DIA LEARNING

Risk Minimisation Measures

Virtual Live Training Course
8-10 April 2025 | 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 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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

09:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

09:30 SESSION 1

INTRODUCTION TO RISK MANAGEMENT

Anita Volkers

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

10:15 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

12:00 BREAK

12:30 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)

13:30 END OF DAY 1

DAY 2

09:00 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
- Group Work Part 1

10:00 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

11:30 BREAK

12:00 SESSION 6

MEASURING EFFECTIVENESS

Mark Perrott and Anita Volkers

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

13:30 END OF DAY 2

DAY 3

09:00 SESSION 7

RISK MINIMISATION MEASURES FINDINGS FROM AN ASSESSOR'S PERSPECTIVE

Anita Volkers

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

10:30 BREAK

11:00 SESSION 8

EVOLVING LANDSCAPE AND FUTURE OUTLOOK

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

- Open discussion and Q&A
- Group Work Part 2

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.*

Customized Professional Development for Your Team

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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

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 # 25542
8-10 April 2025 | 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 11 Feb 2025	MEMBER valid from 12 Feb 2025	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 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:

http://www.diaglobal.org/EUterms

Date	Signature