and registries used in the efficacy follow-up planning
- Matching efficacy concerns with the efficacy follow-up planning

16:00 SESSION 8

OPTIONS FOR RISK MINIMISATION
Michael Forstner

- Risk minimisation toolbox
- Matching safety concerns with the risk minimisation tools
- Safety communication

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 9

EVALUATION OF RISK MINIMISATION EFFECTIVENESS
Michael Forstner

- Tools and methodologies available
- Levels of metrics
- Required evaluation levels and examples of satisfactory results

10:00 COFFEE BREAK

10:30 SESSION 10

BENEFIT-RISK MANAGEMENT PLAN – CASE STUDIES
Michael Forstner

- Small molecules and generics
- Biologics and biosimilars
- Advanced therapies
- Combination therapies

12:30 LUNCH

13:30 SESSION 11

BENEFIT OPTIMISATION
Michael Forstner

- Benefit management toolbox
- Matching efficacy/effectiveness concerns with the benefit management tools
- Measuring success of benefit optimisation

14:30 SESSION 12

USE OF BENEFIT-RISK MANAGEMENT PLANS IN REGULATORY SUBMISSIONS
Michael Forstner

- Pre-authorisation – DSUR
- Post-authorisation – REMS, EU-RMP and PSUR
- EU-RMP

15:30 END OF DAY TWO

EU-RMP Creation

DAY 3

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

08:45 SESSION 1

INTRODUCTION TO BENEFIT-RISK MANAGEMENT

- Key concepts and terminology
- Essential principles for benefit-risk management

09:15 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

- Overview of the GVP - Module V
- Guidance on the template of the EU-RMP
- Requirements based on the MAA/MAH legal basis

10:00 COFFEE BREAK

10:30 SESSION 3

GROUP WORK - PROJECT MANAGEMENT

- Team work and group discussion

11:15 SESSION 4

SOURCE DATA AND PLANNING PROCESS

- Project team
- Internal template of the EU-RMP
- Data collection (interdepartmental responsibilities)
- Other documentation (safety documents, CTD)

12:00 LUNCH

13:00 SESSION 5

CREATION OF THE EU-RMP – PRODUCT AND DISEASE/ CONDITION OVERVIEWS

- Product overview
- Indication(s) and target population(s)
- Epidemiology of the disease/condition
- Risk factors, comorbidities
- Natural history of the disease, main treatment options

13:30 SESSION 6

SAFETY SPECIFICATION MODULES SII-SVI

- Key findings from the nonclinical development
- Clinical development and populations not studied
- Post-marketing experience
- ATMP

14:15 COFFEE BREAK

14:45 SESSION 7

IDENTIFIED/POTENTIAL RISKS AND SAFETY CONCERNS (MODULES SVII AND SVIII)

- Identification of important identified/potential risks
- Characterisation of identified and potential risks (ATMP versus non-ATMP version)
- Safety concerns

16:15 SESSION 8

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

- Routine pharmacovigilance activities
- Additional pharmacovigilance activities
- Post-authorisation safety studies (PASS) and GVP – Module VIII
- Imposed, specific obligation, required or stated pharmacovigilance activity
- Post-authorisation efficacy studies (PAES)

16:45 NETWORKING RECEPTION

17:45 END OF DAY ONE

DAY 4

08:00 SESSION 9

RISK MINIMISATION PLAN

- Routine risk minimisation measures
- Additional risk minimisation measures
- Evaluation of the effectiveness

08:45 SESSION 10

SUMMARY OF THE EU-RMP AND ANNEXES

- Summary of the RMP
- Annexes to the EU-RMP

09:30 SESSION 11

EXERCISE ON IDENTIFICATION OF SAFETY CONCERNS

10:00 COFFEE BREAK

10:30 SESSION 12

GROUP WORK – WRITING EXERCISE

- Task 1: Key messages of the additional risk minimisation measures
- Task 2: Characterisation of risk

12:00 LUNCH AND END OF TRAINING COURSE

Medical Writing of Periodic Safety Update Reports (PSUR/PBRER)

DAY 4 continued

12:30 REGISTRATION

13:15 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30 SESSION 1

INTRODUCTION TO THE PSUR/PBRER

Zuzana Vinterova

- Regulatory legal basis for the PSUR in the EU (GVP Module VII)
- ICH E2C(R2) guideline on safety reports among the ICH regions
- Terminology of aggregate reports

14:15 SESSION 2

GENERAL PRINCIPLES AND STRUCTURE OF THE PSUR/PBRER

Zuzana Vinterova

- Scope of the documents
- Format and overview of contents
- Internal template for the PSUR/PBRER

15:00 COFFEE BREAK

15:30 SESSION 3

PSUR/PBRER PLANNING EXERCISE

Zuzana Vinterova

- Team work and group discussion

16:00 SESSION 4

PLANNING PROCESS AND INTERDEPARTMENTAL RESPONSIBILITIES

Zuzana Vinterova

- Project Team
- Data collection (first QC within the process)

17:00 NETWORKING RECEPTION & END OF DAY FOUR

DAY 5

08:30 SESSION 5

PSUR/PBRER SECTION-BY-SECTION (PART 1) – INTRODUCTORY SECTIONS

Zuzana Vinterova

- Title page
- Executive summary
- Table of contents and other "lists"
- Introduction
- WWMAS
- Actions taken for safety reasons
- Changes to the RSI
- Exposure and use patterns (how to calculate patient exposure)

09:30 SESSION 6

PSUR/PBRER SECTION-BY-SECTION (PART 2) – PRESENTATION OF FINDINGS

Zuzana Vinterova

- Data in summary tabulations
- Overview of findings from interventional/non-interventional clinical studies
- Other reports with impact on the PSUR/PBRER
- Non-clinical data
- Literature
- Late-breaking information

10:15 COFFEE BREAK

10:45 SESSION 7

PSUR/PBRER SECTION-BY-SECTION (PART 3) – DATA EVALUATION

Zuzana Vinterova

- Overview of signals
- Signal and risk evaluation
- Benefit evaluation

12:00 LUNCH

13:00 SESSION 8

PSUR/PBRER SECTION-BY-SECTION (PART 4) – BENEFIT-RISK ANALYSIS

Zuzana Vinterova

- Critical appraisal of presented data
- Conclusions and action
- Appendices

13:30 SESSION 9

QUALITY CONTROL AND REVIEW

Zuzana Vinterova

- Scope of quality control of aggregate reports
- Responsibilities
- Examples from practice

14:00 EXERCISE

- Preparation for medical writing exercise

14:30 COFFEE BREAK

15:00 SESSION 10

MEDICAL WRITING EXERCISE

Zuzana Vinterova

- Team work and group discussion

16:30 END OF TRAINING COURSE

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.

Training Course Venue

COURSE VENUE

Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
Email: reservations@hikensington.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 25 to 30 November 2018 at the rate of GBP 160.00 per standard double room for single use per night including full English breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA".

The room rate is available until 24 October 2018 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Heathrow Airport take the London Underground Victoria line and get off at Gloucester Road.

The hotel is located within 3 min walking distance from the station.

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 29 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 29 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

REGISTRATION FORM

Benefit-Risk and Medical Writing Week # 18561
26-30 November 2018 | Holiday Inn London Kensington Forum hotel | London, UK

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. **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	NON-MEMBER
INDUSTRY	€ 3'320.00 ❑	€ 3'475.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 1'660.00 ❑	€ 1'815.00 ❑

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.

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no additional cost**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.** :+41 61 225 51 51 **Fax:** +41 61 225 51 52

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 here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. 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 Fax 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 #18561 as well as the invoice number to ensure correct allocation of your payment.

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