EMA AI Observatory 2025: How EU Regulators Use AI

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Executive Summary

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), through their joint Network Data Steering Group (NDSG), published the **2025 AI Observatory report** in June 2026. The second annual report tracks AI activity and trends across the European medicines regulatory network (EMRN) and describes 2025 as a period in which AI moved from adoption to practical application (EMA: Artificial intelligence).

The report records regulator-side AI activity alongside applicant discussions; the specific tools and use cases are examined below.

The report documents applicant discussions on generative AI for submission drafting, AI-assisted ICSR management, and external or synthetic control arms. It is not a comprehensive review of AI applications and records observed activities and discussions rather than creating binding requirements (2025 AI Observatory report).

The policy section provides the applicable EU AI Act timeline and explains why obligations depend on the organisation’s role and the system’s intended use.

Introduction and Background

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), the network of heads of national competent authorities for medicines regulation in the European Union (EU), jointly steer a body called the **Network Data Steering Group (NDSG)**, which coordinates data and AI policy across the European medicines regulatory network (EMRN, the collective term for EMA, the European Commission, and the national competent authorities of EEA Member States). Through the NDSG, EMA and HMA published the second annual **AI Observatory report** in June 2026, covering calendar-year 2025 activity. The PDF document itself is dated 12 May 2026 and carries the reference number EMA/67888/2026 (ema.europa.eu). It is foreworded jointly by **Karl Broich**, President of the German Federal Institute for Drugs and Medical Devices (BfArM) and NDSG co-chair, and **Peter Arlett**, Head of EMA's Data Analytics and Methods Task Force and NDSG co-chair.

The report describes 2025 as a move from adoption to practical application and covers policy and guidance, applications, collaboration and engagement, and EU-funded and regulatory-science initiatives (2025 AI Observatory report). The NDSG itself is a relatively new body: at the HMA/EMA multi-stakeholder workshop on AI, independently confirmed by Slovenia's national medicines agency JAZMP as scheduled for "20 and 21 November 2025" (jazmp.si), BfArM's Karl Broich noted the event was the first "under the steering of the Network Data Steering Group (NDSG), which was established earlier this year following the transition from the BDSG" (the prior Big Data Steering Group) (ema.europa.eu). Trade press coverage adds that the reorganized body "combines the former Big Data Steering Group (BDSG) and Network Data Board (NDB) into a single governing body" (raps.org).

Policy and Governance Foundations: The EU AI Act and Network Guidance

Much of the 2025 report's policy narrative is set against the phased rollout of the **EU Artificial Intelligence Act** (Regulation (EU) 2024/1689). According to the European Commission's own AI Act implementation timeline, the Regulation formally entered into force on 1 August 2024 (ai-act-service-desk.ec.europa.eu), general provisions including AI literacy obligations and prohibitions on certain AI practices became applicable on 2 February 2025 (ai-act-service-desk.ec.europa.eu), and rules for general-purpose AI (GPAI) models together with required governance structures applied from 2 August 2025 (ai-act-service-desk.ec.europa.eu). Under the Digital Omnibus amendments, application of the high-risk AI rules is linked to a Commission decision confirming that standards and other support tools are sufficiently available, followed by a transition period. The latest application dates are 2 December 2027 for Annex III systems and 2 August 2028 for high-risk AI embedded in Annex I regulated products. The majority of other AI Act rules applied from 2 August 2026 (ai-act-service-desk.ec.europa.eu). *Table 1* below summarizes the EU AI Act milestones most relevant to medicines regulation.

Milestone	Date	What Applies
Entry into force	1 August 2024	Regulation (EU) 2024/1689 becomes EU law (ai-act-service-desk.ec.europa.eu)

Milestone	Date	What Applies
Prohibitions and AI literacy	2 February 2025	Definitions, Article 4 AI literacy obligations, and Article 5 prohibited AI practices apply (ai-act-service-desk.ec.europa.eu)
General-purpose AI and governance	2 August 2025	Rules for general-purpose AI apply and governance must be in place (European Commission AI Act timeline)
Article 50 transparency	Generally 2 August 2026	Transparency duties generally apply to the providers and deployers specified in Article 50, including certain AI systems that interact with people or generate or manipulate content. Article 50(2) has a transition until 2 December 2026 for certain systems placed on the market before 2 August 2026 (European Commission AI Act implementation timeline)
High-risk AI, standalone (Annex III)	No later than 2 December 2027	Application follows a Commission decision that standards and other support tools are sufficiently available, plus a transition period; 2 December 2027 is the backstop (ai-act-service-desk.ec.europa.eu)
High-risk AI embedded in regulated products (Annex I, e.g. medical devices)	No later than 2 August 2028	Application follows a Commission decision that standards and other support tools are sufficiently available, plus a transition period; 2 August 2028 is the backstop (ai-act-service-desk.ec.europa.eu)

