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2024 AI Observatory

The HMA-EMA Big Data Steering Group 2023-2028 Multi-annual AI workplan asks for the creation of an AI observatory, including horizon scanning, because AI requires constant monitoring both for the emergence of novel systems and impact of AI.

The objective of the observatory is to capture and share experience and trends in AI to inform the European Medicines Regulatory Network (EMRN) for the implementation of its multi-annual AI workplan, in compiling experience gained within the EMRN toward use of AI for personal productivity or automating processes and systems, and, for increasing insights into data and supporting more robust decision-making to benefit public and animal health.

The following information have been compiled as part of this observatory:

- AI use for increasing insights into data and supporting decision-making in medicine life-cycle identified as part of Qualification of novel methodologies for medicine development, Scientific Advice, Innovation Task Force meetings and Portfolio and Technology meetings,
- AI for personal productivity or automating processes and system, including tools available or in development in the Agency and in NCAs.

It has been completed with a 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.

The observatory is for information to the NDSG and the basis of the 2024 AI Observatory report to be reported to EMA Management Board and HMA, and, made public on the EMA website. It could also be posted on the HMA website.

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

I. AI use for increasing insights into data and supporting decision-making in medicine life-cycle

a. Qualification of novel methodologies for medicine development

Identification	Short description
Statistical adjustment on deep learning prognosis covariates obtained from histological slides	Completed Qualification Advice with public Letter of Support
AI-Based Measurement of NASH in liver disease to determine disease activity	Completed Qualification opinion published
Confidential qualification advice + follow-up	Artificial Intelligence for adjudication of clinical events (ML-based model for auto-adjudicating events e.g. cardiovascular death)
Confidential qualification advice	Method aiming to reduce the negative impact of high data variability on "assay sensitivity" by producing baseline prognostic covariates to be used in the treatment effect analyses.
Confidential qualification advice	Machine Learning Algorithms for Scoring of Radiographic Progression in Psoriatic Arthritis.
Confidential qualification advice	Machine Learning Algorithms for Scoring Endoscopy Videos in Ulcerative Colitis

b. Scientific advice procedures

Therapeutic area	Short description
NASH/MASH	Image analysis, support for histopathologists
Multiple Myeloma	Computerised algorithm to assess response to treatment and disease progression
Dravet Syndrome	Digital Twins (DTs)
Autosomal dominant polycystic kidney disease	Deep Learning (DL) based algorithm to analyse kidney segmentations

c. ITF meetings

Therapeutic area	Short description
Retinitis pigmentosa and acute cardiac disease	Use of AI models to automate cell analytical assessment

Major Depression Disorder	Model trained on data to predict clinical outcome
Neurology	Video capture and video analysis capabilities.

d. Portfolio and Technology meetings

Therapeutic area	**Short description**
Various (Immuno-inflammation)	- AI digital twin modelling - Automated scoring methods for image and video-based endpoints
Cardiovascular disorders	AI for endpoint data collection and analysis.
Ophthalmology and Neurodegenerative diseases	AI-generated clinical trials patient selection algorithm (medical imaging)
Oncology	AI-based CT & PET/CT imaging solutions that automate reads and quantify tumour lesion count and three-dimensional size.
Various	AI-based read-outs of e.g., biopsies
Various	- Leveraging of RWE to complement clinical trials - Exploring the use of generative AI in event adjudication models, as well as in imaging (e.g. ECT, PET scans)
Various	AI in medical imaging (Automation of Endoscopic scores, Automation of arthritis scoring)
Dermatology	AI tools, such as computer vision algorithms, to assess skin lesions
Various	General use of use AI and machine learning, as well cloud-based computing, to help innovate and become faster and more agile.
Clinical tials, Pharmacovigilance, CMC (finished product inspection)	- Medical imaging, - LLMs, - risk prediction in subpopulation - AI standards - AI in dosing - Gen AI to assist generation of draft regulatory documentation

Other insights from the applicants of EMA early stakeholder interactions – Portfolio and Technology Meetings (PTM)

In the last call to apply for a PTM, applicants were asked to provide insights on *Artificial intelligence use in drug development and manufacturing* as this is a relevant developing area for regulators. The following paragraphs summarise the feedback received from the developers, including applications under development as well as potential challenges encountered by large pharmaceutical enterprises.

Potential applications:

Early drug development:

- Analyse 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.

- Identify potential fixed dose combinations and the role of digital twins.

- Target identification (which falls outside EMA's remit), knowledge graphs (utilizing ML models to identify patterns and support clinical decision-making), and External Control Arms (ECA) or Synthetic Control Arms (SCA), which involve the use of external and historical patient data to establish comparator arms. AI/ML is considered another drug development tool, such as traditional statistical methods or approaches including model informed drug development.

Quality, Manufacturing and Inspections:

- Automated visual inspection. Guardrails inherent in GMP provide risk mitigation for many of the general risks of AI.
- Manufacturing Processes: optimize manufacturing processes by predicting maintenance needs and improving quality control. This ensures consistent quality and reduces waste.

Clinical phase:

- 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.
    - 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.

- Digital therapeutics and patient monitoring devices to track health metrics and medication adherence, which is particularly important for chronic diseases like diabetes.

Post-authorisation/pharmacovigilance:

- 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.

Increasing process efficiency:

- 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 predict, identify and resolve issues that might slow or compromise clinical trials. Tools are 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.

