Housekeeping notes – Personal data protection notice

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*Throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Housekeeping notes – Q&A

Join at
slido.com
#2213 087

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Classified as public by the European Medicines Agency

Webinar materials sharing

Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page

*1st version of presentation already published, to be updated with final version (if necessary)

Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page

Registered participants *may receive webinar materials (when all available) via email.*

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR Data Governance

2 October 2023, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Isabel Chicharo

SPOR Webinar Series – 2-12 October 2023

An agency of the European Union

SPOR Webinars

EUROPEAN MEDICINES AGENCY

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Goals of the session

Explain how SPOR data is governed

Provide context for the other topics of SPOR week

Explain how the Agile transformation has changed data governance

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Agenda

1. **Welcome**
   10:00 – 10:05
2. **SPOR Data Governance Framework**
3. **Data Governance - Strategy**
4. **Data Governance - Processes**
5. **Data Governance - Policies & standards**
6. **Data Governance - Organisational structure/ Roles & responsibilities**
7. **Data Governance - Enablement**
8. **Key takeaways and Conclusions**
9. **Q&A Session**
   11:45 – 12:00

For Questions: www.slido.com code: #2213087

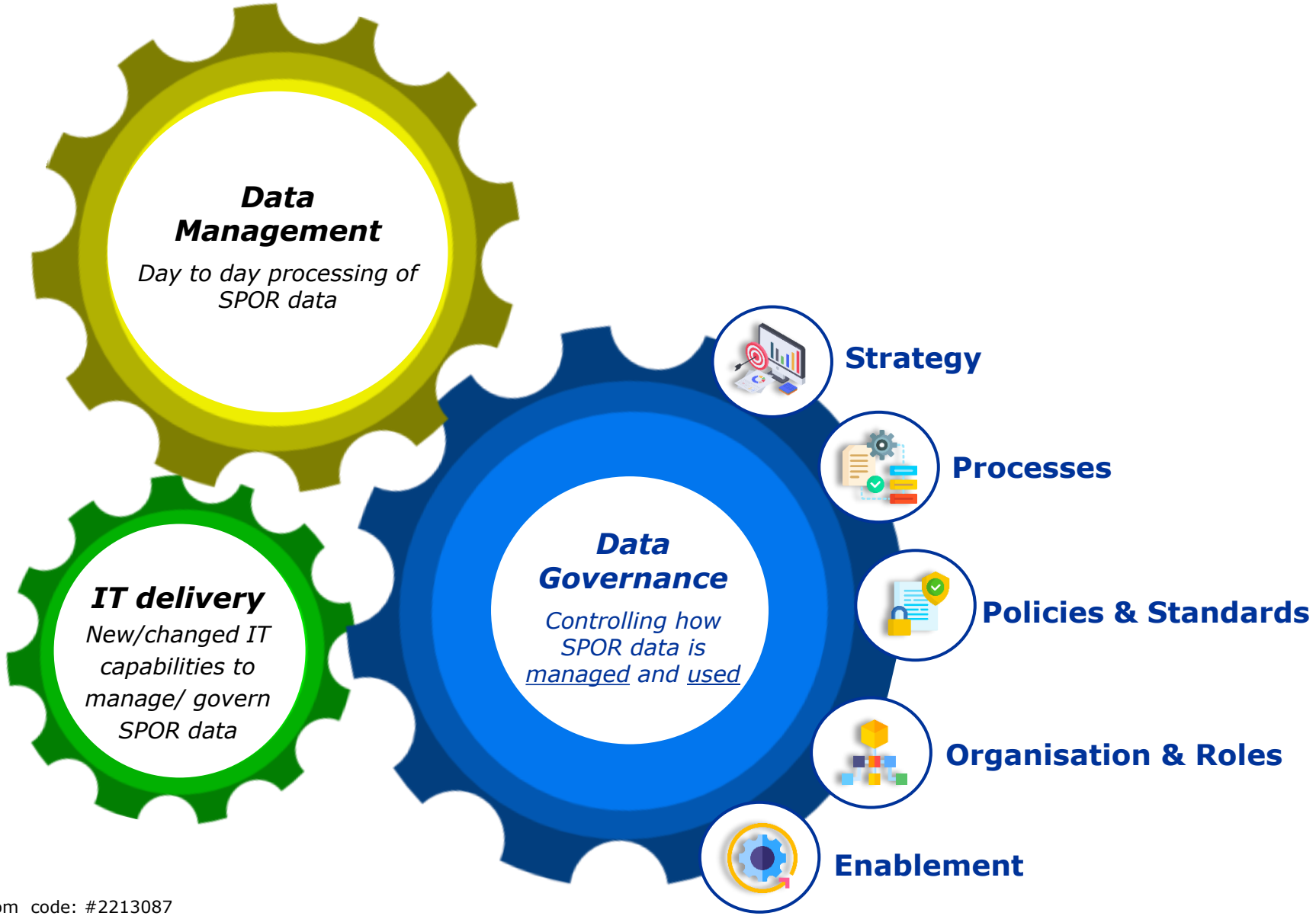
Classified as public by the European Medicines Agency

