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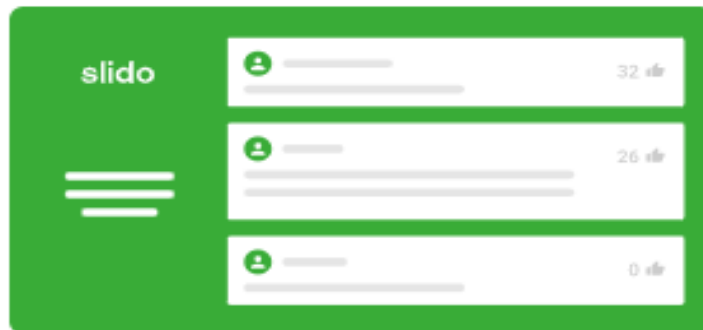
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**Questions not addressed during  
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**subsequent webinars** and/or in  
**FAQ** document in SPOR Portal



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## SPOR Data Governance

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17 April 2023

SPOR Week – 17-20 April 2023

SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
 <a href="#"><u>SPOR Data Governance</u></a>	17 April 2023	10:00-12:00 CET
<a href="#"><u>Service Desk for SPOR and XEVMPD</u></a>	17 April 2023	14:00-16:00 CET
<a href="#"><u>Referentials Management Service (RMS)</u></a>	18 April 2023	10:00-12:00 CET
<a href="#"><u>Organisation Management Service (OMS)</u></a>	18 April 2023	14:00-16:00 CET
<a href="#"><u>Substance Management Service (SMS)</u></a>	19 April 2023	10:00-12:00 CET
<a href="#"><u>Product Management Service (XEVMPD)</u></a>	19 April 2023	14:00-16:00 CET
<a href="#"><u>Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</u></a>	20 April 2023	10:00-12:00 CET
<a href="#"><u>EMA Account Management</u></a>	20 April 2023	14:00-16:00 CET



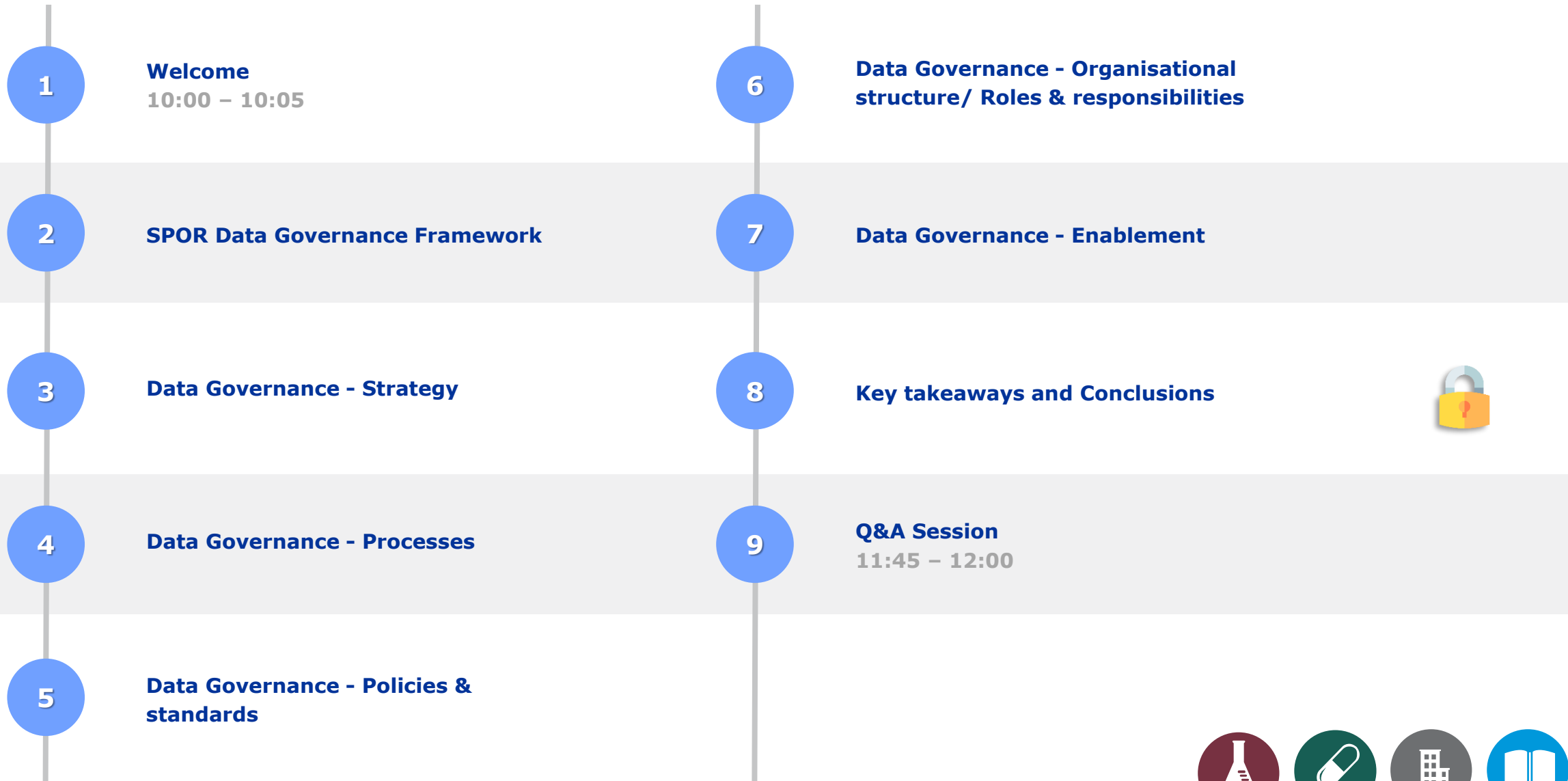
Explain how SPOR data is governed



Provide context for the other topics of SPOR week



Explain how the Agile transformation has changed data governance





# SPOR Data Governance Framework

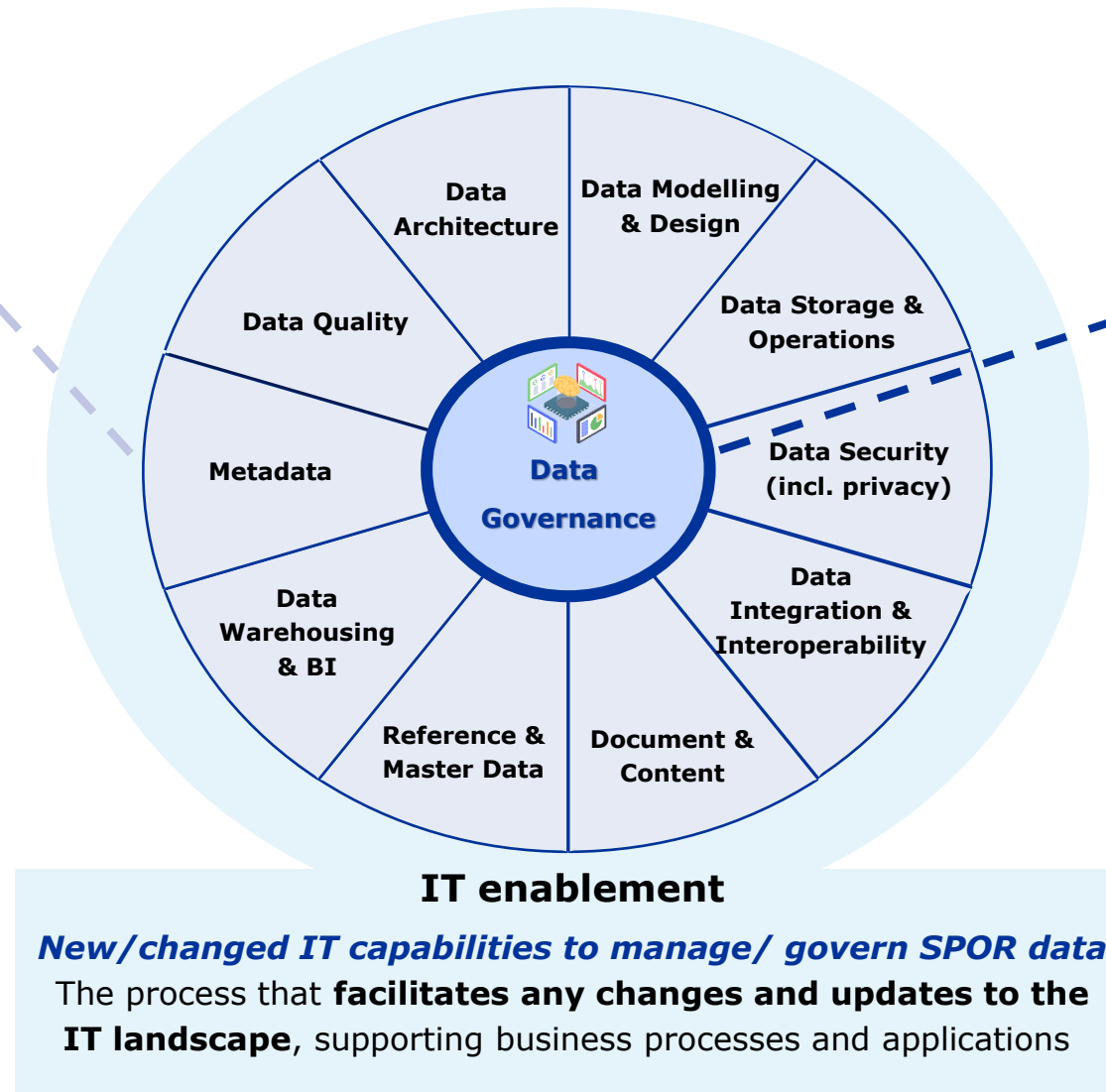
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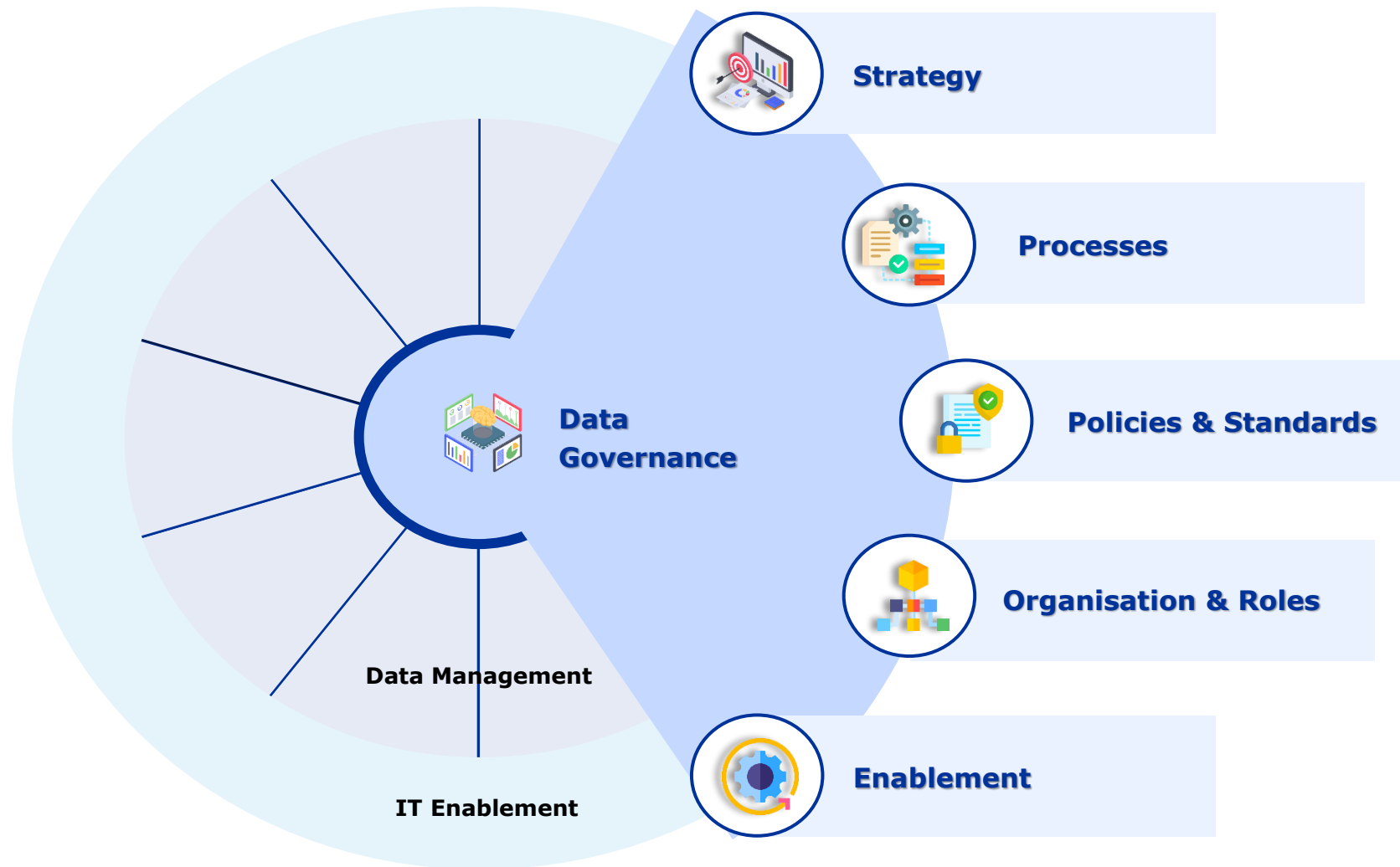
## Data Management

