

Network data strategy: Analysis of data and use of tools, Knowledge and change management

28 November 2024

Session 4 of the HMA/EMA Big Data Stakeholder Forum: Unlocking the value of data
with the EMRN data strategy

Presented by Kristine Aasen, Senior Enterprise Architect, NOMA
Network Data Board member and NICTAC member

About the speaker



Kristine Aasen

Enterprise Architect, The Norwegian Medical Products Agency

Kristine Aasen has the role as senior enterprise architect in NOMA. In this role she is working for national and international interoperability through data standardisation. Kristine has a master's degree in information science, and she is certified for TOGAF and ITIL. Her experience spans from work with master data, to primary use of data in hospital and to secondary use of data for research. Kristine is a member of the European Medicines Agency's Network ICT Advisory Committee and has been a member of the Network Data Board.

Contact

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EMRN Data strategy goal and objectives

The EMRN has implemented Artificial Intelligence for maximising evidence generation, increasing productivity, data insights and strengthened decision-support.

Obj. 10 – Additional business value is generated by using and interconnecting EMRN data assets

Obj. 11 - Value from information and data available in unstructured sources is generated

Obj. 12 – Tools for analysis are available for the EMRN to enrich and improve scientific, regulatory, and corporate processes

AI Experimentation at EU Network: examples



PHAIR: PHarmacovigilance by AI Real-time

Jesper Kjaer

Inhouse LLM at DKMA

As a tool to drive GDPR compliant digital transformation



XLMeQA + NLP Platform + MedDRA Terms

Ongoing AI projects at AEMPS

Ana López de la Rica, AEMPS



Regulatory memory machine

Customized LLM applications to search from regulatory documents

Antti Hyvärinen, Elina Asikanius



AI@MPA

Putting regulatory AI in production for EU network use

Gabriel Westman
Head of Artificial Intelligence, Swedish Medical Products Agency



ChatGPT@EMA pilot

A pilot to explore ChatGPT use at EMA

Jakub Hasiec, Data Scientist - Analytics Centre of Excellence, TDT, EMA

TTS automated case adjudication

Can we use ML to streamline the review of ICSRs?

