DIA Learning

Risk Minimisation Measures

Virtual Live Training Course

18-20 June 2024 13:00-17:30 CEST

OVERVIEW

The proactive planning of risk minimisation measures (RMMs) in the context of optimizing the benefit-risk profiles of medicinal product is a challenging task. RMMs should be commensurate to the risk in relation to the clinical benefit of the product and should work for the intended patient population without adding undue burden on the healthcare systems. They should also allow for rapid evaluation of their effectiveness and adaptation to a changing healthcare environment, if and when necessary.

In this course, we will share experiences and challenges in designing, implementing, and evaluating RMMs in different regulatory settings and different therapeutic areas, as well as presenting an outlook on what may be the next generation of RMM tools.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- design a risk management strategy
- select the appropriate tools for risk minimisation
- choose the right measures to evaluate effectiveness

KEY TOPICS

- Introduction to risk management
- Regulatory framework for risk management
- Designing a risk minimisation measures strategy
- Tools for risk minimisation
- Implementation of risk minimisation measures
- Measuring effectiveness
- Risk minimisation measures findings from an assessor's perspective
- Evolving landscape and future outlook

WHO WILL ATTEND

This intermediate level virtual live training course is intended for professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, risk management and regulatory affairs. Ideally, participants should have an experience in risk management.

FACULTY

Michael Forstner
Head of Global Safety Science
SOBI
Switzerland

Anita Volkers
Pharmacovigilance Assessor
Medicines Evaluation Board (MEB)
Netherlands

Chia Yin Lim
Patient Safety Partner and Risk Management Plan Implementation Coordinator
Roche Products
United Kingdom

Omar Aimer
President of the ISoP North American Chapter
ISoP
Canada

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

13:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30 SESSION 1

INTRODUCTION TO RISK MANAGEMENT

Michael Forstner

- What are "risks"
- What do we want to "manage"

14:30 SESSION 2

REGULATORY FRAMEWORK FOR RISK MANAGEMENT

Anita, Volkers, Chia Yin Lim, Omar Aimer

- Different country/region requirements
- Harmonisation initiatives

16:00 BREAK

16:30 SESSION 3

DESIGNING A RISK MINIMISATION MEASURES STRATEGY

Anita Volkers, Michael Forstner

- Prioritising risks
- Defining strategic goals of risk minimisation
- Selecting the strategic approach

17:30 END OF DAY 1

DAY 2

13:00 SESSION 4

TOOLS FOR RISK MINIMISATION

Omar Aimer

- What is available and how can the best tool be selected
- Examples of tools that worked and others that failed

14:30 SESSION 5

IMPLEMENTATION OF RISK MINIMISATION MEASURES

Omar Aimer, Chia Yin Lim

- Practical considerations on implementation process
- Working with the health care systems in different countries
- Oversight of implementation and compliance

15:30 BREAK

16:00 SESSION 6

MEASURING EFFECTIVENESS

Michael Forstner, Chia Yin Lim, Anita Volkers

- Process and outcome parameters
- Tools
- Learnings from previous experience (incl. REMS)

17:30 END OF DAY 2

DAY 3

13:00 SESSION 7

RISK MINIMISATION MEASURES FINDINGS FROM AN ASSESSOR'S PERSPECTIVE

Anita Volkers

- PPP (for example, Valproate, oral retinoids)
- Digital access
- Qualitative data collection

14:30 BREAK

15:00 SESSION 8

EVOLVING LANDSCAPE AND FUTURE OUTLOOK

Michael Forstner, Anita Volkers, Omar Aimer, Chia Yin Lim

Open discussion and Q&A

17:30 END OF VIRTUAL LIVE TRAINING COURSE

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Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Technical Requirements

To test your system compatibility, please click on the link:

https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:

https://www.diaglobal.org/General/System-Requirements

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary 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 does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia.

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 via email to basel@diaglobal.org.

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REGISTRATION FORM | Virtual Live Training Course

Risk Minimisation Measures #24542
18-20 June 2024 13:00-17:30 CEST

DIA Learning

REGISTRATION FEES

Registration fee includes admission to the full virtual live course, electronic access to training course material, access to course recordings. **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 EARLY-BIRD valid until 23 Apr 2024	MEMBER valid from 24 Apr 2024	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'215.00 ❑	€ 1'350.00 ❑	€ 1'610.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 ❑	€ 935.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's 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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: Basel@DIAglobal.org **Mail:** DIA, Küchengasse 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 https://www.diaglobal.org/General/Photography-Policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/About-Us/Privacy-Policy.

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

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 #24542 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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