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2025 AI Observatory report

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Forewords by Karl Broich, President of BfArM and NDSG co-chair, and Peter Arlett, Head of Data Analytics and Methods Task Force at EMA and NDSG co-chair

AI accelerates innovation across the entire medicines lifecycle and transforms regulatory practice.

It brings extraordinary opportunity but also the challenge of navigating at the same time a rapidly evolving technological and regulatory ecosystem.

The AI Observatory plays an important role in this transformation by offering a clear, system wide view of ongoing initiatives and use of AI.

It will help to reveal emerging trends and help the EMRN to anticipate future needs so that the network can lead with confidence, readiness, and foresight the use of AI in medicines regulation.

Karl Broich, President of BfArM, NDSG co-chair

The EMRN shares a clear ambition: to harness AI safely and responsibly across the medicines lifecycle to advance public and animal health.

In 2025, AI was moving from concept to practice, with industry increasingly integrating AI into development across most domains of the medicines development lifecycle and regulators adopting AI to enhance insight, efficiency, and system performance.

To guide this transformation, the EMRN must set clear, values-driven expectations so AI tools are robust, transparent, fair, and aligned with public trust. Providing predictable guardrails for industry is equally essential to support responsible innovation.

Staying ahead requires continuous reflection on progress, learning from current regulatory submissions, and using these insights to steer the network and its stakeholders toward an AI-enabled future.

Peter Arlett, Head of Data Analytics and Methods Task Force at EMA, NDSG co-chair

1. Executive summary

Artificial Intelligence (AI) is fast evolving and is rapidly transforming the development and supervision of medicines. The EU AI Act entered into force in 2024 and 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. In 2025, it moved from adoption to practical application.

To keep abreast of such change and to support the development and evaluation of AI in the medicines' lifecycle, every year the Network Data Steering Group (NDSG) monitors information on activities, trends and emerging AI domains and publishes the network 'AI observatory'.

In line with the NDSG workplan, the 2025 AI Observatory report provides an overview of guidance and policy, applications of AI, ongoing collaborations and engagement activities with stakeholders and partners, as well as a high-level overview of progress in EU-funded initiatives and regulatory science research. It covers both the human and veterinary domains and does not attempt to be a comprehensive and systematic review of all applications of AI. However, further details are included in the Annexes.

Policy and guidance on AI

Additional general guidance on AI was developed in 2025 through the EMA/FDA Guiding principles of good AI practice in drug development. For specific domains of the medicines development lifecycle, the EMRN initiated several steps to prepare for further guidance development, including a key public consultation on guidelines for the product manufacturing domain. In parallel and in light of the proposed European Biotech Act, the NDSG workplan 2026-2028 foresees the development of a coordinated roadmap for future AI-related guidance, to ensure consistency and strategic alignment. At international level, the Artificial intelligence in pharmacovigilance CIOMS Working Group report was also published.

Applications of AI

Multiple AI applications were discussed with applicants, including industry, in 2025. Most applications of AI relate to data handling and analysis, across several domains of the medicines development lifecycle, highlighting the growing potential of AI in medicines development. New applications of AI were primarily discussed during early regulator-stakeholder interactions, such as in Portfolio and Technology or Innovation Task Force meetings. These early interaction between applicants and regulators allows discussion on the likely regulatory acceptability of different applications of AI while providing the EMRN visibility on the emerging pipeline. This in turns enables the EMRN to build knowledge, anticipate trends, and prepare for future regulatory needs.

In 2025, for regulators at both national and EMRN level, applications of AI primarily focused on knowledge mining, personal productivity and automation of processes and systems. Expanded access to data is expected to enable the development of tools that enhance data insights and support evidence-based regulatory decision-making. In parallel, progress was made in increasing internal network transparency on AI tools used across the EMRN via the Network AI Tools framework and catalogue adopted in 2025.

An additional 61 Network use cases were collected in 2025 and those prioritised will be implemented through a collection of validated and reusable prompts, focusing on AI solutions for drafting/summarization of information and validation/quality assurance. This will be supported by the launch of a pilot for an EMRN Prompt Community as agreed in 2025. Finally, an ecosystem of AI

assistants will be developed to optimise and enhance knowledge retrieval on different source of information.

Collaboration and engagement on AI

Collaboration and engagement efforts intensified in 2025 through a comprehensive multi-layered approach, balancing capability building, policy alignment, methodological innovation, and building trust:

- Intra-EU/EMRN cohesion, to ensure strategic alignment, effective implementation, expert collaboration, knowledge exchange, skills development and cross-agency cooperation.
- International convergence, to strengthen global strategic collaboration, sharing experience and practices.
- Open dialogue with all stakeholders and partners to listen to stakeholders' perspectives, increase transparency and build trust in the EMRN work on AI.

EU-funded initiatives and other regulatory science research initiatives

Several EU-funded initiatives are underway to explore the application of AI to medicines development, reflecting the strong momentum in exploring application of AI across domains of the medicines development lifecycle. Despite the breadth of scientific research, gaps remain in the area of AI tools for regulatory assessment (including model validation, audit frameworks, regulatory grade acceptability), as well as veterinary AI initiatives, and AI monitoring. While scientific research and technological innovation are advancing quickly, translating the findings into regulatory practice will be critical to meet regulatory requirement to integrate findings in regulatory decision-making and deliver value to the EMRN and medicines regulation.

