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2024 AI Observatory report

The 2024 adoption and entry into force of the EU AI Act represents a significant step towards ensuring that AI is developed and used in a trustworthy, transparent and ethical way, while encouraging its uptake and creating a supportive environment for innovation.

The European Medicines Regulatory Network (EMRN) aims to enhance efficiency and strengthen decision-making through digital transformation, including AI. This involves continuous experimentation across the Network as it explores and makes use of emerging technologies. [i]

Because of its rapid evolution, AI in medicines development and regulation requires monitoring for the emergence of novel uses and systems and impact. Therefore the HMA-EMA Big Data Steering Group 2023-2028 Multi-annual AI workplan foresees the creation of an AI Observatory, including horizon scanning.

The Observatory has the objective to capture and share experience and trends in AI to inform the EMRN in support of the implementation of its multi-annual AI workplan.

The Observatory compiles experience gained from the EMRN on using AI to enhance personal productivity, automate processes, and increase insights into data and supporting decision-making in the medicine life-cycle. It includes a high-level horizon scanning report based on a review of peer-reviewed journals, preprints and EU-funded research and development project to identify gaps, challenges and opportunities for AI implementation in the medicines lifecycles. Both the experience compilation and the horizon scanning report are annexed to this annual summary report.

With regard to AI use in the medicine life-cycle, interaction with marketing authorisation holders and applicants in 2024 have still mainly taken place at the pre-authorisation stage, i.e. in scientific advice, qualification procedures, Portfolio and Technology or Innovation Task Force meetings, or via the Quality Innovation Group (QIG). Despite this preponderance in the pre-authorisation stage, in 2024, there has been growing interest in discussing AI throughout the medicine life-cycle, at various stages of the development as illustrated in Table 1. Applicants are also investigating use of Generative AI tools to assist in the generation of the draft regulatory documentation, including the drafting of the Clinical Study Report.

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Examples of AI applications in medicine life-cycle discussed within the EMRN	
Scope of application	*Publication related to specific AI use*
• *M*anufacturing process monitoring and control • Discovery of drug target • Imaging and histological analyses • Patient selection in clinical trial • Event adjudication • Predictions (of prognostic covariates, response or adverse event) • Digital Twins • Precision dosing • Pharmacovigilance (Adverse event detection and reporting) • Leveraging of RWE to complement clinical trials	• Preliminary QIG Considerations regarding Pharmaceutical Process Models • Statistical adjustment on deep learning prognosis covariates obtained from histological slides • Draft qualification opinion for artificial intelligence-based measurement of non-alcoholic steatohepatitis histology in liver biopsies to determine disease activity in NASH/MASH clinical trials

In term of automating processes and enhancing systems or personal productivity, the Network is developing AI Knowledge Mining capabilities tools to search, extract, and identify information from various sources. In March 2024, EMA introduced Scientific Explorer[ii] for EU regulators which is an AI-enabled knowledge mining tool enabling easy, focused and precise search of regulatory scientific information from Network sources to support decision-making and simplify processes, both for human medicines and veterinary medicines. Scientific Explorer is a search engine to aid the EMRN scientific staff to search regulatory and scientific information for regulatory precedents, in particular scientific advice letters. Users can work with the search results and visualise all source documents. The Swedish Medical Products Agency has shared with the Network a product information cross search tool (PICROSS) and a tool to identify relevant guidelines and approved products of relevance for a specific procedure (M-RECON). Other tools are being experimented within the Agency and the Network for knowledge mining or in the pharmacovigilance field. A survey within the Network confirmed a shared interest, with the main needs focussing on Knowledge Mining capabilities. The results of the survey will help define a collaborative framework across the Network to develop and utilise AI tools for enhancing medicines evaluation processes.[iii] Finally, Generative AI tools are under experimentation and undergoing risk assessment as office assistants.

Other 2024 highlights of the AI workplan are presented in the BDSG 2024 report[iv]. Based on experience gained in 2024, the AI workplan has been updated as part of the Data and AI in medicines regulation workplan 2025-2028.

In January 2025, "the Network Data Steering Group (NDSG)", superseding the BDSG, has been established as the strategic advisory group to maximise data interoperability, exchange and use across the Network, access to data and generation of evidence and the use of AI. It supports the implementation of the EMAN strategy, specifically actions focused on leveraging data, digitalisation and artificial intelligence. In preparation for the full application of the AI Act, the Agency also closely works with the European Commission's AI Office, the EDPS, and the EU Agencies Network.

This first version of an EMRN AI observatory has consisted in a snapshot of experience collected in 2024. Learnings from the experience of compiling this first EMRN AI observatory report will be considered by the NDSG to improve future reports.

Annexes:

I. AI observatory - compilation of 2024 experience,

II. Horizon Scanning Short Report on AI/ML applications in medicines lifecycle

[i] https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-draft_en.pdf
[ii] Scientific Explorer - Frequently Asked Questions
[iii] https://www.ema.europa.eu/en/documents/report/big-data-steering-group-bdsg-2024-report_en.pdf
[iv] https://www.ema.europa.eu/en/documents/report/big-data-steering-group-bdsg-2024-report_en.pdf