News from the EMA

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New clinical trial map launched in the EU

March 3, 2025

A new clinical trial map is now accessible from the public website of the Clinical Trials Information System (CTIS). The map is designed to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials conducted in their area, increasing access to clinical research in the (European Union) EU.

Building on the public information contained in CTIS, the map improves how people use the system and find information about clinical trials. Users can look for ongoing trials by geographic area and medical condition. The search supports queries in lay language and includes an autocorrect system that provides suggestions in case of misspellings. Search results offer investigator's contact details, enabling members of the public to directly enquire about potential enrolment into a given trial. The first version of the map is provided in English. Additional EU languages will be added in future releases.

The creation of the map is an action of the Accelerating Clinical Trials in the European Union (ACT EU) initiative workplan for 2025–2026. It responds to requests for a simple, patient-friendly dashboard for CTIS to help stakeholders, particularly patients, locate clinical trials of interest in Europe. EMA hosted a public webinar on March 7, 2025, to provide a live demonstration on how to use all the features. A recording of the session will be available.

CTIS includes a public searchable database for healthcare professionals, patients and citizens to deliver the high level of transparency foreseen by the Clinical Trials Regulation. The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while EMA is responsible for maintaining CTIS. The European Commission oversees the implementation of the Clinical Trials Regulation.

