

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

Omar Aimer

President of the ISO-P North American Chapter
ISO-P
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 (MEB)
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?

14:30 SESSION 2

REGULATORY FRAMEWORK FOR RISK MANAGEMENT

Omar Aimer, Chia Yin Lim, Anita Volkers

- Different country/region requirements
- Harmonisation initiatives

16:00 BREAK

16:30 SESSION 3

DESIGNING A RISK MINIMISATION MEASURES STRATEGY

Mark Perrott, Anita Volkers

- Prioritising risks
- Requested (features of) aRMM (regulator view)
- 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

Mark Perrott, 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

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

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.



| Technical Requirements

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

<https://diaglobal.zoom.us/test>

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- 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
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REGISTRATION FORM | Virtual Live Training Course

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



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 <input type="checkbox"/>	€ 1'350.00 <input type="checkbox"/>	€ 1'610.00 <input type="checkbox"/>
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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, Kuchengasse 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

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ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

☐ Prof ☐ Dr ☐ Ms ☐ Mr

Last Name

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Date

Signature