Welcome and introduction

1.1: Follow up actions arising from previous meeting

1.2: Overview of 2024 feedback survey and 2025 topic proposals

Presented by Maria Filancia, Industry liaison specialist

Actions arising from the 11th ISG meeting

Topic	Action	Follow up
2.2 Update on Shortage Mitigation Plan (SMP)/ Shortage Prevention Plan (SPP)	• The EMA to communicate on the SPP, SMP pilot phase. • ISG members to familiarise themselves with the templates and participate to the pilot phase as needed.	• Pilot launched. Information shared with relevant MAHs and published.
2.3 Update on the development of the European Shortages Monitoring Platform	• Industry stakeholders to review CAPs and non-CAPs data via PMS API and PLM PUI systems; to submit pack sizes for non-CAPs for Union list of critical meds to XEVMPD by Feb 2025; enrichment of structured manufacturers data and pack sizes for non-CAPs (ULCM) in PUI by December 2025; optional submission of data carrier identifier in PUI from January 2025. • Industry stakeholders to take part to relevant events and activities (as outlined on slides 13 and 14).	• ESMP full functionality launched on 29th of January. • ESMP training on crisis and MSSG led-preparedness reporting for MAHs (19/02/2025)
3.1 Regulatory/HTA interface under the HTA regulation	Industry stakeholders (human, medical devices) to undertake preparedness activities for the implementation of the HTA regulation provisions.	On-going.
4.1. EMAN strategy to 2028 updates	• ISG members to contribute to the public consultation by 30th of November 2024. • EMA to provide details on the multi-stakeholder (virtual) meeting planned for the 13th of February 2025.	• Public consultation closed. • Overview of comments presented at the European medicines agencies network strategy (EMANS) to 2028 webinar (13/02/2025) • Updated strategy published.
4.6 EMA international activities: Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative	A small industry working group will be set up early 2025 to discuss the scope of the survey between EMA and Industry. Relevant Industry EU (trades) organisations to survey members on challenges preventing OPEN applications and report back at the next ISG meeting in March 2025.	• Cross-industry presentation at 12th ISG meeting (28/03/2025)

Actions arising from the 11th ISG meeting and other updates/reminders

Topic	Action	Follow up
5. ISG feedback survey and 2025 topic proposals	ISG members to participate to the feedback survey by EOB 20th December 2024.	• Overview of feedback and topic proposals to be presented at 12th ISG meeting (28/03/2025)
6. International Coalition of Medicines Regulatory Authorities (ICMRA)	Publication of Collaborative assessment pilot report; Collaborative hybrid inspection report	• Both report published and both pilots extended.
7. Early engagement fostering innovation survey	The survey was conducted in 2024. Meetings in scope: Innovation Task Force, SME Briefing Meetings, Product and Technology Meetings, Quality Innovation group (listen and learn focus group and one to one meetings)	• Report to be published soon on Pharmaceutical industry and Supporting Innovation webpages.
8. IRIS transition: Initial MAA procedures & updated roadmap ⚠	MAHs to be ready to IRIS transition for Initial MAA. EMA to provide updated roadmap.	• Key updates including the roadmap, actions for MAHs and guidance are published on the IRIS forum and PLM newsletter.
9. PMS info day registration ⚠	21/05/2025 (9:00 – 17:30 (CEST)) - Product Management Service Info-Day (event web page). Registration open until 11th April. Additional seats available for in person participation: up to 4 representatives per trade organisation.	• Register via the survey: Register here by 11th April!

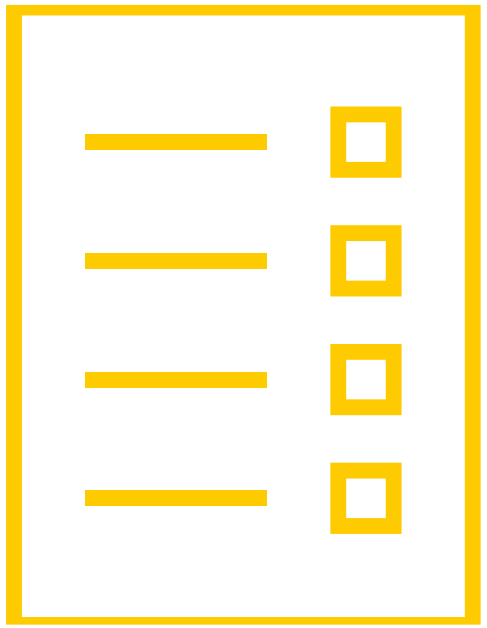
⚠ Important reminder/action required.