Finally, several regulatory science research initiatives were launched in 2025 to proactively inform researchers and funding bodies on regulatory needs and to address knowledge gaps in regulatory science.

This 2025 AI Observatory report will inform future network engagement and priorities for the implementation of the NDSG 2026-2028 workplan and the European Medicines Agencies Network Strategy to 2028 (EMANS to 2028).

2. Introduction

AI is fast evolving and is rapidly transforming the development and supervision of medicines. The EU AI Act entered into force in 2024 and 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. In 2025, it moved from adoption to practical application.

To keep abreast of such change and support the use and evaluation of AI across the medicines lifecycle, annually, the Network Data Steering Group (NDSG) is monitoring activities, trends and emerging AI domains through the Network AI observatory, as per the NDSG workplan.

The 2025 AI Observatory report provides an overview of available guidance and policy, applications of AI, ongoing collaborations and engagement activities with stakeholders and partners, as well as progress in EU-funded initiatives and regulatory science research. It covers activities in the human and veterinary domains. The report does not intend to provide a comprehensive and systematic review of all applications of AI. Further details are included in the Annexes.

The 2025 report builds on the first (2024) AI Observatory. It will inform future engagement and implementation priorities under the NDSG Data and AI 2026-2028 workplan and the European medicines agencies network strategy to 2028.

3. Policy and guidance on AI

In 2025, the EU AI Act moved into practical application, starting with prohibited AI uses (Article 5) and AI literacy obligations (Article 4), followed by general-purpose AI obligations (Chapter V) and governance structures (Chapter VII).

Additional general guidance was developed in 2025 through the EMA/FDA Guiding principles of good AI practice in drug development, providing a common reference point for the use of AI in medicines development.

At EU level, the European Medicines Regulatory Network (EMRN) advanced preparatory actions to support the development of domain-specific guidance across the medicines lifecycle and the public consultation was completed on guidelines for the product manufacturing domain. In parallel and in light of the proposed European Biotech Act, the NDSG workplan 2026-2028 foresees the development of a coordinated roadmap for future AI-related guidance, to ensure consistency and strategic alignment on guidance.

At international level, the Artificial intelligence in pharmacovigilance CIOMS Working Group report was published.

A full list of available guidance and policy is provided in Annex 1: Policy and guidance on AI.

4. Applications of AI

4.1. Applications of AI discussed with Applicants

Multiple new interactions on AI with Applicants, including Industry stakeholders, took place in 2025. Most AI applications relate to data handling and analysis, across several domains of the medicines development lifecycle, showing great potential for AI to support medicines development.

New applications of AI have been discussed primarily in Portfolio and Technology Meetings (PTM) and Innovation Task Force (ITF) meeting, and to a lesser extent to Quality Innovation Group (QIG) meetings and Qualification Advice (QA) and Scientific Advice (SA) procedures. These early interactions between applicants and regulators allow discussion on the likely regulatory acceptability of different applications of AI while providing the EMRN visibility on the emerging pipeline. This in turns enables the EMRN to build knowledge, anticipate trends, and prepare for future regulatory needs.

Domains	Types of applications of AI
Across all medicines lifecycle stages	• Generative AI is used or explored to assist draft regulatory submissions and technical documentation or generate answers to queries – *NEW PTM*
Pre-clinical development	• Drug discovery and evidence generation – *NEW ITF*
Clinical development and Clinical Trials	• Clinical outcome prediction – *NEW QA, ITF, PTM* • Clinical trial and patient selection – *NEW PTM*

Domains	Types of applications of AI
	• Medical imaging – *NEW Qualification opinion published* • Endpoint assessment – *NEW PTM* • Digital endpoints - *NEW PTM* • Patient-reported outcome measure – *NEW ITF* • Generative AI-based assistants – *NEW ITF* • Safety biomarker identification – *NEW ITF* • In silico trial – *NEW SA*
Product manufacturing	• Predictive Stability Modelling and Shelf-life Testing – *NEW PTM* • Pharmaceutical process models, including digital twins - *NEW QIG* • GMP - *NEW PTM, ITF*
Post-marketing authorization	• Generation of RWE - *NEW PTM* • ICSR management - *NEW PTM*

The list of types of applications of AI discussed with applicants is provided in Annex 2: Applications of AI discussed with Applicants.

4.2. Applications of AI in the EU Network

At both national and EMRN level, tools were rolled out for use in 2025. At present, AI applications used within the EU network are primarily focused on knowledge mining, personal productivity support and automation of processes and systems. Examples, publicly communicated to stakeholders in line with the NDSG workplan, include:

- Scientific Explorer has been available to EU regulators since March 2024. It initially focused on improving searches related to EMA scientific advice procedures for human and veterinary medicines. In 2025, its functionalities were expanded to include information on initial marketing authorisation applications of human medicines.
- The AI@MPA toolbox has been available for EU regulators since 2024. It is a web-based suite of 6 AI applications provided by the Swedish Medical Products Agency. The toolbox includes several AI tools supporting assessors in navigating product information, automatically identifying relevant guidelines, European Public Assessment Reports (EPARs) and qualification. In 2025, it was further expanded to include the generative AI tool REGULUS (Regulatory universal support) for document processing and answering regulatory questions, as well as PACKSIM for drug-package similarity search and SCHEMA (SMILES chemical embeddings map) enabling read-across of preclinical and clinical safety data to new small molecules.