*Day to day management of SPOR data as agreed*

The development, **execution and monitoring** of initiatives, policies, applications and processes that deliver, control, protect and enhance the value of data and information assets throughout their lifecycle









**Strategy** Provides focus and a high-level course of action towards high-level goals on data



**Processes**

- Provide operating models for data management in business operations.
- Provide processes for consistent and adequate processing of data



**Policies & Standards**

Provide principles that structure how data is handled through its lifecycle in day-to-day operations



**Organisation & Roles**

Define consultation, reporting and decision-making structures



**Enablement**

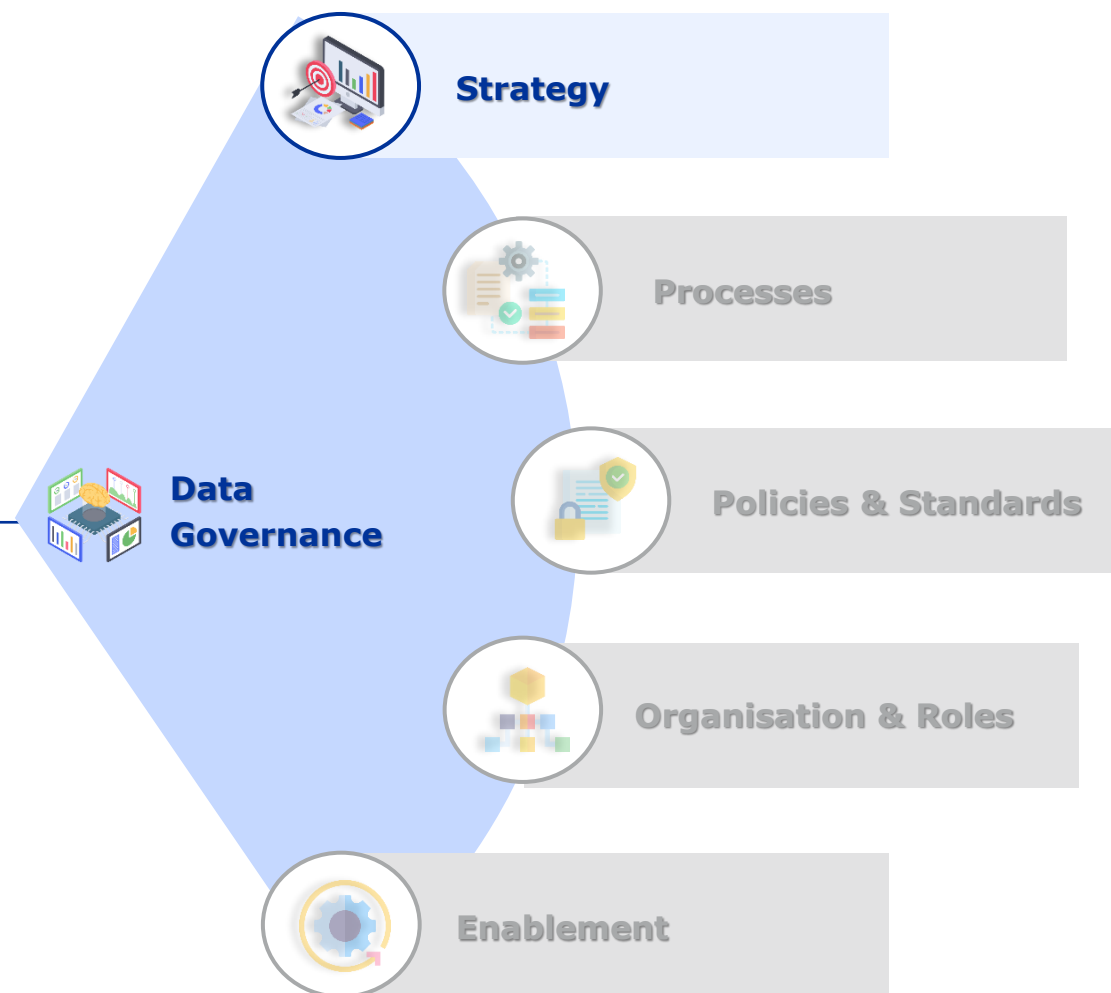
Ensures continuous improvement of data management and builds a data-driven culture



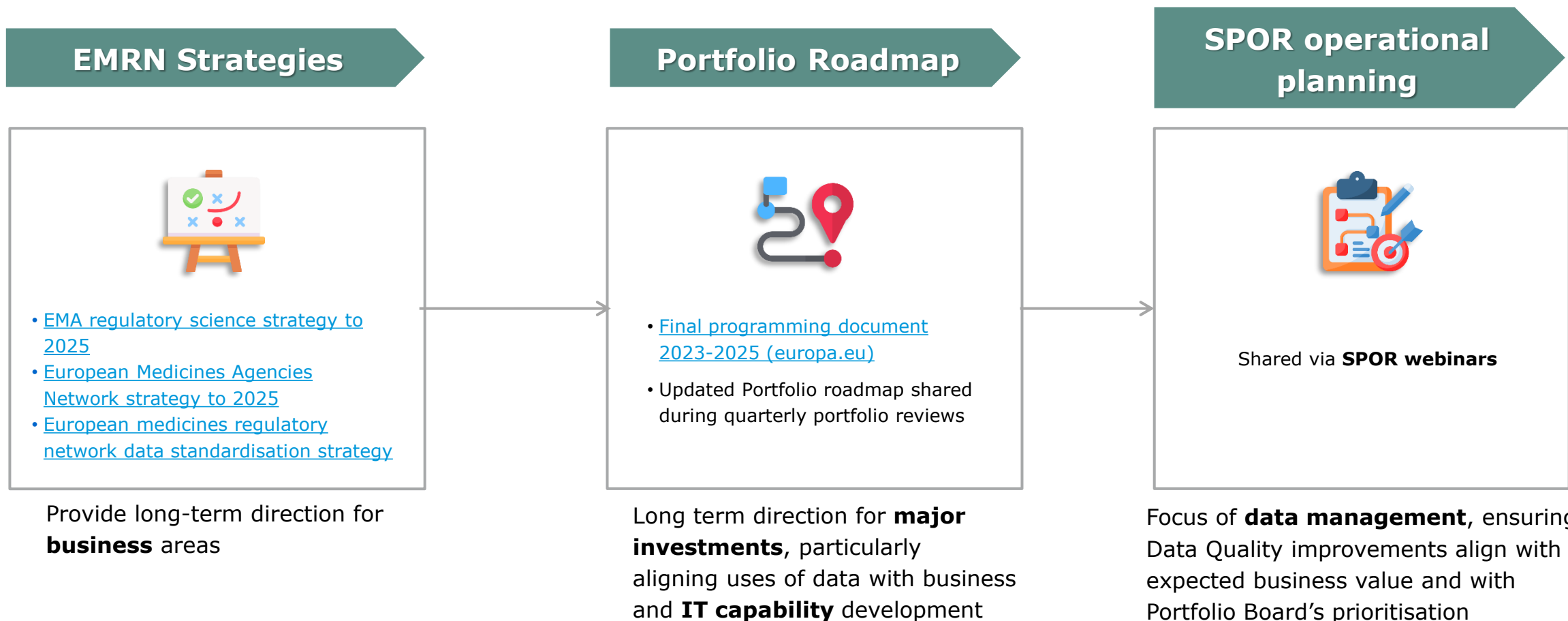
**Data  
Governance**



# Strategy



EMA provides master data quality services on **Substances, Products, Organisations and Referentials** that enhance the quality of the medicinal product data used by the Network, the pharmaceutical industry and other stakeholders and **support regulatory activities in EU.**



## Long-term direction for business areas

### EMRN Strategies



- [EMA regulatory science strategy to 2025](#)
- [European Medicines Agencies Network strategy to 2025](#)
- [European medicines regulatory network data standardisation strategy](#)

➤ EMA regulatory science strategy to 2025 → **SPOR supports the key goals** of the strategy

➤ European Medicines Agencies Network strategy to 2025 → **SPOR is specifically referred to in 5 of the 6 priorities** of the strategy

- **Availability and accessibility of medicines**
- **Data analytics, digital tools and digital transformation**
- **Innovation**
- Antimicrobial resistance and other emerging health threats
- **Supply-chain challenges**
- **Sustainability of the network and operational excellence**

➤ European medicines regulatory network data standardisation strategy → Contains a chapter dedicated to **SPOR/IDMP and standardisation of Medicinal Product data**

## Aligning uses of data with business and IT capability development priorities

### Portfolio Roadmap



- [Final programming document 2023-2025 \(europa.eu\)](#)
- Updated Portfolio roadmap shared during quarterly portfolio reviews



	Portfolio activities supporting SPOR IT enablement	Example	Portfolio activities driving SPOR operational work	Example
Referentials	None. Major IT enablement completed in 2017	NA	Preparing lists for new solutions	Real World Data lists
Organisation	None. Major IT enablement completed in 2017	NA	Mapping & registration of new organisations to support onboarding of new stakeholders	Manufacturers of medical devices
Substance	Some IT enablement completed in 2019, remaining work now on Portfolio roadmap	SMS UI – access and transparency around substance data SMS-EU-SRS integration – improved substance data quality	Enrichments of data to support new developments	Antimicrobial Sales and Use (ASU) data reporting
Product	Major IT enablement work now on the Portfolio roadmap	Work on Product management services (PMS) supports other portfolio activities  PLM - Web-based eAF for variations and ePI MON – European Shortages Management Platform	PMS SIAMED & XEVMPD data migration	Data cleansing in CP database (SIAMED) CAP compliance check



## Deliver efficient and effective regulatory data services

- Maintain and improve **customer services**
- Maintain and improve **data management services**
- Maintain and improve **data quality**



## Improve customer satisfaction and success

- Provide **easy to use documentation** for customers
- Showcase the **value** of data and data services



## Modernise Data & Information Management

- Support **Information Management Modernisation**
- Enable **prioritised IT work** with data, e.g. eAF, IRIS, ePI, shortages