Luis Pinheiro, EMA and Julie Durand, EMA

M-RECON

Medicines regulatory context engine

PICROSS

Product information cross search

PACKSIM

Mock-up similarity search

PhaVAI triage

API for triage of ADR reports

Paul-Ehrlich-Institut



BMG-KIMERBA - intelligent in-house automation of regulatory workflows

BMG-BLOODVIR - knowledge accumulation for AI assessment

BMG-RENUBIA - assessment and validation of AI-based tools in medicinal products



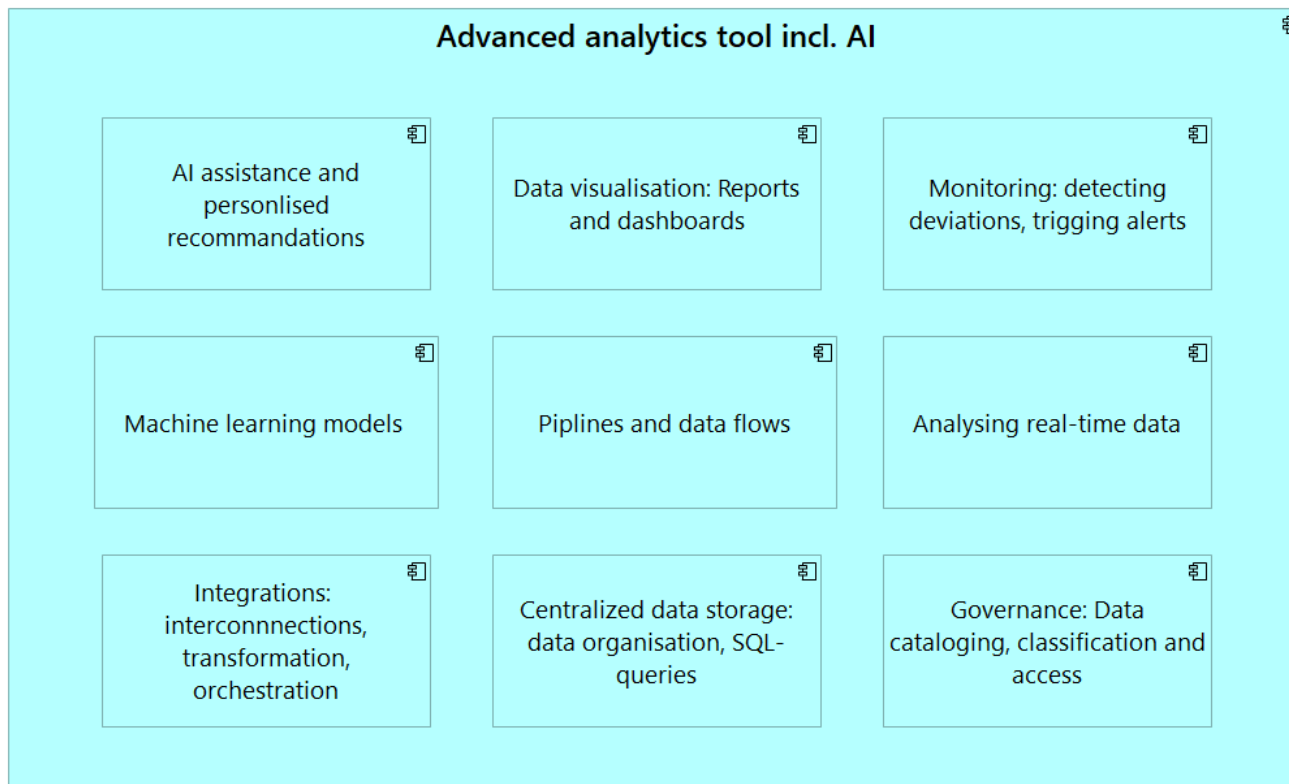
NOMA Project proposals and use cases for analytics tool

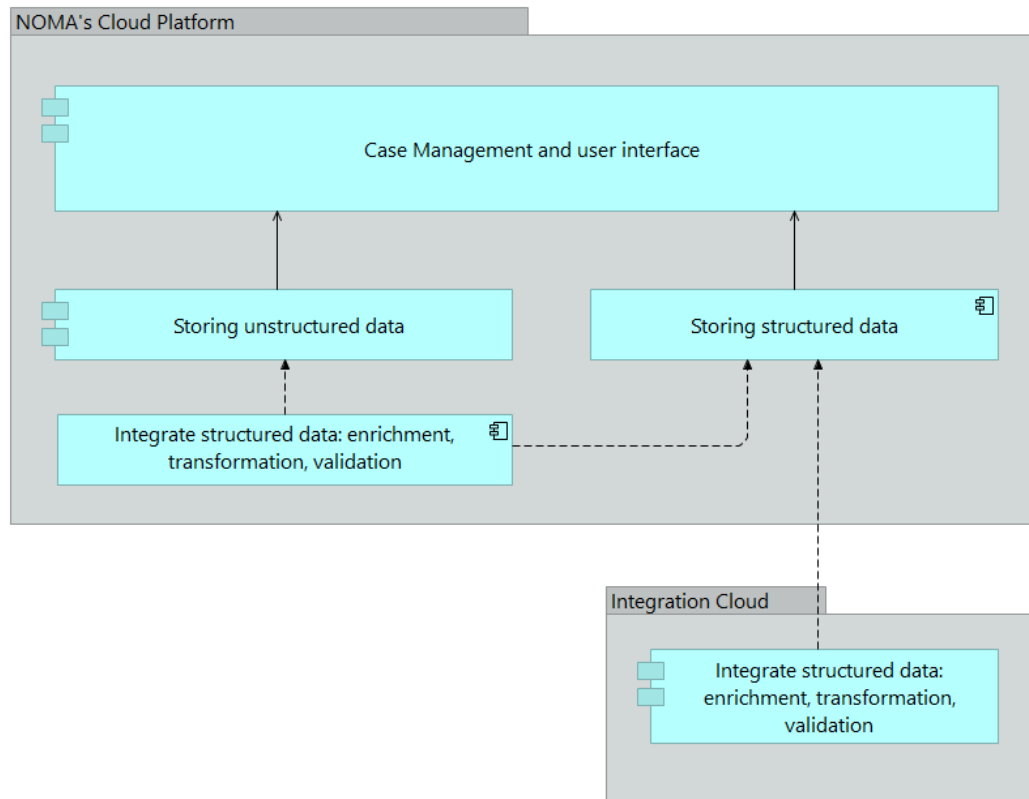
Use case 1: NOSMP – Monitoring the supply chain for preparedness and shortages