NDSG is working on several ways to improve information on available AI tools used within the EMRN. In 2025, the NDSG adopted the Network AI Tools framework and catalogue for the EMRN. It is intended to provide a list of tools available and to support the sharing and development of AI tools across the Network (human and veterinary domain), and to foster collaboration, integration and reuse of tools and models. The use cases for these tools include:

- Knowledge mining, such as searching across regulatory documents, and information extraction including from SmPCs.

- Personal productivity, such as writing support, personal assistance, document comparison and meeting minutes generation.
- Process automation, such as invoicing, email distribution and automation of regulatory workflows.
- Process improvements such as scientific literature ADR screening, pharmacovigilance triage.
- Anonymization and data protection, as well as automated identification of commercially confidential information.

Some of the technology used by these tools include discriminative and generative AI, including Large Language Models, Natural Language Processing, Speech recognition and Optical Character Recognition tools.

In 2025, NDSG continued to serve as a forum for discussing national AI initiatives across the medicines lifecycle. A series of workshops with national competent authorities (across human and veterinary domains) was organised to collect AI use cases and explore existing or potential solutions for their implementation. 61 uses cases were identified, spanning 4 main AI areas:

- drafting and summarization of information,
- validation and quality assurance,
- knowledge mining and retrieving of information,
- and other divers use cases

The first two areas will be supported through a collection of validated and reusable prompts, focusing on AI solutions, allowing harmonisation and standardisation of AI use across the Network. To further strengthen Network-wide expertise in prompting and generative AI practices, in 2025 NDSG agreed to establish an EMRN Prompt Community, starting as a pilot, and aiming at enabling the effective delivery and use of AI assistants.

To adopt a comprehensive approach to information retrieval, an ecosystem of AI assistants will be developed to optimise and enhance knowledge retrieval areas on different source of information.

5. Collaboration and engagement on AI

5.1. EU Regulatory Network collaboration on AI

Several areas of collaboration were initiated or continued in 2025. These aimed to strengthen EMRN and EU coherence, harmonise regulatory approaches, build collective AI readiness and support strategic cross-agency cooperation. These included:

At EMRN level:

- The EMANS to 2028 was published in 2025 and recognised that the emergence of AI will transform the development and regulation of medicines across the network.
- General AI literacy training was rolled out across the Network in early 2026.
- The European Specialised Expert Community (ESEC) Specialised Interest Areas (SIA) in AI and data science met regularly in 2025, providing a forum for collaboration and knowledge sharing across the network.
- Also in 2025, the NDSG agreed to establish a new AI training strategy, under the framework of the EU Network Training Centre (EU-NTC), with oversight by the CHMP Methodology Working

Party (MWP). This strategy will provide an overarching framework for AI training across the EMRN, including initiatives such as the EU4Health Joint Action 'IncreaseNET' supporting increased capacity and competence building of the EU medicines regulatory network.

At EU level:

- EMA is chairing the EU Agencies Network Working Group on AI (EUAN WG on AI). It aims to support the Agencies and Joint Undertakings at the EU agencies network on the implementation of AI, fostering knowledge sharing and increasing the AI maturity level to provide guidance and common approaches. In 2025, the annual plenary meeting took place in June at the EMA premises, with participation of thirty-three EU Agencies and Joint Undertakings. The working group shared expertise, showcased agencies PoCs and use cases, discussed topics including AI systems procurement, the EUAN staff exchange programme, AI factories and the development of the AI maturity assessment to inform 2026 priorities. It also contributed to assessing needs related to the EU AI Act implementation and discussed the GPT@EC pilot plans, including survey insights on IT and security, data protection, AI Act compliance and intellectual property considerations.
- Since 2024, the One Health Agencies (EMA, ECHA, ECDC, EFSA, EEA) have hosted the One Health Agencies Technology Innovation Workshop on a rotating basis. These workshops provide a platform for participants to share experiences and best practices, and to explore opportunities for collaboration in areas such as AI, interoperability, and innovation.

