DIA Learning

Benefit-Risk Management

26-27 November 2018
Holiday Inn London Kensington Forum hotel, London, UK

OVERVIEW

This course is part of the Benefit-Risk and Medical Writing week offering

This intensive course explores current opportunities made possible by the legislation, advances in information technology and a new scientific methodology to enhance and modernise the approaches in the product lifecycle management.

The course starts with the current regulatory thinking about the benefit-risk methodology, including the relevant projects of the European Medicines Agency (EMA) / Committee for Medicinal Products for Human Use (CHMP). It gives a basis for the second part of the course, exploring the new European benefit-risk management planning - a notion stemming from the experience gathered over the past ten years with the EU Risk Management Plans (EU-RMPs). Participants will learn how to take advantage of the efficacy follow-up options given by the EU law and guidelines. A practical training in solving key aspects of the Benefit-Risk management based on real-life examples is included.

Participants will be provided with preparatory material in order to better participate at the group exercises onsite.

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
- Optimise benefits and minimise risks of products, including the best use of an evidence-based toolbox
- 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

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

WHO WILL ATTEND

Professionals most likely to benefit from this training have experience in pharmacovigilance, drug safety, regulatory affairs, quality assurance, risk management, medical affairs or similar positions within the pharmaceutical industry. Those in charge of the design and maintenance of risk management systems, pharmacovigilance auditing or inspecting, Qualified Persons for Pharmacovigilance (QPPVs) and heads of benefit-risk management, patient safety, or lifecycle management will learn all the essential aspects needed for successful Benefit-Risk management. Examples are presented for small as well as large organisations.

FACULTY

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

Steve Mayall
Principal Consultant
Huron, United Kingdom

Jan Petracek
CEO
PrimeVigilance
Czech Republic

KEY TOPICS

- Legal possibilities for benefit optimisation and risk minimisation of products in the EU
- Designing benefit-risk management systems using current regulatory tools, including EU Risk Management Plans (EU-RMPs), Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR)
- Best study designs for safety and efficacy follow-up, and how to measure their effectiveness

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

08:45 SESSION 1

INTRODUCTION TO BENEFIT-RISK MANAGEMENT

Jan Petracek

- 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

Jan Petracek

13:45 SESSION 5

DOS AND DON'TS IN SAFETY SPECIFICATION

Jan Petracek

14:00 SESSION 6

TOOLBOX FOR PHARMACOVIGILANCE PLANNING

Steve Mayall

- 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

Jan Petracek

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

12:30 LUNCH

13:30 SESSION 11

BENEFIT OPTIMISATION

Steve Mayall

- Important factors when designing benefit-risk communications
- Choice of channels, including digital approaches
- Rolling out benefit-risk communications

14:30 SESSION 12

USE OF BENEFIT-RISK MANAGEMENT PLANS IN REGULATORY SUBMISSIONS

Jan Petracek

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

15:30 END OF TRAINING COURSE

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 11.75 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.75 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 Management # 18533
26-27 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	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
Registration fees for all 3 courses (ID #18561): Benefit-Risk Management, EU-RMP Creation AND Medical Writing of Periodic Safety Update Reports (PSUR/PBRER)		
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 www.diaglobal.org/en/get-involved/membership. 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 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 www.diaglobal.org/en/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 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 #18533 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