As the table shows, the obligations already in force as of August 2026 depend on the organisation's role and the system's intended use. They can include AI literacy and prohibited-practice rules, GPAI-model obligations for relevant providers, and Article 50 transparency duties for the providers and deployers specified in that Article. Whether an AI system is high-risk requires a case-by-case assessment under Article 6, including its intended purpose, any Annex I regulated-product connection, any Annex III use case, and the applicable Article 6(3) exclusion; clinical or manufacturing use alone does not determine the classification (EUR-Lex: Artificial Intelligence Act). The AI Observatory report itself does not adjudicate the AI Act's scope for particular medicines research-and-development uses.

Beyond the AI Act, EMA and FDA have jointly identified ten principles for good AI practice across the medicines lifecycle. EMA and HMA also provide guiding principles for network staff using large language models, including safe data input, critical thinking and output cross-checking, continuous learning, and escalation of concerns (EMA: Artificial intelligence). Looking ahead, the report's annex records that "the NDSG workplan 2026-2028 foresees the development of a coordinated roadmap for future AI-related guidance, to ensure consistency and strategic alignment" (ema.europa.eu), including domain-specific commitments to guidance on AI in clinical development and pharmacovigilance (ema.europa.eu).

AI Applications Discussed with Marketing-Authorisation Applicants

The report catalogues AI applications that pharmaceutical and biotech companies discussed with EMA and national regulators during 2025, primarily in **Portfolio and Technology Meetings (PTM)** and **Innovation Task Force (ITF)** meetings, with additional discussions in Quality Innovation Group meetings and Qualification Advice and Scientific Advice procedures (2025 AI Observatory report).

Across the medicines lifecycle, applicants reported using or exploring generative AI "to assist draft regulatory submissions and technical documentation or generate answers to queries," flagged as a new item in 2025 (ema.europa.eu). In pharmacovigilance and safety operations, companies discussed AI "to support the intake and management of individual case safety reports, including information extraction, MedDRA coding, translation, narrative generation and medical review," also new for 2025 (ema.europa.eu).

In clinical development, the report retains **External Control Arms (ECA)** and **Synthetic Control Arms (SCA)** from the 2024 PTM survey. It describes them as involving "the use of external and historical patient data to establish comparator arms" (ema.europa.eu). A separate, more exploratory discussion in a 2025 Scientific Advice procedure referenced "AI-based in silico clinical trials" as part of a development strategy to simulate long-term outcomes, though regulators did not scrutinize the AI methodology itself in detail. Machine learning was also reported to help predict clinical trial site enrolment rates, and companies explored AI to streamline data cleaning and create synthetic control arms in real-world evidence generation, both flagged as new discussion topics in 2025.

The report does not present these applications as validated or approved regulatory methodologies; it records discussion topics at varying stages of maturity. One example with a formal outcome is **AIM-NASH**, for which EMA's human medicines committee issued a qualification opinion in March 2025; EMA updated the opinion in April 2025 (EMA: Artificial intelligence).

AI Inside the EU Regulatory Network: Scientific Explorer and Beyond

A separate section of the report covers AI tools that regulators themselves use, as distinct from tools applicants bring to them. The centerpiece is **Scientific Explorer**, described in EMA's own frequently-asked-questions document as "a search engine to aid European Medicines Regulatory Network's" staff in locating scientific and regulatory information, "firstly launched on 4 March 2024" (ema.europa.eu), initially focused on EMA scientific advice procedures, before "the third major release of Scientific Explorer expanded the tool to include European public assessment reports for the initial marketing authorisation applications" (ema.europa.eu).

Two governance details are notable for anyone assessing what Scientific Explorer is and is not. First, access is tightly restricted: EMA states the tool "is for European Medicines Regulatory Network use only" (ema.europa.eu), meaning applicants and outside consultants cannot query it directly. Second, on the model itself, EMA notes that AI-extracted information has been validated against manual extraction, with "F1 scores for the AI extractions in Scientific Explorer" ranging "from 0.89 to 0.94" (ema.europa.eu), using a version of the underlying large language model that EMA describes as "private to EMA's use." An F1 score is a performance metric that balances precision and recall; EMA's reported range pertains to the validated AI extraction outputs, rather than to every search or chat function of Scientific Explorer.