5.2. International regulators collaboration on AI

At international level, global strategic collaboration continued in 2025, primarily to share experiences and practices in this rapidly evolving field, with a view to support more strategic global alignment and cooperation in the future. This included:

- EMA and the U.S. Food and Drug Administration (FDA) have jointly identified ten principles for good AI practice in the medicines lifecycle. These principles guide the use of AI in evidence generation and monitoring across all phases of a medicine development, from early research and clinical trials to manufacturing and safety monitoring. They apply to both human and veterinary medicines (see also section 3 on Policy and guidance on AI).
- Under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA):
  - 4 ICMRA Regulatory Forums were organised in 2025. Most included discussion on experience and progress on AI, including opportunities and challenges of using AI for medicines registration analysis, data and AI strategy, and guiding principles for good AI practice in medicines development.
  - As part of the ICMRA Innovation Regulatory Network, the ICMRA AI Steering Committee met to exchange information and share development on AI, including the use of AI chatbot as first line interaction for clinical trial applications, an AI-assisted structured assessment tool for reviewing the quality of generic products applications, and approaches for assessing risk in machine learning based tools.
  - In October 2025 the ICMRA annual summit was hosted by EMA. It brought together regulators and experts from regulatory authorities around the world together with the World Health Organization. A dedicated session discussed the use of AI in regulatory processes and how ICMRA and its members can support the development of robust, ethical, and future-ready AI practices. Across the ICMRA community, considerable experimentation on AI is ongoing alongside capacity-building efforts and effort to

harmonise approached with global partners. The need for ICMRA to advance towards globally agreed principles for the ethical use of AI in medicines regulation was recognised.

- Collaboration between EMA and FDA continued in 2025 under the EMA-FDA AI in pharmacovigilance cluster, with PMDA and Health Canada as observers (human medicines).
- n the area of manufacturing and GMP, EMA QIG is collaborating with FDA CDER Emerging Technology Team (ETT) and CBER on guidance development and when relevant on meeting with applicants.
- EMA contributed to the ICH Reflection Paper on Advanced Pharmaceutical Manufacturing, including AI-based models.
- EMA contributed to CIOMS Working Group XIV, supporting international alignment on guiding principles for the use of AI in Pharmacovigilance.
- Finally, EMA participated as an observer in the European Blockchain Sandbox (Phase IV), focusing on synthetic data generation for secure and privacy-compliant health data, including applications relevant to the European Health Data Space (EHDS).

5.3. Other stakeholder engagement on AI

In 2025, stakeholder engagement continued, aiming to listen to stakeholders, increase transparency and build trust in the EMRN work on AI. This included:

- The HMA/EMA multi-stakeholder workshop on artificial intelligence (AI). Held in November 2025 this was one of the key events of the NDSG workplan to discuss the evolving regulatory environment and HMA/EMA activities on AI. Thousands of stakeholders participated online and in-person in the event to benefit from keynotes on AI state-of-the-art and discuss the evolving regulatory environment, HMA/EMA activities on AI and AI use cases across the medicines' lifecycle. The event emphasized a shift from the promise of AI to its practical implementation, highlighting the need for ethical guardrails, responsible innovation frameworks, and strong collaboration across regulators, industry, patients, and the wider health ecosystem. It also underscored the growing momentum behind regulatory use of AI, showcased emerging tools across the medicine's lifecycle, and called for greater international convergence and clearer regulatory expectations to support safe, effective, and future ready adoption of AI in medicines regulation.
- In 2025, NDSG established the HMA-EMA group focused on AI with industry stakeholders (covering both human and veterinary domains). The group aims to facilitate open dialogue on the development and use of AI in the medicines lifecycle. Its first meeting took place in November 2025 and focussed on clarifying AI use cases and regulatory expectations, gathering feedback from industry, and identify opportunities to support safe and responsible AI innovation.
- In 2025, QIG break out session with stakeholders on the Preliminary QIG Considerations regarding Pharmaceutical Process Models, specifically on the decision tree to guide pharmaceutical process models risk determination.

6. EU-funded initiatives and other regulatory science research initiatives

6.1. EU funded initiatives

Several EU-funded initiatives are ongoing to explore the application of AI to the development of medicines. A full list of examples of EU-funded initiatives is provided in Annex 3: EU funded initiatives.

The current landscape of EU-funded AI initiatives reveals strong momentum in exploring the application of AI across different domains of the medicines development lifecycle. Notably:

- In the pre-clinical domain, initiatives are exploring on in-silico toxicology predictions, disease modelling, and AI-supported drug repurposing.
- In clinical development, the focus includes digital pathology, patient stratification, integrating large datasets, and AI-enhanced clinical decision support (e.g. for personalised medicine, oncology and amyotrophic lateral sclerosis and multiple sclerosis).
- In the manufacturing domain, activities include AI-enabled decentralised production and personalized, cell-based therapy mass production.
- In the post-marketing domain, initiatives are exploring AI powered signal detection for pharmacovigilance.
- Cross-domain initiatives focus on multi-modal data, generative AI, regulatory sandboxes and capacity-building.

Despite the breadth of scientific research, some area for future investment remains. These include AI tools for regulatory assessment (such as model validation, explainability evaluation, audit frameworks, regulatory-grade acceptability), initiatives in the veterinary domains, and AI robustness, testing and continuous monitoring.

While scientific research and technological innovation are advancing rapidly, effective translation of the findings into regulatory practice will be critical to meet regulatory requirements and to deliver benefits for, drug development, medicines regulation and ultimately, patients.

6.2. Other regulatory science research initiatives

Besides EU funded research, several regulatory science research initiatives in the domain of AI were launched in 2025 to address knowledge gaps in regulatory science and support the development and evaluation of medicines. These initiatives aimed to proactively inform researchers and funding bodies on regulatory needs while also establishing a platform for information-sharing with academia.

