EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP Module VIII - Post-authorisation safety studies

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

22 November 2023

Presented by Carla Jonker | Real World Evidence office

Revision of GVP Module VIII

EUROPEAN MEDICINES AGENCY

- Revision of module VIII and templates required due to entry into force in Jan 2022 of the **new EC Clinical Trial Regulation**

- What will we do?
  - adapt **definitions** (e.g., clinical study, clinical trial, non-interventional study)
  - explore the need to **align** with new/updated **guidelines** (e.g., EMA guideline on registry-based studies) and international standards (e.g., HARPER)
  - integrate appendix I and addendum I, as needed
  - implement changes based on the **experience** of PASS assessors
  - opportunity to amend **templates** for format and content of PASS protocol and report

- Will be subject to **public consultation** (2024)