SPOR Data Governance Framework

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

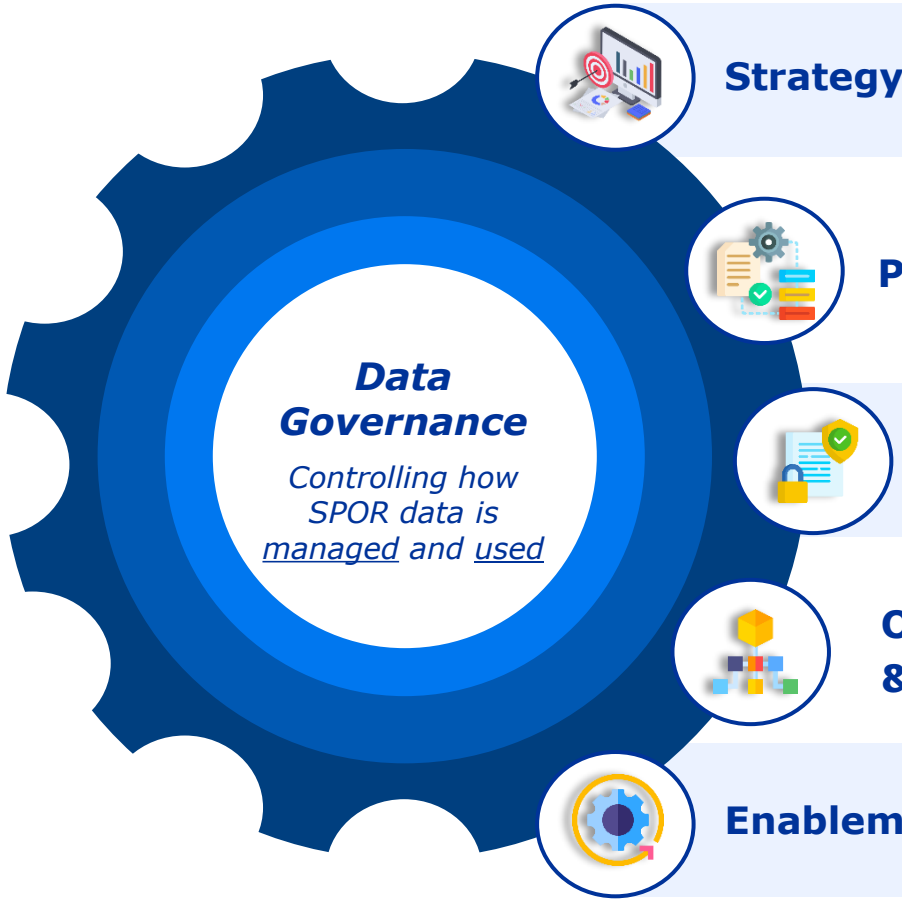
Key concepts



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR Data Governance Framework



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

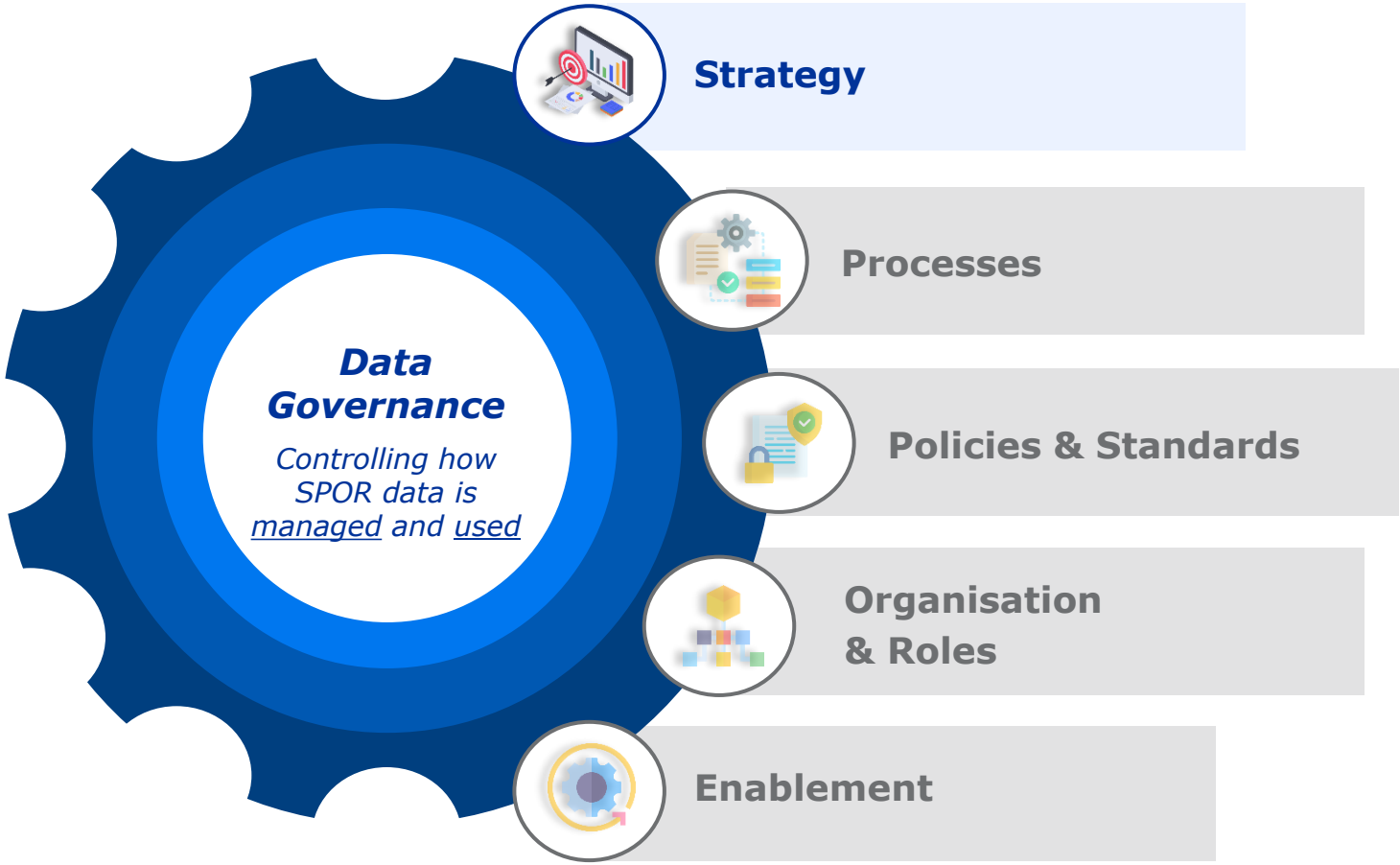
Enablement

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

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Strategy



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Data Governance - turning strategy into planning

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.**

EMRN Strategies

- EMA regulatory science strategy to 2025
- European Medicines Agencies Network strategy to 2025
- European medicines regulatory network data standardisation strategy

Provide long-term direction for **business** areas

Portfolio Roadmap

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

Long term direction for **major investments**, particularly aligning uses of data with business and **IT capability** development

SPOR operational planning

Shared via **SPOR webinars**

Focus of **data management**, ensuring Data Quality improvements align with expected business value and with Portfolio Board's prioritisation