In late 2025, the NDSG adopted 'Network AI research priorities' (manuscript in-press), covering both the human and veterinary domains. Informed by a multi-stakeholder survey, these priorities are intended to guide researchers and funding bodies in addressing key uncertainties and supporting the safe and effective use of AI across medicines lifecycle. 7 domains were identified:

- Research integrity & intellectual property, such as responsible conduct of AI-enabled research, with appropriate attribution of contributions and proprietary rights management for data, models, and outputs.
- Accuracy and reliability of AI tools, such as performance characteristics, explainable outputs, transparent validation practices, and robustness.

- Data governance, confidentiality, and consent, such as secure, lawful, and ethical handling of patient and user data, including consent and privacy protections.
- Regulation and oversight, such as accountability and liability frameworks, best practices and guidance, and applicability of current laws and rules to AI tools.
- Ethics, fairness and bias prevention, such as ethical development and deployment that avoids bias and discrimination against a group of people and promotes equity.
- Resources and support for AI use, such as people, funding, infrastructure, environmental impact, and tools required for safe, effective, and compliant AI adoption.
- Impact on jobs and skills, such as how AI reshapes roles, demands for skills, and workforce transitions.

The European Platform for Regulatory Science Research was launched in March 2025 and brings together academia and regulators to advance research in regulatory science. Its aim is to advance research for new regulatory tools, methodologies and approaches, including the use of AI, that medicine developers and regulators use throughout a medicine lifecycle to support their regulatory decisions.

An updated list of EMRN regulatory science research needs , including AI-related topics, was published in 2025 to encourage researchers and funding organisations to address these needs in their work and programmes.

7. Annexes

7.1. Annex 1: Policy and guidance on AI

Domains	Guidance & Policy	Additional notes
Across all medicines lifecycle stages	*EMA* • EMA/CHMP/CVMP Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle • Q&A on Qualification of Digital Technology-Based Methodologies to Support Approval of Medicinal Products • EMA/FDA Guiding principles of good AI practice in drug development – *NEW* *Note: In 2025, EMA and FDA have agreed on principles of AI us in medicines lifecycle which have published early 2026.* *EU* • High-Level Expert Group on AI's Ethics guidelines for trustworthy AI • EU Artificial Intelligence Act (entered into force in August 2024) ○ In 2025, the EU AI Act moved into practical application, starting with prohibited AI uses (Article 5) and AI literacy obligations (Article 4) in February 2025, followed by general-purpose AI obligations (Chapter V) and governance structures (Chapter VII) in August 2025.	• A regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act) is being proposed. It will include the need for further AI guidance development in multiple domains of the medicine's lifecycle. • The NDSG workplan 2026-2028 foresees the development of a coordinated roadmap for future AI-related guidance, aligned with the proposed Biotech Act. This will ensure that all guidance activities proceed in a consistent and strategically aligned manner.
Pre-clinical development	*EU*	• AI is increasingly being integrated into non-clinical (NC) development to enhance predictive toxicology and to strengthen

Domains	Guidance & Policy	Additional notes
	• In the domain of genotoxicity assessment, in silico models are formally embedded in regulatory frameworks like ICH M7, where tools such as statistical, machine-learning-based (Q)SAR model — are used alongside expert rule-based systems to predict mutagenic potential of impurities for regulatory submissions, providing rapid, data-driven assessments that inform weight-of-evidence evaluations by assessors.	the scientific basis for decision-making, particularly through coupling New Approach Methodologies (NAMs) such as organ-on-chip, high-content imaging, and systems biology with machine-learning algorithms to interpret complex biological responses. These AI-augmented NAMs enable more efficient pattern recognition, mechanistic insight, and risk stratification than traditional methods alone, helping to reduce reliance on animal studies and to improve human relevance. • In line with these advances, the Non-clinical domain (Non-Clinical Working Party and 3Rs Working Party) will actively track developments in AI and related methodologies over the next years as part of its strategic priorities outlined in the Non-clinical Domain Work Plan 2026-2028 to ensure emerging tools are appropriately evaluated and, where suitable, incorporated into regulatory science.
Clinical development and Clinical Trials	-	• AI uses in clinical trials are growing and include uses for trial country and site selection, patient identification, covariate prognosis, estimation of missing values, imaging assessments, biopsies scoring, assessment criteria using various tools (including Digital therapeutics or Generative AI-based assistants), adjudication of clinical events, to create external control, to predict risk in subpopulation, define dosing, to identify safety biomarker, to run AI-based in silico trial or improve clinical trial efficiencies. • The HMA/EMA Network Data Steering Group workplan 2026-2028 foresees the development of guidance on AI in clinical development (MWP guidance).
Product manufacturing	*EMA*	

Domains	Guidance & Policy	Additional notes
	• Preliminary QIG Considerations regarding Pharmaceutical Process Models (currently under revision following the stakeholder consultation) *EU* • EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22 – *NEW public consultation completed in 2025*	
Post-marketing authorisation	*International* • Artificial intelligence in pharmacovigilance CIOMS Working Group report – *NEW published in 2025*	• The HMA/EMA Network Data Steering Group workplan 2026-2028 foresees the development of guidance on AI in Pharmacovigilance.
Veterinary		• The HMA/EMA Network Data Steering Group workplan 2026-2028 foresees the development of guidance on AI in Pharmacovigilance. • Intention of the next iteration of the Veterinary Data Strategy is to give AI guidance on relevant topics to Veterinary stakeholders

7.2. Annex 2: Applications of AI discussed with Applicants

Below table lists the cumulative AI use reviewed or discussed as part of regulatory procedures, including Portfolio and technology meeting (PTM), Innovation Task Force meeting (ITF), Quality Innovation Group (QIG) meetings, Qualification procedure (QP), Scientific Advice (SA) and Marketing authorisation (MA).

