

## Risk Minimisation Measures

Virtual Live Training Course

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



### Overview

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The proactive planning of risk minimisation measures (RMMs) in the context of optimizing the benefit-risk profiles of medicinal products is a challenging task. RMMs should be commensurate with 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

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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

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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 experience in risk management.

### Key Topics

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- 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

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#### 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

*Anita Volkers*

- What are “risks”
- What do we want to “manage”
- What is challenging in risk management?

14:15 SESSION 2

### REGULATORY FRAMEWORK FOR RISK MANAGEMENT

*Anita Volkers, Chia Yin Lim and Omar Aimer*

- Different country/region requirements
  - EU, UK, US, Middle East, LATAM, China, Taiwan
- Harmonisation initiatives
- GVP Module XVI Rev 3
- Introduction to Group Work

16:00 BREAK

16:30 SESSION 3

### DESIGNING A RISK MINIMISATION MEASURES STRATEGY

*Mark Perrott and Anita Volkers*

- Defining strategic goals of risk minimisation
- Selecting the strategic approach
- Prioritising risks
- Requested (features of) aRMM (regulator view)

17:30 END OF DAY 1

## DAY 2

13:00 SESSION 4

### TOOLS FOR RISK MINIMISATION

*Omar Aimer and Mark Perrott*

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

14:00 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 GROUP WORK

16:30 SESSION 6

### MEASURING EFFECTIVENESS

*Mark Perrott and 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

*Anita Volkers, Omar Aimer, Chia Yin Lim and Mark Perrott*

- Group work presentation and discussion
- Panel discussion and Q&A

17:30 END OF VIRTUAL LIVE TRAINING COURSE

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.



## Group Discounts

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

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](mailto:basel@diaglobal.org).

*\*Terms and Conditions apply. Please contact DIA EMEA office for more information.*



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The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

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



# 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
INDUSTRY/ REPRESENTATIVE	€ 1'215.00 <input type="checkbox"/>	€ 1'350.00 <input type="checkbox"/>	€ 1'610.00 <input type="checkbox"/>
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.**

### DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at [DIAGlobal.org/Membership](https://www.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](https://www.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](mailto:Basel@DIAGlobal.org) **Mail:** DIA, KÜchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAGlobal.org](https://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.

**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

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### Privacy Policy

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## PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

**If you have not received your confirmation within five working days, please contact [basel@diaglobal.org](mailto:basel@diaglobal.org).**

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

These are available from the office or online by clicking:

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Date	Signature
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