Use case 2: NODAMED – Monitoring safety reports for signal detection

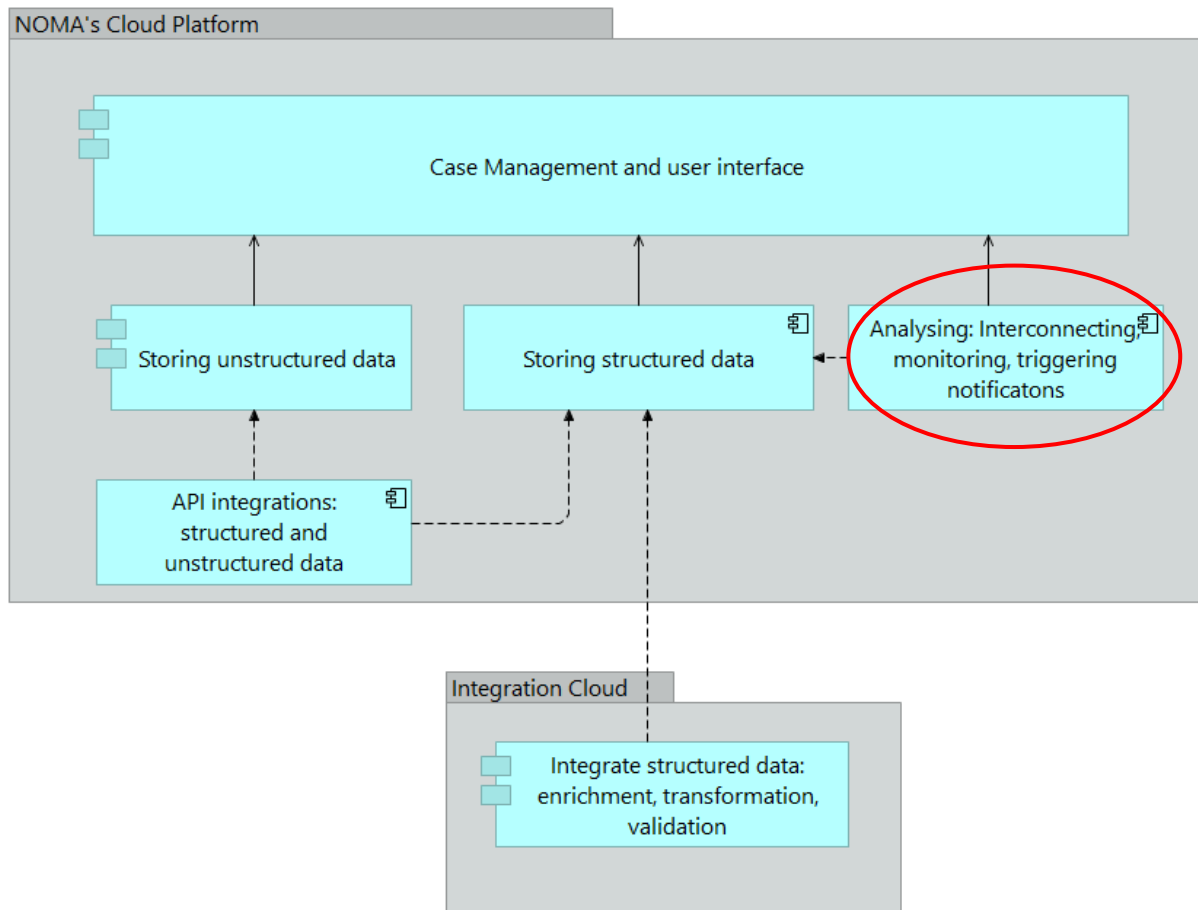
Use case 3: Inspections – Monitoring activity in NMVS for targeted inspection