7.2.1. Across all medicines lifecycle stages

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Document drafting	Confidential	Gen AI to assist generation of draft regulatory documentation	PTM 2024
Document drafting	Confidential	Generative AI is used or explored to help draft regulatory submissions and technical documentation or generate answers to queries.	PTM 2025 – *NEW*

7.2.2. Pre-clinical development

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Drug candidate identification	Confidential	Analyze large datasets, predict drug-target interactions, and optimize drug design. This helps in identifying potential drug candidates more efficiently and enhancing clinical trials through patient stratification and predicting trial outcomes.	PTM survey 2024
Drug candidate identification	Confidential	Identify potential fixed dose combinations	PTM survey 2024
Drug candidate identification	Confidential	Target identification	PTM survey 2024
Drug discovery and evidence generation	Confidential	Inference of disease-relevant molecular pathways and potential application to elucidate mechanism of action, toxicity prediction, and biomarker identification	ITF meeting 2025 – *NEW*

7.2.3. Clinical development and Clinical Trials

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Clinical outcome prediction	MesoNet and HCCnet	Statistical adjustment on deep learning prognosis covariates obtained from histological slides	Qualification Advice: public Letter of Support
Clinical outcome prediction	Confidential	Method aiming to reduce outcome variability by producing baseline prognostic covariates to be used in the treatment effect analyses.	Qualification advice 2024
Clinical outcome prediction	Confidential	Model trained on data to predict clinical outcome in Major Depression Disorder	ITF meeting 2024
Clinical outcome prediction	confidential	use of prognostic models, including machine learning-based models, to develop time-matched prognostic scores for use in the PROCOVA-MMRM statistical methodology	QA 2025 – *NEW*
Clinical outcome prediction	Confidential	Machine learning algorithm to estimate reference serum values when missing	ITF meeting 2025 – *NEW*
Clinical outcome prediction	Confidential	Machine learning is used to build prognostic values of response for multiple diseases from clinical trial data, which can explain the variability of clinical endpoints and hence improve clinical trial sample size planning.	PTM 2025 – *NEW*
Clinical trial and patient selection	Confidential	AI-generated clinical trials patient selection algorithm (medical imaging)	PTM 2024
Clinical trial site and patient selection	Confidential	Machine learning is used to predict enrolment rates at potential clinical trial sites to identify those most likely to complete a study faster through faster enrolment of patients.	PTM 2025 – *NEW*
Clinical trial site and patient selection	Confidential	AI is used to support clinical trial country and site selection, and patient identification.	PTM 2025 – *NEW*
Medical imaging	Confidential	Machine Learning Algorithms for Scoring of Radiographic Progression in Psoriatic Arthritis.	Qualification advice 2024
Medical imaging	Confidential	Machine Learning Algorithms for Scoring Endoscopy Videos in Ulcerative Colitis	Qualification advice 2024
Medical imaging	Confidential	Deep Learning (DL) based algorithm to analyse kidney segmentations	Scientific advice 2024
Medical imaging	Confidential	AI in medical imaging (Automation of Endoscopic scores, Automation of arthritis scoring)	PTM 2024
Medical imaging	AIM-NASH	AI-Based Measurement of NASH in liver disease to determine disease activity	Qualification opinion published in April 2025 – *NEW*
Medical imaging	Confidential	Image analysis of NASH/MASH, support for histopathologists	Scientific advice 2024
Medical imaging		AI-based read-outs of e.g., biopsies	PTM 2024

