

Pre-workshop assignment



This pre-workshop assignment is aimed at getting familiar with the basic concepts and with the format of Risk Management Plans (RMP).

Please *do not* send your completed assignment to the workshop leader, *but bring it to the workshop*. Assignments will be discussed during a group exercise.

Pre-workshop assignment (I)

Task I (Ia + Ib). To complete this task, please download the GVP Annex I (Definitions) at the link below:

https://www.ema.europa.eu/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf

Ia. The definitions listed in the next page are needed for the workshop. Please read them carefully and bring any questions to the workshop.

Pre-workshop assignment (1a)

- Identified risk
- Potential risk
- Missing information
- Important identified and important potential risk
- Important identified risk
- Important potential risk
- Risk-benefit balance
- Risk management plan
- Risk management system
- Risk minimisation activity (measure)
- Safety concern

Pre-workshop assignment (Ib)

Ib. Answer this question:

What is the main difference between identified / potential risks
versus
important identified / important potential risks?



Pre-workshop assignment (II)

II. Get familiar with the RMP format. Based on the table of content provided in the next pages, assign to each section one of the aims provided below:

Aims:

- Risk detection
- Risk characterisation
- Risk management
- Risk communication



Notes:

- For each relevant section, hints about the content are provided (*italics*) for your reference.
- Different aims may be assigned to the same section.

Table of Contents (I)

Part I Product(s) overview

Part II Safety specification

- Module SI Epidemiology of the indication(s) and target population(s) *[including incidence, prevalence, mortality of indication; risk factors and higher risk for adverse events in target patients]*
- Module SII Non-clinical part of the safety specification *[significant non-clinical findings that could be safety concerns]*
- Module SIII Clinical trial exposure *[patients' clinical trial exposure]*
- Module SIV Populations not studied in clinical trials *[exclusion criteria that could represent missing information]*
- Module SV Post-authorisation experience *[patients' post-authorisation exposure]*
- Module SVI Additional EU requirements for the safety specification *[potential for misuse of medicinal product]*

Table of Contents (II)

- Module SVII Characterisation of identified and potential risks and missing information *[including risk frequency and seriousness; patient outcome; potential mechanisms leading to the risk; impact of risk on benefit-risk profile]*
- Module SVIII Summary of the safety concerns *[important identified risks, important potential risks, missing information]*

Part III Pharmacovigilance plan *[pharmacovigilance activities including post-authorisation safety studies (PASS); might be needed to further characterise the safety concerns in post-authorisation settings]*

Part IV Plans for post-authorisation efficacy studies (PAES) *[might be needed to further characterise benefit in post-authorisation settings]*

Part V Risk minimisation measures *[for each safety concern]*

Part VI Summary of the risk management plan *[to be published by the Health Authority]*

Part VII Annexes