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

EMRN Strategies

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**

Classified as public by the European Medicines Agency

Portfolio Drivers

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

- Research & Development Value Stream - SMS UI/Portal to support access and transparency to substance data
- Research & Development Value Stream - SMS-EU-SRS integration to improve substance data quality
- Product Lifecycle Mgmt Value Stream - Work on Product management services (PMS) which supports other portfolio activities
- No specific portfolio activities for RMS & OMS as major IT enablement was completed in 2017

Portfolio activities driving SPOR operational work

- RMS is preparing new lists for different projects e.g. Real World Data lists
- OMS is mapping, revising rules and registering new organisations e.g. Manufacturers of medical devices
- SMS is enriching data to support Antimicrobial Sales and Use (ASU) data reporting
- PMS is increasing the monitoring of medicinal product data to minimise migration/synchronisation issues across databases (xEVMPD/SIAMED-PMS-IRIS-DADI)

For Questions: www.slido.com code: #2213087

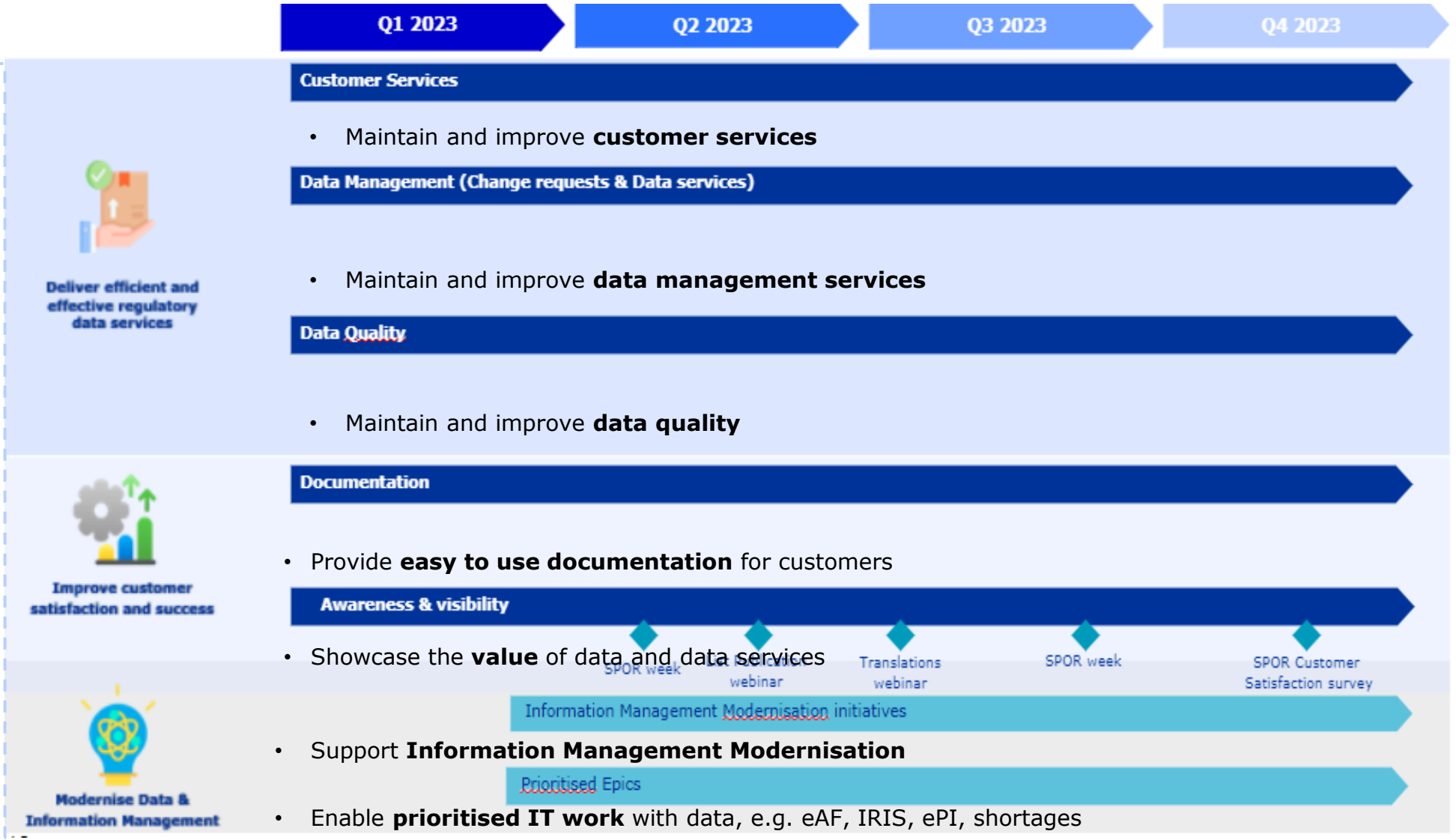
Classified as public by the European Medicines Agency

