EMA Risk Management Information Day

21 November 2024
13:30 – 17:30 CEST | Virtual Event

PROGRAMME COMMITTEE

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| OVERVIEW

The **revised guideline on good pharmacovigilance practice (GVP) module XVI on risk minimisation measures (RMM)** has come into effect in summer 2024.

The focus of this interactive Information Day will be on implications and first experiences with implementing GVP module XVI (Revision 3) from regulators', industry, patients' as well as health-care professionals' perspectives.

Different aspects of the revised guideline will be discussed such as concepts and principles of risk minimisation, its life-cycle management with stakeholders' engagement, the specifics and development of risk minimisation measure (RMM) tools and points to consider for requesting additional RMM tools. Furthermore, success factors for RMM effectiveness, regulatory impact of results of RMM effectiveness evaluation, the role of the marketing authorisation holder (MAH) as well as the coordination of RMM for generic products and the national approval of RMM materials will be discussed.

Preparatory reading is highly recommended:
- GVP module XVI - Risk minimisation measures (Revision 3)
- GVP module XVI - Addendum II: Methods for effectiveness evaluation

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 04 November 2024 latest to emaevents@diaglobal.org

| KEY TOPICS

- Tools of risk minimisation measures (RMM)
- Risk minimisation measure (RMM) effectiveness studies
- Engagement of patients and HCPs and implementation of RMM in clinical practice
- Regulatory impact research

| TARGET AUDIENCE

- Individuals experienced in risk management, risk minimisation development and evaluation at small to medium enterprises (SMEs)
- Marketing authorisation applicants (MAAs)/MAHs for generic products
- Marketing authorisation applicants (MAAs)/MAHs for innovator products
- Contract Research Organisations (CROs)
- Assessors at National Competent Authorities (NCAs)
- Risk communication experts
- Patients and Healthcare Professional (HCP) group representatives
- Qualified persons responsible for Pharmacovigilance (QPPVs)

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AGENDA | 21 NOVEMBER 2024 | 13:30 – 17:30 CET

13:30 WELCOME NOTE

SESSION 1 – GVP MODULE XVI - THE 3RD REVISION- FIRST EXPERIENCES AND PRACTICAL ASPECTS

Session chair : Ulla Wändel Liminga, MPA, SE

13:40 **INDUSTRY INSIGHTS: NAVIGATING THE IMPLEMENTATION OF GVP MODULE XVI REVISION 3**
Harshil Patel, Novartis, IN & **Luvanka Hanxhari**, Novartis, CH

14:00 **INDUSTRY PERSPECTIVE REGARDING JOINT PASS STUDIES**
Robert Massouh, GSK, UK

14:20 **GVP XVI (REV. 3) AND CONSIDERATIONS FOR DIGITAL ARMM**
Vicki Edwards, AbbVie, UK, Member of EFPIA Digital tools working group & **Ryan Marshall**, AstraZeneca, UK

14:45 **USE CASE - ADDITIONAL RISK MINIMIZATION DESIGN AND DELIVERY BOOSTED BY AI**
Jan Petracek, IVIGEE, CZ

15:00 **Q&A**

15:20 BREAK

SESSION 2 – THE 3RD REVISION

Session chair : Sabine Straus, EMA, EU

15:50 **THE REVISED GVP MODULE XVI – WHAT TO FOCUS ON FOR IMPLEMENTING THE GUIDANCE**
Priya Bahri, Lead PhV and Risk Management Guidance and Policy, PhV Office, EMA, EU

16:10 **CONCEPTIONAL APPROACH TO RMM EFFECTIVENESS EVALUATION**
Thomas Goedecke, PRAC Impact Strategy Lead, PhV Office, EMA, EU

16:30 **IMPACT RESEARCH FROM A REGULATORY PERSPECTIVE**
Liana Martirosyan, PRAC Vice-chair, MEB, NL

16:50 **ENGAGEMENT OF PATIENTS AND HEALTHCARE PROFESSIONALS IN RMM**
Roberto Frontini, Former-Director of Pharmacy, Centre for Patient Safety Leipzig, DE

17:05 **Q&A AND PANEL DISCUSSION**

17:25 WRAP UP

17:30 END OF THE INFORMATION DAY