Advanced analytics tool incl. AI - Application components





Expanding NOMA's Cloud Platform (TO-BE)

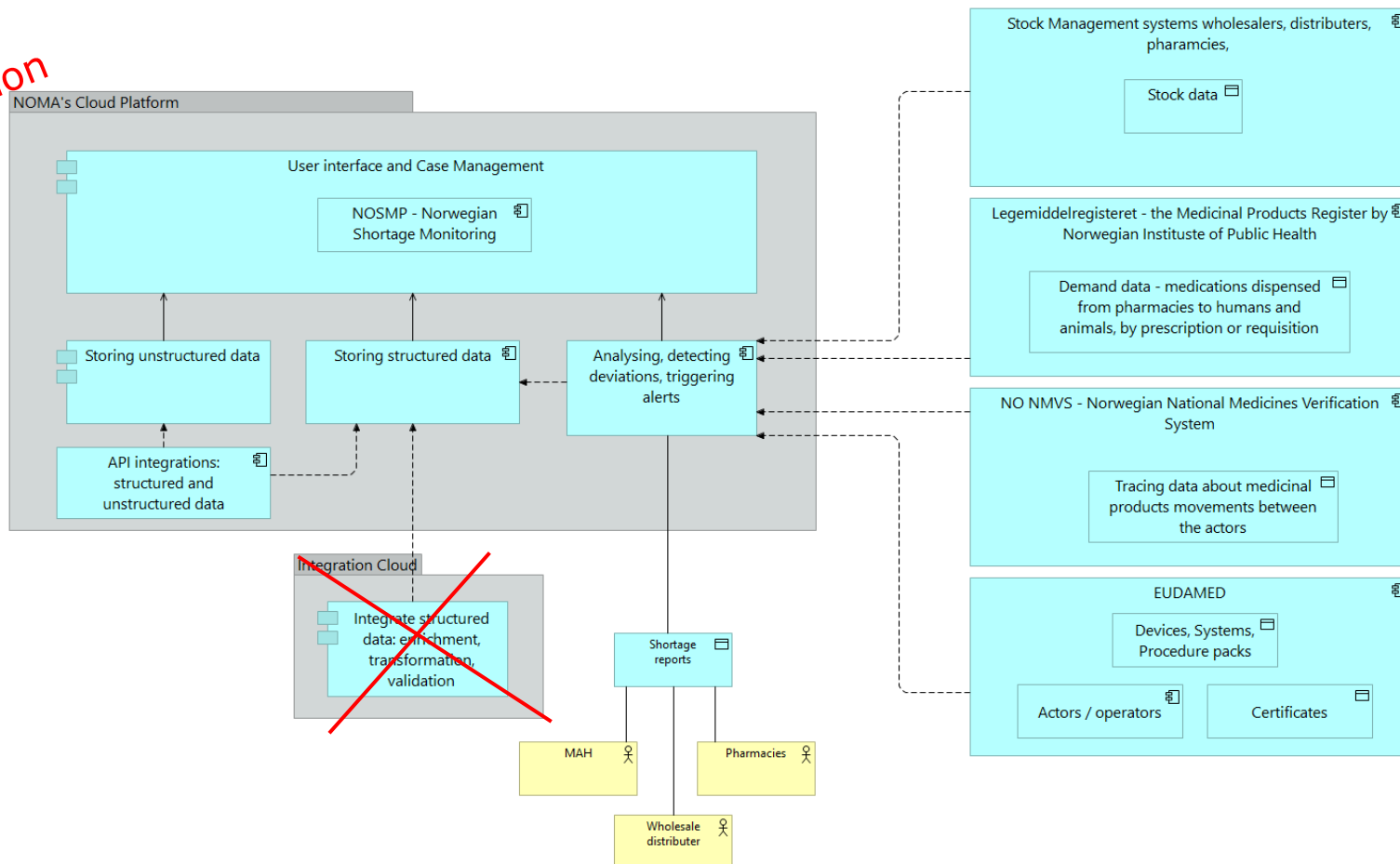


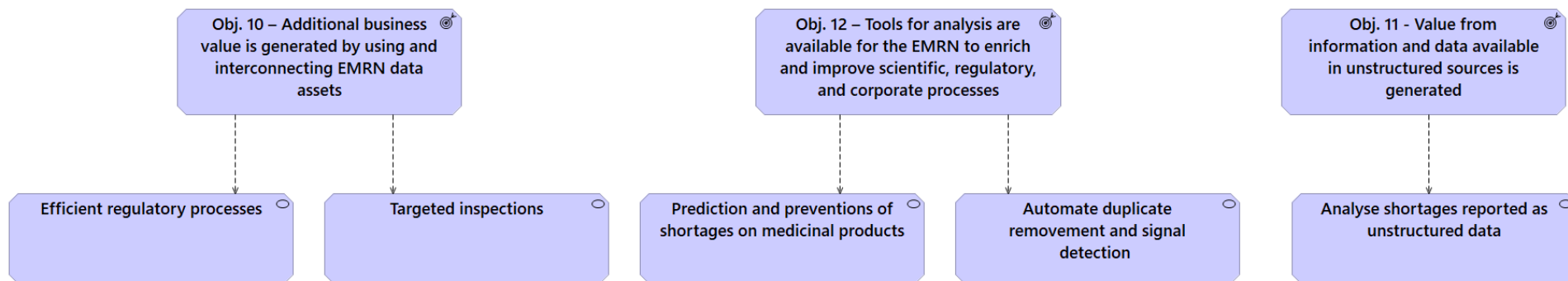
Use Case 1: NOSMP – monitor and prevent shortages



EUROPEAN MEDICINES AGENCY

Draft vision





- A holistic view on the business
- Standardised and cleansed data
- Clear use cases and business objectives
- Pilots and validation
- Monitoring and maintenance
- Strong governance and access control
- Digital maturity

Digital and Big Data training offers

EU Network Training Centre Newsletter



Training by the Network for the Network



BIG DATA, AI

First modules of the Data Science curriculum now available

The Data Science curriculum is a series of trainings on data science that have been specifically designed for the European Medicines Regulatory Network (EMRN) to enhance knowledge and develop skills in this field.

Data science curriculum

DIGITAL

Digital Academy intro module and collection on Design Thinking

In this new Digital Academy 30-minute interactive e-learning module and accompanying learning resources collection, you will learn about Design Thinking.



[more](#)

BIG DATA, RWD, RWE

How to ensure data quality in the generation of real-world evidence (RWE)

The course has been developed by the EMA Data Analytics and Methods Task Force, Real-World Evidence Workstream in liaison with Healthcare Data colleagues at EMA.



[11](#) date | 03/07

ARTIFICIAL INTELLIGENCE, PHARMACOVIGILANCE

Challenges and future role of artificial intelligence learning in pharmacovigilance

This is a recording of a webinar held on 26 July 2024 on the challenges and future role of artificial intelligence and machine learning in pharmacovigilance. The webinar was delivered by Dr Dirk Mentzer, Head of Safety of Biomedicines and Diagnostics Division, Paul Ehrlich Institut.