SPOR Operational Planning

EUROPEAN MEDICINES AGENCY

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

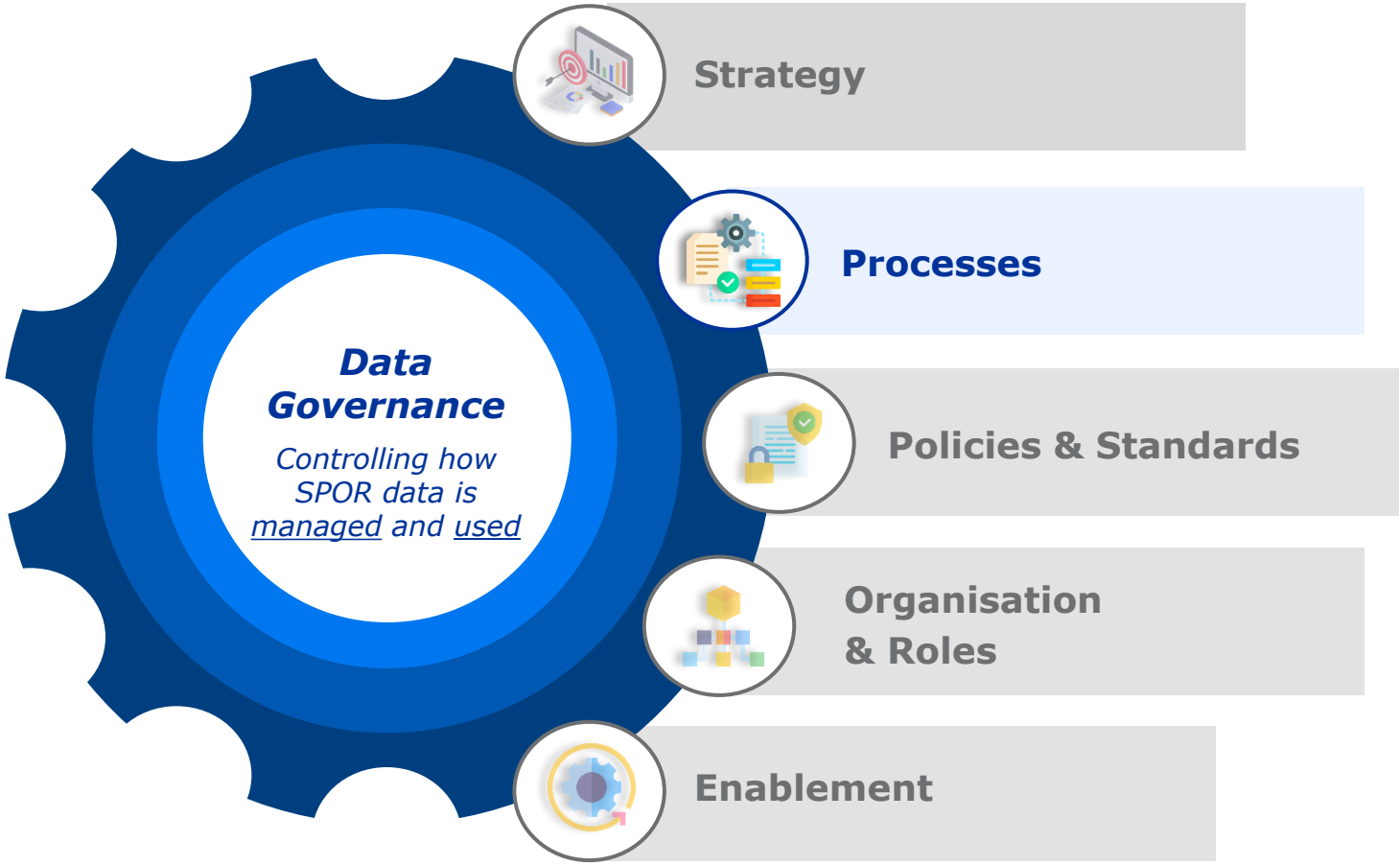
- SPOR data service **objectives** translated into annual operational plans
- 1 plan **per SPOR domain**
- operational plans shared in **SPOR webinars** 2x a year



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Processes



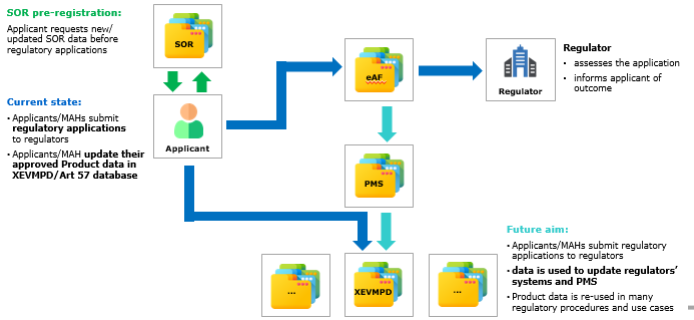
For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Different levels of processes

