# DIA LEARNING

# Risk Minimisation Measures

## Virtual Live Training Course
## 2-4 June 2026 | 09:00-13:30 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.

After the recent updates to GVP XVI, it's clear that they should also allow for rapid evaluation of their effectiveness to enable evidence-based adaptation to achieve their objectives or align 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 experience in risk management.

## Key Topics

- Introduction and overview of changes to risk management
- Regulatory framework for risk management
- Designing global risk management 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

**Mark Perrott**
Managing Partner
Axian Consulting, United Kingdom

**Anita Volkers**
Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

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# Schedule-At-A-Glance

## DAY 1

**09:00**  WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS, INTRODUCTION TO GROUP WORK

**09:45**  SESSION 1

### INTRODUCTION AND OVERVIEW OF CHANGES TO RISK MANAGEMENT

*Anita Volkers*

- Risks classifying for inclusion RMP (evolvement)
- New challenges in risk management

**10:15**  SESSION 2

### REGULATORY FRAMEWORK FOR RISK MANAGEMENT

*Anita Volkers and Omar Aimer*

- Updates in GVP Module XVI Rev 3
- Different country/region requirements in the EU, UK, US and brief overview of other regions
- Harmonisation initiatives

**11:45**  BREAK

**12:15**  SESSION 3

### DESIGNING GLOBAL RISK MANAGEMENT STRATEGY

*Mark Perrott and Anita Volkers*

- Aligning risk management strategy and structured benefit-risk assessment
- Defining strategic goals of risk minimisation
- Prioritising risks and defining risk management objectives
- Requested (features of) aRMM (regulator view)

**13:30**  END OF DAY 1

## DAY 2

**09:00**  SESSION 4

### TOOLS FOR RISK MINIMISATION

*Omar Aimer and Mark Perrott*

- Turning risk management objectives into customer-focussed tools
- Engaging with internal colleagues and the customer
- Examples of 'traditional' paper-based approaches and digital tools designed to achieve various outcomes
- Group Work Part 1

**10:30**  SESSION 5

### IMPLEMENTATION OF RISK MINIMISATION MEASURES

*Omar Aimer*

- Key updates on RMM implementation in GVP Mod XVI Rev 3
- Practical considerations in planning RMM implementation and strategy
- Working with health care systems in different countries
- Oversight of RMM implementation and compliance

**12:00**  BREAK

**12:30**  SESSION 6

### MEASURING EFFECTIVENESS

*Mark Perrott and Anita Volkers*

- The effectiveness measurement challenge
- Do the FDA and EMA approaches conflict or align
- Aligning risk management objectives with measures of effectiveness
- What are the regulatory expectations at submission and beyond

**13:30**  END OF DAY 2

## DAY 3

**09:00**  SESSION 6 CONT.

### MEASURING EFFECTIVENESS

*Anita Volkers and Mark Perrott*

- PASS Studies
- Potential for digital tools to provide new approaches
- Specific interventions and their measurement, e.g. Valproate

**09:30**  SESSION 7

### RISK MINIMISATION MEASURES FINDINGS FROM ASSESSOR'S PERSPECTIVE

*Anita Volkers*

- Digital access/dissemination
- RM control tools
- Barriers and enablers of effectiveness (qualitative data)

**10:30**  BREAK

**11:00**  SESSION 8

### EVOLVING LANDSCAPE AND FUTURE OUTLOOK

*Anita Volkers, Omar Aimer and Mark Perrott*

- Future trends in RMM implementation
- Common implementation barriers
- Future digital approaches / platforms for risk management and implications
- Open forum for participant insights and experiences

**12:00**  SESSION 9

### GROUP WORK PART 2

**13:00**  Q&A

**13:30**  END OF VIRTUAL LIVE TRAINING COURSE

## 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.

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

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## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

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

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.

# REGISTRATION FORM

**RMMs Virtual Live Training Course # 26542**
**2-4 June 2026| 09:00-13:30 CEST**

# DIA LEARNING

## 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 6 May 2026 | MEMBER valid from 7 May 2026 | 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.

### 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
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Job Title
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Telephone Number
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Attendee email required for course material access

## 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.

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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