



EMRN Data Standardisation Strategy

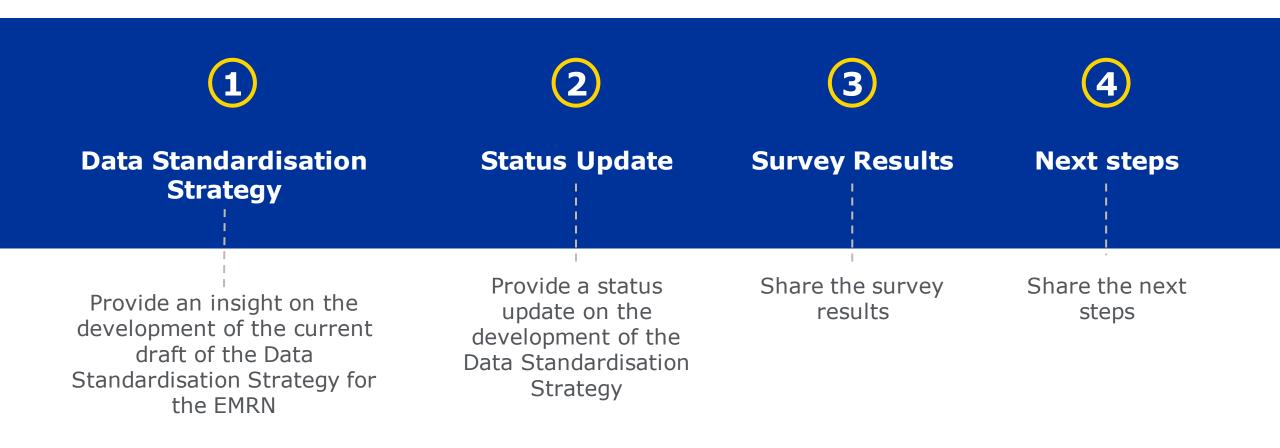
Development process & status

Data Standardisation Strategy Stakeholder Workshop Virtual Meeting, 18 May 2021 Presented by: Nick Halsey EMA

Data Analytics and Methods Taskforce









Data Standardisation Strategy | Development



Landscape Analysis

 Analyse and understand the landscape and environment of EU policies, IT systems and (mature and in development of) standards by SDOs



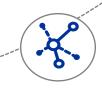
Interviews

- Understand and gather input on preferred direction of stakeholders
- Identify goals & objectives



Survey & Workshop

- Understand and gather input on preferred direction of stakeholders
- Identify goals & objectives



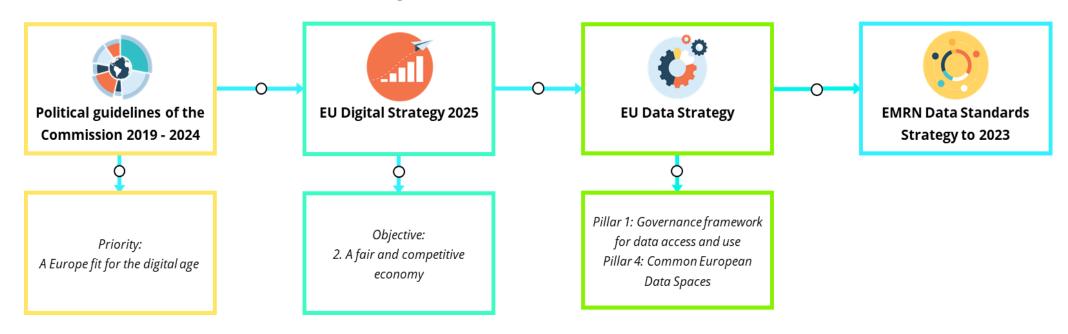
Data Standardisation Strategy

 Draft Data Standardisation Strategy document based on input and direction of stakeholders