Operating Model

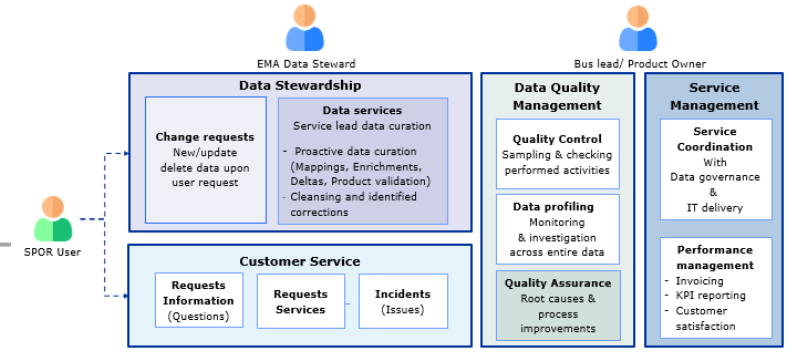
Data mgt in the regulatory business context



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

Data Mgmt processes

High-level data mgt processes carried out



- EMA provides Data stewardship and Customer services to Stakeholders
- Data Quality mgt and Service mgt processes are in place to guarantee high level data quality and service performance

Data operations

Actions performed on data

- Create
- Update/merge/unmerge/ nullify
- Delete – EMA never permanently deletes any data!

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR & XEVMPD Operating Model (Human) – In the regulatory business context

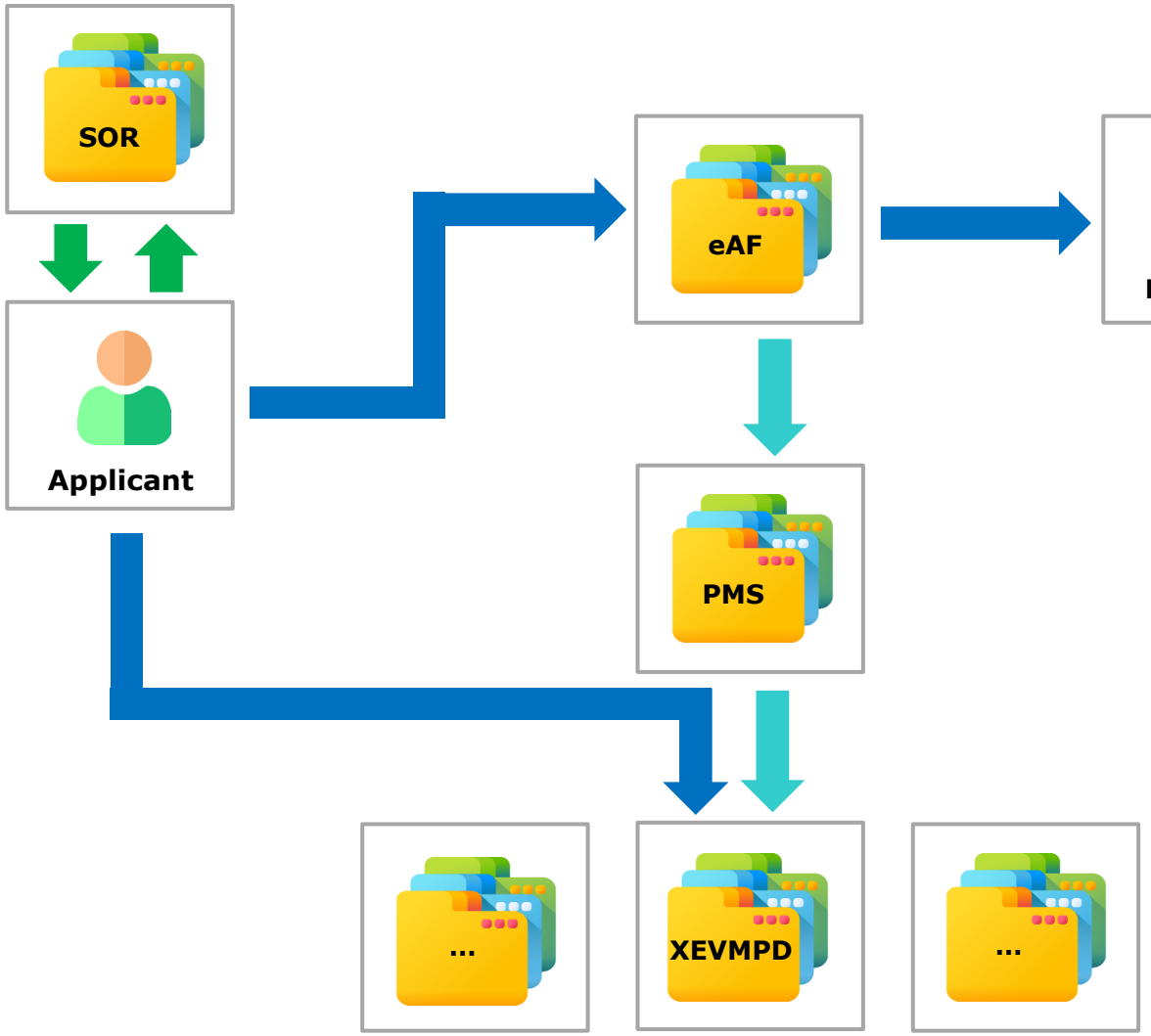
EUROPEAN MEDICINES AGENCY

SOR pre-registration:

Applicant requests new/ updated SOR data before regulatory applications

Current state:

- Applicants/MAHs submit **regulatory applications** to regulators
- Applicants/MAH **update their approved Product data in XEVMPD/Art 57 database**



Regulator

- assesses the application
- informs applicant of outcome

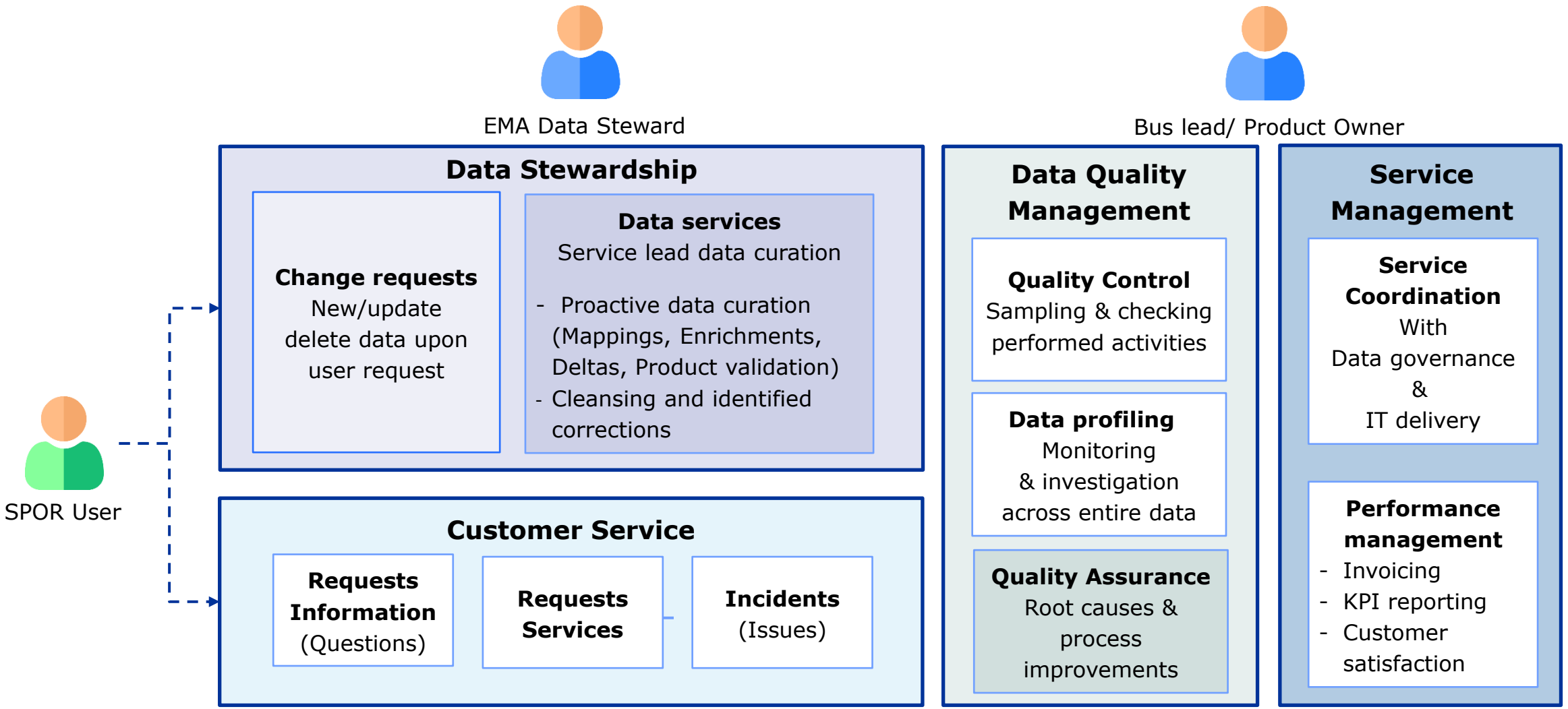
Future aim:

- Applicants/MAHs submit regulatory applications to regulators
- **data is used to update regulators' systems and PMS**
- Product data is re-used in many regulatory procedures and use cases