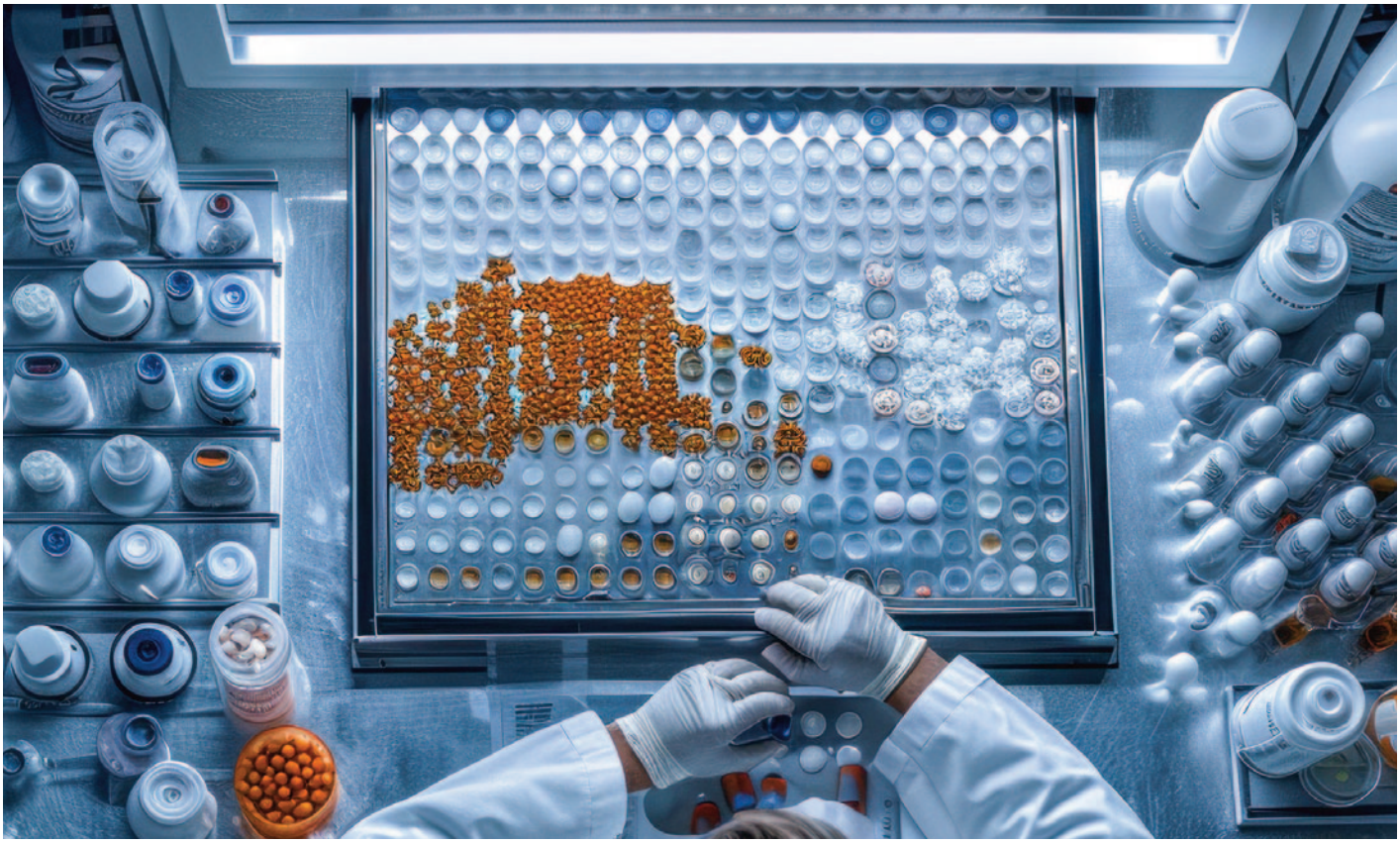

Photo: Freepik

Joint strategy sets direction of EMA and EU medicines regulatory agencies to 2028

March 18, 2025

EMA and the Heads of Medicines Agencies (HMA) have published their joint EU medicines agencies' network strategy to 2028 (EMANS), following its recent adoption by the HMA and the EMA Management Board.

The strategy, titled "Seizing opportunities in a changing medicines landscape",[1] is a comprehensive update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). The updated document will guide the European medicines regulatory network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

Prepared in a post-pandemic setting, the strategy draws on the extensive experience gained from tackling COVID-19. It also takes into account the ongoing revision of the EU's pharmaceutical legislation, laying the groundwork for its implementation. The six focus areas of the strategy to 2028 build upon those in the EMANS to 2025 with the updated strategy placing more emphasis on the competitiveness of the EU in the development and manufacture of medicines, as well as the use of artificial intelligence throughout the medicines' lifecycle.

The "One Health Approach" is introduced as a key aspect of the strategy, recognising that the health of humans, animals and the wider environment are closely intertwined. The six strategic focus areas of EMANS to 2028 are as follows:

1. Accessibility – to facilitate pathways for access to medicines through healthcare systems in the EU.
2. Leveraging data, digitalisation and artificial intelligence – to improve decision making, optimise processes and increase efficiency.
3. Regulatory science, innovation and competitiveness – to create a regulatory and research environment that accelerates the translation of innovation and improves competitiveness of the EU's healthcare sector.
4. Antimicrobial resistance and other health threats – to prepare the EU for potential threats including antimicrobial resistance.
5. Availability and supply – to strengthen the availability of medicines to protect public and animal health.
6. Sustainability of the network – to ensure that the network has available resources to support its scientific and regulatory decision making, taking full advantage of technological advances.

The strategy was developed through extensive collaboration with experts and stakeholders across the EU medicines regulatory network. A public consultation took place in late 2024, during which 77 submissions from the public and stakeholders provided valuable feedback which helped shape the strategy. EMA and the HMA, in partnership with the EU Polish presidency, also held a webinar with stakeholders in February 2025 to further refine and finalise the text.

EMA and HMA will now implement the strategy via their respective multi-annual workplans and at national level. The network will monitor its implementation, report back and adjust as needed. The final strategy is published with an overview of the comments received during the public consultation.

Reference

1. Seizing opportunities in a changing medicines landscape: The EMA network strategy 2018. Available from: https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf doi:10.2809/8994389

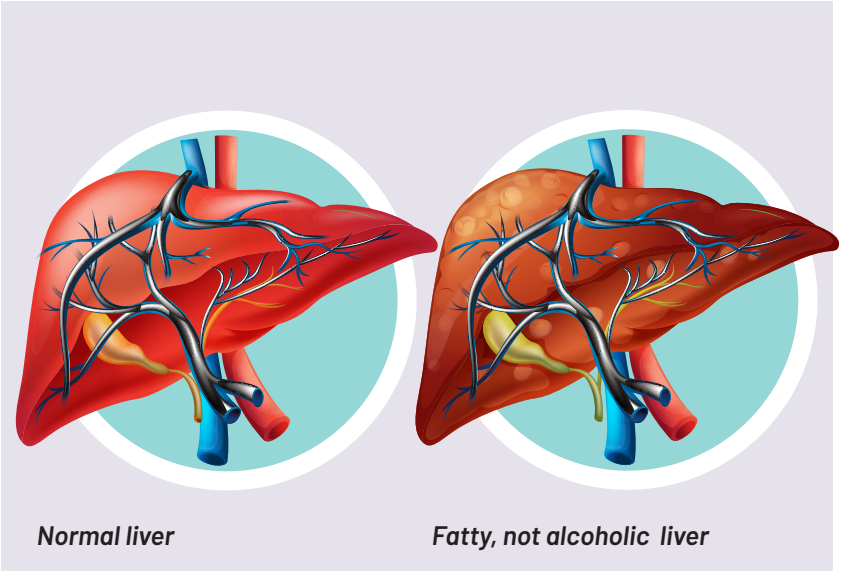

Photo: Freepik

EMA qualifies first artificial intelligence tool to diagnose inflammatory liver disease (MASH) in biopsy samples