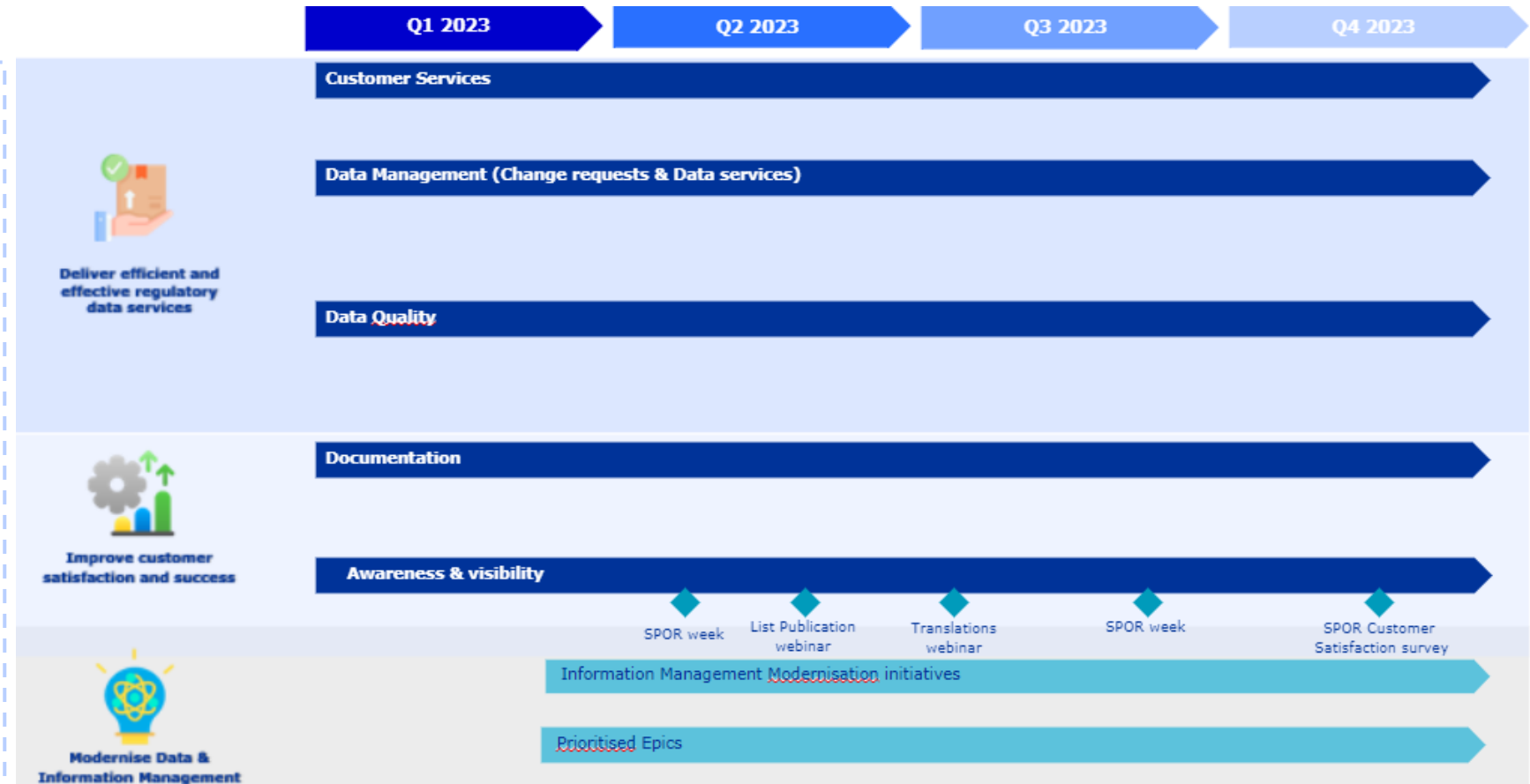
### Objectives

Data Management

Data Governance &  
IT enablement

## *Ensuring Data Quality improvements align with expected business value and with Portfolio Board's prioritisation*

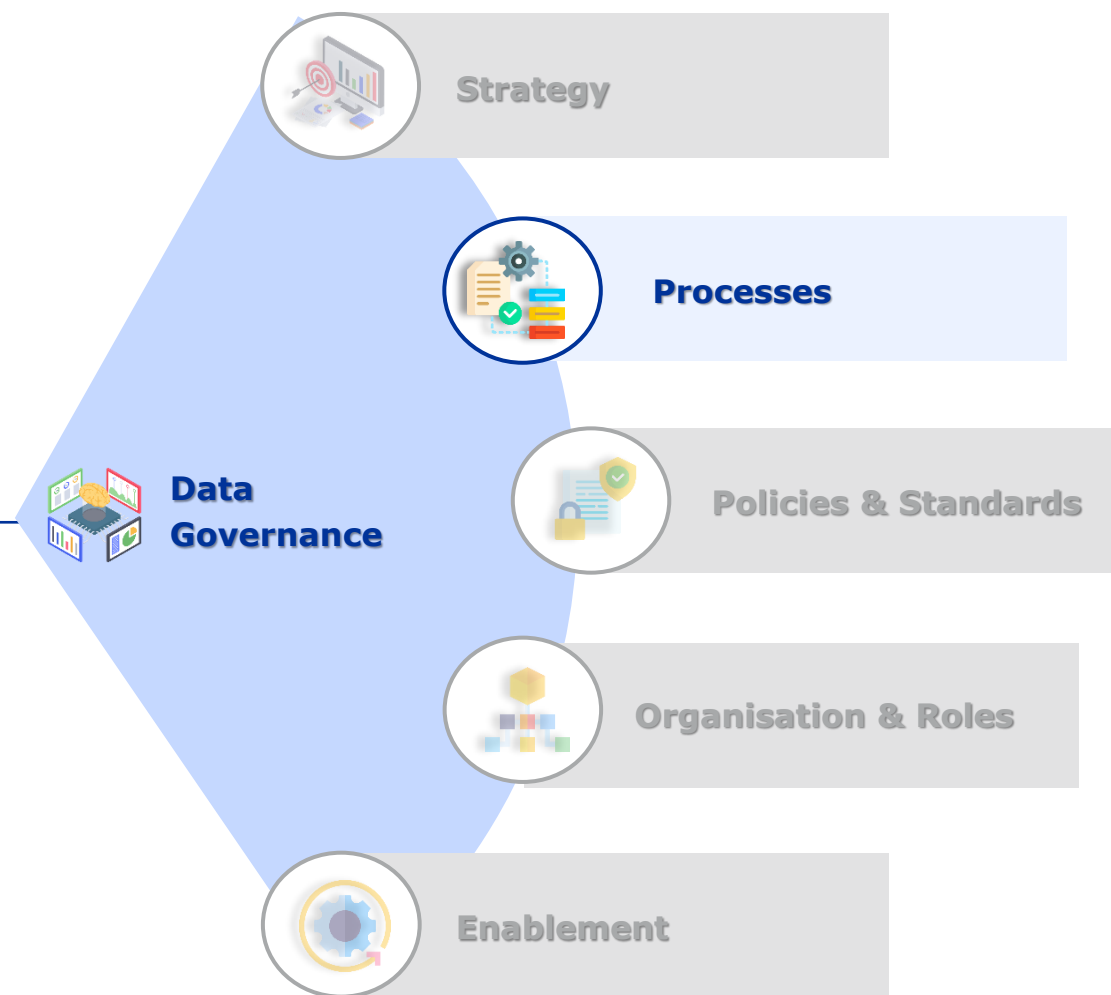
- SPOR data service **objectives** translated into annual operational plans
- 1 plan **per SPOR domain**
- operational plans shared in **SPOR webinars** 2x a year

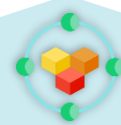






# Processes





## Operating Models

Provide a holistic and agreed upon view of data management activities in the context of business operations

### SPOR Operating Model

Industry and NCAs **pre-register or update SPOR data** before regulatory applications or submissions



Defined and agreed by the **SPOR Task Force** (Human and Vet Industry Associations, NCAs and EMA)

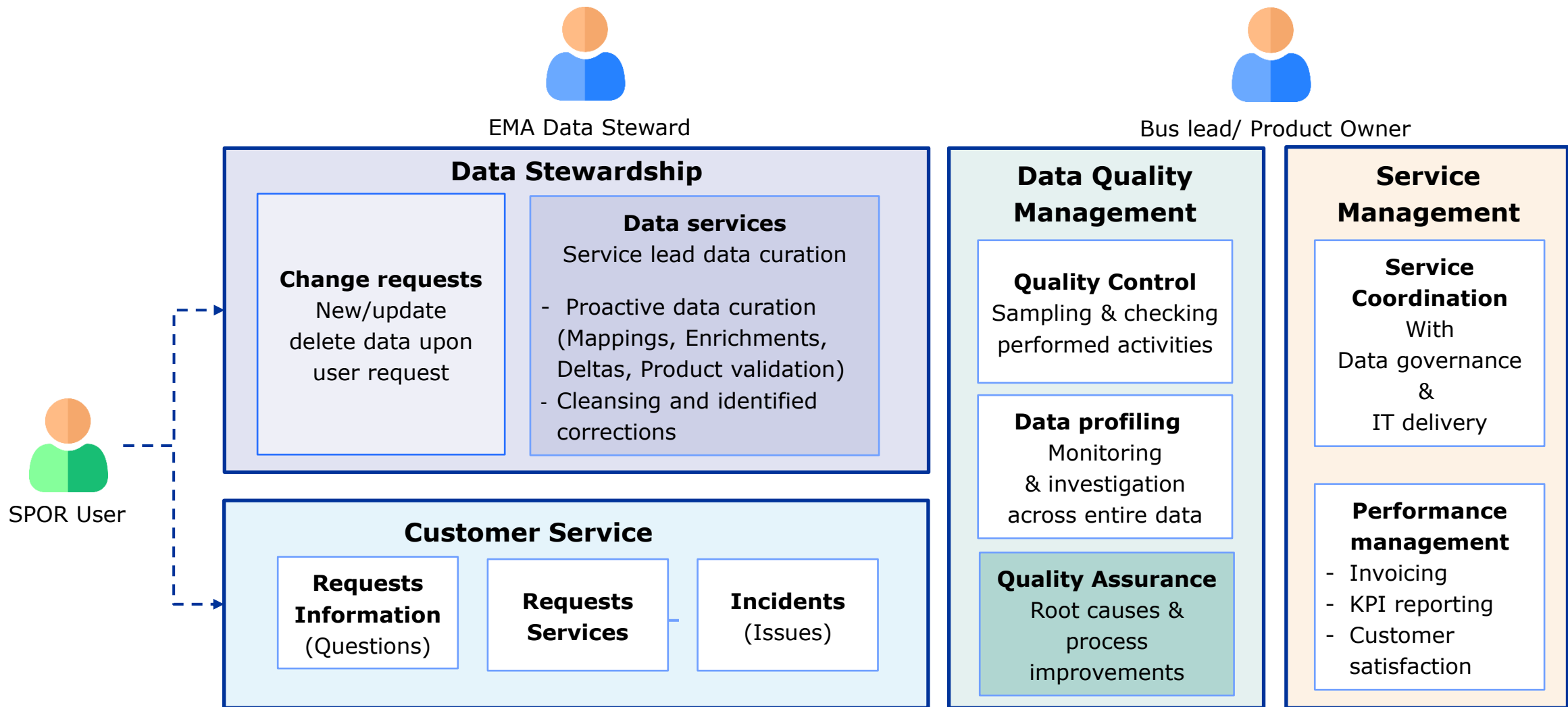
### XEVMPD Operating Model

- Industry **submits authorised product data**;
- EMA requests Industry to **standardise data** or EMA standardises certain elements on Industry's behalf