Scientific Explorer is not the only internal network tool the report documents. Sweden's Medical Products Agency (Läkemedelsverket) states it became "one of the first medicines authorities in Europe" to deploy a locally-hosted, in-house generative AI service, in March 2025 (lakemedelsverket.se), describing the resulting system, REGULUS (Regulatory Universal Support), as intended "to generate text drafts based on processing of input documents and to answer regulatory questions" (lakemedelsverket.se). By July 2025, a press release distributed via TT (Sweden's national news agency) confirms REGULUS had been made available, through the agency's AI@MPA toolbox cloud service, to "22 different medicines authorities in 20 countries within the EU/EEA" (via.tt.se), a rollout funded through the EU4Health IncreaseNET project (discussed below). The same AI@MPA toolbox also bundles narrower

applications, including "semantic search of product information and guidelines" and "computer vision for matching medicine packaging to reduce confusion risk" (via.tt.se). More broadly, the AI Observatory report states that an additional **61 Network use cases were collected in 2025**, spanning four main AI areas (ema.europa.eu), including process improvements such as scientific literature adverse-drug-reaction (ADR) screening and pharmacovigilance triage. FDA states that its Emerging Drug Safety Technology Meeting Program is specifically focused on the use of AI in pharmacovigilance for postmarketing activities (fda.gov).

International Collaboration and the NDSG 2026-2028 Workplan

The 2025 report devotes a full section to collaboration, both within the EU network and internationally. Within ICMRA, an AI Steering Committee, which Australia's Therapeutic Goods Administration (TGA) describes as "facilitating dialogue and shared knowledge regarding AI usage in drug development, regulatory tools, emerging technologies and best practices" (tga.gov.au), exchanged experience on tools including AI chatbots for first-line clinical trial application interaction and AI-assisted assessment of generic-product application quality. The AI Observatory report records that "4 ICMRA Regulatory Forums were organised in 2025" (ema.europa.eu), culminating in the ICMRA annual summit, hosted by EMA in October 2025, whose own meeting report records that "120 delegates, a record number, participated" in three sessions covering communication, reliance among regulators, and AI in regulatory processes (icmra.info). At that AI session, South Africa's health products regulator, SAHPRA, presented internal results estimating "a reduction of 75-85% of the time spent on compliance checks" using AI tools (icmra.info), an agency-reported internal estimate that was not independently benchmarked across the network.

Bilateral EMA-FDA work continued through the EMA-FDA AI in pharmacovigilance cluster, with Japan's PMDA and Health Canada participating as observers. FDA's own materials confirm this is an active priority, noting that the agency "is collaborating with international colleagues through initiatives such as the Council for International Organizations of Medical Sciences (CIOMS) working group on AI in PV, which is developing principles for the use of AI in PV" (fda.gov). That working group, CIOMS Working Group XIV, published its final report, formally titled "Artificial intelligence in pharmacovigilance," on 4 December 2025 (cioms.ch), with an objective "to establish and promote principles and guidance for the use of artificial intelligence or intelligence augmentation in the field of pharmacovigilance" (cioms.ch), addressing what CIOMS calls "a rapidly emerging cross-disciplinary field that is at the intersection of pharmacovigilance, computer science, mathematics, regulation, law, medicine, human rights, psychology and social science" (cioms.ch). The working group warns explicitly that efficiency-focused automation risks "eliminating the value added by humans in the loop" in ways that "could ultimately compromise the unique strength of the pharmacovigilance system" (cioms.ch). CIOMS’s official publication page describes the report as providing terminology and conceptual understanding for the evaluation and decision-making needed in AI-enabled pharmacovigilance (CIOMS: Artificial Intelligence in Pharmacovigilance).

Stakeholder engagement expanded significantly in 2025. The HMA/EMA multi-stakeholder workshop on AI drew "thousands of stakeholders" participating online and in person (ema.europa.eu). EMA's Executive Director, Emer Cooke, opened the November 2025 workshop by noting that "while previous AI workshops explored the promise of AI, this workshop focuses on the practice of AI"; its meeting report records that FDA had received over 800 submissions involving AI at that time (ema.europa.eu). In parallel, the NDSG ran an EU-wide survey to gather stakeholder input for its AI research priorities, which JAZMP's independent posting confirms "closed" with a "deadline" of "17 October 2025" (jazmp.si).