March 20, 2025

EMA's human medicines committee (CHMP) has issued the first Qualification Opinion on an innovative development methodology based on artificial intelligence (AI). The tool, called AIM-NASH, helps pathologists analyse liver biopsy scans to identify the severity of MASH (metabolic dysfunction associated steatohepatitis; formerly known as non-alcoholic steatohepatitis, NASH) in clinical trials.

MASH is a condition where fat builds up in the liver, causing inflammation, irritation and scarring over time, without significant alcohol use or other reasons for liver injury. MASH is linked to obesity, Type 2 diabetes, high blood pressure, abnormal cholesterol, and belly fat. If untreated, it can lead to advanced liver disease. The AIM-NASH tool is expected to enhance the reliability and efficiency of clinical trials for new MASH treatments by reducing variability in measuring disease activity (inflammation and fibrosis).

Testing new MASH treatments often relies on liver biopsies, where small pieces of liver tissue are taken to confirm inflammation and scarring. These biopsies are the gold standard for demonstrating the efficacy of new, investigational medicines. However, high variability in MASH/ NASH clinical trials is a challenge, as specialists who review biopsy samples may not always agree on the severity of inflammation or scarring. AIM-NASH is an AI-based system that employs a machine learning model trained on more than 100,000 annotations from 59 pathologists who assessed over 5000 liver biopsies across nine large clinical trials. The qualified tool is "locked" which means the machine learning model cannot be modified or replaced.

The evidence submitted to CHMP shows that AIM-NASH biopsy readings, verified by one expert pathologist, can reliably determine MASH disease activity with less variability than the current standard used in clinical trials, which relies on a consensus by three independent pathologists. Following a public consultation, CHMP issued an opinion to qualify this method, which means that the committee can accept evidence generated by the tool as scientifically valid in future applications. CHMP agreed that the tool can increase reproducibility and repeatability in assessments for new MASH treatments. It can help researchers obtain clearer evidence on the benefits of new treatments in clinical trials that include fewer patients. Ultimately, this can bring effective treatments to patients faster.

CHMP encourages the optimisation of the model, acknowledging that major changes may require re-qualification of the tool. All EMA's activities on AI are co-ordinated under the multi-annual AI workplan by EMA and the HMA, aiming to ensure safe and responsible use of AI across the European medicines regulatory network.

Photo: Freepik

EMA establishes regular procedure for scientific advice on certain high-risk medical devices

March 24, 2025

EMA, in close collaboration with the European Commission, has established a standard procedure for manufacturers of certain high-risk medical devices to request scientific advice on their intended clinical development strategy and proposals for clinical investigation.

Manufacturers of class III devices and class IIb active devices intended to administer or remove medicines can now submit their request for advice via a portal and consult the medical device expert panels at different stages of the clinical development. Advice given by the medical device expert panels is a key tool to foster innovation and promote faster patient access to safer and more effective devices. This regular scientific advice procedure follows a pilot launched in February 2023,[1] which has helped to establish this procedure and gathered positive feedback from manufacturers and panel experts. EMA will publish a report on the pilot in the coming weeks.

There are currently no fees associated with these requests. More information on the submission process, including step-by-step instructions for applicants and monthly submission deadlines is available on EMA's website. Manufacturers of high-risk medical devices intended for the treatment of a rare condition should apply for advice via the ongoing pilot programme to support orphan medical devices.

Reference

1. Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices Interim report on the experience with the pilot from February 2023 to December 2024. Available from https://www.ema.europa.eu/en/documents/report/pilot-advice-expert-panels-manufacturers-high-risk-medical-devices-interim-report-experience-pilot-february-2023-december-2024_en.pdf.

Photo: Freepik

First report on EU-wide sales and use of antimicrobials in animals

March 31, 2025

For the first time, all the 27 countries of the European Union (EU27) together with Iceland and Norway, have collected and reported data on both sales and use of antimicrobials in animals in their countries. The findings are presented in the first European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance report.[1] The data cover the year 2023, marking the beginning of a regular exercise that will result in yearly reports.

