DIA

Workshop on Benefit-Risk Strategy

15-16 June 2017

Grand Majestic Plaza, Prague

OVERVIEW

Benefit-risk guidelines continue to evolve with the EMA publishing guidance revisions as recently as this March. This workshop provides you the tools to address these changes by giving you:

1. Overview of benefit-risk assessments
2. Examples of challenges and solutions across different departments
3. Impacts and interpretations of the new guidelines

This workshop is structured to help you navigate the evolving benefit/risk guidelines by providing you with real-world examples from experts across regulatory and industry, and by offering tangible ways to improve your best practices.

WHO SHOULD ATTEND?

Professionals involved in benefit-risk strategy from various departments, e.g. pharmacovigilance, regulatory, clinical, drug safety, medical affairs, or medical writing.

Program leads who oversee the clinical development, dossier preparation, and post-marketing phases of the medicines life cycle.

LEARNING OBJECTIVES

What will you gain?

New benefit-risk regulations call for a more structured and formalised process. This workshop will:

- Increase your understanding of the current benefit and risk landscape
- Empower you to perform benefit-risk management more effectively within your organisation
- Give you a toolkit to address tactical components of risk assessments, including data collection and digital innovation

PROGRAMME COMMITTEE

Martin Huber
PRAC Member, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Steve Mayall
Principal Consultant, PopeWoodhead, UK

Jan Petracek
CEO, PharmInvent, Czech Republic

Steffen Thirstrup
Director, NDA Group, UK

SwAPP AND SGPM CREDITS

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

This workshop has been accredited with 11 credits.

FPM RCP CREDITS

DIA has been awarded with Continuing Professional Development (CPD) credits from the Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom for selected meetings and training courses. Physicians who are eligible for these credits can find more information about registering for CPD on https://www.fpm.org.uk/revalidationcpd/CPD/cpd. Already registered CPD members can claim the applicable credits directly on https://www.revalidation.fpm.org.uk/login.

This workshop has been accredited with 11 credits.

LEARN MORE

Visit **www.DIAglobal.org/BenefitRisk** for programme updates or contact **EMEA@DIAglobal.org** with questions.

Workshop on Benefit-Risk Strategy

DAY ONE | THURSDAY, 15 JUNE

08:30 REGISTRATION AND WELCOME COFFEE

09:30 KEYNOTE SPEECH

STRUCTURED BENEFIT-RISK FRAMEWORKS: HAVE WE REACHED THE END? OR JUST THE BEGINNING...

Francesco Pignatti, Head of Oncology, Haematology, Diagnostics, European Medicines Agency (EMA), UK

10:00 SESSION 1

ICH GUIDELINE ON BENEFIT-RISK INFORMATION

Session Chair:
Steve Mayall, Principal Consultant, PopeWoodhead, UK

This session will explain the recent changes in the ICH guideline on benefit-risk assessment, placed in the context of other benefit-risk initiatives. The session will address:

- Updated ICH M4E (R2) guideline
- Benefit-risk assessment evolution over the past several years
- Impact of structured benefit-risk assessment on stakeholders

ICH M4E (R2) Guideline: What's New (and What's Not)
Francesco Pignatti, Head of Oncology, Haematology, Diagnostics, European Medicines Agency (EMA), UK

The Changing Face of Benefit-Risk Assessments - Initiatives and Implications
Leslie Wise, Managing Director, Wise Pharmacovigilance and Risk Management, UK

Benefit-Risk Assessment Evolution and Current Landscape
Steve Mayall, Principal Consultant, PopeWoodhead, UK

11:00 REFRESHMENT BREAK

11:30 SESSION 2

IMPLEMENTING BENEFIT-RISK MORE EFFECTIVELY

Session Chair:
Steffen Thirstrup, Director, NDA Group, UK

The session will walk you through the do's and don'ts of benefit-risk implementation. It will reflect a number of case studies that clarifies potential risk areas. The essential elements of the session are:

- What benefit-risk information to include in the clinical overview
- Choosing the right qualitative or quantitative framework

Case Studies
Lesley Wise, Managing Director, Wise Pharmacovigilance and Risk Management, UK

Case Studies
Bill Richardson, Medical Advisor, NDA Group, UK

13:00 LUNCH

14:00 SESSION 3

IMPACT ON BUSINESS PROCESSES AND DATA COLLECTION

Session Chair:
Steve Mayall, Principal Consultant, PopeWoodhead, UK

The session has been structured to reflect not only the theoretical but also pragmatic side of data collection and applicable business processes. The following will be the focus of the session:

- Performing a benefit-risk assessment
- Selecting appropriate methodologies
- Inclusion of patient voice with preference studies

Performing Benefit-Risk Assessments: Organisational Challenges
Steve Mayall, Principal Consultant, PopeWoodhead, UK

Considerations for the Selection of Benefit-Risk Assessment Methodologies
Shahrul Mt-Isa, Associate Principal Scientist, HTA Statistics, BARDS Europe, MSD, UK

Inclusion of the Patient Voice in Benefit-Risk Assessment
Kimberley Hockley, Global Benefit-Risk Management Scientist, Amgen, UK