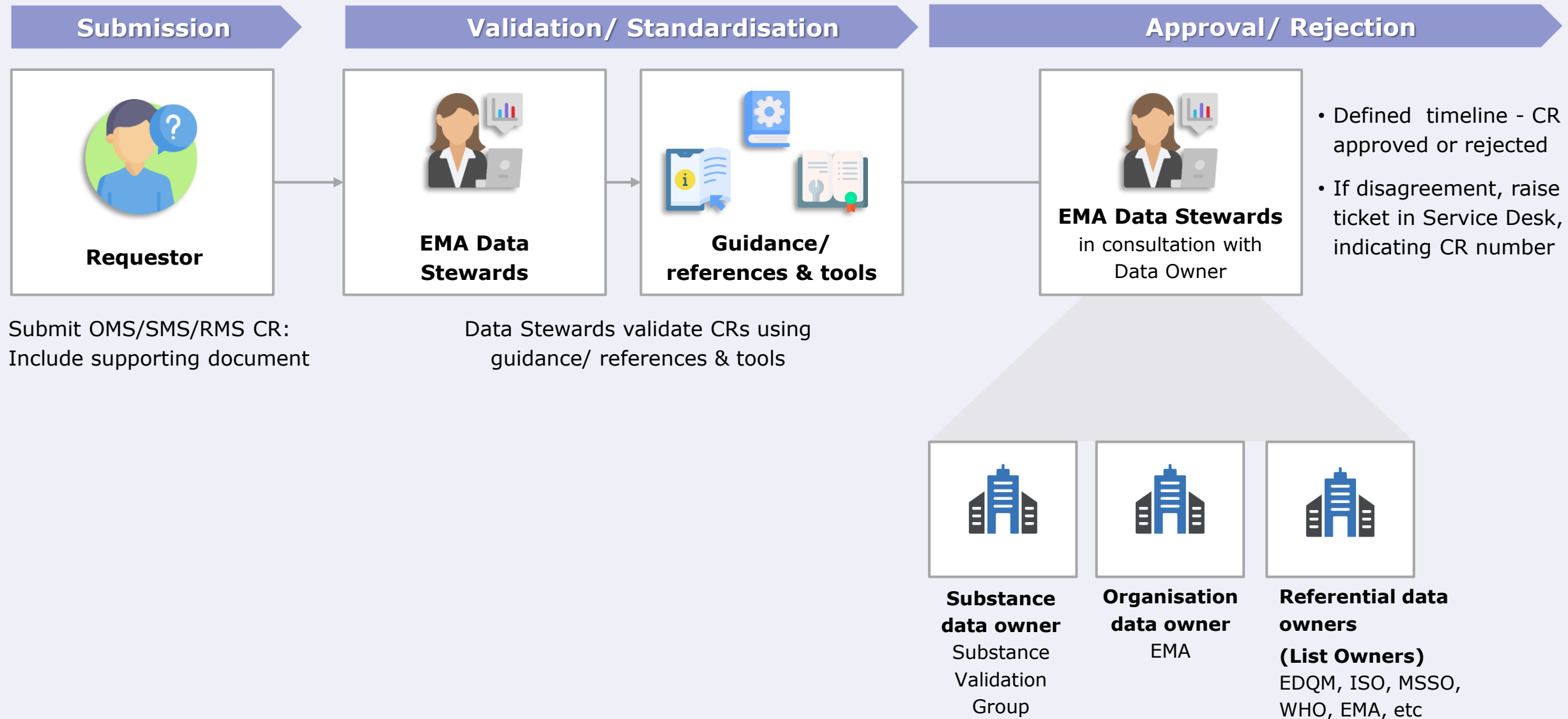
Defined and agreed by **Art 57 Implementation Working Group** (Human Industry Associations and EMA)





Data management processes are defined, operational and are monitored/reported on  
Details for each SPOR domain elaborated in individual webinars this week.

# SPOR Change Request (CR) process at a glance





## Delta Tasks



- **Continuous updates** from major systems and review of changes to data in source system
- **Result: Minimised burden on SPOR users** by removing need for change requests

## Enrichments



- **Proactively completing** SPOR data with reference information
- **Result:** improved data quality in support of regulatory use of data

## SPOR Data Services

## Mappings

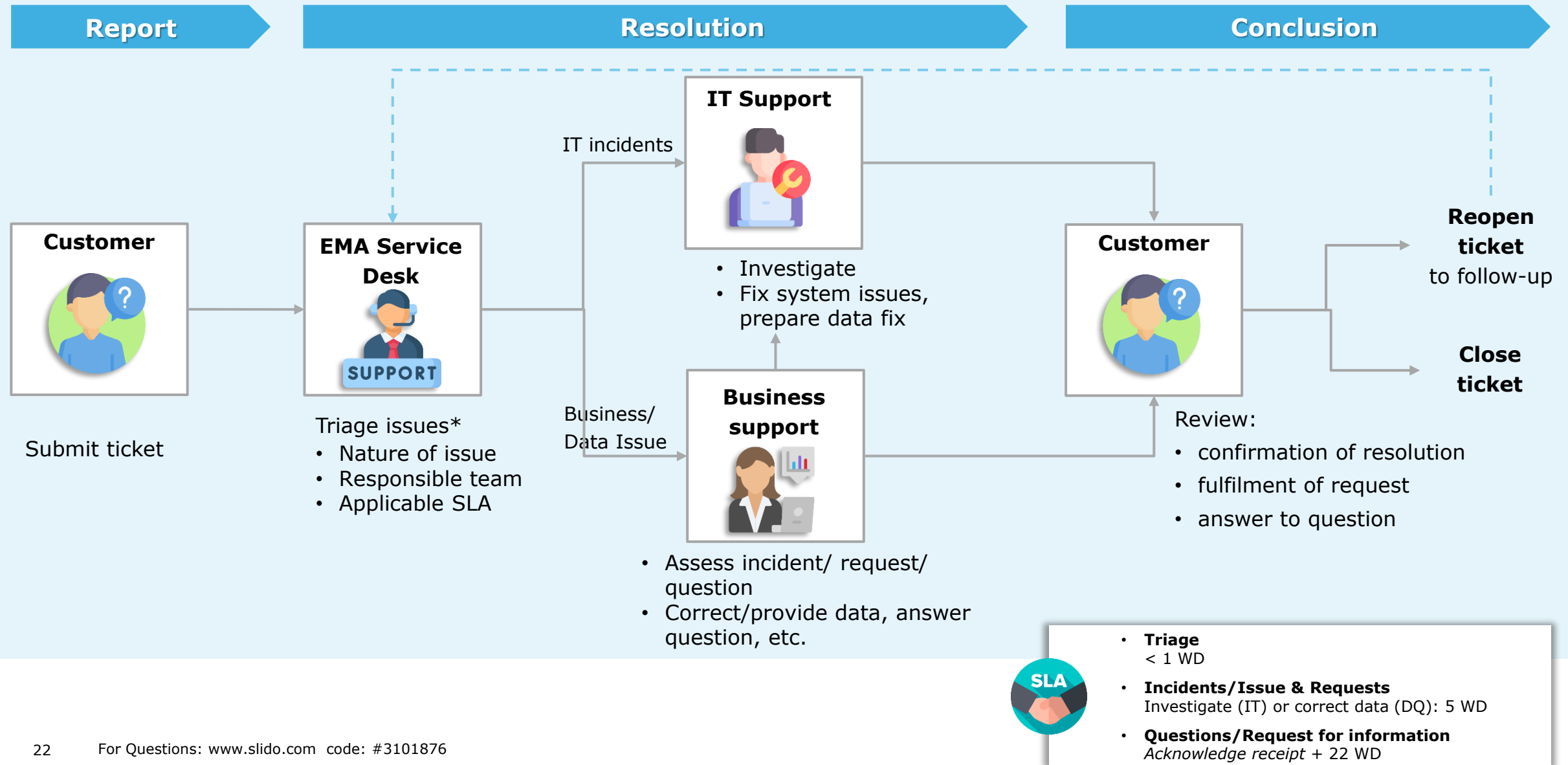


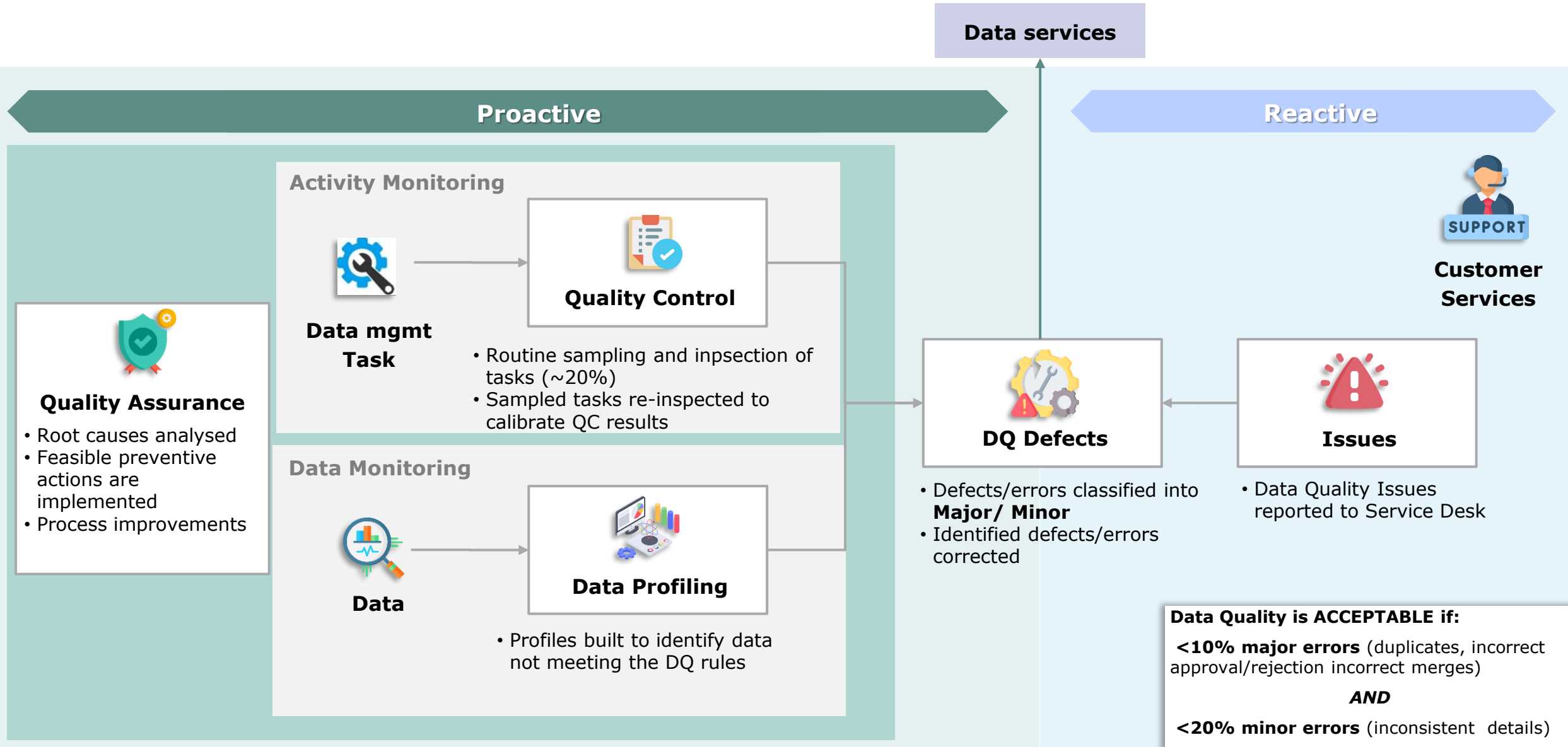
- **Matching data existing in legacy systems to SPOR;** create and update data in SPOR as needed
- **Result: data migrations** enabled and **implementation of SPOR** in other systems enabled

## Cleansing/ corrections



- Review SPOR data to **identify errors in order to correct and standardise** against established reference information
- **Result: Minimised burden on SPOR users** due to improved data quality and avoiding change requests

