DIA Training Course

Benefit/Risk Management

Course #13523
13-14 May 2013
Mercure Hotel Stoller, Zurich, Switzerland

Faculty

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Former Head of Risk Management, European Medicines Agency, EU

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Overview

The balance of benefits and risks of a product is the basis for all key decisions in the pharma industry. Thus the balance must not be left to chance – it can be and should be effectively managed. 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 five years with the EU Risk Management Plans (EU-RMPs). Participants will learn how to take advantage of the efficacy follow-up options given by both the European Paediatric Regulation and the Advanced Therapies Regulation. A practical training in drafting key aspects of the regulatory submissions is included.

Although a lot of things may be planned and controlled, there are always unforeseen scenarios. 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.

Key Topics

- Take advantage of the new legal possibilities for benefit optimisation and risk minimisation of your products in the EU
- Enjoy a comprehensive and practical training in designing benefit/risk management systems using current, as well as new, regulatory tools, including EU Risk Management Plans (EU-RMP), 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)
- Learn which study designs are best for safety and efficacy follow-up, and how to measure their effectiveness
- Get trained for situations when benefit-risk of your product is at stake and you need to manage a media, legal and regulatory crisis

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 included in this course.

Learning Objectives

At the conclusion of this course, participants should 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

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

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MONDAY | 13 MAY 2013

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

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

TUESDAY | 14 MAY 2013

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 I
  - Introduction for case studies for Day II

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

15:00 WRAP UP

15:15 END OF TRAINING COURSE

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Mercure Hotel Stoller Zurich
Badenerstrasse 357
8040 Zurich

Tel: +41 (0)44 405 47 47
Fax: +41 (0)44 405 48 48
E-Mail: h5488@accor.com

at the special rate of:
EUR 170.00 (CHF 210.00) per room inclusive of breakfast and VAT.
To make your reservation, please use the booking form available on the DIA website.

IMPORTANT: Please complete your reservation by 12 April 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

Unless otherwise disclosed, DIA Europe 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 Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

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REGISTRATION FORM

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ID #13523

FEES

	Member*	Non-Member*
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€ 683.00 ❑	€ 798.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*All fees will be subject to the Swiss VAT at 8 %

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

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

Registration fee includes: refreshments, lunches and training course material

TOTAL AMOUNT DUE: _____

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

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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

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❑ **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 #13523 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.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: 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 Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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