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR Data management processes



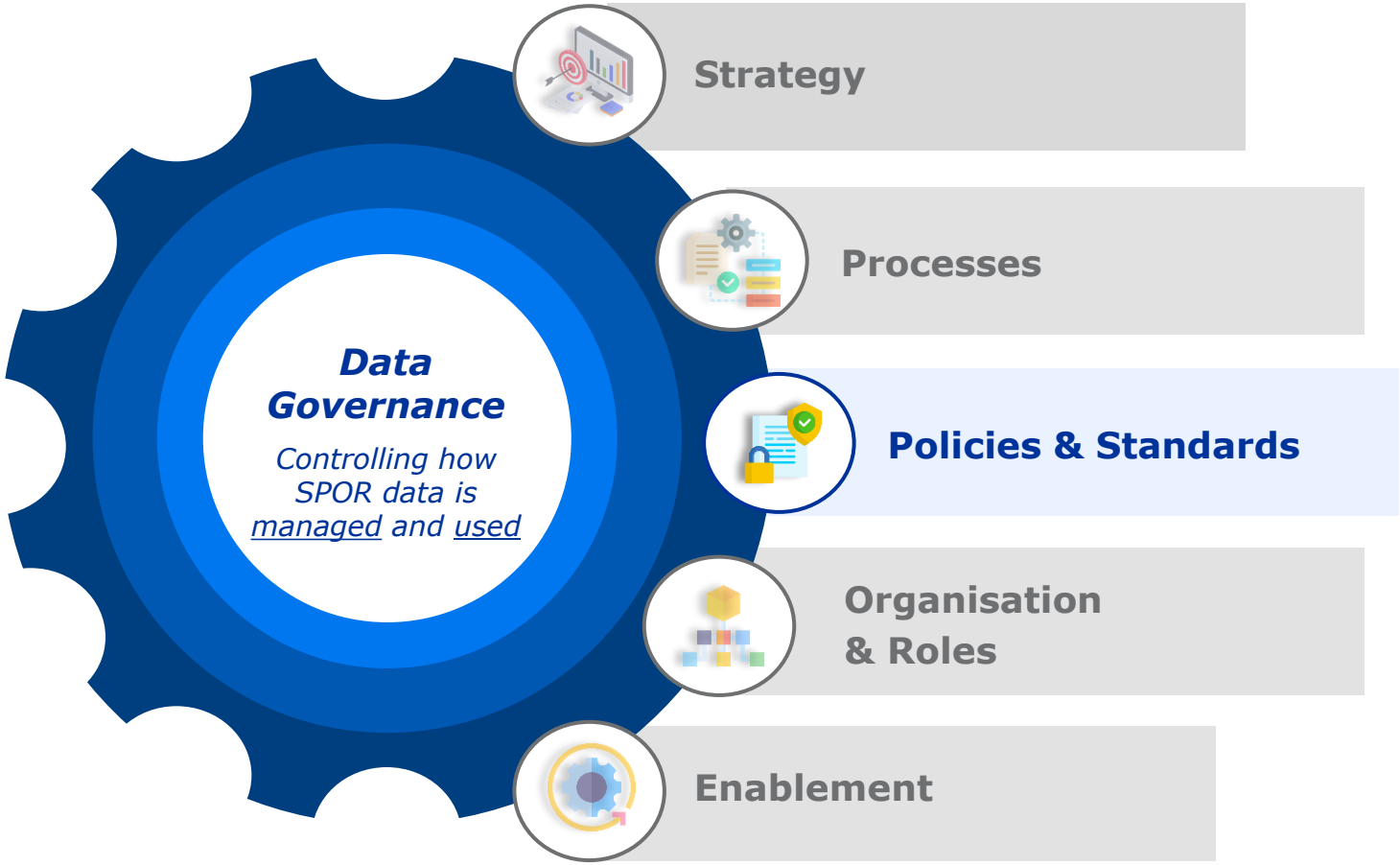
Data management processes are defined, operational and are monitored/reported on

Details for each SPOR domain elaborated in individual webinars in current & next week.

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Policies & standards



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

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 Data Quality rules, RMS list information, XEVMPD guidance