Data Standardisation Strategy | Strategic direction

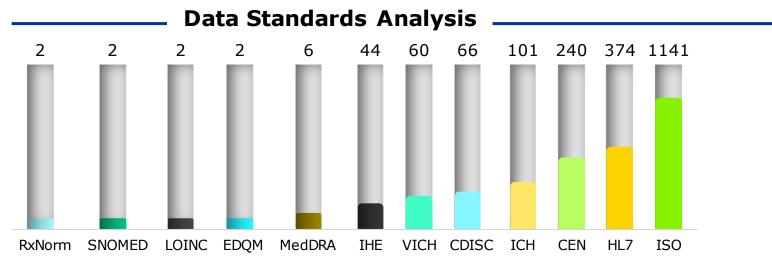
The overall goals of the Data Standardisation Strategy are aligned with the guidelines of the European Commission and follows this strategic direction;





Data Standardisation Strategy | Development

From December 2020 an in-depth analysis has been performed on the overall IT, policies and data standards landscape within the FMRN.



2040 Data Standards available and under development have been considered as part of the data analysis, of which 1547 are Mature and 489 Developing. In total 12 SDOs and maintenance organisations have been examined and the work of 397 Technical Committees and 93 subcommittees.

IT Systems Analysis



40 IT systems in use in regulation of medicines at EU level have been considered as part of the IT Systems landscape analysis.

Data Standardisation Strategy | Development

From December 2020 an in-depth analysis has been performed on the overall IT, policies and data standards landscape within the FMRN.

Background Documents*

Data

Standards

Strategy

European Interoperability Framework

Telematics Implementation Roadmap 2019-2020

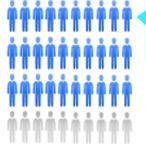
EMA Policy Documents & Digital Transformation Tools

EU Policies Human & Vet

Recommendations of HMA-EMA Big Data Task Force

EMA Work Programme(s) 2020-2021 & Beyond

Interviews

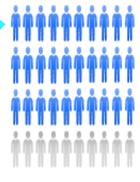


369 Use Cases

82 People have been interviewed as part of the landscape analysis.

194 Use Cases

70 organisations/ associations responded to the survey



EU Digital Strategy 2025
EU Data Strategy

EMA Regulatory Science

EU Medicines Agencies

Network Strategy to 2020

Political Guidelines of the Commission 2019-2024

Chemical Strategy for

Information Management

Strategy 2019-2021

Strategy 2025

Sustainability

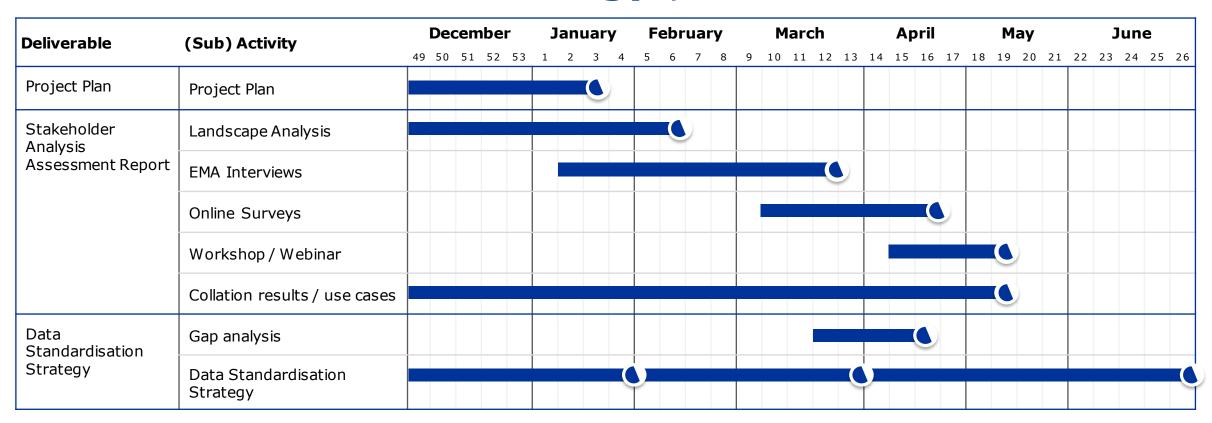
* Please note that this is a non-exhaustive overview