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Adjudication of clinical events	Confidential	Artificial Intelligence for adjudication of clinical events (ML-based model for auto-adjudicating events e.g. cardiovascular death)	Qualification advice 2024
Adjudication of clinical events		Exploring the use of generative AI in event adjudication models, as well as in imaging (e.g. ECT, PET scans)	PTM 2024
Endpoint assessment	Confidential	AI for endpoint data collection and analysis. Cardiovascular disorders.	PTM 2024
Endpoint assessment	Confidential	Computerized algorithm to assess response to treatment and disease progression in Multiple Myeloma	Scientific advice 2024
Endpoint assessment	Confidential	Video capture and video analysis capabilities. (Neurology)	ITF meeting 2024
Endpoint assessment	Confidential	Automated scoring methods for image and video-based endpoints for various therapeutic area including Immuno-inflammation	PTM 2024
Endpoint assessment	Confidential	AI-based CT & PET/CT imaging solutions that automate reads and quantify tumour lesion count and three-dimensional size.	PTM 2024
Endpoint assessment	Confidential	AI tools, such as computer vision algorithms, to assess skin lesions	PTM 2024
Digital endpoints	Confidential	The use of AI is considered to support the development and validation of digital endpoints for cognition measurement in Alzheimer's disease.	PTM 2025 – *NEW*
Endpoint assessment	Confidential	AI is being explored to evaluate motor function impact to support the assessment of drug effect.	PTM 2025 – *NEW*
Patient-reported outcome measure	Confidential	AI platform to collect patient data on different domains of quality of life	ITF meeting 2025 – *NEW*
Comparator	Confidential	Digital Twins (Dravet Syndrome)	Scientific advice 2024
Comparator	Confidential	AI digital twin modelling Various therapeutic areas including Immuno-inflammation	PTM 2024
Comparator	Confidential	External Control Arms (ECA) or Synthetic Control Arms (SCA), which involve the use of external and historical patient data to establish comparator arms.	PTM survey 2024
Dosing	Confidential	AI in dosing	PTM 2024
Clinical outcome prediction	Confidential	risk prediction in subpopulation	PTM 2024

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Clinical trial site and patient selection, Dosing, Clinical outcome prediction	Confidential	Help identify candidates for clinical trials, assess DHT-derived digital endpoints, identify predictors of long-term clinical outcomes, and increase the statistical power of clinical trials. Projects under development include: • A ML approach to developing a biomarker signature linking longitudinal multi-omic profiles with long term clinical outcomes to optimize phase II dose-response and proof of concept studies. • A ML approach to covariate adjustment to increase precision and statistical power in RCTs for use in a phase III study with a long-term time to event outcome. • o Exploratory work on a ML model to predict disease criteria/ lab parameter supporting patient enrolment, and primary or secondary endpoint assessment for a phase 2/3 trial.	PTM survey 2024
Digital endpoints	Confidential	Digital therapeutics and patient monitoring devices to track health metrics and medication adherence, which is particularly important for chronic diseases like diabetes.	PTM survey 2024
Generative AI-based assistants	Confidential	New software technology that enables clinical trial participants to complete various clinical tasks through interaction with generative artificial intelligence (called digital clinical assistants)	ITF meeting 2025 – *NEW*
Clinical trial site and patient selection Clinical trial efficiencies	Confidential	With respect to clinical trial efficiencies, natural language processing is being used to extract external and internal knowledge to develop better protocols for clinical trials in less time, other AI tools to identify the study sites with the best chance of recruiting patients. For studies underway, the company is using advanced analytics and AI to improve clinical trials efficiencies . Tools are also being investigated to streamline drafting of regulatory submissions, and speed access to regulatory information to facilitate health authority interactions and respond to information requests in a timely manner.	PTM survey 2024
Safety biomarker identification	Confidential	AI platform used to investigate association in large genomic datasets	ITF meeting 2025 – *NEW*

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
In silico trial	confidential	"AI-based in silico clinical trials" mentioned as part of the development strategy to simulate long-term outcomes and validate net treatment benefit; no detailed discussion as part of the SA request	SA 2025 – *NEW*

7.2.4. Product manufacturing

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Pharmaceutical process models, including digital twins		Several meetings with applicants on process models including digital twins, AI applied to CAR-T cell manufacturing, AI platform approach to characterize cell-derived products, Computer Vision AI algorithm for automatic counting of microcarriers and determination of colonization percentage, Building an AI-driven donor selection platform for cell therapy MFN and data-driven/consistent manufacturing, Classification of AI Model Use as Low Risk and Low Regulatory Impact.	QIG 2023-2025 – *NEW*
Digitalization of processes		QIG LLFG meeting October 2023 (digitalization, AI)	QIG 2023
Pharmaceutical process models		QIG LLFG meeting June 2024-process models	QIG 2024
Cell analytics	Confidential	Use of AI models to automate cell analytical assessment (Retinitis pigmentosa and acute cardiac disease)	ITF meeting 2024
GMP	Confidential	Automated visual inspection. Guardrails inherent in GMP provide risk mitigation for many of the general risks of AI.	PTM survey 2024
Manufacturing Processes	Confidential	Optimize manufacturing processes by predicting maintenance needs and improving quality control. This ensures consistent quality and reduces waste.	PTM survey 2024

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Predictive Stability Modelling and Shelf-life Testing	Confidential	Machine learning is used to accurately predict attribute values using various product characteristics and initial lot-release data values without long-term stability data.	PTM 2025 – *NEW*
GMP	Confidential	AI is used or explored to support manufacturing and supply processes or activities.	PTM 2025 – *NEW*
GMP	Confidential	Traceable robotics to be used in aseptic environments to reduce human intervention. Deep learning is used for sensing and recognition (e.g., objects)	ITF meeting 2025 – *NEW*