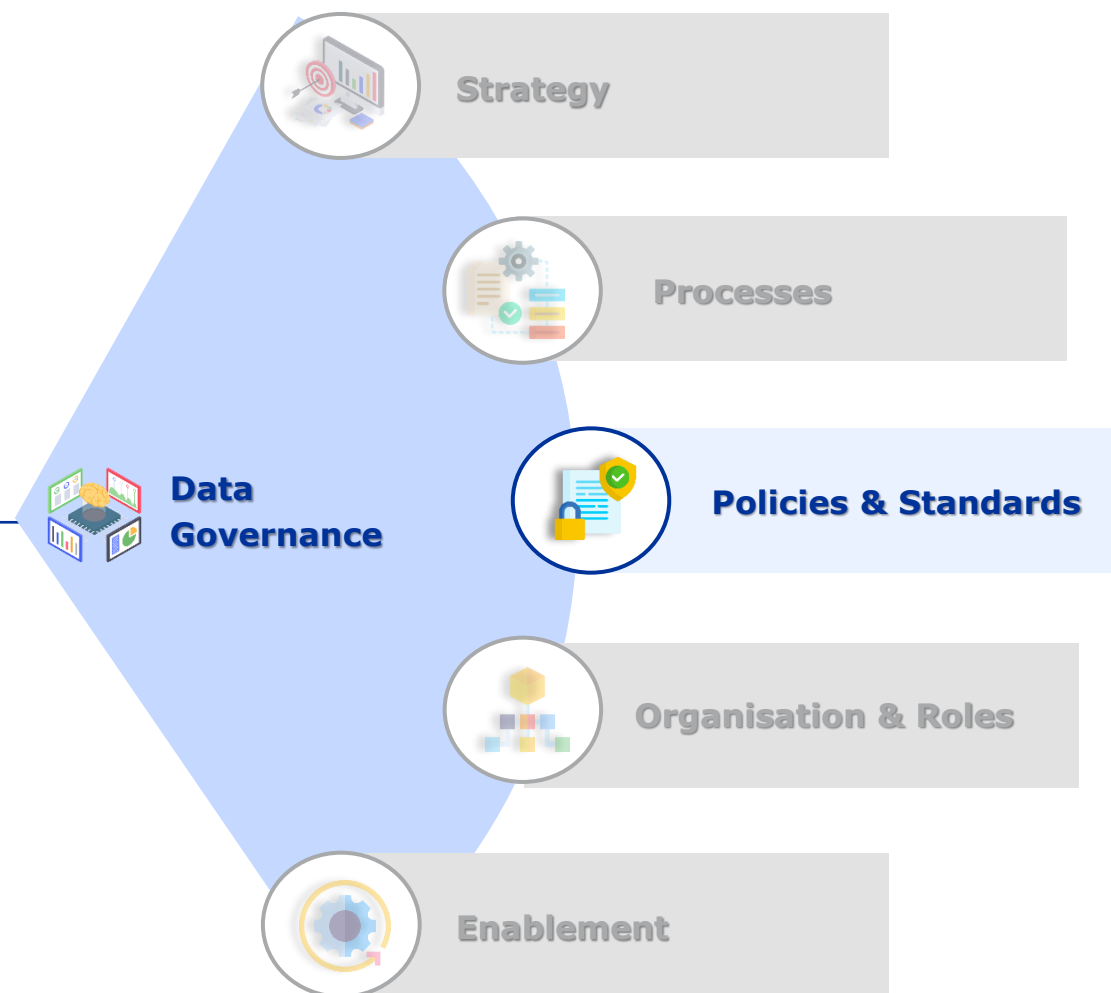








## Policies & standards





- **Policies & Standards**

- provide broad principles of operation
  - give structure to how data handling during its lifecycle in day-to-day operations.
- 
- SPOR applies **International Standards** (ISO IDMP and FHIR)
    - International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
    - HL7 Messaging Specifications: messages used to exchange IDMP information, based on HL7 (Health Level Seven) Standards particularly [Fast Healthcare Interoperability Resources](#)
  - SPOR applies [EMA policies](#)
  - SPOR **policies and data quality rules** are defined in **domain specific documentation**  
e.g., OMS DQ rules, RMS list information, XEVMPD guidance
  - Domain specific policies and rules further elaborated during **SPOR webinars**

## SPOR portal & EV restricted area

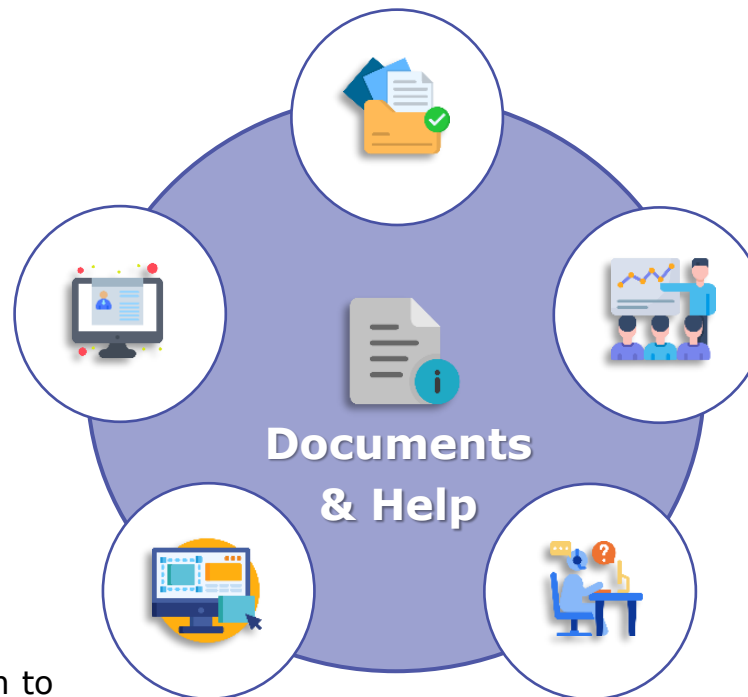
- SPOR reference documentation - primary documentation needed to successfully use SPOR services
- XEVMPD user support section – technical documentation

## EMA Account Management Portal

- Guidance on to obtain access to EMA systems (including SPOR)
- Create a new EMA account and request SPOR user role

## EMA corporate website

- SPOR vision and general introduction to SPOR projects
- SPOR related information and documents
- XEVMPD data submission requirements



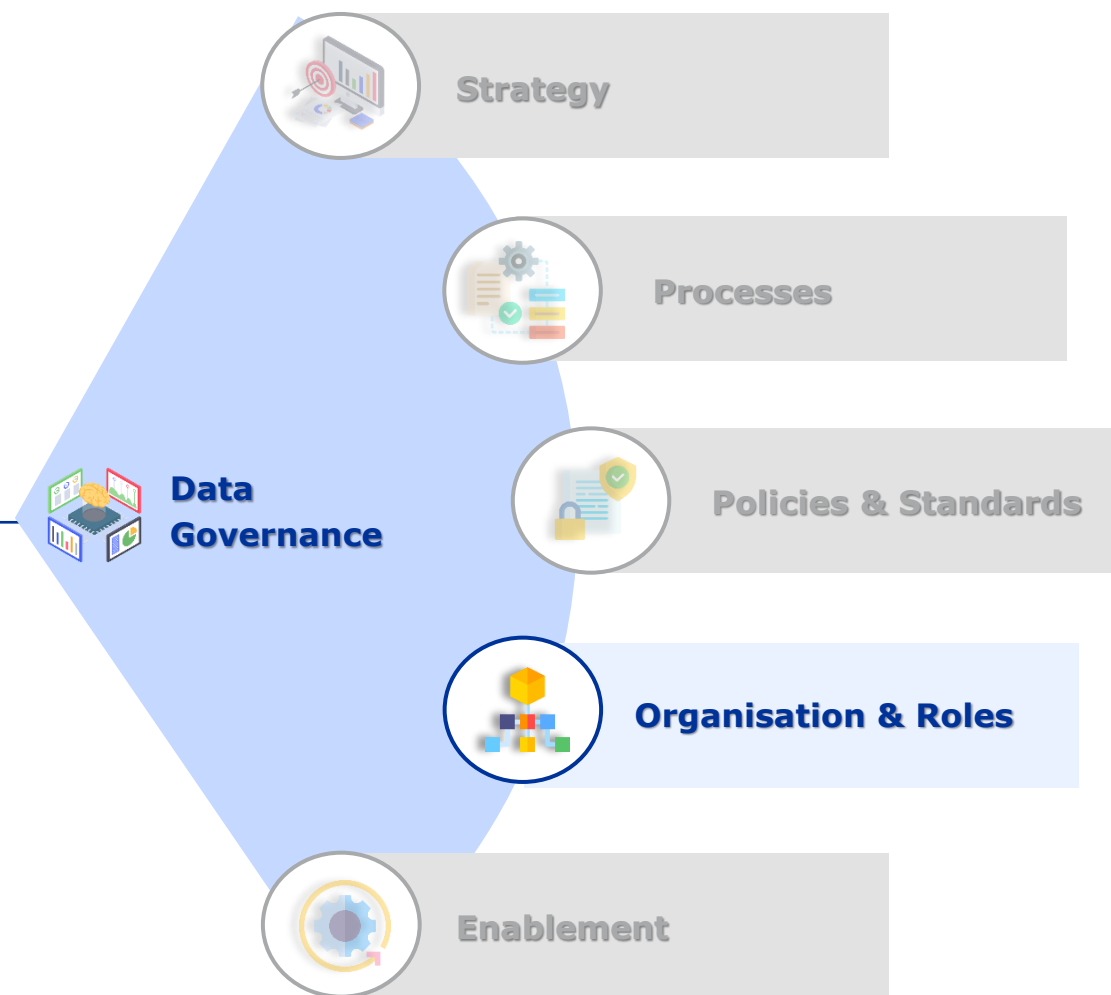
## Training opportunities

- [@emainfo channel](#) contains Videos of SPOR webinars with tips/tricks and questions raised from users
- [XEVMPD e-learning](#) available
- [XEVMPD training organised by DIA](#)

## EMA Service Desk

- For any help needed and not found in other documents
- Including: Service requests, issues, requests for technical support
- submitted through the [ServiceNow Portal](#)

## Organisational structure/ Roles & responsibilities





**Organisational Structure, Roles and responsibilities provide a model in which the stakeholders, reporting and decision-making lines are clearly defined**



## Data Management

**Accountability, responsibility and delivery** of SPOR data management services, ensures that data processes, policies and standards are in place, are being followed



## Data Governance

**Controls** (planning, monitoring, and enforcement) the **management** and **use** of data assets



**Until 2022**

The **SPOR Taskforce, stakeholder groups and focus groups**



**2023 onwards**

**SPOR Key user group** focusing on **data governance of SPOR services** once in operations (not IT delivery) is kept



## IT delivery

**Delivers new capabilities/features** to manage and govern data assets

SPOR **IT delivery governance bodies** transition to **Agile governance**

# Organisation, roles and responsibilities – who does what?



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## SPOR Data Management

### Day to day management of SPOR data as agreed

#### Service Owner & Manager

- Accountability
- Responsibility

#### EMA Data Stewards

- Execute Data mgmt processes (Data stewardship, DQ mgmt, Customer services)

#### SPOR Business Lead

- Collects DQ/process input via EMA service desk/CRs
- Implements changes to SPOR data mgmt



## SPOR Data Governance

### How SPOR data is managed

#### Key User Group

- Collects input from users
- Advises on changes to SPOR data mgmt (Strategy, Process, Policies & standards/ DQ Business rules, comms/CM)

#### SPOR Business Lead

- Decides **small changes** to SPOR data mgmt – changes have no significant impact

#### EU NDB

- Decides on **major changes** to SPOR data mgmt – changes have significant impact



### SPOR Business Lead/ SPOR Product Owner

- Planning & coordination of data mgmt
- Overview of Data mgmt issues
- Decides minor data mgmt changes
- Overview of demand/needs/IT changes
- Coordinates implementation of new data/IT capabilities