Data on sales

Sales of antibiotics for food-producing animals accounted for 98% of total EU sales of veterinary medicines containing substances with antibiotic activity. The highest selling antimicrobial class for food-producing animals were penicillins, followed by tetracyclines and sulfonamides. According to the Antimicrobial Advice Ad Hoc Expert Group (AMEG) categorisation of antibiotics for use in animals for prudent and responsible use, developed by EMA's ad hoc expert group, approximately 65% of total EU sales for food-producing animals corresponded to substances that belong to category D (which should be used as first line treatments, whenever possible), 29% corresponded to category C (which should be considered only when there are no antibiotics in Category D that could be clinically effective), and 6% corresponded to category B (which are critically important in human medicine but use in animals should be restricted to mitigate the risk to public health).

Data on use

Data on use were collected for four main food-producing animal species in 2023: cattle, pigs, chickens and turkeys. Veterinarians played a key role in gathering data, as they were selected as the sole data providers by 16 reporting countries. The remaining 13 reporting countries used other data providers in addition to veterinarians, including pharmacies, feed mills, farmers or breeders, and retailers.

This is the first time that data on use has been collected across the EU. Many countries are still in the process of setting up or improving data collection systems for antimicrobial use. Therefore, the shared data for 2023 were not complete and accurate enough to start reporting quantitative information. Member States are committed to consolidating their use data collection systems, aiming to increase accuracy and coverage. This initiative has already shown a strong cooperation between reporting countries, as those with experience in data collection on antimicrobial use offered guidance and support, fostering a productive and collaborative environment.

Antimicrobial Sales and Use (ASU) Platform

The ESUAvet report builds on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a voluntary initiative between national authorities and EMA to collect reliable sales data across Europe over the course of 12 years. A 50% drop in sales of veterinary antibiotics was observed during this time, thanks to the collective efforts of countries who provided the data and developed national strategies to encourage responsible use as well as to practitioners and farmers in the field.

The ESVAC initiative was considered so successful that it has formalised and expanded under EU legislation to include mandatory data collection on the sales and use of antimicrobials in animals. Member States report their data to EMA via the ASU Platform, a centralised system designed to standardise and streamline the data received from countries.

The data in the annual ESUAvet reports, collected via the ASU Platform, will help to identify trends in antimicrobial consumption in animals more accurately and with more granularity, enabling decision-makers to address the increasing complexity of antimicrobial resistance and to take appropriate measures to protect both animal and human health in Europe.

Reference

1. European sales and use of antimicrobials for veterinary medicine: Annual surveillance report for 2023 (EMA/CVMP/ESUAVET/80289/2025). 2025. https://www.ema.europa.eu/en/documents/report/european-sales-use-antimicrobials-veterinary-medicine-annual-surveillance-report-2023_en.pdf. doi: 10.2809/4487470.

