

Embracing Data Analytics in Medicines Regulation

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Methodology workstream

Data, Analytics and Methods Task Fore



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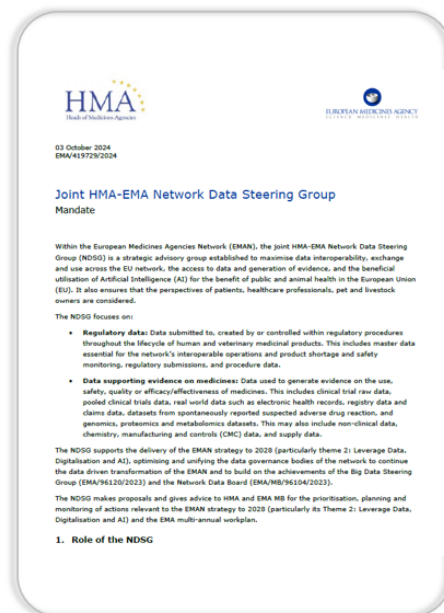
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Joint HMA-EMA Network Data Steering Group mandate

NDSG is the **strategic advisory group** established to:

- maximise data use, exchange and interpretation,
- improve access to data and evidence generation,
- leverage use of artificial intelligence for better decision-making.



Strategy & Data Governance

Data Interoperability

Data analytics

Artificial Intelligence

Stakeholders' engagement, change management and guidance

Theme 2: Leveraging data, digitalisation and AI



Goal 1

- **Maximise the generation, interoperability, use and exchange of data to support EU decision-making**



Objectives:

- Embed the use of healthcare data from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)
- Ensure a high level of interoperability (notably through the use of Master data), standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed



Goal 2

- Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes



Goal 3

- **Realise the network vision on AI across all EMANS focus areas**



Objectives:

- Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network
- Harness the potential of AI throughout the medicines' lifecycle

The NDSG workplan is organised in six workstreams – adopted at March NDSG meeting

Strategy and governance:

- Strategy
- Governance

Data analytics:

- Review of advanced or innovative methodologies and of new data types for evidence generation
- Real World Data, Clinical study data, EudraVigilance data, Non clinical data, Genomic data

Artificial Intelligence :

- Guidance, policy and product support
- Tools & technologies
- Collaboration and change management
- Experimentation

Data interoperability:

- Data asset discovery, cataloguing and metadata management
- Data Quality Management
- Organisational and Semantic interoperability

Stakeholder engagement and change management:

- Change management strategy
- Network skills and knowledge
- Stakeholder engagement and communication

Guidance and international initiatives :

- Guidance
- International initiatives

Network Data Steering Group – unlocking value of data

Key priorities 2025

Strategy and governance	 Support to New Pharma Legislation, EHDS2 and AI Act	 EMRN data strategy, incl. data standardisation strategy, data quality and cataloguing	 EMRN data analytics strategy, incl. strengthening network capabilities
	 Continue ongoing initiatives of DARWIN EU® and clinical study raw data	 Medicines master data implementation - EHDS1 as priority use case	 Artificial intelligence
	 Communication	 Training and guidance	 Stakeholder engagement

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7

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From strategy to implementation...

Have we forgotten
first principles?

The starting point of delivering with any analytics is data

Without data we **cannot** deliver analytics.

Recently the rise of AI and its need for data have reaffirmed the following across multiple industries:

- There is no shortage of data.

But

- What data do we really need? (e.g. MDM and CDE)
- Where are the data? (e.g. Catalogues)
- What is the quality of the data? (e.g. DQM and Standards)
- What does the data mean? (e.g. Metadata)
- And how can we optimally share the data? (e.g. Interoperability)

Each and every point needs specific attention!
Does everyone agree there are foundational steps?

So we have data,
what shall we do with it?

Focus is provided by the EMANS 2028

- **Accessibility** - facilitating access to medicines in the EU
- **Leveraging data, digitalisation and artificial intelligence** - improving decision-making, optimising processes and increasing efficiency
- **Regulatory science, innovation and competitiveness** - helping improve innovation and competitiveness in the EU healthcare sector
- **Antimicrobial resistance and other health threats** - preparing the EU for potential threats including antimicrobial resistance
- **Availability and supply** - strengthening availability of medicines to protect public and animal health
- **Sustainability of the European medicines agencies network** - ensuring available resources to support its scientific and regulatory decision-making

In the [European medicines agencies network strategy 2028](#) (EMANS 2028)

these **six focus areas** are identified



For every one of the EMANS 2028 focus areas there are Data Analytics Use Cases

Examples

Accessibility

Present relevant evidence to HTA bodies and payers

Sustainability

Foster capabilities to use analytics

Anti microbial resistance

Reporting of sales and usage data for antimicrobials

Digitilisation

Provide optimised and more efficient regulatory processes through analytics

Regulatory Science

Improved planning of clinical trials

Availability and supply

Analyse root causes of shortages

What this means: the data analytics value chain needs to be aligned with use cases.

The efforts on data needs to be aligned with the efforts on analytics and AI



Working back from what we need to achieve provides us the focus on which foundational steps we need to focus on. We need to deliver in short bursts. We are not doing data for data's sake or analytics for analytics' sake.



This also means that stakeholders should be engaged where they interact with this clear focus and align on common use cases that have benefit for all stakeholders.



Stating the obvious: A meeting like we just had is important as it focuses where we need to go but it is important that we identify the minimum requirements and potential paths of divergence so that we know where to interact to deliver maximal benefits for the European patients.

Key messages

- Introduce EMA focus from EMANS 2028 – the EU regulatory strategy.
- Going back to basics and working on foundations are critical.
- Call to arms: Identify points of interaction and potential differences.



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Thank you

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