

# Actions arising from previous meeting and other updates

Presented by Maria Filancia, Industry liaison  
specialist



# Actions arising from the 14th ISG meeting

Topic	Action	Follow up
Vulnerability assessment	<ul style="list-style-type: none"> <li>• ISG to provide feedback on Vulnerability Assessment Methodology by 3rd October 2025.</li> <li>• EMA to organise an MSSG-Industry meeting.</li> </ul>	<ul style="list-style-type: none"> <li>• completed</li> </ul>
Update on the Shortage Mitigation Plan (SMP)/Shortage Prevention Plan (SPP)	<ul style="list-style-type: none"> <li>• EMA to share the report of the pilot phase once published.</li> </ul>	<ul style="list-style-type: none"> <li>• Will be shared asap</li> </ul>
Update on the European Platform for Regulatory Science Research	<ul style="list-style-type: none"> <li>• Industry to submit 1 nomination for observer to the European Platform for Regulatory Science Research by EOB 28th October</li> </ul>	<ul style="list-style-type: none"> <li>• completed</li> </ul>
HMA-EMA Catalogues of real-world data sources and studies	<ul style="list-style-type: none"> <li>• Industry to gather the feedback from affiliated member and nominate a speaker to present the consolidated feedback at the next meeting of the ISG in December.</li> </ul>	<ul style="list-style-type: none"> <li>• Topic for discussion at the 15<sup>th</sup> ISG meeting</li> </ul>
Patients Experience Data reflection paper update	<ul style="list-style-type: none"> <li>• ISG members to promote industry members contribution to the PED public consultation (by 31/01/2026) and therapeutic areas survey (by 19/10/2025).</li> <li>• EMA to evaluate a possible workshop after the feedback from the PED reflection paper public consultation.</li> </ul>	<ul style="list-style-type: none"> <li>• ongoing</li> </ul>
AI research needs in medicines lifecycle survey	<ul style="list-style-type: none"> <li>• ISG to promote industry members contribution to the survey by EOB 17th October 2025.</li> <li>• ISG to provide nominations for AI focus group by EOB 24th October 2025.</li> </ul>	<ul style="list-style-type: none"> <li>• completed</li> </ul>

# Other important updates and reminders

Topic	Details
Quarterly System Demo – Q4 2025	<ul style="list-style-type: none"><li>• Tuesday 16 December 2025, 09:30 – 12:35 (CET)</li><li>• 10 product demos: eAF, eCTD4, UPD, PMS, PUI, ePI, RPM/IRIS, CTIS, ASU, DAP</li><li>• Agenda and livestream link on the event page</li><li>• <a href="https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2025">https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2025</a></li></ul>
Product Management Service (PMS) call for industry SME nominations	<ul style="list-style-type: none"><li>• 4 subject matter experts (SMEs) representing large, medium, and small pharmaceutical companies (including small and medium sized enterprises) as well as innovative, generic and biologic pharmaceutical companies.</li><li>• Deadline for nominations 30 January 2026.</li></ul>



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

[emaindustryliason@ema.europa.eu](mailto:emaindustryliason@ema.europa.eu)

Follow us

