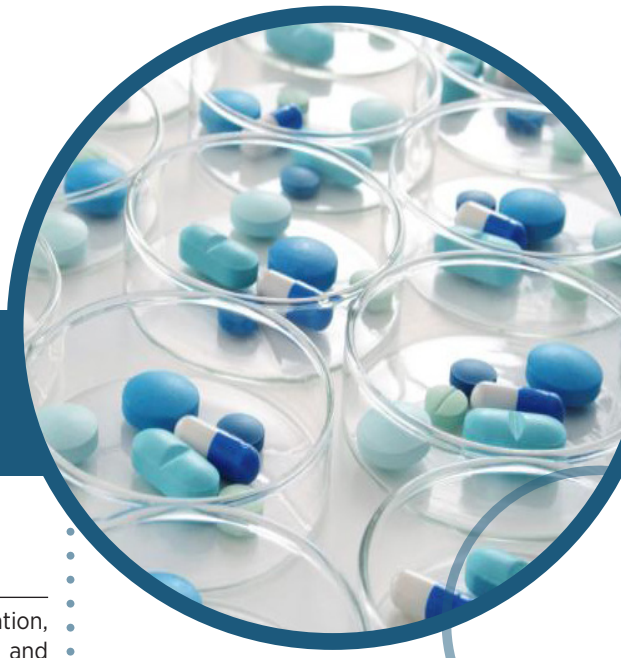
DIA Training Course on

Benefit/Risk Management



Course #15547
3-4 November 2015
Paris, France

OVERVIEW

This intensive course explores current opportunities made possible by the new 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 project 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 eight 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 drafting key aspects of the regulatory submissions is included.

The last part of the course will help participants to deal with the most dangerous ones – when the benefit/risk of the product is suddenly affected by emerging information. Participants will be trained on how to deal with such a situation, using the most effective techniques in risk communication and media crisis management.

LEARNING OBJECTIVES

At the conclusion of this training 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 first three bullet points to key regulatory authorities and health technology assessment bodies
- Measure effectiveness of the planned actions – both risk minimisation and benefit optimisation
- Save the product if things go wrong and benefit/risk seems negative

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 2-5 years of experience in regulatory affairs, risk management, pharmacovigilance, drug safety, medical affairs or similar positions within the pharmaceutical industry. Those charged with the design and maintenance of risk management systems, Qualified Persons for Pharmacovigilance (QPPVs) and heads of benefit/risk management, patient safety, or lifecycle management will find all the necessary information and skills needed for successful benefit/risk management.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

FACULTY

Jan Petracek
CEO, Consultant, PharmInvent, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

Michael Forstner
Head Pharmacovigilance Europe
Boehringer-Ingelheim RCV Gmbh&Co KG, Austria

KEY TOPICS

- New 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), Risk Evaluation and Mitigation Strategies (REMS), Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR), Follow-Up Measures (FUMs), and potentially EU Benefit Risk Management Plan (EU-BRMP)
- Choice of effectiveness of study design for safety and efficacy follow-up
- How to manage a media, legal and regulatory crisis?

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DAY 1

08:00 — **REGISTRATION**

08:30 — **WELCOME AND INTRODUCTION**

08:45 — **SESSION 1**

INTRODUCTION TO BENEFIT/RISK METHODOLOGY

- Key concepts and terminology
- Overview of qualitative and quantitative methods used by US and EU regulators
- Foreseeable developments

09:45 — **SESSION 2**

INTRODUCTION TO RISK MANAGEMENT

- Basic principles of risk management
- Brief history of risk management implementation in the EU and US
- Overview of the current regulatory requirements

10:15 — **COFFEE BREAK**

10:45 — **SESSION 3**

INTRODUCTION TO BENEFIT/RISK MANAGEMENT

- Current options for management of benefits
- Current options for benefit/risk management

11:15 — **SESSION 4**

SAFETY SPECIFICATION

- Non-clinical
- Clinical
- Epidemiology
- Construction of important risks and missing information

12:15 — **LUNCH**

13:15 — **SESSION 5**

EFFICACY AND EFFECTIVENESS SPECIFICATION

- Endpoints, indications, statistical and clinical significance
- Therapeutic value

13:45 — **SESSION 6**

DOS AND DON'TS IN SAFETY AND EFFICACY SPECIFICATIONS

14:00 — **SESSION 7**

PHARMACOVIGILANCE PLAN

- 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 8**

EFFICACY FOLLOW-UP PLAN

- Design of studies and registries used in the efficacy follow-up planning
- Matching efficacy concerns with the efficacy follow-up planning

16:00 — **SESSION 9**

RISK MITIGATION

- Risk minimisation toolbox
- Matching safety concerns with the risk minimisation tools
- Measuring effectiveness of risk minimisation

17:00 — **DRINKS RECEPTION**

18:00 — **END OF DAY ONE**

DAY 2

08:20 — **SESSION 10**

BENEFIT OPTIMISATION

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

08:40 — **SESSION 11**

EXERCISE - CASE STUDY OF AN EU-RMP WITH EFFICACY FOLLOW-UP PLAN

- Self study
- Key learnings from Day 1
- Introduction for case studies for Day 2

08:45 — **SESSION 12**

BENEFIT/RISK MANAGEMENT PLAN - CASE STUDIES

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

09:45 — **COFFEE BREAK**

10:15 — **SESSION 12 CONTINUED**

BENEFIT/RISK MANAGEMENT PLAN - CASE STUDIES

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

11:00 — **SESSION 13**

USE OF BENEFIT/RISK MANAGEMENT PLANS IN REGULATORY SUBMISSIONS

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

11:45 **SESSION 14**

BENEFIT/RISK COMMUNICATION

- Importance of communication
- Communication channels and tools
- Communication planning

12:15 **LUNCH**

13:15 **SESSION 15**

USE OF BENEFIT/RISK MANAGEMENT PLANS IN CRISIS MANAGEMENT

- Potential media, legal and regulatory crisis
- How to prevent a crisis
- How to deal with the crisis
- Case studies to learn from real experiences

14:15 **SESSION 16**

EXERCISE - CRISIS MANAGEMENT

- Group exercise in crisis management
- Dealing with uncertainty, time pressure, when the future of the product and many human lives might be at stake

15:15 **COURSE ASSESSMENT**

15:45 **END OF TRAINING COURSE**

REGISTRATION FORM

Benefit/Risk Management # 15547

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REGISTRATION FEES

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

FEES	MEMBER*	NON-MEMBER*
INDUSTRY	€ 1'420.00 ❑	€ 1'580.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 710.00 ❑	€ 870.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

*All fees will be subject to the French VAT at 20%

Please enter your Company's French VAT number: _____

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

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

The DIA DIA Europe, Middle East & Africa Contact Center 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: diaeurope@diaeurope.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.diahome.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office five working days 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
- Tutorial cancellation € 50.00

If you do not cancel five working days 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

email (Required for confirmation)

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 # 15547 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.diahome.org/EUTerms

Date	Signature