Minor Decisions

Major Decisions



## IT Delivery

### New/changed IT capabilities to manage/ govern SPOR data

#### SPOR Business Lead

- Collects demand/ needs via Process Owners, KUG, EMA service desk

#### VSO & VSM

- Mobilises portfolio

#### PB & NPAG

- Prioritises portfolio

#### EU NDB

- *\*Advise on priority SPOR/ Data new capabilities and IT changes that bring business value through data*



## Data Governance

### How SPOR data is used/ applied in business processes

#### Process Owner (User/ project group)

- Provides data requirements
- Decides how to use SPOR data in its business process/ context

#### SPOR Business Lead

- Collects input via Process Owners and KUG

#### EU NDB

- *\*Advise on process/ data mgmt alignment/ best practices across business areas*



## SPOR Data Management

Day to day management of SPOR data as agreed

### Service Ownership

has overall accountability for SPOR data services and ensures quality and availability of the data services

**Service Owner**

*Head of Information Management*  
Hilmar Hamann

*Head of Core Services*  
Christoph Pillichshammer

**Service Manager**

*Head of Regulatory Data Management*  
Isabel Chicharo

**Data stewardship** ensures that data processes, policies and standards are in place and are being followed

**Substance Business Lead**  
Pedro Batista

**Product Business Lead**  
Marcos Fernandez &  
Veronika Baker

**Organisation Business Lead**  
Debora Martins Braga

**Referentials Business Lead**  
Jaume Gonzalez

**EMA Data Stewards**

**EMA Data Stewards**

**EMA Data Stewards**

**EMA Data Stewards**

**Data ownership** decides how to create/modify the data, share and restrict access to the data

**Substance data owner**  
Substance Validation Group

**Product data owner**  
Industry/MAH

**Organisation data owner**  
EMA

**Referentials data owners**  
EDQM, EMA/BfArm, ISO, MSSO, WHO, EMA



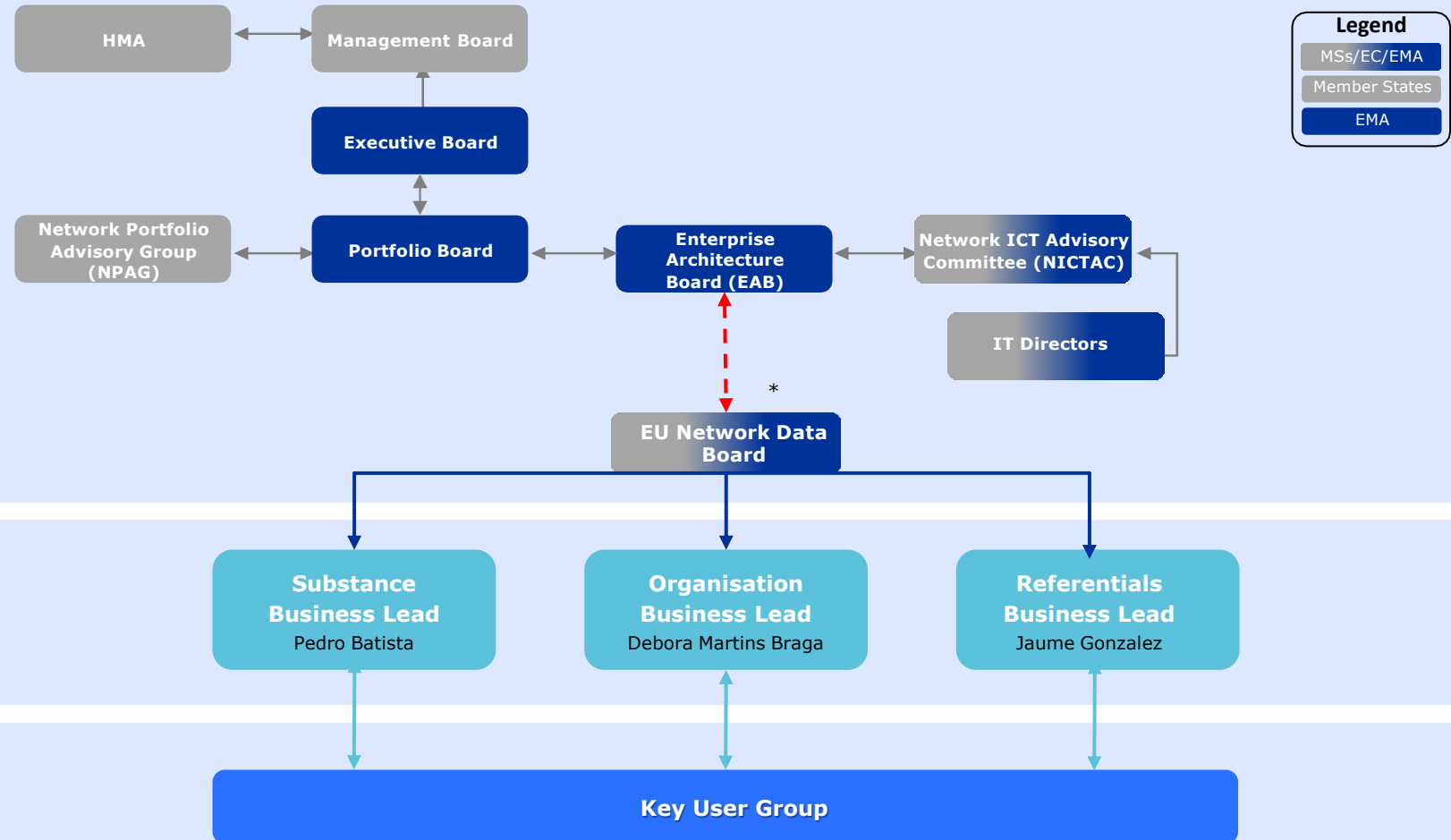
## Data Governance

### How SPOR data is used

**Data Governance** controls the management and use of data i.e. decides on **major changes** to SPOR data mgmt

**Data leadership** ensures agility in data mgmt changes i.e. decides **small changes** to SPOR data mgmt

**User group** ensures stakeholder views are considered

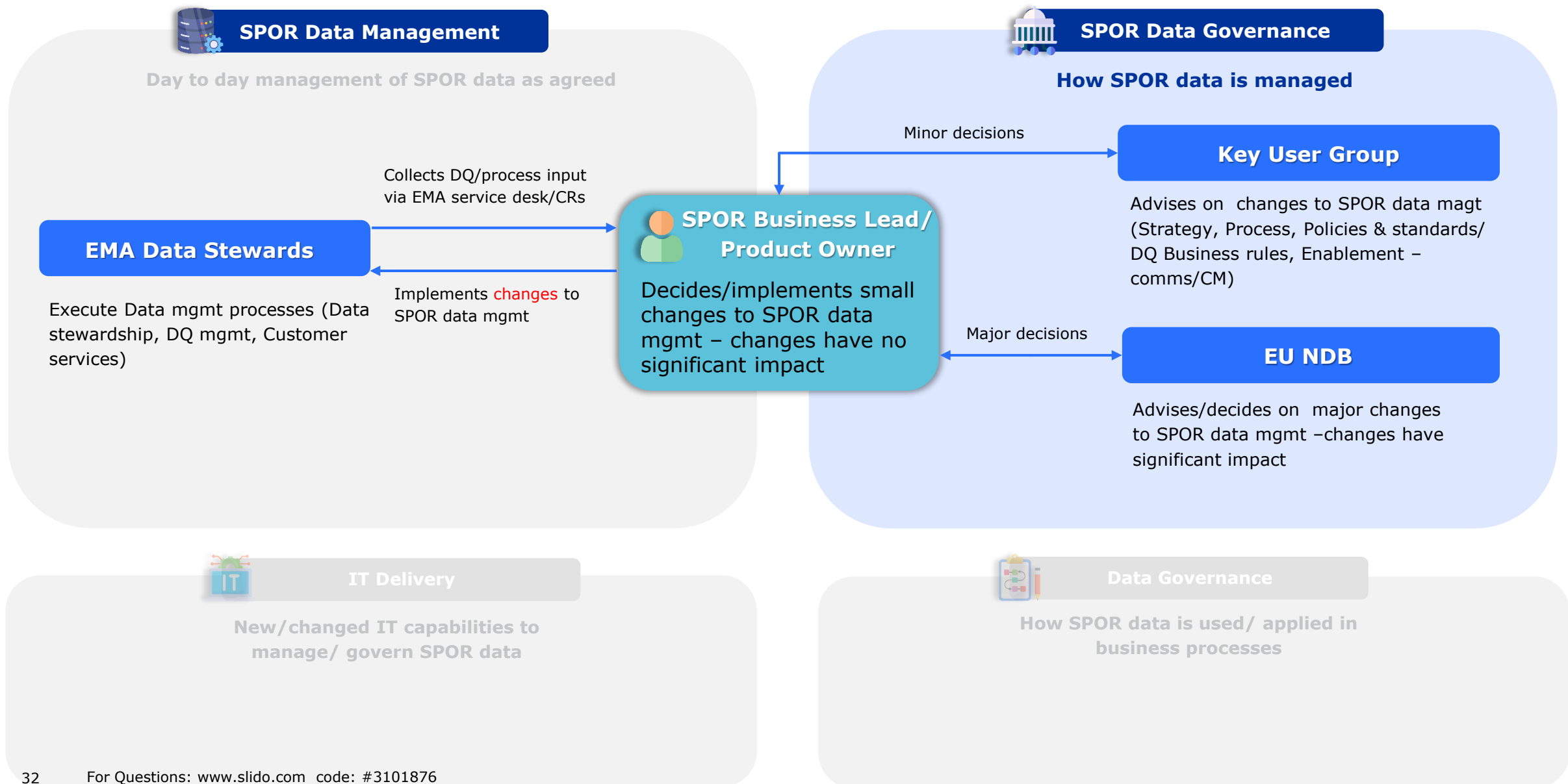




# Flow of events – Governing how SPOR data is managed



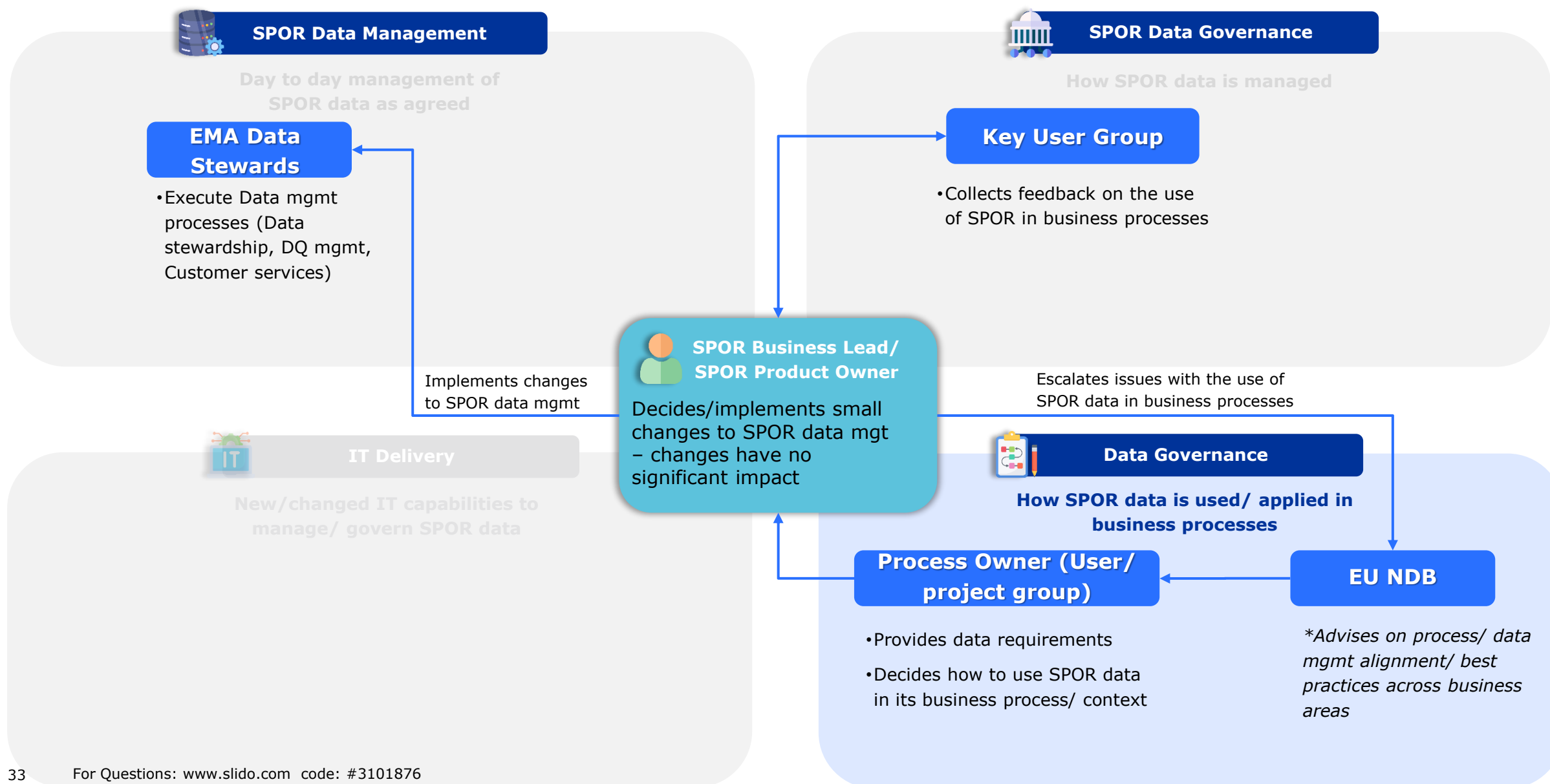
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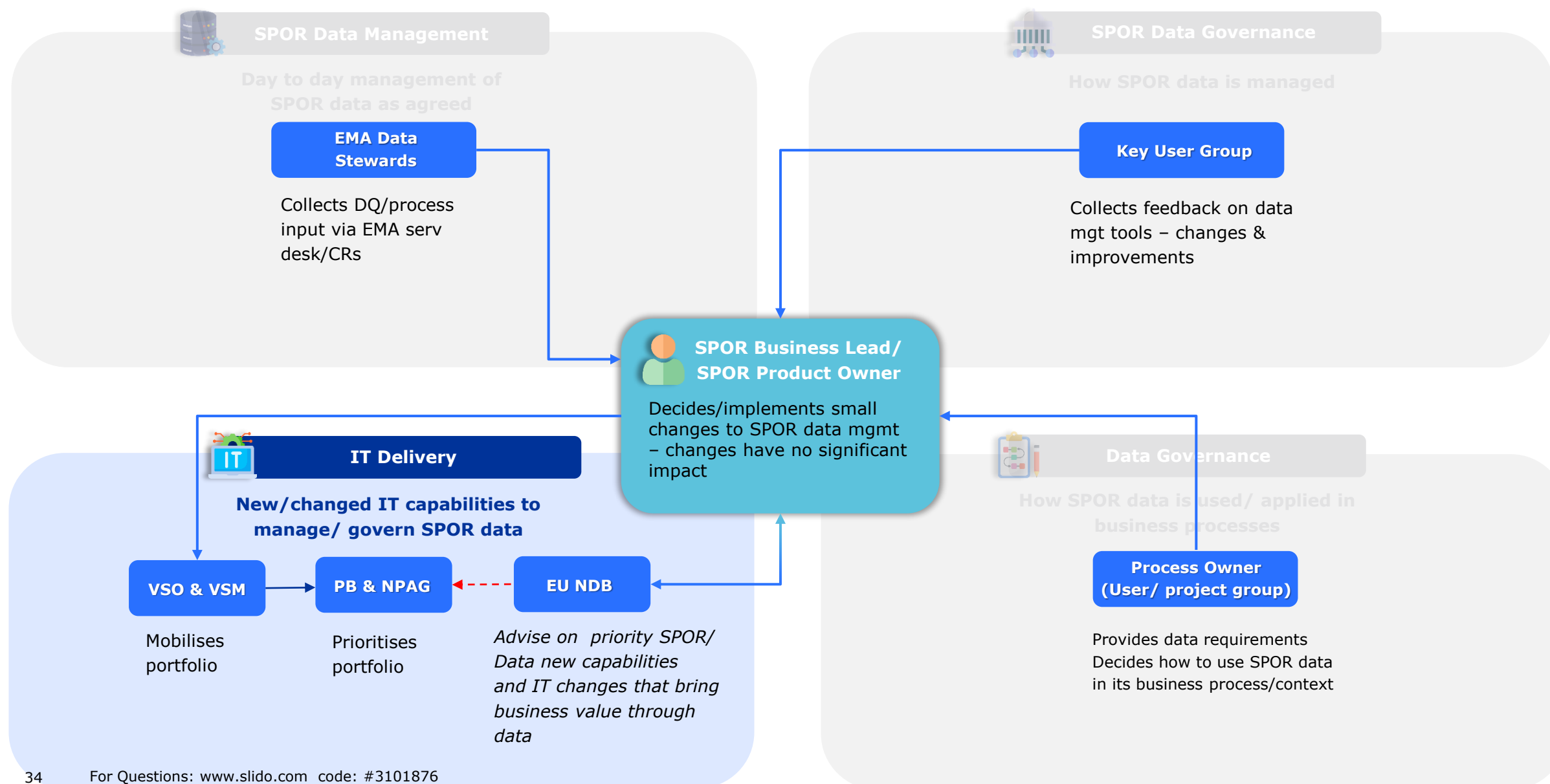


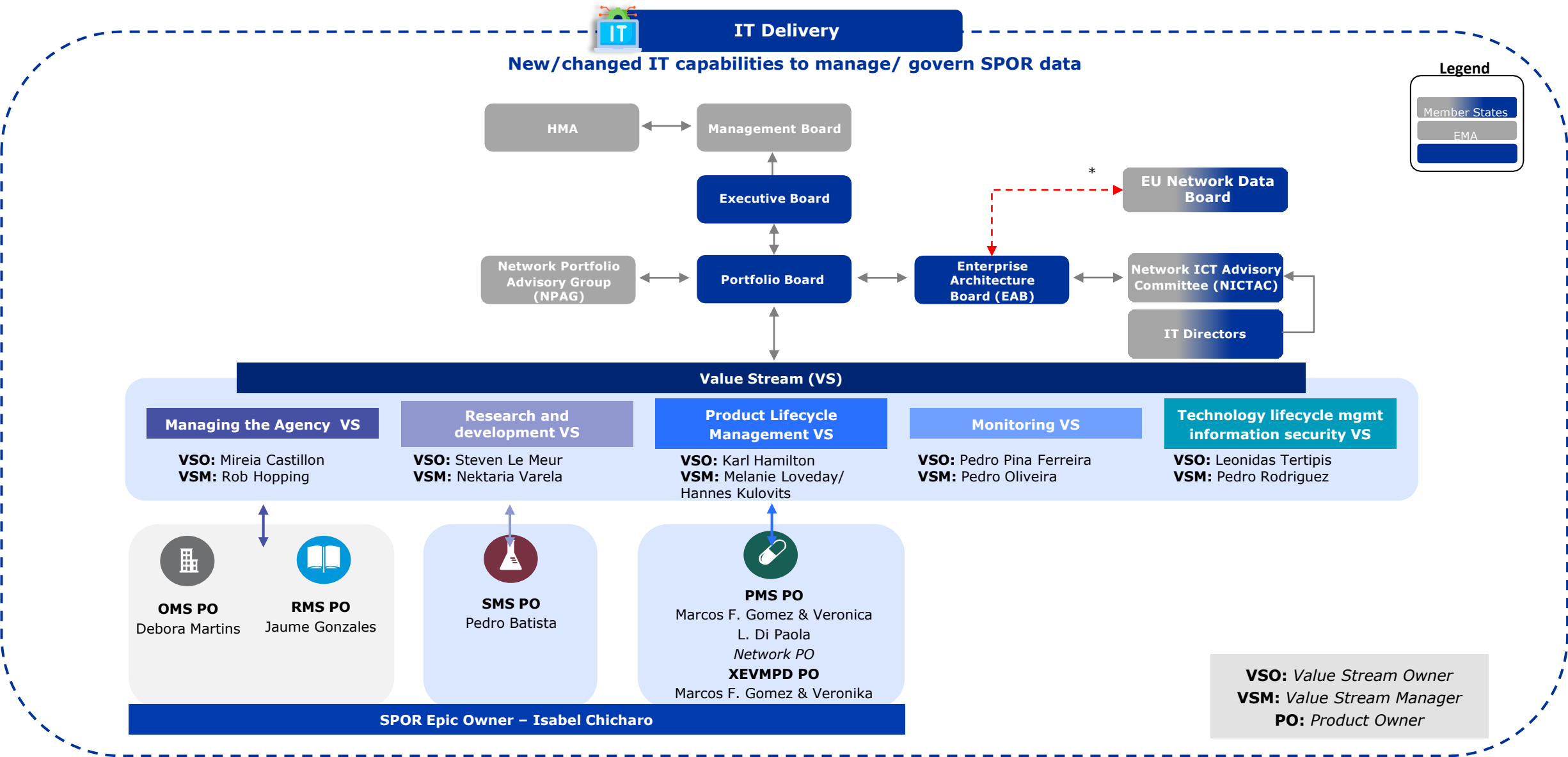
# Flow of events – Governing how SPOR data is used



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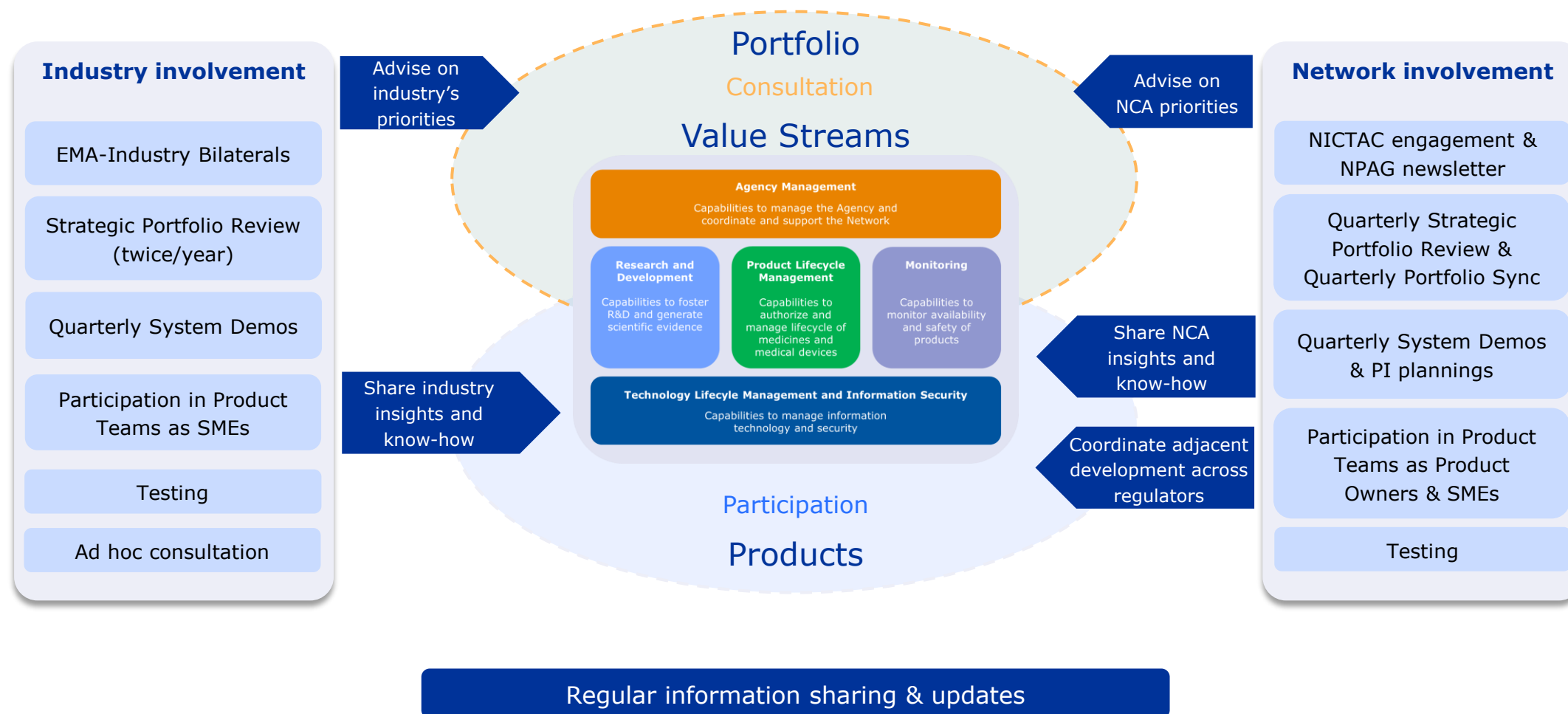






