

Risk Minimisation Measures

Virtual Live Training Course

12-14 November 2024 | 13:00-17:30 CET



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 virtual live training 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

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.

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

Faculty

Omar Aimer

President of the ISoP North American Chapter
ISoP, Canada

Chia Yin Lim

Patient Safety Partner and Risk Management Plan Implementation Coordinator
Roche Products, United Kingdom

Mark Perrott

Managing Partner
Axian Consulting, United Kingdom

Anita Volkers

Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

DAY 1

13:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30 SESSION 1

INTRODUCTION TO RISK MANAGEMENT

Instructor TBC

- What are “risks”
- What do we want to “manage”

14:30 SESSION 2

REGULATORY FRAMEWORK FOR RISK MANAGEMENT

Anita, Volkens, Chia Yin Lim and Omar Aimer

- Different country/region requirements
- Harmonisation initiatives

16:00 BREAK

16:30 SESSION 3

DESIGNING A RISK MINIMISATION MEASURES STRATEGY

Anita Volkens and Mark Perrott

- 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 and 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

Anita Volkens and Mark Perrott

- 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 Volkens

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

14:30 BREAK

15:00 SESSION 8

EVOLVING LANDSCAPE AND FUTURE OUTLOOK

Anita Volkens, Omar Aimer and Chia Yin Lim

- Open discussion and Q&A

17:30 END OF VIRTUAL LIVE TRAINING COURSE



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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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DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China



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>



Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.50 credits.



Unless otherwise disclosed, DIA 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. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

REGISTRATION FORM

RMMS Virtual Live Training Course # 24550
12-14 November 2024 | 13:00-17:30 CET

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **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 17 Sep 2024	MEMBER valid from 18 Sep 2024	NON-MEMBER
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ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 <input type="checkbox"/>	€ 935.00 <input type="checkbox"/>

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.

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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

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

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.

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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.

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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 the **invoice number**, your name and company to ensure correct allocation of your payment. Payments must be net of all bank charges. Bank charges must be borne by the payer.

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Date	Signature
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