

13 October 2026
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Summary notes of the HMA-EMA group focused on AI with industry stakeholders

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

1. Welcome and adoption of draft agenda

Co-chair Peter Arlett (EMA) welcomed the participants and acknowledged the publication of the summary notes from the previous meeting. He also informed the participants about changes in coordination support for this group. The agenda was adopted with a minor adjustment to allow additional discussion time for AI guidance in clinical development.

2. Perspectives on medicines regulatory contribution to enabling AI innovation in Europe

Raja Shankar (ACRO) presented industry perspectives on how medicines regulators could help enable AI innovation across the medicines lifecycle. He highlighted the growing use of AI in drug discovery and development and noted that increasing numbers of AI-discovered and AI-designed medicines may place additional pressure on clinical trial recruitment, increasing the importance of innovative trial methodologies.

Four areas were proposed for consideration:

- Accelerating AI-enabled clinical development through approaches such as synthetic and simulated data, external controls, digital twins, AI-derived endpoints and biomarkers, and AI-supported signal detection.
- Establishing clear and predictable regulatory frameworks for AI use in medicines development.
- Supporting interoperable and AI-ready regulatory data infrastructures.
- Promoting AI discovery and development ecosystems through collaboration with broader European initiatives.

Participants discussed the opportunities and challenges associated with synthetic data, digital twins and external controls. Regulators noted the importance of clearly defining terminology, establishing common understanding of use cases and contexts of use, and recognising that evidentiary expectations may differ depending on the intended regulatory purpose. It was also noted that discussions on synthetic data and digital twins are planned within the Network Data Steering Group (NDSG).

3. Data interoperability

Henri Jonckheere (Europharm SMC) presented industry perspectives on the role of regulatory data in enabling responsible AI. He emphasised that effective AI deployment depends on public regulatory information being accessible, machine-readable, interoperable and reusable. Examples discussed included publicly available information from CTIS, EPARs, product information and pharmacovigilance systems.

The presentation highlighted pharmacovigilance as a mature environment for AI applications, supported by structured safety-reporting systems and established standards. Potential use cases discussed included signal prioritisation, case clustering, trend detection, multilingual analysis and literature monitoring, while maintaining scientific oversight and human decision-making.

Discussion also addressed governance considerations related to AI use and sponsor-submitted data, including confidentiality, transparency and safeguards around the use of proprietary information. Regulators highlighted ongoing work on the EMRN Data Standards Framework and future work on a Data Analytics Framework. Participants agreed that data standards, accessibility, discoverability and governance are important enablers of AI adoption, while also noting that advances in AI technologies may reduce the need for fully harmonised metadata in some use cases.

4. Update on the AI Guidance Coordination Group

Luis Pinheiro (EMA) provided an update on the newly established AI Guidance Coordination Group. The group was created to support coordination of AI-related guidance activities across the European medicines regulatory network and to help ensure a coherent approach across multiple ongoing guidance initiatives.

The group will maintain an overview of AI guidance activities across the medicines lifecycle, facilitate alignment on scope and planning, identify overlaps and gaps, and support coordination with the European Commission. It will not draft or approve guidance and will not replace the responsibilities of existing scientific committees and working parties.

Participants also discussed future horizontal guidance on good machine learning practice and its relationship to ongoing and planned domain-specific guidance activities.

5. International collaboration

Ana Padua (EuropaBio) presented industry perspectives on international collaboration and regulatory convergence in the field of AI. Industry reiterated its support for enhanced global collaboration and identified several priority areas for convergence, including principles, terminology, risk assessment, regulatory submission expectations and validation of AI systems in GxP environments.

Joerg Zinserling (BfArM) updated participants on ongoing international activities. He noted the continued collaboration between EMA and FDA, including work on the joint AI glossary and follow-up activities related to the EMA-FDA guiding principles for good AI practice. He also provided an update on discussions held through the International Coalition of Medicines Regulatory Authorities (ICMRA), where international regulators exchanged experiences and explored opportunities for future harmonisation activities.

Participants discussed challenges related to differing interpretations of concepts such as synthetic data and digital twins and noted that further international exchanges may help support convergence in

these areas. It was also noted that future discussions on AI collaboration are planned between the European Commission, EMA and FDA in November 2026.

6. AI guidance in clinical development

Alison Bond (EUROPE) provided an update on ongoing industry work to prepare consolidated input for the planned AI guidance in clinical development. Industry is developing a technical feedback document aimed at identifying priority areas where additional regulatory clarification would be most valuable. These areas currently include risk categorisation and proportionality, validation and evidence requirements, third-party AI tools, documentation and transparency, lifecycle oversight of adaptive AI systems, and regulatory submission expectations. Industry also intends to identify areas where additional AI-specific guidance may not be necessary.

Gabriel Westman (MPA) presented an update on the regulatory network's work on AI guidance for clinical development. He outlined the rationale for guidance development, highlighting the increasing importance of AI in clinical research and the need for a coherent regulatory framework across multiple legislative domains, including medicines, clinical trials and medical devices.

Participants were informed that a concept paper is currently being finalised and will be followed by public consultation. In parallel, work is progressing on a horizontal guidance document covering general machine-learning principles applicable across the medicines lifecycle. The intention is for the horizontal guidance and the clinical-development guidance to progress in parallel and complement each other. The overall objective is to provide timely, practical guidance that can keep pace with rapid technological developments.

The discussion also covered opportunities for industry engagement. Regulators encouraged submission of technical feedback, noting that input received before or during public consultation would help inform the development of guidance.

Action: Industry associations to submit their technical feedback document on AI guidance in clinical development when available, to support ongoing guidance development activities.

7. AOB and close

Joerg Zinserling reminded participants of the Annual multi-stakeholder data forum and AI workshop to be held on 12-13 November 2026 at the EMA.

He also informed the participants that the next meeting of this group is scheduled for **2 February 2027**.