On EU-funded research, the report names the Horizon Europe/Innovative Health Initiative **BRIDGE project** (Breakthrough Regulatory Innovation and Development throuGh sandbox Environments), which the EU's own CORDIS project database describes as "building a framework in which innovators have the space they need to test their ideas" against a "horizon scanning methodology to continuously identify emerging technologies that challenge existing regulatory systems," AI included (cordis.europa.eu). BRIDGE's own press materials describe a consortium of "28 organisations from 12 countries, of which 13 are public partners and 15 industry partners" (bridge-ihi.eu), whose central technical output is a modular regulatory-sandbox architecture, MOSAIC ("Modular Operational Sandbox for Healthcare Innovation and Compliance") (bridge-ihi.eu). A related initiative, the EU4Health Joint Action **IncreaseNET**, coordinated by Slovenia's JAZMP, is described as a joint action of 30 partners, of which 29 are national competent authorities, that "aims to close the identified gaps in required capacity, competences, and frameworks" (jazmp.si), including AI-related training and capacity building across national competent authorities. Italy's medicines agency AIFA separately confirms the project has "a three-year duration, with an expected conclusion on December 31, 2026" (aifa.gov.it). A separate Horizon Europe/Innovative Health Initiative call, **HORIZON-JU-IHI-2025-11-03**, sought projects on AI-powered signal detection in pharmacovigilance (CORDIS: AI-Powered Signal Detection in Pharmacovigilance). Finally, in late 2025, the NDSG adopted “Network AI research priorities” (manuscript in press), spanning seven domains: research integrity and intellectual property; accuracy and reliability of AI tools; data governance, confidentiality and consent; regulation and oversight; ethics, fairness and bias prevention; resources and support for AI use; and impacts on jobs and skills (2025 AI Observatory report). RAPS Regulatory Focus separately reports the NDSG will also "contribute to the implementation of the revised pharmaceutical legislation for Europe" (raps.org).

Non-binding, Jurisdiction-Specific Implementation Context

For pharmaceutical companies, the practical question is what the AI Observatory report changes about day-to-day regulatory work. The answer is: directly, very little; indirectly, quite a lot. This section offers non-binding implementation context: the EMA/FDA principles are not a prescriptive compliance checklist, FDA material reflects a US regulatory perspective, and neither substitutes for an EU AI Act assessment (EMA/FDA: Guiding Principles of Good AI Practice in Drug Development). A practical interpretation is that companies should consider governance across functions and development phases, rather than treating AI oversight as confined to a single team or use case.

As an editorial implementation recommendation, companies can maintain an inventory of AI use cases, define each system's intended use and accountable owners, and document how outputs are reviewed. This is not a new EMA requirement: the EMA/FDA principles describe good AI practice across the medicines lifecycle, while FDA describes AI management as requiring a risk-based regulatory framework built on robust principles, standards, and best practices (EMA/FDA: Guiding Principles of Good AI Practice in Drug Development, FDA: Artificial Intelligence & Medical Products).

FDA's own guidance underscores the same conclusion from a US regulatory vantage point, describing a cross-center framework spanning its drug, biologic, and device centers under which "AI management requires a risk-based regulatory framework built on robust principles, standards, best practices" (fda.gov). CIOMS warns that efficiency-focused automation can eliminate the value added by humans in the loop and could compromise the pharmacovigilance system (CIOMS: Working Group XIV). For companies, a prudent governance control is a

documented human review before treating an AI-assisted submission artifact, whether a drafted module summary or an ICSR narrative, as regulator-ready; the appropriate control should be assessed case by case for the system and intended use.

For AI-assisted submission workflows, compliance and validation must be assessed for the particular system, records, controls, and intended use; FDA states that Part 11 requirements apply to electronic records created, modified, maintained, archived, retrieved, or transmitted under FDA requirements (FDA: Part 11 scope and application). Applicable submission, GxP, and record-control obligations remain use-case-specific. Organisations should document appropriate human accountability and review, with controls proportionate to the system and its intended use. From that vantage point, the practical reading of the AI Observatory report is less about a single new compliance requirement and more about a widening expectation, echoed across EMA, FDA, and CIOMS material alike, that AI-assisted regulatory workflows need documented accountability and verifiable outputs where AI materially influences a regulatory or safety judgment.