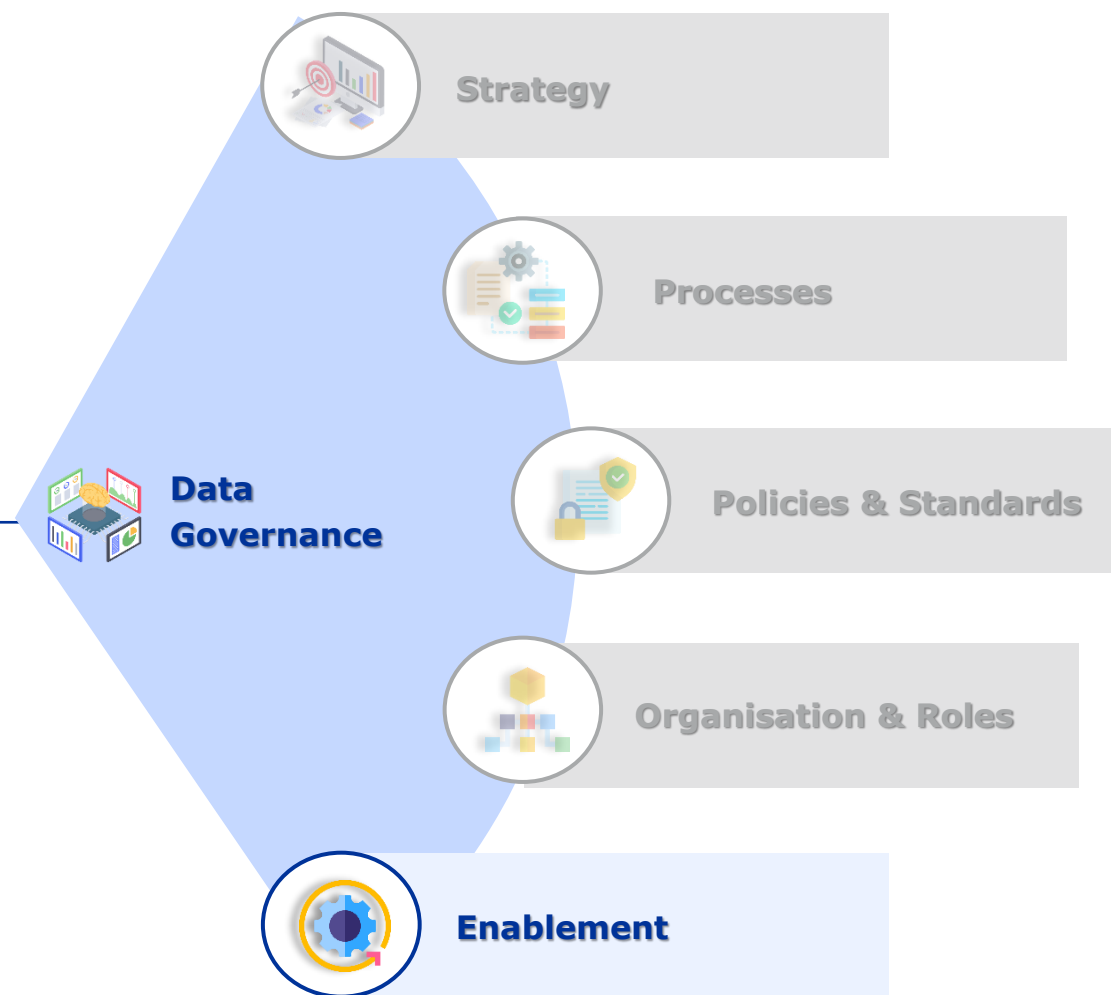
EMA's partners and stakeholders –

Involved and informed to enable you to bring insights on content, needs and priorities





# Enablement



## Continuous improvement

**Key Performance Indicators** (KPIs) defined on:

- **Volumetrics** - what data is managed, growth rates, update rates
- **Data mgmt** - types of activities (CRs, data services, customer services), SLA compliance
- **Service quality** - DQ errors detected & overall level of DQ/activity
- **Data quality** - DQ profiling metrics

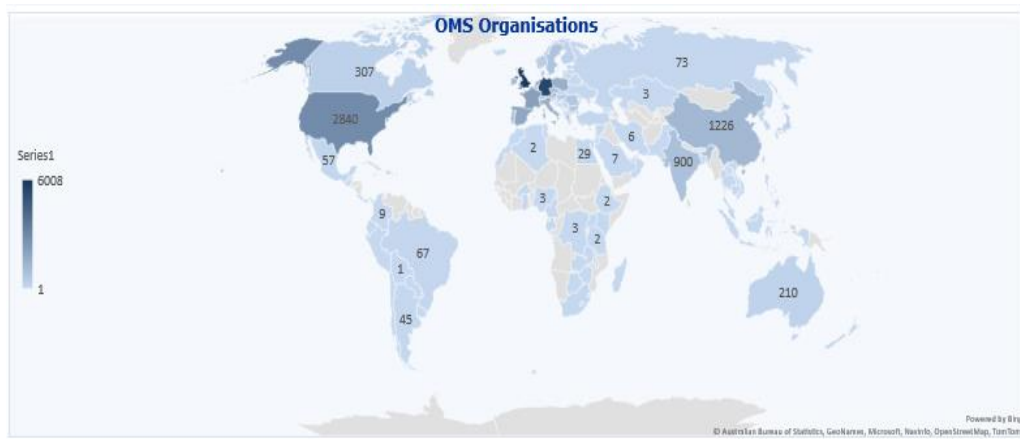
*Monthly/quarterly monitoring and measuring of relevant KPIs*

**Key metrics are shared** with stakeholders for transparency

- Statistics are reported in SPOR webinars 2 times per year and published in SPOR portal
- Aggregated yearly statistics are published with the Customer satisfaction survey in SPOR portal
- Work is ongoing to improve reporting & Business Intelligence capabilities to enhance transparency of data mgmt activities

## Data volume as of January 2023

<b>Substances</b> <b>63.646</b> Substances	<b>Products</b> <b>1.431.78</b> Products
<b>Organisations</b> <b>45.304</b> <b>76.734</b> Organisation s   Locations	<b>Referentials</b> <b>193</b> <b>128.15</b> Lists   Terms



## Change rate in 2022

Growth rate			
<b>Substances</b> <b>1,20%</b> New Substances	<b>2,56%</b> New Names	<b>Products</b> <b>0,99%</b> Products	
<b>Organisations</b> <b>9,58%</b> New Organisation	<b>30,84%</b> New Locations	<b>Referentials</b> <b>5,58%</b> New Lists	<b>0,58%</b> New Terms

Update rate			
<b>Substances</b> <b>14,40%</b> Updated Substances		<b>Products</b> <b>9,94%</b> Updated Products	
<b>Organisations</b> <b>49,86%</b> Updated Organisations	<b>47,40%</b> Updated Locations	<b>Referentials</b> <b>9,98%</b> Updated Lists	<b>1,17%</b> Updated Terms



## Engagement



**SPOR & XEVMPD webinars** are held at minimum 2 times per year

### Customer satisfaction survey



- Sent to registered (active) SPOR users
- Run at the end of each year
- Results are compared with previous year
- Results are published in SPOR portal
- Feedback from users is used to identify areas for improvement
  - **Your opinion matters to us!**
  - **Please reply to the next customer satisfaction survey in Q4 2023!**

### Training



- Videos of SPOR webinars containing tips/tricks and questions raised from users in the @emainfo channel
- XEVMPD e-learning available
- XEVMPD training provided by DIA



Customers continue to perceive us as providing professional and polite communication, **acceptable data quality & timely management** of change requests



Customers are **generally satisfied** with all domains of SPOR data Services



- **77%** of customers rate **Data services** as **Good/Excellent**;
- **17% increase** of customers considering that we provide **excellent** service





- **79%** of customers rate **Data Quality** as **Good/Excellent**;
- **13% increase** of customers considering that we provide **excellent data quality**



**SPOR Customer Satisfaction (CSAT)** is **80%** → **6% increase** (vs 74% in 2021)

## Identified improvements and proposed actions in 2023:

 Improvements	 Proposed actions
Improve <b>SPOR Service desk</b>	<ul style="list-style-type: none"><li>• Review Service Desk Answers</li><li>• <b>Increase QC of answers</b></li></ul>
Improve <b>SPOR documentation</b>	Review, consolidate and <b>simplify</b> documentation
<b>Increase awareness</b> around product validation	<b>Increase XEVMPD webinars &amp; comms</b>
Continue improving <b>OMS Data Services and Data quality</b>	Focus will be given to improve Service Desk and <b>increase data profiling/proactive correction</b>



## Data Governance/ Operations



### **S, P, O & R Webinars H1 2023**

Discussion of new developments, updates in SPOR and new releases.

***17-20 April 2023***



### **S, P, O & R Webinars H2 2023**

Discussion of new developments, updates in SPOR and new releases.

*Sept-Oct 2023  
Announced via EMA's  
Website Events Pages*



### **SPOR customer satisfaction survey**

Feedback from users

*Oct-Nov 2023  
Announced via SPOR  
webinars & email*



## Key takeaways and conclusions

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## Strategy

EU strategies, Network Portfolio roadmap and SPOR Operational planning are in place and enable to focus actions around data value



## Processes

Operating Models and Data mgmt processes are defined and operational. Data is consistently and adequately processed.



## Policies & Standards

SPOR applies international standards (IDMP, FHIR) and EMA policies. Domain specific policies and Data Quality rules are available.



## Organisation & Roles

Governance structures (reporting and decision making lines) are defined. Data mgmt, SPOR Data Governance, Data Governance and IT delivery roles and responsibilities are defined.



## Enablement

Metrics, monitoring and reporting are in place and made available to stakeholders. Engagement takes place via webinars and Customer satisfaction survey.



## Data Governance



EMA has a **structured approach** to SPOR data governance based on the data management **best practices**.



EMA's Agile transformation is changing how IT enablement is planned and executed and influences what the SPOR data management teams priorities are.



EMA's SPOR team provides day-to-day data services that cover data management, data governance and support IT enablement.

This presentation explained **how SPOR data is currently managed and governed** and therefore provides an introduction and context to the remaining webinars in the SPOR & XEVMPD week.

*More details will be covered in subsequent webinars.*



# Any questions on the webinar?

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SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
<a href="#"><u>SPOR Data Governance</u></a>	17 April 2023	10:00-12:00 CET
<a href="#"><u>Service Desk for SPOR and XEVMPD</u></a>	17 April 2023	14:00-16:00 CET
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<a href="#"><u>EMA Account Management</u></a>	20 April 2023	14:00-16:00 CET



## Further information

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