

Benefit-Risk Management

2-3 July 2018

DIA, Europe, Middle East, and Africa office, Basel, Switzerland



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

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

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/NTTB

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

Michael Forstner

- 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 TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

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

DIA, EUROPE, MIDDLE EAST, AND AFRICA OFFICE

Küchengasse 16

4051 Basel, Switzerland

Tel: +41 61 225 51 51

Email: basel@diaglobal.org

The office is located within 1 min walking distance from the Basel SBB train station.

HOW TO GET THERE

Route from the EuroAirport Basel Mulhouse Freiburg

Please exit the Airport through the Exit to Switzerland.

Take Bus Nr 50 towards Basel SBB.

Arrival by Train

From Germany: exit at station Badischer Bahnhof and take Bus Nr 30 towards Basel SBB.

From Switzerland: exit at station Basel SBB.

Arrival from Zurich Airport

There is a direct train service every hour from Zurich Airport to Basel SBB (travel time approx 1 h 30 min).

Hotel Accommodation

Participants are kindly requested to make their own hotel bookings at any of the nearby hotels.

www.basel.com



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.



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 # 18559

2-3 July 2018 | DIA, Europe, Middle East, and Africa office | Basel, Switzerland



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 <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 Swiss VAT

Please enter your company's Swiss 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-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, Kuchengasse 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 #18559 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