[more](#)

DIGITAL, DATA, DATA PROTECTION

Digital Academy intro modules and collections on Data Literacy and Data Protection

Increase your data literacy and data protection skills with the new Digital Academy interactive e-learning modules and accompanying learning resource collections



[more](#)

REAL-WORLD EVIDENCE, METHODOLOGY

Joint HMA/EMA Big Data Steering Group Workshop on RWE methods: Harnessing Real-World Data for Regulatory Use

The training consists of a recording of a one-day hybrid Big Data Steering Group (BDSG) workshop held on 14 June 2024. The programme was developed by the EMA Data Analytics and Methods Task Force, Real-World Evidence Workstream.



[more](#)

BIG DATA, RWD, RWE

RWD in support of regulatory work in paediatrics – example of the RWD extrapolation framework with a pilot study in dermatomyositis and polymyositis - Real World Academy session 4

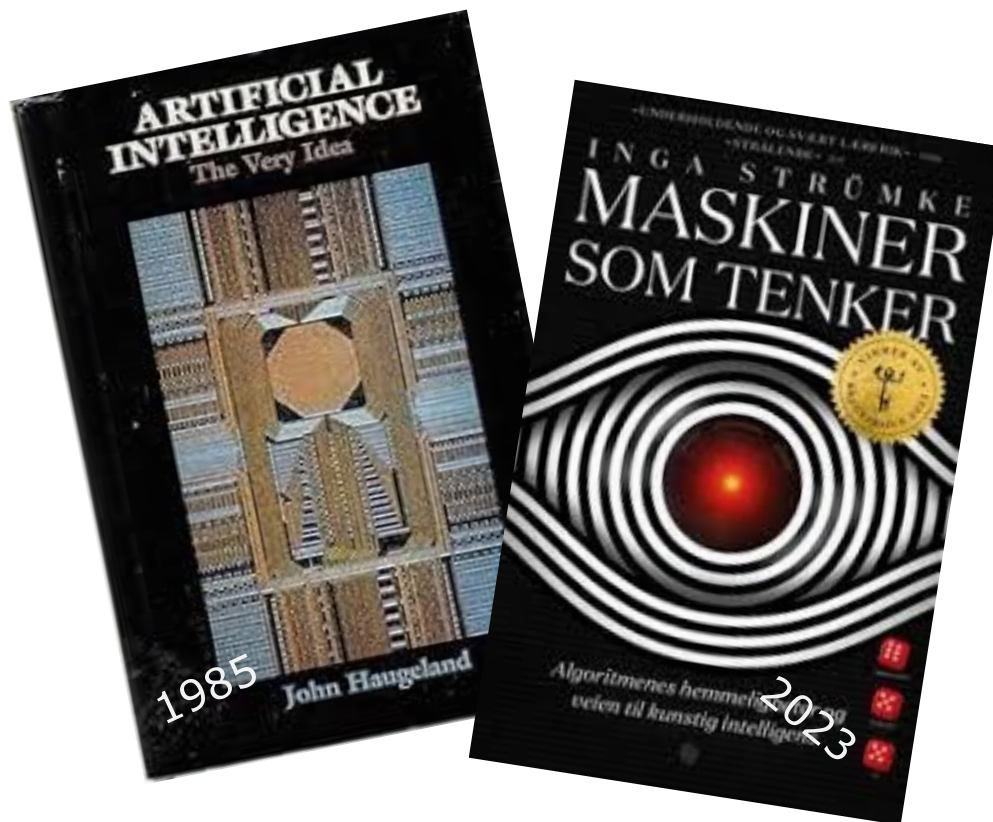
This 4th session of the Real World Academy focuses on the use of RWD to inform and support regulatory work in paediatrics.



[11](#) date

| 04/10/2024

From my bookshelf



Thank you for listening

Disclaimer: Some of this slides are created with help of AI ;-)

Further information



See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union



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