Questions/feedback from the developers:

"We would like to understand the regulatory oversight in the context of using AI for medicines development. We believe that the EU AI Act R&D exemption described in Recital 25, Articles 2.6 and 2.8) should apply to Pharma R&D processes if treatment of patients is not directly affected. How does EMA define and assess the relative risk of AI (in the context of application of medicines legislation) for different uses in the medicine lifecycle, and the framework being used for such assessments."

"We encourage EMA to further develop its thinking in this area. For AI applications in drug development, there is increasing interest in how to use AI/ML as a lever to automate, e.g., data capture/verification, monitoring, use of digital tools, and potential for developing algorithms for diagnosis and predictive models to identify which patients would benefit most from a new treatment. Key principles in these areas would be useful."

"We believe that current regulatory frameworks for pharmaceutical oversight are generally sufficient for the oversight of AI/ML use across drug development and appreciated the clarity provided by EMA's "Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle_240903". We would welcome globally aligned good machine learning principles, and a nimble approach from EMA to fill gaps in existing regulatory recommendations to encourage further investment in the use of AI/ML across drug development."

II. AI for personal productivity or automating processes and system

a. EMA tools

AI system	Description	Type of AI	Status in the Agency
ChatGPT@EMA	Chat to provide GPT capabilities to EMA staff	Personal productivity	Under pilot
Speech-to-text	Tool providing support with transcribing, translating and summarising the text from audio files and from the microphone input	Speech services (Azure Cognitive Services), gen AI	Under pilot
Paralel Distribution	Tool automating the comparison between the EPAR documents content and the Industry leaflet and labelling documents	Azure AI Document Intelligence (Azure Cognitive Services)	In production

Anonymization tool	Tool supporting anonymization of the personal data in the EMA corporate website comments	NLP (Azure Cognitive Services)	In production
PDF Vendor Invoicing	Tool to automate the extraction of EMA vendor invoice data and streamline the population of SAP.	Azure AI Document Intelligence	In production
Automatic Referral Template Editor (ARTE)	The ARTE application extracts automatically data from the FREUD database and inserts them it in the corresponding fields of the referral templates.	Azure AI Document Intelligence	In production
Automated email distribution of invoices for OIAs operational approvals		Azure AI Document Intelligence	In production
Commercially Confidential Information data automatic recognition tool (CCIDAR)	The project goal for CCIDAR is to provide assessors (Access to Document team) a reliable tool for CCI search in all EPARs and public domain	Azure AI Document Intelligence	In development

b. EMA Health Data Lab

AI system	Description	Type of AI	Status in the Agency
EurEKA	• Extracts and allows exploring ADR data from SmPCs	Uses regex on top of a pre-trained ML model, LLM enabled EurEKA uses open data (EPAR/SmPC)	Pilot, aiming to deploy in early 2025
MNEMOSiNE	• Structures, exposes and uses Signal detection tracking table to improve prioritization of signal review	Discriminative and Generative AI (LLM)	Pilot
AERGIA	• Automated adjudication of adverse reactions	Discriminative AI	Pilot

ERATO	• Supports screening of scientific literature for safety signals	Generative AI	Pilot, aiming to deploy in early 2025
OWLS	• Identifies case reports and case series in scientific literature to reduce duplicates in the EV database and generate case reports	Discriminative AI	Being maintained

c. NCAs tools

AI system	**Description**	**Type of AI**	**Status in owning Agency and others**
PHAIR: PHarmacovigilance by AI Real-time	• All Danish health data from registries, EHR, GPs and DKMA ICSRs – transferred via FHIR and analysed on National Genome Centre HPC • Covid19 vaccine as initial use case	• Uses technologies from Natural Language Processing – such as transformers and BERT	DKMA

Deploy LLama2-chat on DKMA's private cloud	• Use cases for LLM:
	  • Integrating datasources
	  • Interactively search Docs
	  • Build applications
	  • Writing support
	  • Personal assistance
			DKMA

BMG-KIMERBA - intelligent in-house automation of regulatory workflows	• Medical information extraction in pharmacovigilance	LLM	PEI
BMG-BLOODVIR - knowledge accumulation for AI assessment	• Detection of viral contaminants in blood plasma	LLM	PEI

BMG-RENUBIA - assessment and validation of AI-based tools in medicinal products	• Assessment of off-target and neoantigen prediction	LLM	PEI
Customized LLM applications to search from regulatory documents	• The LLM based search engine will use both confidential and publicly available documents, such as EPAR, SmPC, AR, overview, Scientific Advice, Qualification opinion • Returns in addition to the answer, links to relevant documents -> actual documents will be used as reference and not the answer by the LLM	LLM	FIMEA

M-RECON	• As part of AI@MPA
	• Medicines regulatory context engine
	• Semantic matching between a document of choice and the openly available regulatory context
	• Currently vector database includes:
	  ○ EMA guidelines, EPARs and EMA qualification opinions/letters
	  ○ FDA regulatory guidance and product information
			MPA – in production

PICROSS	• As part of AI@MPA • Product information cross search		MPA – in production
PACKSIM	• As part of AI@MPA	LLM	MPA – in production

	• Mock-up similarity search • Reducing medication errors by ensuring visual non-similarity among drug packages		
PhaVAI triage	• As part of AI@MPA • AI model for triage of ADR reports, for detecting reports likely to be upgraded from non-serious to serious during assessment		MPA – in production
XLMeQA	• Answer questions about medicine leaflets.	LLM	AEMPS
NLP Platform	• Development of components that allow improving the quality of AEMPS data sources	LLM	AEMPS
MedDRA Terms	• MedDRA terms discovery in AEMPS data sources.	LLM	AEMPS
NLP approach to cluster text describing uncertainties	Using an NLP approach on the European Public Assessment Reports	NLP	MEB