EMA
EUROPEAN MEDICINES AGENCY

Draft GVP V and RMP template rev 3.0

21st Industry Stakeholders platform meeting - operation of EU pharmacovigilance

20 October 2026

Presented by Emil Cochino

Human Medicines Division, EMA



Updates since last info day

✓ Initial planned drafting was completed spring 2026, MS and Committees consultation.

However, EMA received additional comments on making the GVP V and RMP assessment process more resilient to the NLP

We are taking GVP V and RMP Template back to the drafting group:

✓ Further simplification for RMP Part II

✓ Better coordination between clinical safety assessment and the safety concerns list drafting & assessment

✓ Comprehensive approach on safety concerns' follow-up and activities in PSUR and/or through the PhV planning and RMM in the RMP

✓ Focus the RMP on additional activities/measures

Anticipated impact on the public consultation: 6 months delay

We will communicate more when we progress through the Committees

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Thank you

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