15 June 2026
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Summary notes of the HMA-EMA group focused on AI with industry stakeholders

2 June 2026, - co-chaired by Joerg Zinserling (BfArM) and Peter Arlett (EMA), virtual

1. Welcome and adoption of draft agenda

Co-chair, Peter Arlett (EMA) opened the meeting by welcoming participants and presented the agenda, which was adopted with no changes.

2. Network Data Steering Group workplan: AI workstream progress update

Francois Domergue provided work-planning highlights of the Network Data Steering Group (NDSG) AI workstream, structured around three main areas:

1. Guidance, policy and product support:

- Publication of the EMA-FDA guiding principles for good AI practice.
- Ongoing work on AI guidance for clinical development and pharmacovigilance.
- Progress on an AI glossary development in collaboration with the FDA.
- Imminent publication of the 2025 AI Observatory report, which will provide an overview of AI trends and activities within the regulatory network.

2. Tools and innovation:

- Expansion of Scientific Explorer tool to include information on initial marketing authorisation applications of human medicines including public assessment reports.
- Ongoing work on regulatory network's AI ecosystem focusing on capabilities of knowledge retrieval, drafting and summarisation as well as validation and quality assurance.
- Upcoming publication of AI research priorities, informed by a stakeholder survey last year.

3. Collaboration and change management:

- Roll-out of EMA's AI Literacy Training to support compliance with the EU AI Act across the regulatory network.

- Active participation in the International Coalition of Medicines Regulatory Agencies (ICMRA) to support discussion and knowledge sharing on AI related topics.

3. AI guidance in clinical development

Gabriel Westman (MPA) provided an update on the current status of guidance development for AI in clinical development. He noted that the work remains in the scoping and drafting phase, with a concept paper being prepared for public consultation, followed by formal guidance development targeted for completion in 2027.

Alision Bond presented the industry perspective, highlighting that industry associations are broadly aligned around three overarching themes:

- Need for trusted AI across the medicines lifecycle;
- Importance of robust data and evidence ecosystems;
- Development of practical, proportionate, and implementable regulatory frameworks.

She outlined key questions and considerations for discussion across four thematic areas:

- Risk categorisation and proportionality;
- Validation and documentation expectations;
- Lifecycle oversight and adaptive AI;
- Operational implementation.

A common message across these themes was the need for practical, risk-based and implementable guidance that provides clarity, supports proportionate implementation, and enables innovation while maintaining confidence in patient safety and evidence generation.

Participants discussed the scope of the guidance, including its coverage of both clinical trial applications (CTA) and marketing authorization applications (MAA), and the importance of aligning with existing frameworks such as ICH M15 and FDA draft guidance to support international harmonization.

It was further noted that additional clarity is expected in the coming months regarding the mandate of an NDSG-led coordination group on AI guidance. The mandate is anticipated to extend across the full regulatory network, encompassing both clinical-trials regulation and the marketing-authorisation aspects of clinical development.

The co-chairs encouraged industry to provide early input on priority topics and areas where guidance might not be needed, suggesting that a short technical feedback document would be valuable for the drafting team confirming that public consultation will occur on the draft concept paper.

Action: industry associations to consider submitting technical feedback in writing in the coming weeks or feeding such feedback into the data and AI forum planned for 12-13 November 2026.

4. AI guidance in pharmacovigilance

Julie Durand (EMA) updated the participants on the development of AI guidance in pharmacovigilance (human and vet), noting that the guidance will be developed as a Q&A to ensure flexibility that may help to support new question when there will be new case study, with a stakeholder survey launched in May 2026 to gather input on key topics, and a public consultation on the draft guidance anticipated for spring 2027.

Thomas Brookland presented industry's views on the topic, noting industry's support for a Q&A format, which is seen as practical and flexible approach. He summarised industry priorities for the Q&A, including validation and performance monitoring, human oversight, transparency and governance, and expectations for pharmacovigilance inspections. Regulators noted that these priorities align well with the structure of the stakeholder survey.

Thomas Brookland also raised questions regarding the legal status of the Q&A under the Biotech Act, the process for stakeholder feedback, the potential value of a dedicated workshop, and the applicability of the Q&A to the veterinary domain. Regulators expressed openness to organising a workshop, clarified that the Q&A will contribute to the Biotech Act guidance, confirmed that the survey is targeting both human and veterinary stakeholders and that the Q&A will address both sectors, with strong engagement already observed from veterinary participants.

5. International collaboration

Joerg Zinserling (BfArM) and Luis Pinheiro (EMA) provided a brief update on ongoing international collaboration on AI. Luis Pinheiro noted the publication of EMA-FDA guiding principles for good AI practice and the joint development of a shared glossary of AI terminology, with publication expected in Q4. He also highlighted that the International Coalition of Medicines Regulatory Authority (ICMRA) continues to serve as a global forum for knowledge sharing and convergence, with recent discussions focusing on AI in pharmacovigilance and operational exchanges among regulators.

Ana Padua presented industry's feedback, expressing strong support for early regulatory convergence, emphasising its benefits for innovation and patient safety. She identified key areas where harmonisation could be advanced through ICH and VICH initiatives, including principles, terminology, risk assessment and validation approaches. Veterinary sector representatives confirmed their intention to raise the topic of AI guidance convergence at the upcoming VICH Steering Committee meeting in November 2026.

AOB and close

Joerg Zinserling reminded participants that the next focus group meeting is scheduled for 5 October. He also announced the new format for the multi-stakeholder AI and Data Forum, combining previously separate events into a single workshop to be held on 12-13 November 2026.

The meeting concluded with no additional items raised for discussion.