7.2.5. Post-marketing authorization

Type of applications of AI	AI Tool identification	Brief description	Reference/Year
Social media screening	Confidential	Monitor and identify potential safety cases from social media accounts in fulfilment of regulatory requirements. Social media screening presents unique challenges, including the high volume of unstructured data. A company developed an approach with AI that may yield improved efficiency, faster detection of adverse events, and enhanced patient safety compared. to traditional approaches.	PTM survey 2024
Generation of RWE	Confidential	AI approaches are explored in the generation of real-world evidence for example, to streamline data cleaning or create synthetic control arms.	PTM 2025 – *NEW*
ICSR management	Confidential	AI is used or explored to support the intake and management of individual case safety reports, including information extraction, MedDRA coding, translation, narrative generation and medical review.	PTM 2025 – *NEW*

7.2.6. Consolidated list of types of applications of AI discussed with Applicants

Domains	Types of applications of AI
Across all medicines lifecycle stages	• Generative AI is used or explored to assist draft regulatory submissions and technical documentation or generate answers to queries – *NEW PTM*
Pre-clinical development	• Drug candidate identification • Drug discovery and evidence generation – *NEW ITF*
Clinical development and Clinical Trials	• Clinical outcome prediction – *NEW QA, ITF, PTM* • Clinical trial and patient selection – *NEW PTM* • Clinical trial efficiencies • Medical imaging – *NEW Qualification opinion published* • Adjudication of clinical events • Endpoint assessment – *NEW PTM* • Digital endpoints - *NEW PTM* • Patient-reported outcome measure – *NEW ITF* • Comparator • Dosing • Generative AI-based assistants – *NEW ITF* • Safety biomarker identification – *NEW ITF* • In silico trial – *NEW SA*
Product manufacturing	• Pharmaceutical process models, including digital twins • Digitalization of processes • Cell analytics

Domains	Types of applications of AI
	• Manufacturing Processes • Predictive Stability Modelling and Shelf-life Testing – *NEW PTM* • GMP - *NEW PTM, ITF*
Post-marketing authorization	• Generation of RWE - *NEW PTM* • Social media screening • ICSR management - *NEW PTM*
Authorisation	-

7.3. Annex 3: EU funded initiatives

Domains	EU funded initiatives names

Across all medicines lifecycle stages	• Apply AI strategy: The European Virtual Human Twins initiative
	• EU's Digital Europe Program: SHAIPED project
	• Horizon Europe project
	  ○ HORIZON-HLTH-2025-01-DISEASE-04: Leveraging artificial intelligence for pandemic preparedness and response
	  ○ HORIZON-HLTH-2025-01-TOOL-03: Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)
	  ○ BRIDGE project (Breakthrough Regulatory Innovation and Development throuGh sandbox Environments): to design and operationalise regulatory sandboxes for healthcare innovation in Europe for emerging health technologies including AI-based health technologies

Domains	EU funded initiatives names
	• EU4Health Joint Action IncreaseNET - WP7 - Efficient use of resources: Overview of use of AI related to medicines assessment + Support for replication of AI projects between NCAs + Support for AI related training and capacity building • CollaboRARE: pilot an AI-based patient-validated methodology to capture and use patient experience data (PED) for orphan medicines

Pre-clinical development	• Horizon Europe project
	  • QUANTUM-TOX: application of AI to develop computational toxicology and improve in silico toxicity predictions
	  • Ai4Cilia: artificial intelligence-enabled microfluidic analysis of ciliary beat defects for drug discovery, biomedicine, and disease screening
	  • TClock4AD: develop novel artificial intelligence-, proteolysis targeting chimeras- and multitarget-based strategies for new circadian clock drug candidates, targeting Circadian Clock Dysfunction in Alzheimer's Disease
	• EU4Health Programme
	  • NEWROAD: develop an open, collaborative in silico platform for the repurposing of drugs in oncology based on Augmented Intelligence (AuI) architecture layered on top of Artificial Intelligence (AI) algorithms, initially targeted at rare and paediatric cancer research.

Clinical development and Clinical trials	• Horizon 2020 Framework Programme
	  • BRAINTEASER: integration of large clinical datasets with novel personal and environmental data collected using low-cost sensors and apps from patients with amyotrophic lateral sclerosis and multiple sclerosis
	  • PHIRE: Photoacoustic imaging and AI-based theranostic approach for cancer
	  • OPTIMA: first interoperable and GDPR compliant European real-world oncology data and evidence generation platform that aims to strengthen shared decision-making based on innovative data and AI-driven technology and tools

Domains	EU funded initiatives names
	• KATY: AI-empowered Personalized Medicine system that can bring medical "AI-empowered knowledge" to the tips of the fingers of clinicians and clinical researchers • Horizon Europe project • Histotype Px: application of AI to digital pathology for the stratification of colorectal cancer patients into low, intermediate, or high risk prior to chemotherapy • AI4LUNGS: AI-based tools and computational models to improve patient stratification optimising diagnosis and treatment of infectious and non-infectious respiratory diseases
Product manufacturing	• Horizon 2020 Framework Programme • AIDPATH: application of AI to the decentralised production of advanced therapies in hospitals • Horizon Europe project • AiPSC: AI-powered platform for autologous iPSC manufacturing
Post-marketing authorisation	• Horizon Europe project • HORIZON-JU-IHI-2025-11-03-two-stage: Develop AI-Powered Signal Detection in Pharmacovigilance
Marketing authorisation	-
Veterinary	-