

Session 3: Building a medicines data ecosystem

The European Medicines Agencies Network Data Strategy

Georg Neuwirthner (AGES, NDSG member), Annual Data Forum, 9 December 2025

Today's outline



First, let's hear from you



Key insights on the EMRN data strategy



Data strategy in action: testimonies from partners and stakeholders



Take home message





Let's hear from you!

Let's hear from you!

“

Trusted medicines by unlocking the value of data

EMRN's data vision
[NDSG workplan 2025-2028](#)

**In one word:
Which data aspect is most important to you in achieving this vision?**





Insights on the EMRN data strategy

Medicinal Product Data Flow (e.g. Austria)



Why is the EMRN data strategy needed?

Organisation-level problems:

- Data not findable, accessible nor reusable
- Data quality monitoring & fix not systematic/ standardised
- Roles, responsibilities & definitions in data management vary and are not formalised
- Difficulties to solve issues on data matters between systems
- Different working standards & structures, unclear processes
- Manual processing/ use of data is time-consuming, risk for errors, inconsistent outcomes

Maximising the value of:

- **ISO IDMP** = Common semantic for describing medicinal product (worldwide)
- **EU Implementation Guides** = EU specifics how to express information about authorisation in CPs or NAPs
- **SPOR** = IT-Systems providing standardised terms (e.g. route of administration) and dictionaries (Organisations)

The EMRN Data Strategy: scope

- It supports the transformation of the EMRN into a data-driven regulatory eco-system with principles to be followed and strategic objectives. It will inspire local and EU-wide implementation initiatives
- It covers:
 - **Regulatory submissions data** – sent by marketing authorisation holders or applicants to demonstrate the safety, efficacy, and quality of a medicine;
 - **Substance, product, organisation and referential (SPOR) master data** - essential for the network's cross operations including the monitoring of medicines' safety and shortages;
 - **Spontaneously reported adverse drug reactions**
 - **Clinical trials data from CTIS**


HMA
Heads of Medicines Agencies
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

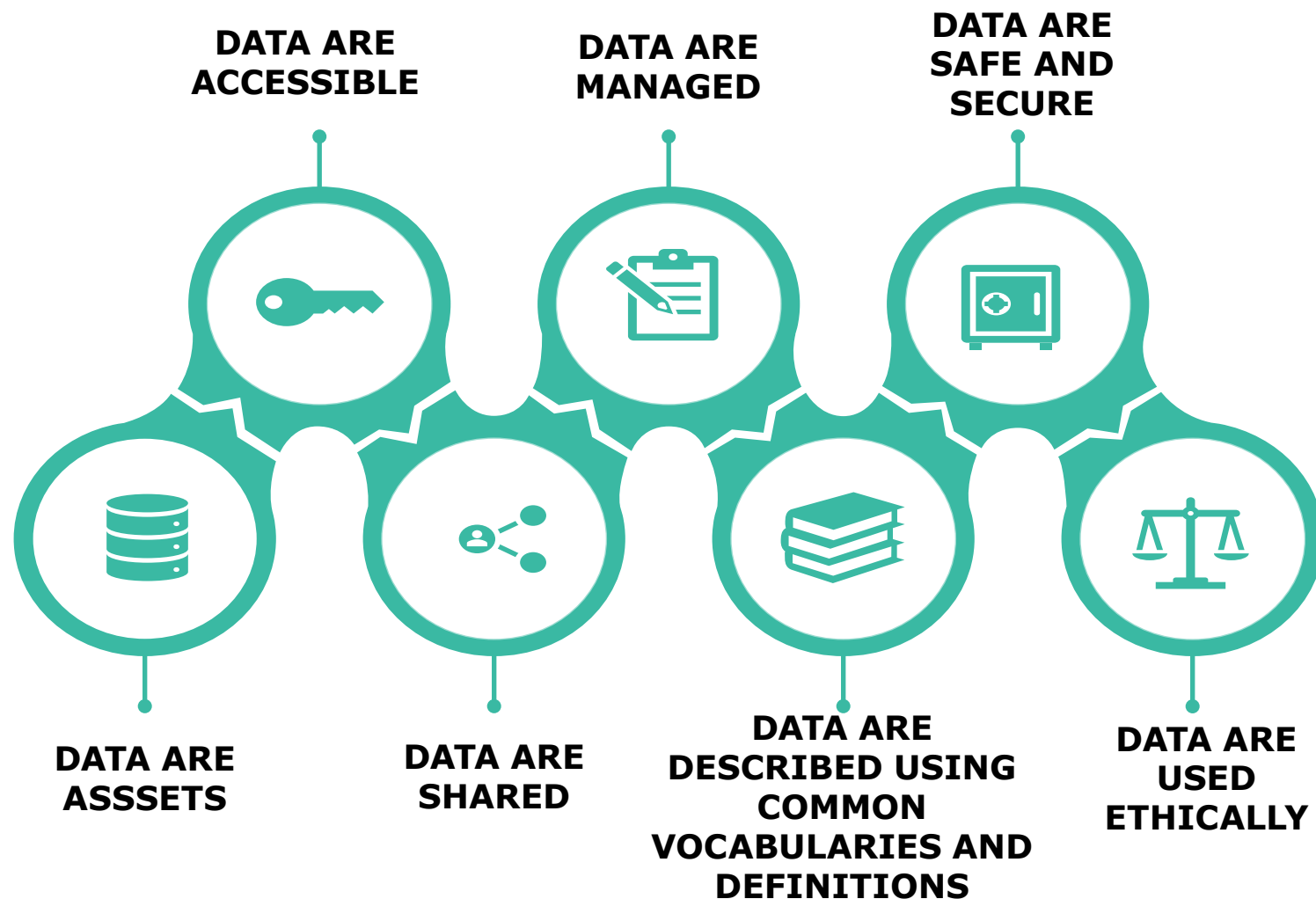
2 October 2025
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European Medicines Agency

