

Benefit-Risk Management

24-25 April 2017

NH Berlin Alexanderplatz, Berlin, Germany



OVERVIEW

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

Managing Director, Head of Risk Management & Business Process Management Practice
Mesama Consulting International, Switzerland

Jan Petracek

CEO, PharmInvent, Czech Republic
President, PrimeVigilance, United Kingdom
Former Head of Risk Management, European Medicines Agency, EU

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

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

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

08:20 SESSION 9

EVALUATION OF RISK MINIMISATION EFFECTIVENESS

Michael Forstner

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

09:45 COFFEE BREAK

10:15 SESSION 10

BENEFIT-RISK MANAGEMENT PLAN – CASE STUDIES

Jan Petracek

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

12:15 LUNCH

13:15 SESSION 11

BENEFIT OPTIMISATION

Jan Petracek

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

14:15 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

15:15 END OF TRAINING COURSE

Training Course Venue

NH Berlin Alexanderplatz

Landsberger Allee 26-32
10249 Berlin, Germany
Tel: +49 30 422 61 30
Email: nhberlinalexanderplatz@nh-hotels.com
www.nh-hotels.com/hotel/nh-berlin-alexanderplatz

DIA has booked a limited number of hotel rooms at the rate of EUR 96.90 per standard single room per night including breakfast, service charges and VAT.

If you would like to make a booking, please contact the hotel directly and quote the reference "DIA":
Tel: +49 30 2238 02 33 or +800 0115 0116 Email: reservierungen@nh-hotels.com

The room rate is available until 26 March 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Airport Berlin Tegel:

Travel by bus TXL until S+U Alexanderplatz Station.
Transfer to the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.
The hotel is located across the street from the tram station.
Alternatively, travel by taxi for a 15-20 minute trip.

From Airport Berlin-Schönefeld:

Travel on the S9 train towards Westkreuz and exit at Alexanderplatz.
Transfer to either the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.
The hotel is located across the street from the tram station.
Alternatively, travel by taxi for a 30-35 minute trip.

www.bvg.de/en



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 11.25 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.25 credits.



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 Vishal.Bharadwaj@DIAglobal.org for a custom group rate.

REGISTRATION FORM

Benefit/Risk Management # 17533

24-25 April 2017 | NH Berlin Alexanderplatz | Berlin, Germany



REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

| FEES | MEMBER | NON-MEMBER |
|---|-------------------------------------|-------------------------------------|
| INDUSTRY | € 1'450.00 <input type="checkbox"/> | € 1'605.00 <input type="checkbox"/> |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | € 725.00 <input type="checkbox"/> | € 880.00 <input type="checkbox"/> |

All registration fees are subject to applicable German VAT

Please enter your company's German 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 non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

I do not want complimentary membership

The DIA Europe, Middle East & Africa 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: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, KÜchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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.

PHOTOGRAPHY POLICY

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 # 17533 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 Europe, Middle East and Africa.**

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