2024 ISG meetings feedback

- Survey sent to all ISG members who attended one or more meeting in 2024.
- Feedback requested on:
  - Meeting ISG objectives
  - Presentations level of details, clarity and Q&A sessions
  - Pre and post meeting activities
  - 2025 topic proposals
- 17 individual responses received

Presentations

- General satisfaction with level and clarity of information shared.
- Need to dedicate more time to Q&A sessions flagged.



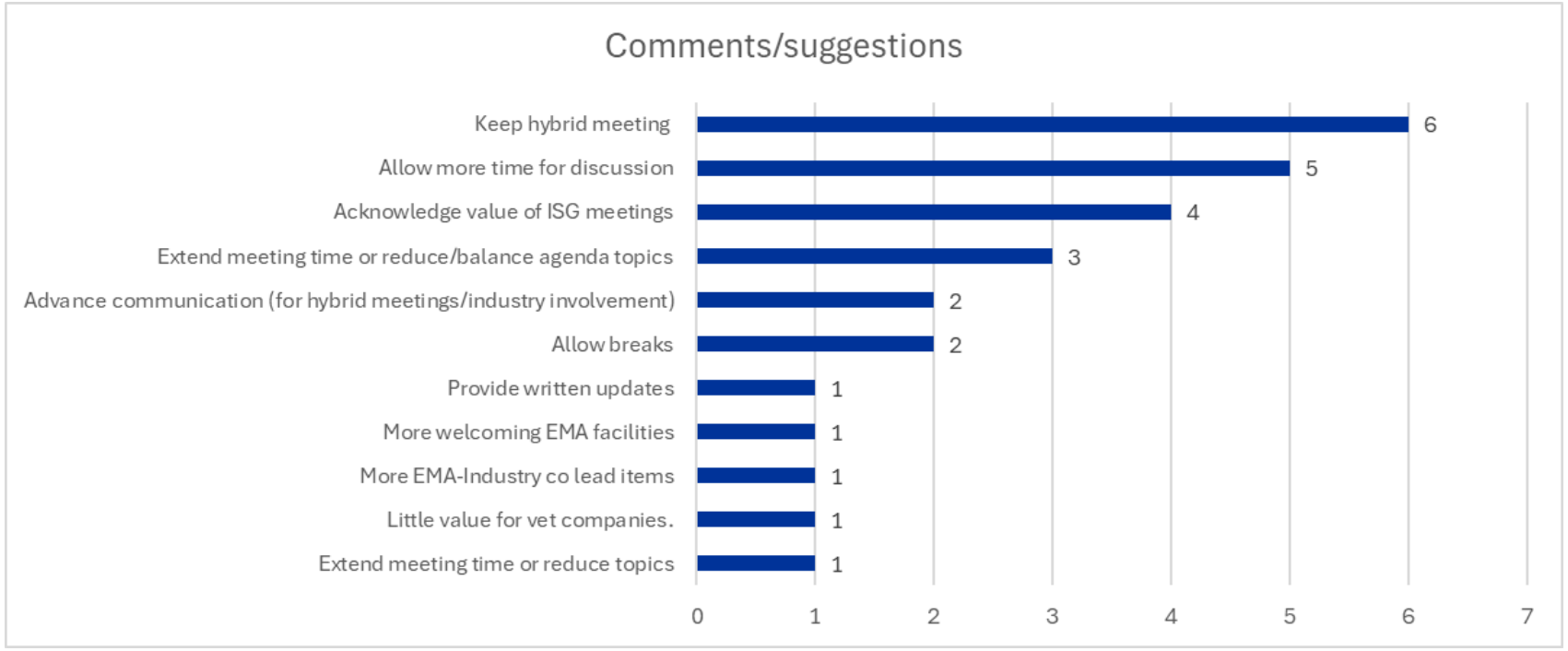
ISG objectives

General agreement with ISG meeting its objectives.

Pre-post meeting activities

- General satisfaction with organisational aspects and support in keeping 2 hybrid meetings.
- Need to provide earlier confirmation of hybrid meetings and speakers flagged.