The European Medicines Agencies Network Data Strategy

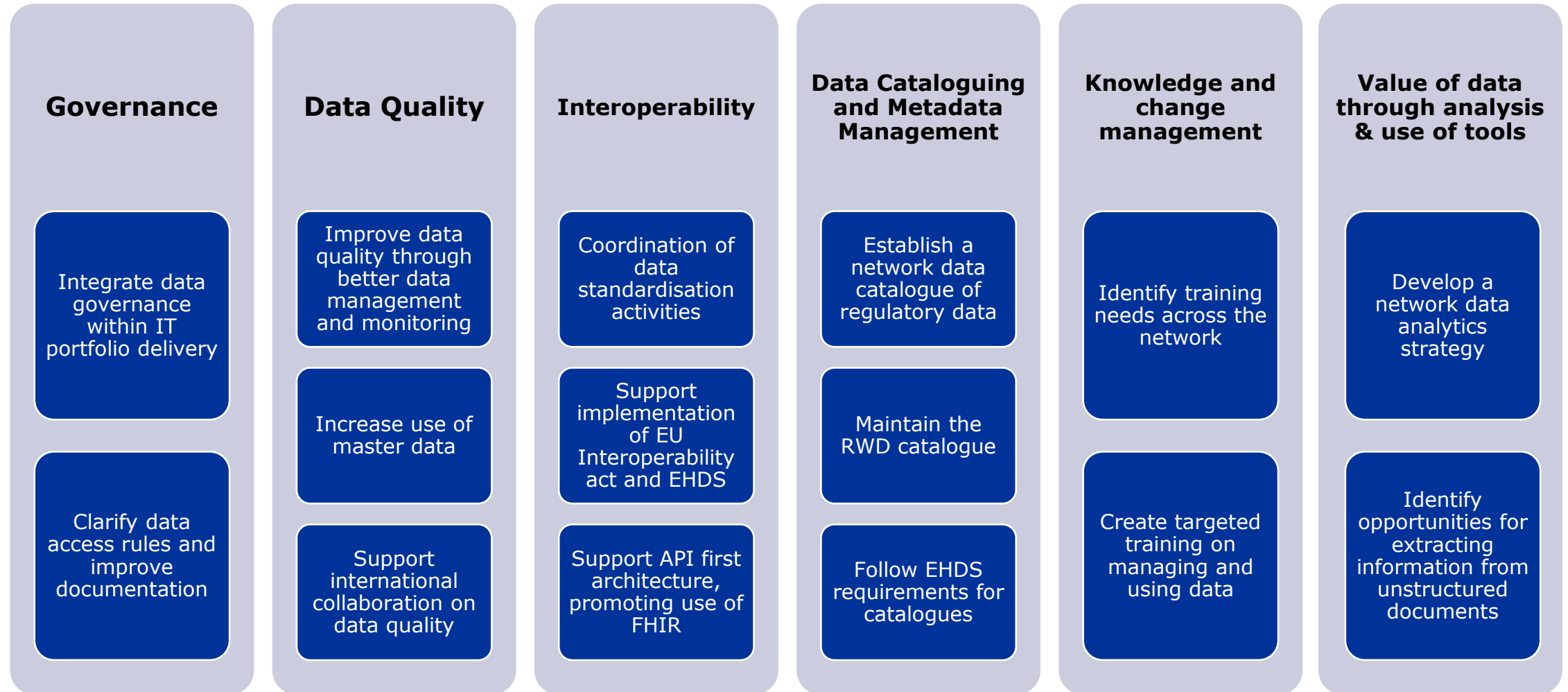
Increasing the value of data for the benefit of public and animal health

Adoption by Network Data Steering Group	27 June 2025
Endorsed by Heads of Medicines Agencies	12 September 2025
Endorsed by EMA Management Board	2 October 2025

The EMRN Data Strategy: principles



Identified shared objectives





Data strategy in action

Testimonies from partners and stakeholders



Take home message

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The common principles and objectives helps

- In achieving consistency and trust in data across all EMRN partners.
- In improving efficiency and interoperability, reducing duplication of effort.
- In strengthening regulatory decisions with high-quality, reliable evidence.
- In accelerating innovation and patient benefit through better data use.

**Apply it, consider it, write to us
for any questions**

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Thank you

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