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Guiding principles for the EMA - US FDA cluster teleconferences on Artificial Intelligence in Pharmacovigilance

The European Medicines Agency (EMA) and the US Food and Drug Administration (US FDA) have agreed the following:

1. Objectives

The EMA/FDA cluster on artificially intelligence (AI) should ideally fulfil the following objectives:

- Exchange information and views on (upcoming) policies, guidance documents and regulations relevant to the use and regulation of AI in PV;
- Explore alignment between each agency's vision and approach on the use and regulation of AI in PV;
- Foster leadership and collaboration on international regulatory initiatives related to AI in PV;
- Share experience and lessons learnt on the application of AI to PV use cases by each agency;
- Discuss research needs pertinent to AI in PV.

The work of the cluster is conducted within the confidentiality arrangements in place between the participating parties.

2. Participants

Participants will include EMA/FDA staff members with experience in AI and/or pharmacovigilance. The teleconferences will be co-chaired by the EMA and the US FDA.

The EMA and the US FDA have agreed to the participation of observers from PMDA and Health Canada.

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Observers from regulatory authorities of other regions may participate in cluster activities at a later stage subject to agreement of both the EMA and the US FDA and appropriate confidentiality arrangements being in place.

3. Timing

Meetings will be held every 2-3 months taking into consideration other relevant milestones.

Each meeting will last 60-120 minutes.

4. Agenda setting

For each regular teleconference, topics should be selected by mutual agreement of EMA and FDA for discussion in line with the objectives described under section 1 (see also Appendix I). The topics should be selected on the grounds that they are relevant to both agencies and that exchange on these topics is anticipated to be beneficial for both agencies.

A proposed draft agenda will be sent by either EMA or FDA about two weeks in advance of a teleconference for mutual agreement and to ensure availability of relevant colleagues.

5. Confidentiality

Confidentiality of the information shared within the cluster is covered under the bilateral information sharing Confidentiality Arrangements (CA) that exist between members and observers. Cluster members and observers are responsible for the implementation and maintenance of these arrangements.

Cluster members, as well as observers and guests, shall not disclose publicly or do anything that would lead to the disclosure of information shared or discussed during meetings without prior authorization of the members that provide such information.

The chair will inform meeting attendees if there are participants from outside of member or permanent observer organizations.

6. Records and supporting documents

EMA and FDA will co-develop short action points as the summary record of the teleconference.

The teleconferences may be supported by presentations, (draft) guidance documents and scientific papers.

If agreed by both EMA and FDA, an online sharing platform (e.g.,Microsoft Teams) may be used between teleconferences to streamline communication and exchange of content.

Appendix I - Potential topics

Category	Topic ideas (not mutually exclusive)

Use cases	• Sharing of project data/algorithms between two agencies
	• Extraction of adverse events from prescribing information
	• Case processing
	  ○ Medical literature screening for ICSRs
	  ○ De-duplication
	  ○ ICSR completeness check
	• Signal detection
	  ○ Extraction of important clinical information from ICSRs
	  ○ Triage based on AE labelledness
	  ○ Identification of signals from literature
	• Signal evaluation
	  ○ Identification of ICSRs with most useful information
	  ○ Identification of duplicates
	  ○ Case adjudication
	  ○ Causality assessment
	• Identification of drug labelling safety-related changes contributing to research
	• Probabilistic phenotyping of adverse events
	• Prediction of drug abuse
	• Off-label use

Operational practices	• How are projects pipelined/prioritised • Project lifecycle: research and development, user acceptance, result validation, implementation • Threshold for an AI application to be qualified • Data ingestion, programmatic access, APIs • Training datasets Value monitoring
Policy	• AI papers: vision, principles, PV-specific aspects, stakeholder's feedback, next steps

Category	Topic ideas (not mutually exclusive)
	• Legislative/regulatory ecosystems (e.g., EU AI Act, GDPR…) • …
Concepts and principles	• Risk-based approach • Explainability • AI trustworthiness • Access to applicants' data • Data protection • Ethics and privacy • Audits and inspections • …
Engagement beyond cluster	• CIOMS WG XIV – AI in PV • Interactions with stakeholders: industry, academia, public… • Feedback from relevant fora (ISoP…)
'Hot' topics / future vision	• Building a multi-stakeholder research agenda • Large language models and agentic AI • Leveraging multiple/multimodal data sources (e.g. chemical structure, drug targets…) • Knowledge graphs • Alternatives to traditional disproportionality tools • Unsupervised learning/clustering • Masking effect • Knowledge mining De-skilling

Appendix II – Documents and resources

- US FDA - Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products – Discussion Paper and Request for Feedback
- US FDA - Artificial Intelligence in Drug Manufacturing – Discussion Paper
- EMA - Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
- Ball R, Dal Pan G. "Artificial Intelligence" for Pharmacovigilance: Ready for Prime Time? Drug Saf. 2022 May;45(5):429-438. doi: 10.1007/s40264-022-01157-4. Epub 2022 May 17. PMID: 35579808; PMCID: PMC9112277.
- Hines PA, Herold R, Pinheiro L, Frias Z, Arlett P. Artificial intelligence in European medicines regulation. Nat Rev Drug Discov. 2023 Feb;22(2):81-82. doi: 10.1038/d41573-022-00190-3. PMID: 36411368.
- Pinheiro LC, Kurz X. Artificial intelligence in pharmacovigilance: A regulatory perspective on explainability. Pharmacoepidemiol Drug Saf. 2022 Dec;31(12):1308-1310. doi: 10.1002/pds.5524. Epub 2022 Sep 8. PMID: 35959980.
- ICMRA Informal Innovation Network - Horizon Scanning Assessment Report – Artificial Intelligence
- HMA/EMA Joint Big Data Steering Group
- EMA Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities
- FDA Draft Guidance on Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products
- CIOMS Working Group XIV – Consensus report on AI in pharmacovigilance
- EMA-FDA Guiding Principles of good AI practice in drug development
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