Data Analysis and Evidence

While the AI Observatory report is primarily qualitative, several figures anchor its findings and are worth examining together. *Table 2* summarizes representative applications by user and maturity during the 2025 reporting period.

Application	Primary User	Status as of the 2025 Report
AIM-NASH imaging biomarker tool	Applicants (formally assessed by EMA)	Qualification opinion issued in March 2025; subsequently updated in April (EMA: Artificial intelligence)
Generative AI for drafting submissions	Applicants	Discussed with regulators via PTM; new in 2025 (2025 AI Observatory report)
AI-assisted ICSR management	Applicants (pharmacovigilance)	Discussed with regulators via PTM; new in 2025
External / synthetic control arms	Applicants (clinical development)	Previously recorded in the 2024 PTM survey; retained in the 2025 report

The table underscores an asymmetry: Scientific Explorer has documented validation metrics and a formal rollout, while REGULUS is described as a deployed regulator-side tool. Applicant-side AI applications are, for the most part, still at the discussion stage rather than the subject of formal regulatory guidance or validated performance benchmarks.

Table 3 below summarizes the collaboration and research infrastructure the report describes, since these initiatives shape what future guidance is likely to cover.

Initiative	Participants	2025 Milestone
EMA/FDA Guiding Principles of Good AI Practice	EMA, FDA	Presented at ICMRA summit; ten principles published early 2026 (icmra.info)
CIOMS Working Group XIV	CIOMS, EMA (contributor), international experts	Final report on AI in pharmacovigilance published 4 December 2025 (cioms.ch)

Initiative	Participants	2025 Milestone
ICMRA AI Steering Committee	International medicines regulators	Facilitated dialogue on AI in drug development and regulatory tools (tga.gov.au)
BRIDGE (Horizon Europe/IHI)	28 organisations, 12 countries	Consortium launched; MOSAIC sandbox architecture in development (bridge-ihi.eu)
IncreaseNET (EU4Health)	30 partners (29 national competent authorities)	Three-year Joint Action, concluding December 2026 (aifa.gov.it)
FDA cross-center AI framework	CBER, CDER, CDRH, Office of Combination Products	Framework paper issued March 2024, revised February 2025 (fda.gov)

Implications and Future Directions

The international initiatives discussed above signal efforts toward alignment and a shared vocabulary, but they do not establish harmonised legal requirements. Companies operating across jurisdictions should assess the requirements applicable to each system and use case.

Second, the detailed AI Act application schedule is set out in Table 1. The report points to future network guidance and identifies continuing gaps in validation, audit frameworks, and regulatory-grade acceptability of AI tools (2025 AI Observatory report).

Third, the NDSG's 2026-2028 workplan points to areas for future network guidance, including clinical development and pharmacovigilance. The revised EU pharmaceutical package remains pending: the Council and Parliament reached a provisional agreement, which still requires endorsement, formal adoption and publication in the *Official Journal* before it enters into force (Council of the EU). For regulatory, safety, clinical, data, and submission teams, 2026 to 2028 is therefore a planning period rather than a settled compliance outcome.

Frequently Asked Questions (FAQs)

What is the EMA 2025 AI Observatory report?

It is the second annual report from the EMA/HMA Network Data Steering Group (NDSG), covering 2025 AI-related activity across the European medicines regulatory network, including policy and guidance, applications, collaboration, stakeholder engagement, and research (ema.europa.eu).

How is AI used in EU pharmacovigilance?

The report records applicant discussions and regulator-side uses in pharmacovigilance; it does not present every applicant-side workflow as a validated regulatory method. Human oversight remains a case-by-case governance consideration.

How does the EU AI Act affect medicines regulators and applicants?

The Act's applicable obligations depend on the organisation's role and the AI system's intended purpose. High-risk status is assessed case by case under Article 6: the system must meet the Annex I regulated-product test or fall within an Annex III use case, subject to the Article 6(3) exclusions for certain Annex III systems. Clinical or manufacturing use alone does not make a system high-risk (EUR-Lex: Artificial Intelligence Act).

What is the Network Data Steering Group workplan for 2026-2028?

It is the NDSG's forward planning document. The report indicates that it will inform future network priorities and anticipates coordinated AI guidance, including for clinical development and pharmacovigilance.

Conclusion

The 2025 AI Observatory report is a structured status update, not a rulebook. It distinguishes emerging discussion topics from formally assessed tools and identifies areas where future network guidance may develop. Teams should use the report alongside the applicable AI Act analysis for each system’s role and intended use.