Data Standardisation Strategy | Current Status

Activity Milestone



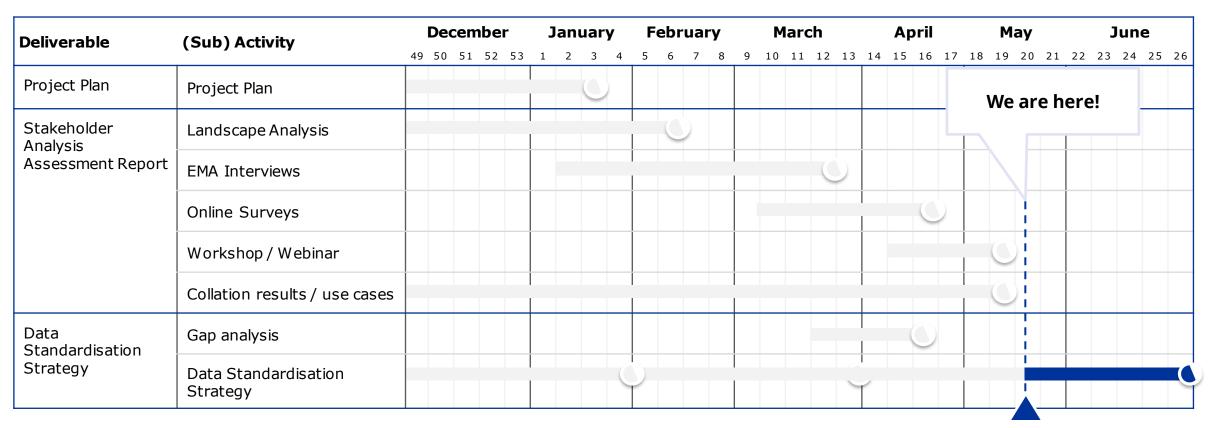




Data Standardisation Strategy | Current Status

Activity Milestone







Data StandardisatioACn Strategy | Current Status

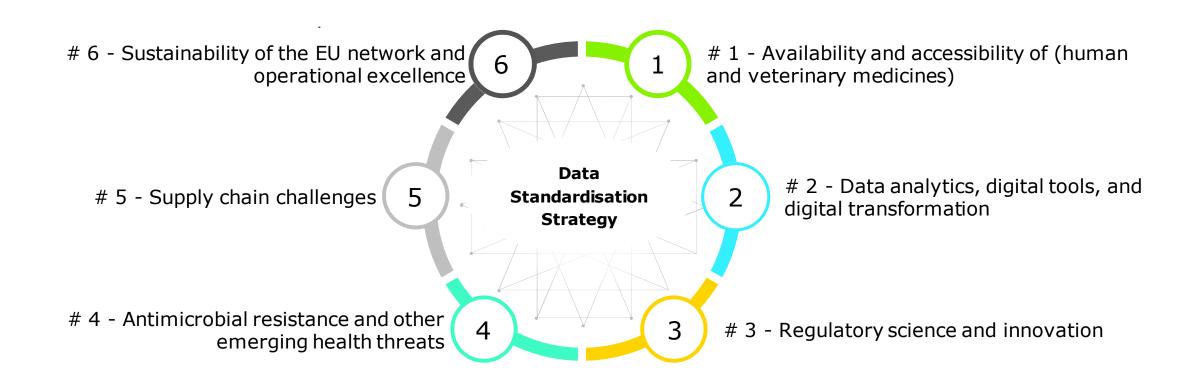
The Data Standardisation Strategy document will contain the following sections;

- List of Acronyms
- Executive Summary
- Introduction
- Strategic Reflection
- Strategic Goals & Objectives
- o Recommendations
- Conclusion
- References
- Annexes

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Data Standardisation Strategy | Strategic Goals & Objectives





Next Steps | Following the Data Standardisation Strategy stakeholder workshop



 Recommendations will be completed and affected projects and expert groups will be consulted

Step 1

 Based on consultation and endorsement process, the publishing date will be determined:

Step 2

- ✓ BDSG- consulted
- ✓ EUNDB- consulted
- Management Board & HMA- endorsement
- The time period for the revision of the Data Standardisation Strategy will be planned for and announced in September following the BDSG workplan update

Step 3

 Planning of recommendations implementation and telematics plan review

Step 4