Progress towards a data-driven regulatory system

Network Data Steering Group: 2025 highlights and looking forward

Karl Broich, NDSG co-chair (BfArM)

Annual Data Forum, 9 December 2025

EMANS to 2028: collaborative vision for tomorrow

1. Accessibility

3. Regulatory science, innovation and competitiveness

4. Antimicrobial resistance and other health threats

5. Availability and supply

6. Sustainability of the network

EMA HMA Heads of Medicines Agencies

Vision of the Network Data Steering Group
"Trusted medicines by unlocking the value of data"

Network Data Steering Group – driving data transformation

EMANS 2028

Leads Theme 2 (Data & AI) implementation

Multidisciplinary collaboration

Comprises expertise and diverse perspectives from partners and stakeholders

Data and AI workplan 2028

Steers roadmap to guide use data and AI to improve medicines regulation

Key achievements

The **first data strategy** for medicines regulation defined a clear approach to ensure the Network's data assets are well governed, meet high standards and quality and deliver value to stakeholders.

DARWIN EU® – turning real-world data into impactful evidence for decision making

>100 studies initiated

31 data partners in 16 EU countries

Data from ~188 mln patients

Studies available publicly

HMA-EMA Catalogue of Real-World Data Sources and Studies

To date: **3235 studies (inc. DARWIN EU)** and **272 data sources**

e.g. Non-Small Cell Lung Cancer (NSCLC) and immunotherapy treatments

Findings on the benefit of immunotherapy were in line with results from clinical trials.

e.g. Respiratory Syncytial Virus (RSV) disease epidemiology

Results were used as evidence to support the argument of unmet clinical need for the 50-59 age group, supporting preparation of vaccine effectiveness studies.

e.g. Juvenile polymyositis (JPM) and dermato-myositis (JDM)& disease natural history in paediatric population

Largest European study showing increased prevalence over time and clinical manifestations, used to start a controlled clinical trial.

Exploring the potential of genetic information to improve treatments and patients care

11 recommendations spanning regulation, national healthcare uptake, real-world data use and EU-funded research impact

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COMMENT | 21 November 2025

Advancing pharmacogenomics in medicines regulation and clinical practice: a call for collaborative action

The full potential of pharmacogenomics to improve drug development and clinical practice has yet to be realized. Here, we present recommendations to address barriers to its implementation.

By Jasmine Gratton, Peter Arlett, Falk Ehmann, Daniel Prieto-Alhambra, Patrice Verpillat, Emmanuel Cormier, Irene Norstedt, Aimad Torqui, María Jesús Lamas Díaz, Carmen Laplaza Santos & Munir Pirmohamed

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Moving from AI promise to AI practice

- Network-wide: AI use cases; literacy training; & tools sharing framework
- Observatory report
- Research priorities for AI
- Guiding principles for good AI practice in medicines lifecycle - *coming soon*

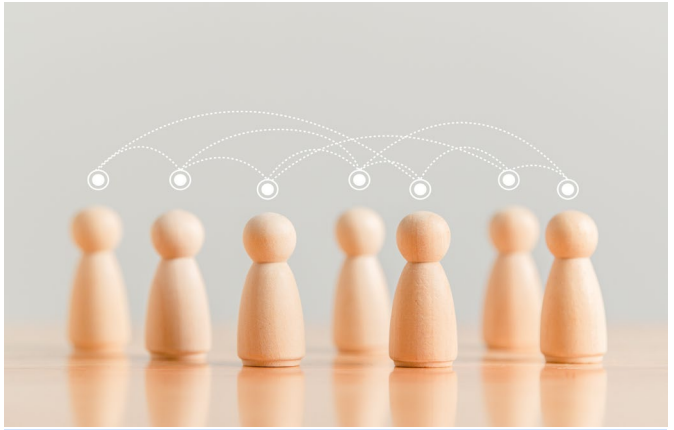
Key recommendations for implementing **master data** for human medicines laid the foundation for a shared EU-wide repository of medicinal product information.

Collaborating for impact

5 key topics I~5000 participants

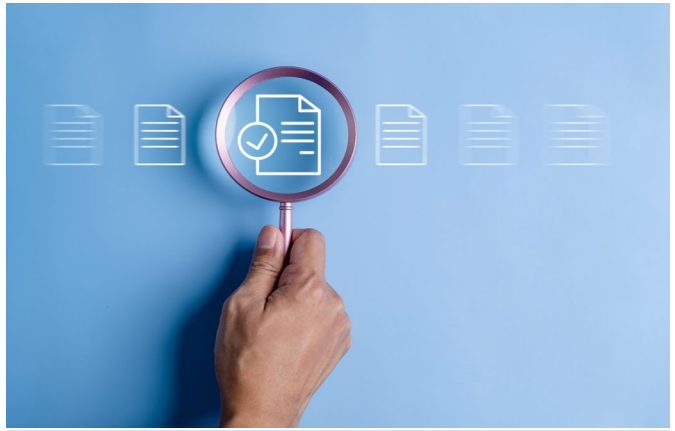
- Produce Management Service (PMS) Info Day
- Mechanistic models
- External controls
- Eudravigilance & signal detection
- Artificial intelligence

Expert guidelines to strengthen evidence and decision making



Methodology Working Party

- 3-year rolling plan published
- European Specialist Expert Community (ESEC) comprises 209 experts from 21 European countries



Reflection Papers

- RWD use in non-interventional studies to generate RWE
- **Public consultations** on patient experience data and concept of using external controls in evidence generation

International guidelines

- ICH M14 principles for non-interventional studies using RWD in medicines safety
- ICH M11 clinical study protocol template and technical specifications (*publishing shortly)*
- **Public consultation** on ICH M15 general principles for model-informed drug development

A glimpse into the future

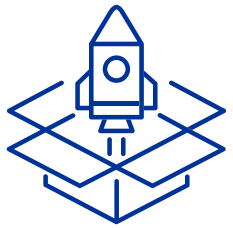
Seizing opportunities in a changing medicines landscape

EU legislative changes

- Reform of pharmaceutical legislation
- European Health Data Space
- AI Act

EU medicines regulatory network strategy 2028

- Theme 2: leverage data, digitalisation and AI
- Maximise generation, interoperability, use and exchange of data
- Realise the network vision on AI across all EMANS focus areas



Key deliverables 2026

- Revision of the NDSG workplan
- DARWIN EU Stage II
- Data standardisation framework
- Data analytics framework
- AI guidance for clinical development and pharmacovigilance

Collaboration is key

Thank you

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