DIA Learning

Risk Management Plan Creation

Best Practice in Medical Writing of the EU-RMP (GVP Module V)

Virtual Live Training Course

14-16 September 2021 09:00-13:00 CEST

OVERVIEW

This virtual live course is aimed at the practical aspects of the EU Risk Management Plan (EU-RMP) creation process. We will demonstrate the various uses of the EU-RMP within the lifecycle of medicinal products, medical writing process and RMP management process. It will provide a detailed understanding of the GVP Module V (Rev. 2) with all potential implications for the marketing authorisation holders.

The participants will learn the best practice in medical writing of the EU-RMP. The solutions will be demonstrated in practical exercises included throughout the course.

LEARNING OBJECTIVES

At the conclusion of this virtual live course, participants will be able to:

- Understand requirements of the EU Good Pharmacovigilance Practice Module V and Guidance on the format of the RMP
- Learn the best medical writing practices for EU-RMP and consistency check with other parts of the dossier
- Understand the project management challenges
- Deal with uncertainties and gaps in the data sets

KEY TOPICS

- Objectives and structure of the EU-RMP
- Source data and planning process
- EU-RMP for generic medicinal products (and other “Article 10” products)
- Product and disease/condition overviews
- Safety specification modules SII-SVI
- Identification and characterisation of safety concerns (Modules SII-SIII)
- RMPs outside of the EU
- Pharmacovigilance Plan and Post-Authorisation Efficacy Studies
- Risk minimisation measures
- Summary of the EU-RMP and Annexes
- Monitoring of EU-RMP quality

WHO WILL ATTEND

This course is intended for the professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, regulatory, and medical affairs or similar positions, who are involved in the medicinal product lifecycle. This course would be especially beneficial for junior and medium level experience professionals involved in preparation of the EU-RMP and working within the pharmaceutical industry, service providers, and research institutions.

FACULTY

Zuzana Vinterova
Strategic Advisor, Medical Writing
PrimeVigilance s.r.o., Czech Republic

Nuria Semis-Costa
Scientific Officer
European Medicines Agency, Netherlands

Jan Kolouch
Head of Pharmacovigilance and Clinical Safety
PVpharm, Czech Republic

DAY 1

09:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

09:15 SESSION 1

BACKGROUND TO THE EU RISK MANAGEMENT

Zuzana Vinterová

- Terminology
- History of RMP in the EU
- Legal framework in the EU

10:00 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

Zuzana Vinterová

- Structure and content of the RMP
- EU-RMP versus Periodic Benefit-Risk Evaluation Report (PBRER)
- RMP updates

10:30 SESSION 3

GROUP WORK I - PROJECT MANAGEMENT

Jan Kolouch, Núria Semis-Costa, Zuzana Vinterová

11:00 COFFEE BREAK

11:15 SESSION 4

SOURCE DATA AND PLANNING PROCESS

Zuzana Vinterová

- Project plan
- Data sources (interdepartmental responsibilities)

11:45 SESSION 6

PRODUCT AND DISEASE/CONDITION OVERVIEWS

Zuzana Vinterová

- Product/-s overview
- Indication/-s and target population/-s
- Epidemiology of the disease/condition
- Risk factors, comorbidities
- Natural history of the disease, main treatment options

12:15 SESSION 7

SAFETY SPECIFICATION (MODULES SII-SVI)

Zuzana Vinterová

- Key findings from the nonclinical development programme
- Clinical development programme and populations not studied
- Post-marketing experience

13:00 END OF DAY 1

DAY 2

09:00 SESSION 8

IDENTIFICATION AND CHARACTERISATION OF SAFETY CONCERNS (MODULES SVII AND SVIII)

Núria Semis-Costa

- Identification of important identified/potential risks (important and non-important risks)
- Characterisation of identified and potential risks (ATMP versus non-ATMP version)
- Safety concerns (points to consider)

10:00 SESSION 10

GROUP WORK II - SAFETY CONCERNS

Jan Kolouch, Núria Semis-Costa, Zuzana Vinterová

10:45 COFFEE BREAK

11:00 SESSION 12

RISK MINIMISATION MEASURES

Núria Semis-Costa

- Routine risk minimisation measures
- Additional risk minimisation measures
- Evaluation of the effectiveness of risk minimisation measures

12:00 SESSION 15

GROUP WORK III - RISK MINIMISATION

Jan Kolouch, Núria Semis-Costa, Zuzana Vinterová

12:45 QUESTIONS AND ANSWERS

13:00 END OF DAY 2

Group Discounts

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

- 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
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/ academia.

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.

DAY 3

09:00 QUESTIONS AND ANSWERS

09:15 SESSION 11

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Zuzana Vinterová

- Routine pharmacovigilance activities
- Additional pharmacovigilance activities
- Post-authorisation efficacy studies (PAES)

10:00 SESSION 5

EU-RMP FOR GENERIC MEDICINAL PRODUCTS (AND OTHER 'ARTICLE 10' PRODUCTS)

Jan Kolouch

- Risk-proportionality principle
- HaRP project
- Specifics of RMPs for generic medicinal products

11:00 COFFEE BREAK

11:15 SESSION 9

RMPS OUTSIDE OF THE EU

Zuzana Vinterová

- ICH founding members (Japan, United States)
- Canada, Australia, United Kingdom, Switzerland
- Other countries

11:45 SESSION 13

SUMMARY OF THE EU-RMP AND ANNEXES

Zuzana Vinterová

- Summary of the RMP
- Annexes to the EU-RMP

12:15 SESSION 14

MONITORING OF EU-RMP QUALITY

Núria Semis-Costa, Zuzana Vinterová

- Feedback from the EMA on quality of submitted RMPs

12:45 QUESTIONS AND ANSWERS

13:00 END OF THE TRAINING COURSE

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

System Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

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REGISTRATION FORM | Virtual Live Training Course

EU-RMP Creation #21545
14-16 September 2021 09:00-13:00 CEST

DIA Learning

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 20 July 2021	MEMBER valid from 21 July 2021	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'115.00 ❑	€ 1'240.00 ❑	€ 1'425.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 ❑	€ 805.00 ❑
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 CET. **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. You agree that your personal data will be transferred to DIA in the US.

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 METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **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 your name, company, Course ID #21545 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature