



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMRN Data Standardisation Strategy

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## *Development process & status*

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



1

## Data Standardisation Strategy

Provide an insight on the development of the current draft of the Data Standardisation Strategy for the EMRN

2

## Status Update

Provide a status update on the development of the Data Standardisation Strategy

3

## Survey Results

Share the survey results

4

## Next steps

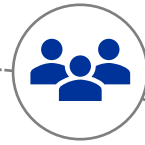
Share the next steps

# 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



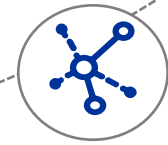
## Interviews

- 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

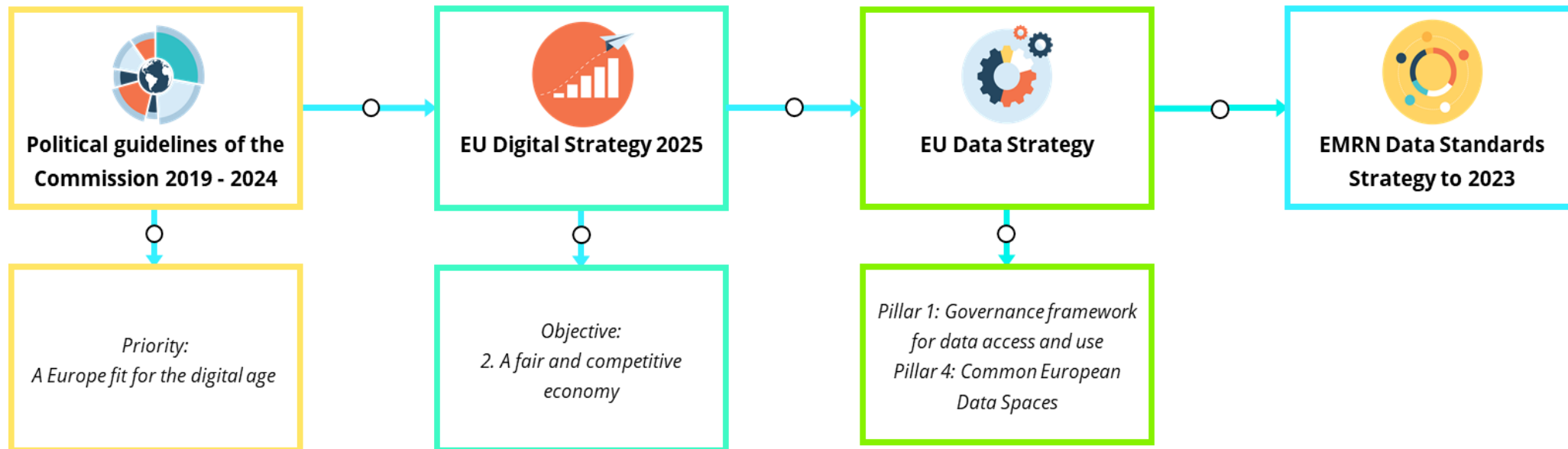


## Data Standardisation Strategy

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

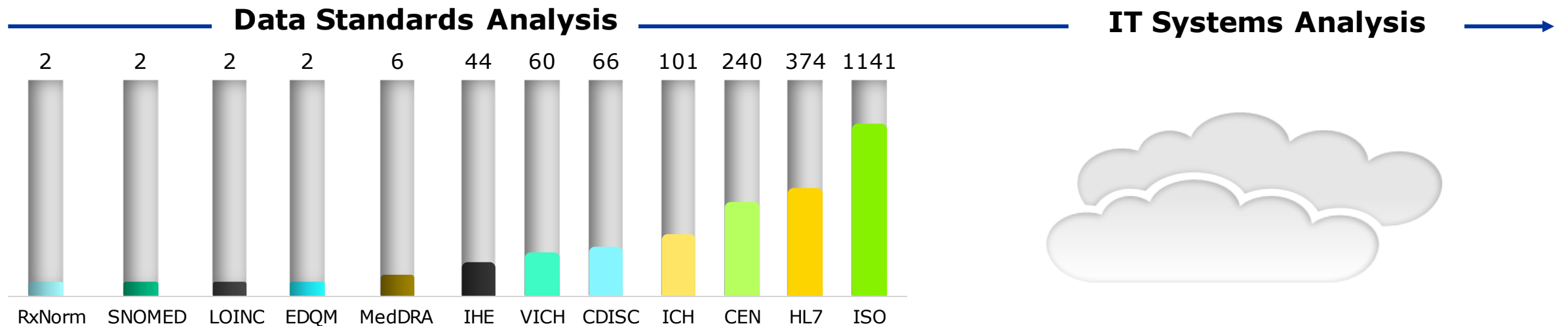
# Data Standardisation Strategy | Strategic direction

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 EMRN.



**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.

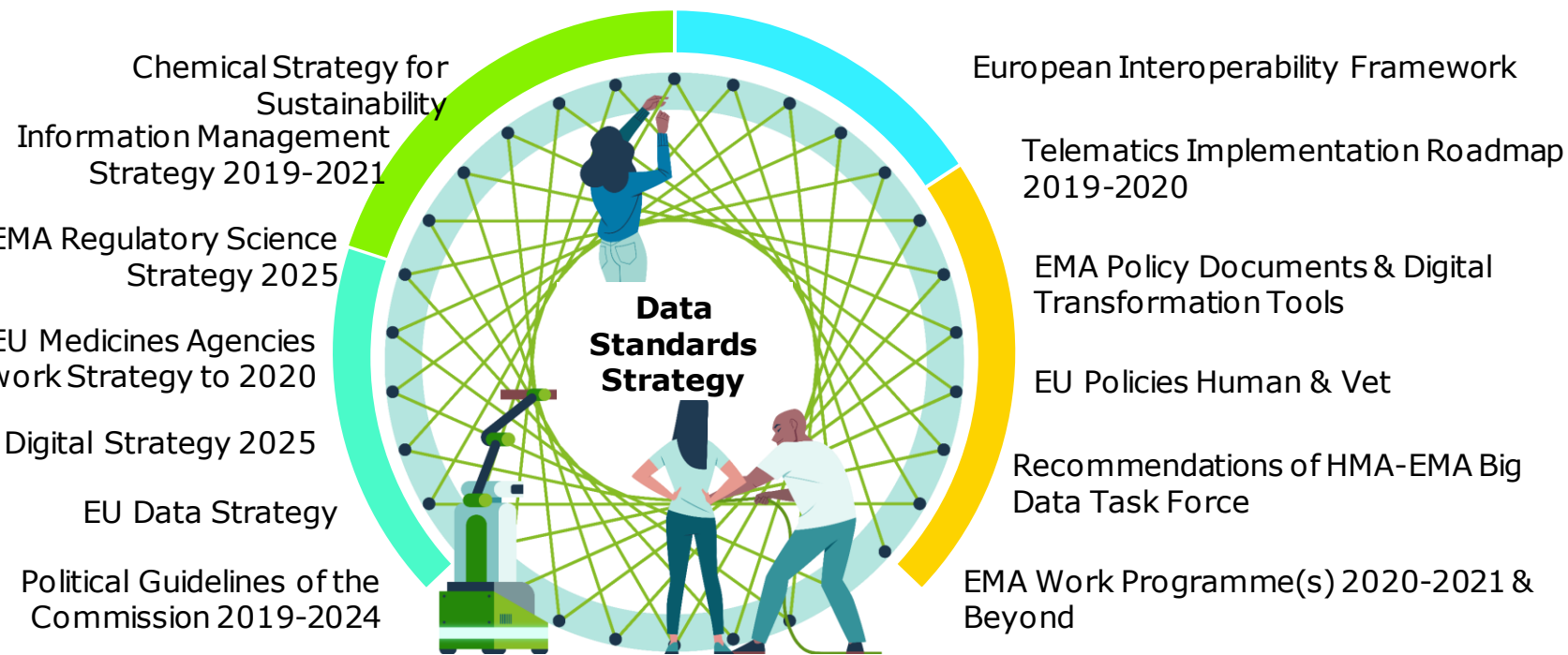
**40 IT systems** in use in regulation of medicines at EU level have been considered as part of the IT Systems landscape analysis.

# 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 EMRN.

## Background Documents\*

## 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

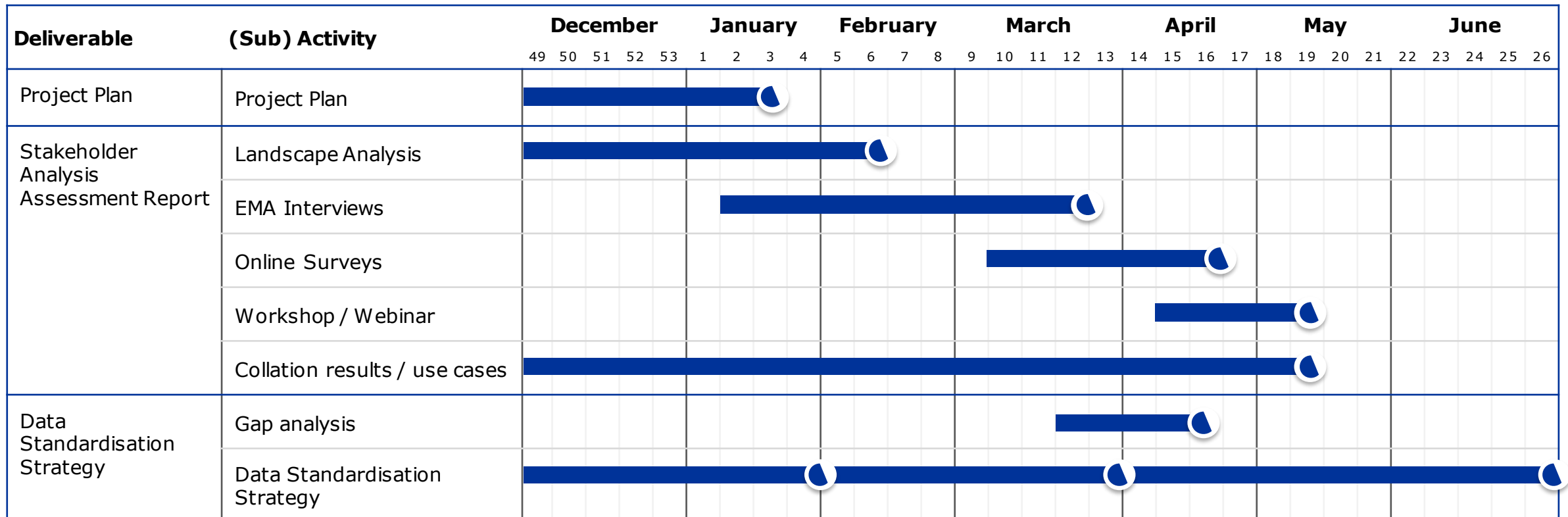
\* Please note that this is a non-exhaustive overview

# Data Standardisation Strategy | Current Status



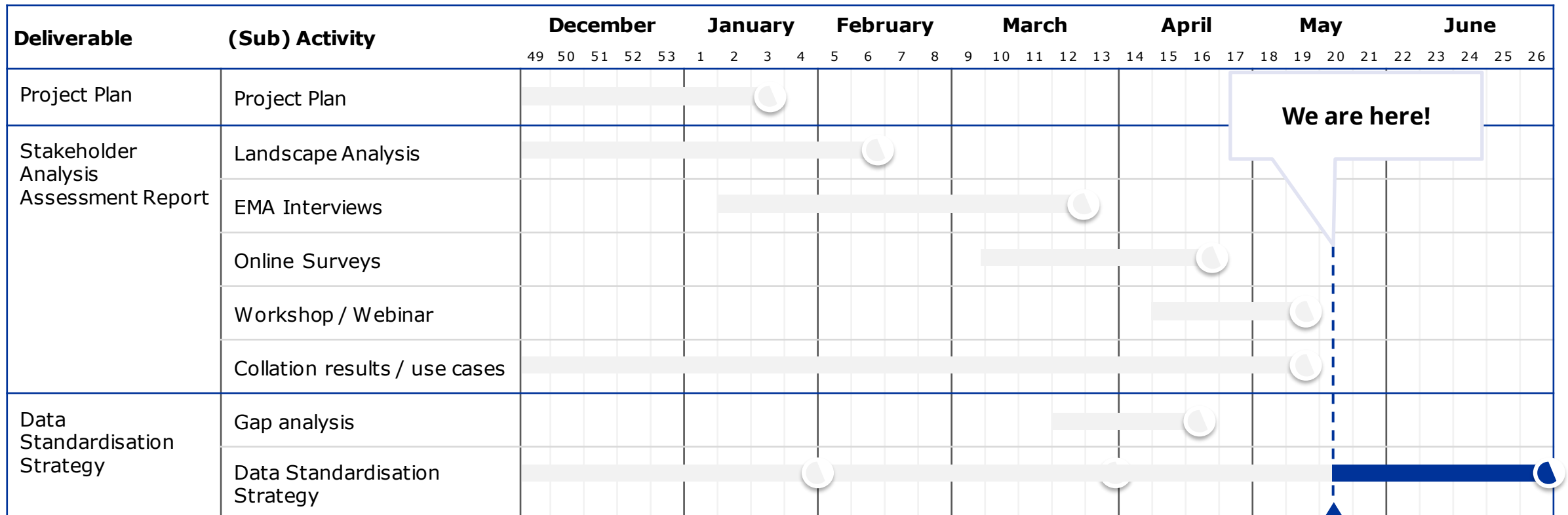
Activity



Milestone



# Data Standardisation Strategy | Current Status

 Activity   
 Milestone 




# Data Standardisation Strategy | Current Status

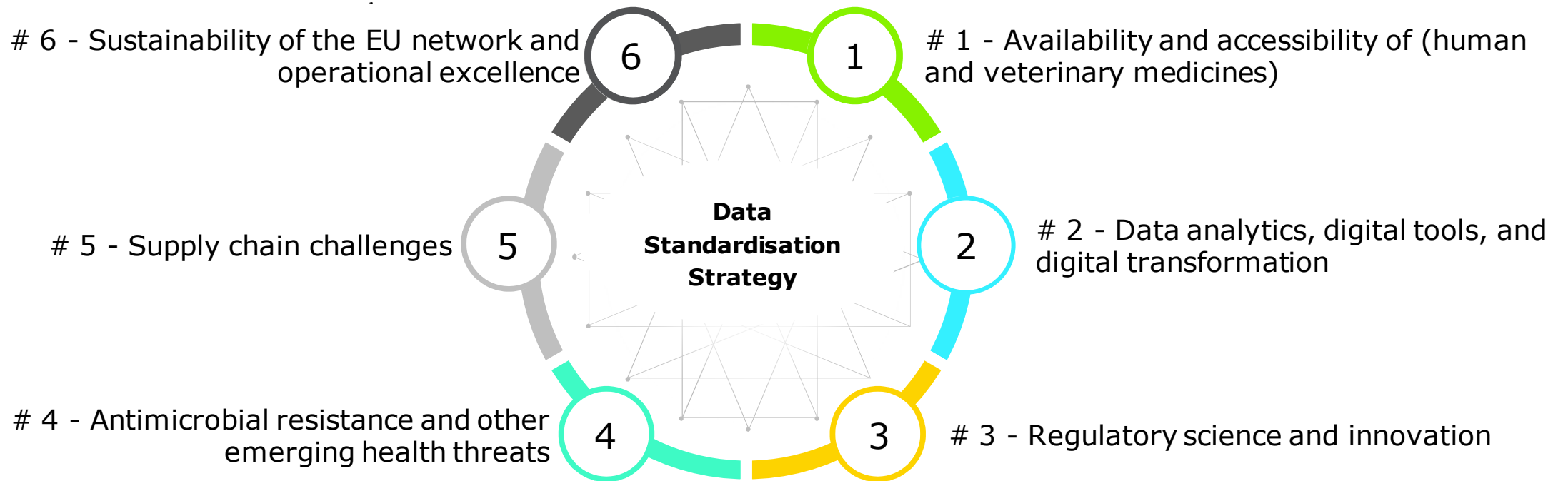
The Data Standardisation Strategy document will contain the following sections;

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

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# Data Standardisation Strategy | Strategic Goals & Objectives



# Next Steps | Following the Data Standardisation Strategy stakeholder workshop