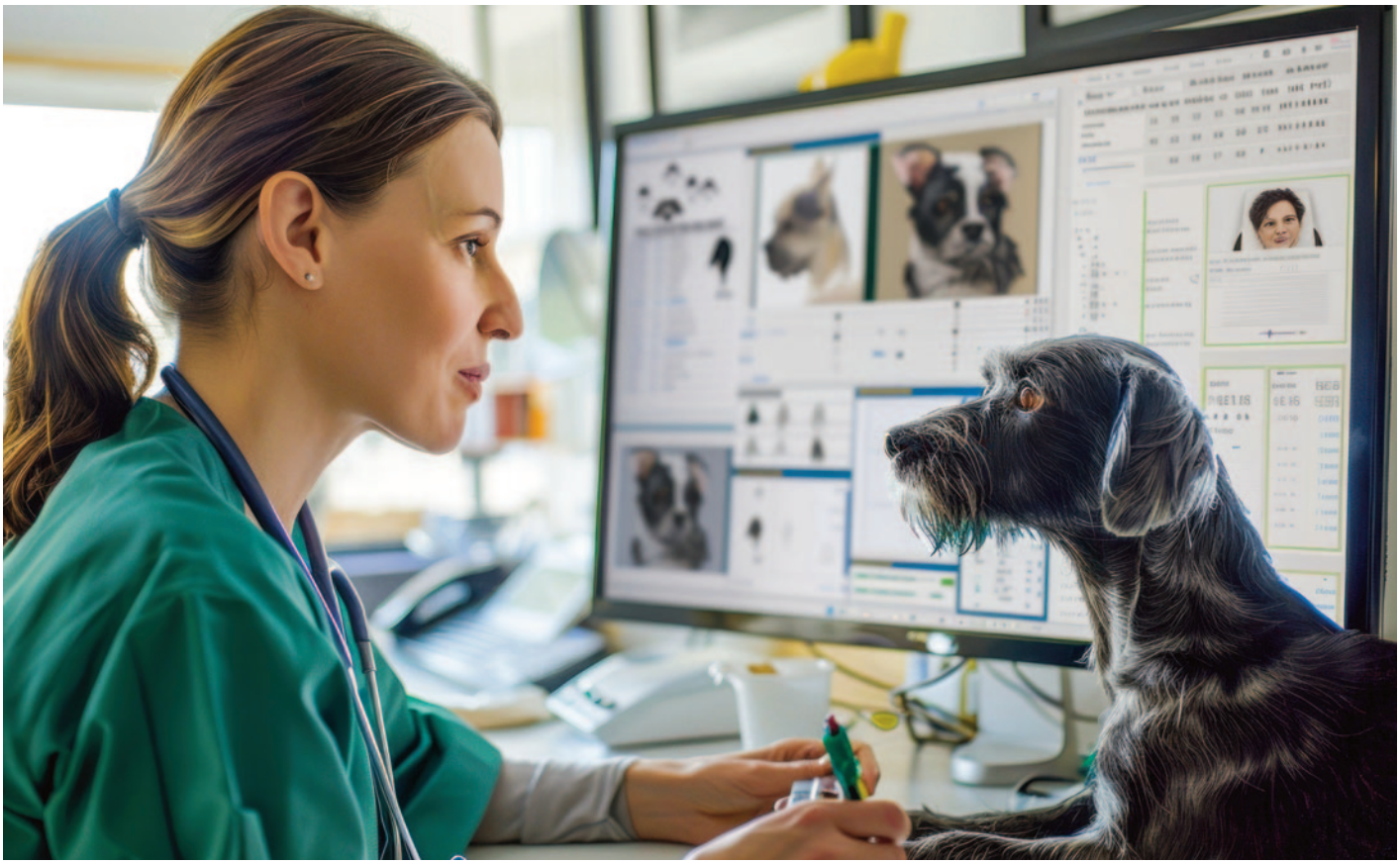

Photo: Freepik

Leveraging the power of data for public and animal health

May 7, 2025

EMA and the HMA have published a joint workplan "Data and AI in medicines regulation to 2028".[1] It sets out how the European medicines regulatory network plans to leverage large volumes of regulatory and health data as well as new tools to encourage research, innovation, and to support regulatory decision making for better medicines that reach patients faster.

The workplan lays out a roadmap for managing, analysing, and sharing data across the network, while adhering to high security and ethical standards. It also provides a framework for coordination to address new legislative initiatives in the European Union (EU), notably the pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act. This new strategic advisory group, combining the former Big Data Steering Group and the Network Data Board, will oversee the implementation of the workplan.

The workplan translates the objectives of the European medicines agencies network strategy to 2028 into concrete deliverables. These include strengthening the network's data analytics capabilities to generate high-quality evidence using both established and novel methods. The clinical study data pilot by EMA's CHMP will continue to clarify the benefits and practicalities of accessing individual patient data from clinical trials. The Data Analysis and Real World Interrogation Network, DARWIN EU®, will further expand and deliver evidence that helps fill knowledge gaps and understand the use, safety and benefits of medicines.

A review of methodologies, including biostatistics, modelling and simulation, AI and pharmacoepidemiology and lesser-used data types, including genomic data, synthetic data, digital twins data and patient experience data, will help the network establish shared understanding and position the future use of such methods and data types.

The workplan aims to enable efficient discovery, access, and use of the network's data assets through cataloguing and strengthening data quality, starting with real world data, adverse drug reaction data and medicinal product master data. Master data, the core data needed for the operations of the network, is essential for increasing the interoperability of data assets and systems. The workplan will advance and harmonise the implementation of the Product Management Service (PMS), recognised as the network's source of product master data for all EU medicinal products, supporting EU-wide use cases.

AI offers clear opportunities across the medicines lifecycle. Key initiatives of the workplan include supporting EMA's scientific committees and the pharmaceutical industry in evaluating AI through the medicines lifecycle, developing guidance on AI in clinical development and in pharmacovigilance, fostering EU-wide and international collaboration, and providing the network with training on AI and a framework for sharing and collaborating on AI tools. The aim is to facilitate safe and responsible use of AI that benefits public and animal health.

Reference

1. Network Data Steering Group workplan 2025-2028: Data and AI in medicines regulation. Joint HMA/EMA Network Data Steering Group VERSION 1.1 – May 2025. Available from https://www.ema.europa.eu/en/documents/other/network-data-steering-group-workplan-2025-2028_en.pdf.