DIA Training Course on

Benefit/Risk Management

Course #12594 15-16 October 2012 Mercure Paris Montmartre Sacre Coeur, Paris, France



Faculty

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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 FU
- 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

- 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.

PharmaTrain recognised





MONDAY | 15 OCTOBER 2012

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 | 16 OCTOBER 2012

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

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.

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

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.



HOTEL INFORMATION

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

Mercure Paris Montmartre Sacre Coeur

3 rue Caulaincourt 75018 - PARIS France

Email: H0373@accor.com Tel: 0033 8 258 0 7979

Fax: 0033 1 446 97071

Mahaita http://www.m

Website: http://www.mercure.com/gb/hotel-0373-mercure-parismontmartre-sacre-coeur/index.shtml

at the special rate of:

EUR 173.00 per standard room, single occupancy inclusive of buffet breakfast and VAT.

In order to make your reservation please use the hotel booking form available on the DIA website.

Important:

Please complete your reservation by 14 September 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

REGISTRATION FORM

Benefit/Risk Management Training Course

15-16 October 2012 | Mercure Paris Montmartre Sacre Coeur, Paris, France



If DIA cannot verify your membership upon receipt of the registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY		Member Fee* Non-Member Fee*
Industry		€ 1'365.00 □ € 1'480.00 □
Government/Charitable/Non-profit/Academia (Full-Time)		€ 683.00 □ € 798.00 □
		*All fees are subject to local French VAT of 19.6%
loin DIA now to qualify for the memb	ber rate	Fee € 115.00 □
TOTAL AMOUNT DUE: € NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT		
GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION		
RESPONSIBILITY/INTEREST AREA Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.		
CMC Clinical Data Management/ eClinical Clinical Research & Development Clinical Safety/Pharmacovigilance Document Management/ eSubmissions Medical Communications	Medical Writing Non-clinical Outsourcing Comparative Effectiv ment/ Evidence-based Mec Pricing/Reimbursement	ent
ATTENDEE DETAILS		PAYMENT METHODS - Credit cards are the preferred payment method.
PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN		D. Diene also we would be sould. Conditioned as we state by VICA. Markey and an AMEY and be used as
SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE		☐ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be
□ Prof □ Dr □ Ms □ Mr		accepted.
Last Name		U VISA UMC AMEX
First Name		Card Number
Company		Expiry Date
Job Title		Cardholder's Name
Street Address / P.O. Box		Date Cardholder's Signature
Postal Code	City	Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland
Country	Telephone	
Fax (Required for confirmation) Email		■ 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." including your name, company, Meeting ID #12594 as well as the invoice number to ensure correct allocation of your payment.
Please enter your company's European VAT number:		Payments must be net of all charges and bank charges must be borne by the payer.
Please indicate your professional category:	□ Academia □ Government □ Industry □ Contract Service Organisation	
CANCEL ATION BOLICY		

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00 Regretfully, if you do not cancel five working days prior to the course 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.

IMPORTANT:

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration.

Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org

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