15:30 REFRESHMENT BREAK

16:00 SESSION 4

INNOVATIVE WAYS FOR CAPTURING AND PRESENTING THE DATA

Session Chair:
Jan Petracek, CEO, PharmInvent, Czech Republic

This session will give you a good understanding of how the regulators are expecting to see the data presented now and going forward. The session will also give hands-on tools to improve your benefit-risk data visualisation. The following will be discussed:

- Visual methods & graphical presentation
- IMI-PROTECT (IMI project developing new ways to present benefit-risk data)

Innovative Ways for Capturing and Presenting the Data for Benefit-Risk Management
Mick Foy, Group Manager, Vigilance Intelligence and Research Group, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Monitoring the Expected Benefit-Risk Profile of a Vaccine Using an Interactive Dashboard
Kaatje Bollaerts, Senior Statistician, P-95, Belgium

Case Study
Jan Petracek, CEO, PharmInvent, Czech Republic

17:30 NETWORKING RECEPTION

18:30 END OF DAY 1

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DAY TWO | FRIDAY, 16 JUNE

08:30 WELCOME COFFEE

09:00 SESSION 5

UPDATE OF GVP MODULE V – IMPROVING THE RISK MANAGEMENT SYSTEMS

Session Chair:
Martin Huber, PRAC Member, Federal Institute for Drugs and Medical Devices (BfArM), , Germany

EMA has recently published an update to the GVP module V, which guides risk management systems. This session will welcome regulators from EMA, national authority and PRAC as well as industry to discuss their recommendations for implementation of the updates. Focus of the session will be on:

- Major changes in GVP Module V
- Amended definitions: important identified risks and important potential risks
- Interpretation of the new requirements
- Implications for regulators and industry

GVP V Update – What We Would Like to Achieve
Martin Huber, PRAC Member, Federal Institute for Drugs and Medical Devices (BfArM), Germany

GVP V and RMP Template Rev 2 – What Is New? Practical Advice for Implementation and Transition
Emil Cochino, Scientific Officer, Anti-infectives and Vaccines, SRM Department, European Medicines Agency (EMA), UK

Major Revision of the GVP Module V from the Industry Perspective
Zuzana Vinterova, Associate Director, Medical Writing, PharmInvent, Czech Republic

10:30 REFRESHMENT BREAK

11:00 SESSION 6

PRAC REFERRALS – LESSONS LEARNED

Session Chairs:
Martin Huber, PRAC Member, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Martin Votava, Chief Medical Officer, Managing Director, PharmInvent, Czech Republic

Pharmacovigilance referrals are important tools to address concerns over the safety profile or the benefit-risk balance of a medicine or a class of medicines. This session will look into finished referrals but will also reflect on future challenges both from a regulator's and industry perspective. The following aspects will be discussed:

- Describing the evolution of referrals including recent trends
- Reflecting on what can be learnt from experience gathered so far
- Looking into future challenges – what can be improved?

Referrals at PRAC – Recent Trends and Future Challenges
Álmath Spooner, Vice-chair, PRAC; Pharmacovigilance and Risk Management Lead, Health Products Regulatory Authority (HPRA), Ireland

Implementing CHMP/PRAC Conditions: Pitfalls and Challenges
Vera Tóth, Medical Expert, Gedeon Richter, Hungary

12:00 LUNCH

13:00 SESSION 7

DIGITAL TOOLS FOR MINIMISING RISKS

Session Chair:
Martin Votava, Chief Medical Officer, Managing Director, PharmInvent, Czech Republic

This session presents different tools and means to minimise risks that are already in use. It is a perfect place to benchmark the practices in place in your organisation and discuss the pros and cons of each tool. The session will discuss the following:

- Presenting different tools and options
- How to harness digital tools to minimise risks and evaluate effectiveness
- Examples of using digital tools in patient and HCP engagement in real life

Digital Tools and Benefit-Risk: Wheat from Chaff
Priya Singhal, Senior Vice President and Global Head of Safety and Benefit Risk Management, Biogen, United States

Pragmatic Application of Digital Tools in Managing Medicinal Product Benefit-Risk: Opportunities and Challenges
William W. Gregory, Senior Director, Worldwide Safety and Regulatory, Pfizer, United States

15:00 END OF CONFERENCE

Conference Venue

Hotel Grand Majestic Plaza
Truhlářská 16
110 00 Prague 1 - Czech Republic

Phone: +420 211 159 100 | reception@hotel-grandmajestic.cz
www.hotel-grandmajestic.cz

A limited number of rooms are available at the reduced rate of €140 (superior room standard, single occupancy) including breakfast, WIFI, local tax and VAT. Reservations can be done by phone or email, reservation code: **#176497, DIA**

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 Zsofia.Molnar@diaglobal.org for a custom group rate.

REGISTRATION FORM | ID# 17117

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DIA

Early-bird discount available for members: Register by 3 May 2017

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'230.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

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Please provide your European VAT number

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, Event ID#17117 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 online by clicking **here.**

Date	Signature

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DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

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

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA 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 EMEA office of any such substitutions as soon as possible.

Photography and Video 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.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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