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 (Ia)

- 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)

Table of Contents (II)