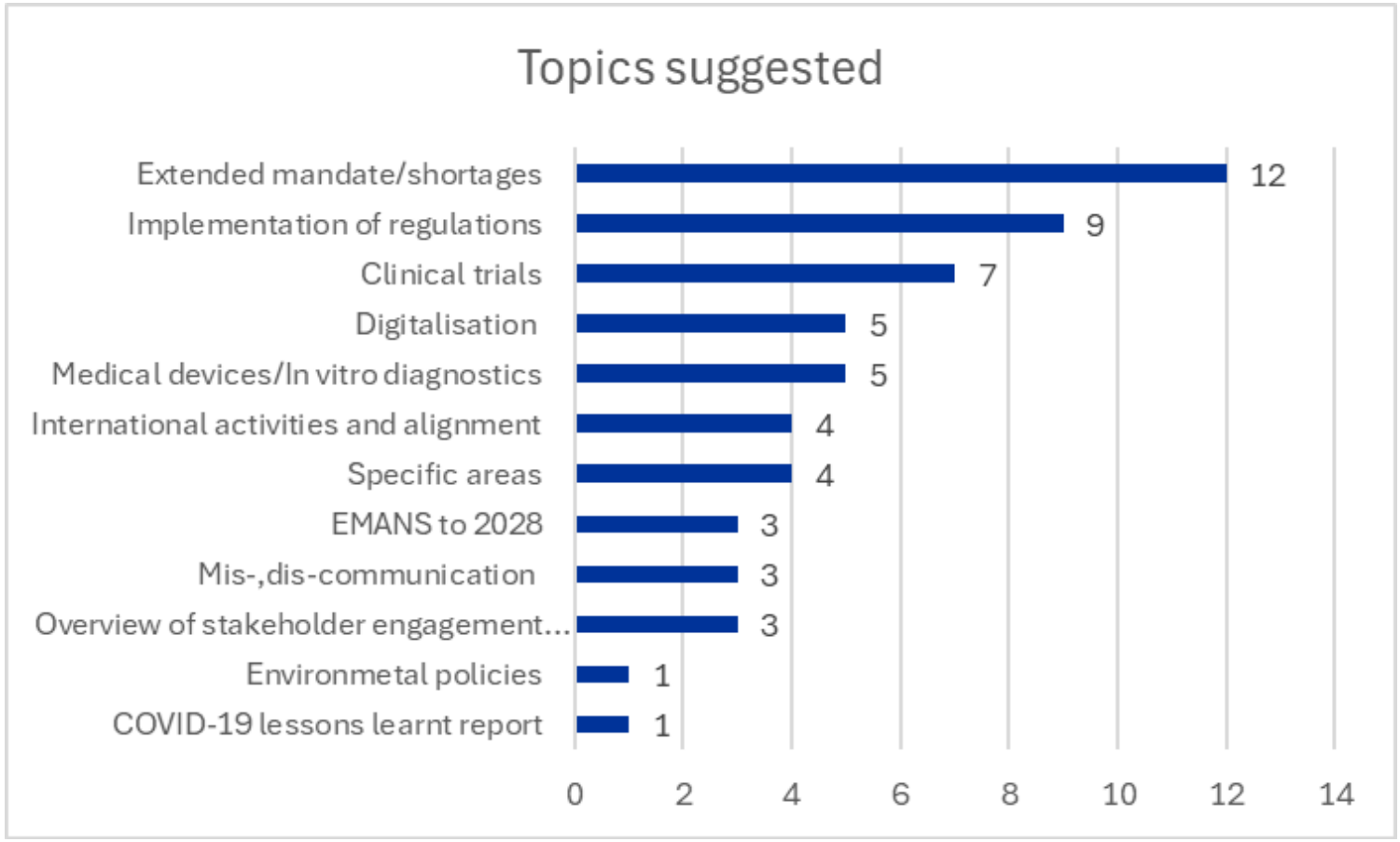
Comments/suggestions



Suggestions provided will be implemented as possible.

- ✓ Hybrid setting is kept for 2 out of 4 meetings.
- ✓ More focus on Q&A.
- ✓ Balanced agenda topics.
- ✓ Advance communication.

2025 topic proposals



- ✓ Topics linked to extended mandate, implementation of regulations (i.e. HTA) as well as strategic topics (EMANS, international activities) will stay in ISG.
- ✓ Less strategic topics will be discussed in relevant available groups/platforms but could be key updates will be discussed at ISG when needed.
- ✓ Other more technical topics will be taken by the relevant group/platform.

Examples of topics allocation

Clinical trials regulation, CTIS, COMBINE

ACT EU, CTIS forum, COMBINE forum

New methodologies, co-development strategy for companion diagnostics, overview of R&D focus groups

R&D platform

ePI, variation guidelines, new fee regulation, regulatory challenges for biological medicines, overview of CP focus groups

CP platform

Compliance with GDP, EudraGMP

GMDP Inspectors Working Group

Use of AI in lifecycle management

Big data steering group, AI workshops

Communication, mid-, dis- information

ISG

2025 topic proposals

- Overview on how each proposal is addressed shared with ISG members as part of the pre-mailing.
- Overview of stakeholder's meetings and dates: we will keep providing overview of ISG and platforms meeting and other relevant events included in the agenda topics. For other activities consult our event page.
- Overview of public consultations: already available in our "Open consultations" page.
- Consider subscribing to relevant newsletters.

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Thank you

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