- Domain specific policies and rules further elaborated during **SPOR webinars**

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR & xEVMPD Documents & Help

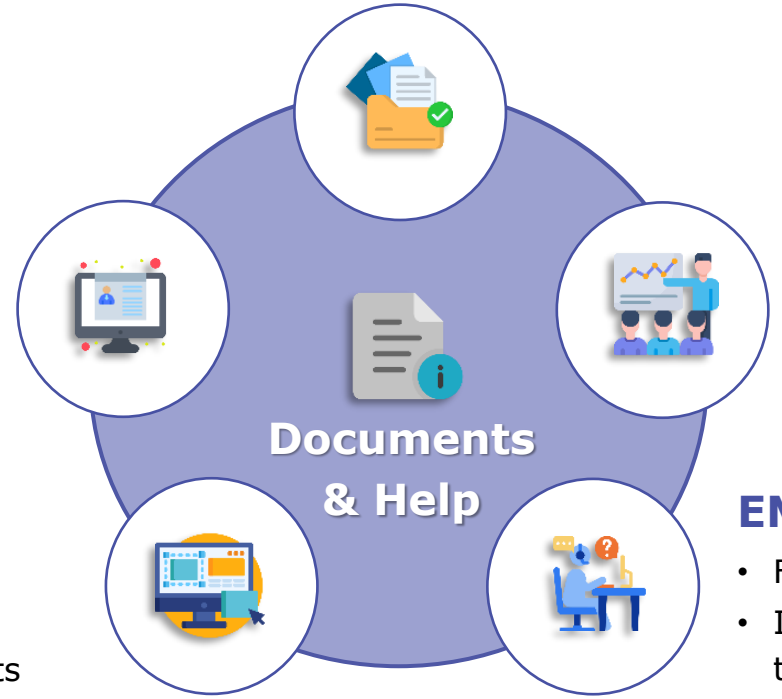
EUROPEAN MEDICINES AGENCY

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



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 corporate website

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

EMA Service Desk

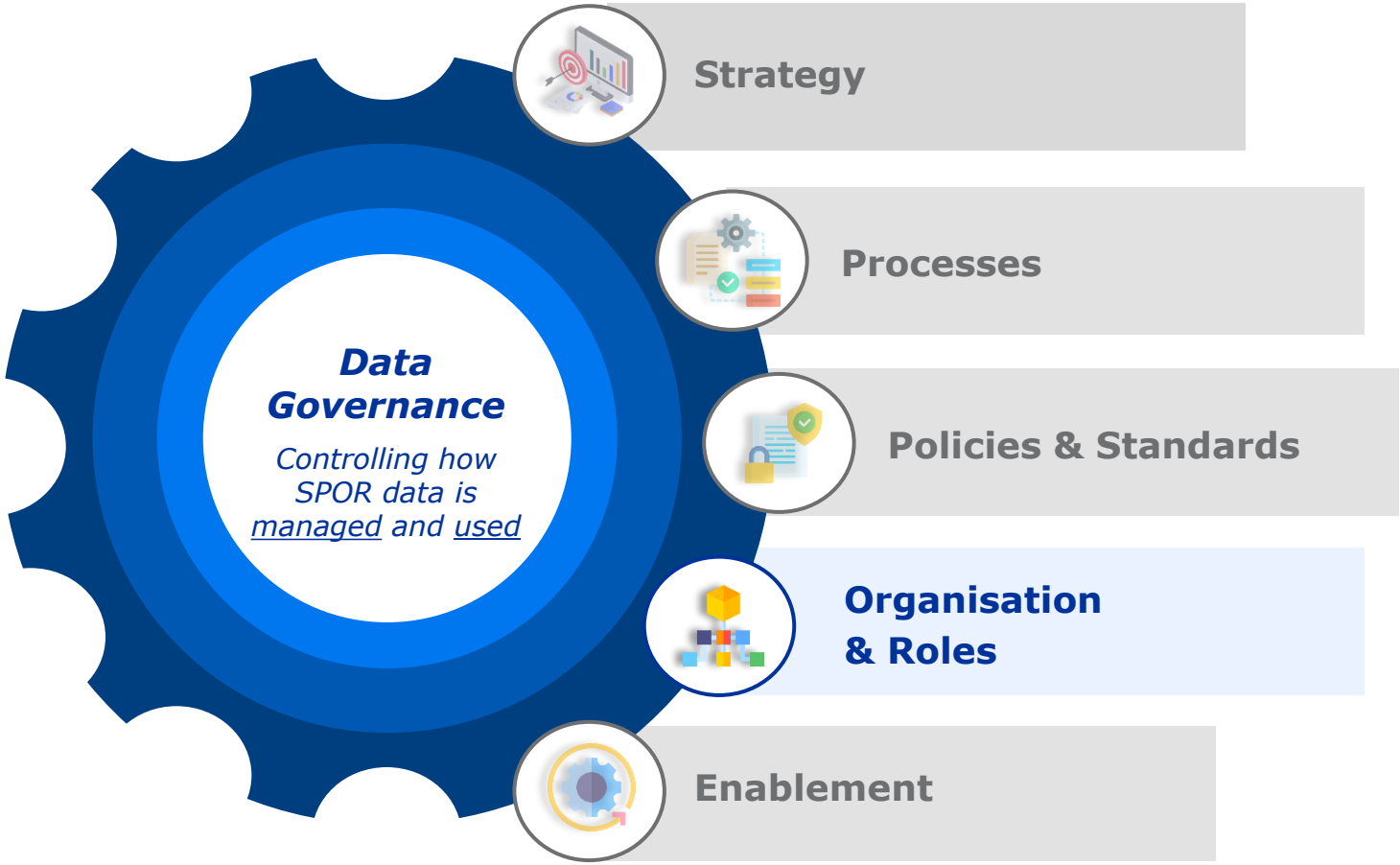
- For any help needed and not found in other documents
- Including: Service requests, issues, requests for technical support
- submitted through the ServiceNow Portal

Find demos and further details in other SPOR webinars, as documents are domain-specific

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Organisational structure/ Roles & responsibilities



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Organisation, roles and responsibilities – who does what?

EUROPEAN MEDICINES AGENCY

SPOR & XEVMPD Data Management

Day to day management of SPOR data as agreed

- Service Owner & Manager
- EMA Data Stewards

SPOR Data Governance

How SPOR data is managed

- Key User Group
- Network Data Board

SPOR Business Lead

IT Delivery

New/changed IT capabilities to manage/ govern SPOR data

- Value Stream Owner
- Agile Governance Bodies
- Network Data Board

Data Governance

How SPOR data is used/ applied in business processes

- Process Owner (User/ project group)
- Network Data Board

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR & XEVMPD data management Structure

EUROPEAN MEDICINES AGENCY

SPOR & XEVMPD 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	Product Business Lead	Organisation Business Lead	Referentials Business Lead
Pedro Batista	Marcos Fernandez & Veronika Baker	Debora Martins Braga	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	Product data owner	Organisation data owner	Referentials data owners
Substance Validation Group	Industry/MAH	EMA	EDQM, EMA/BfArm, ISO, MSSO, WHO, EMA

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

How SPOR data is managed

EUROPEAN MEDICINES AGENCY

EMA Data Stewards execute day to day data mgmt (Data stewardship, Customer services, Data Quality mgmt)

1

"Decides" on specific tasks e.g. Change requests, Service Desk tickets

Business lead coordinates all activities across Data mgmt, Data Governance and IT delivery for that domain (domain specific service mgmt)

2

Decides on what task/ cleaning to do first and where to prioritise resources for the domain

Service Manager is responsible for quality and availability across the SPOR data services (service mgmt across all domains) - escalation point for operational issues/concerns

3

- Ensures adequate processes & resources are in place, ensures compliance with SLAs and SQIs.
- Deals with any complaints about a particular service provided.

Service Owner has overall accountability for SPOR data services – escalation point for strategic issues

4

Deals with strategic issues e.g. where is big investment/ modernisation needed

Data Owners may be involved to decide how to create/modify the data, share and restrict access to the data

For Questions: www.slido.com code: #2213087

** These aspects are still under discussion*

Classified as public by the European Medicines Agency

Data Governance Structure

EUROPEAN MEDICINES AGENCY

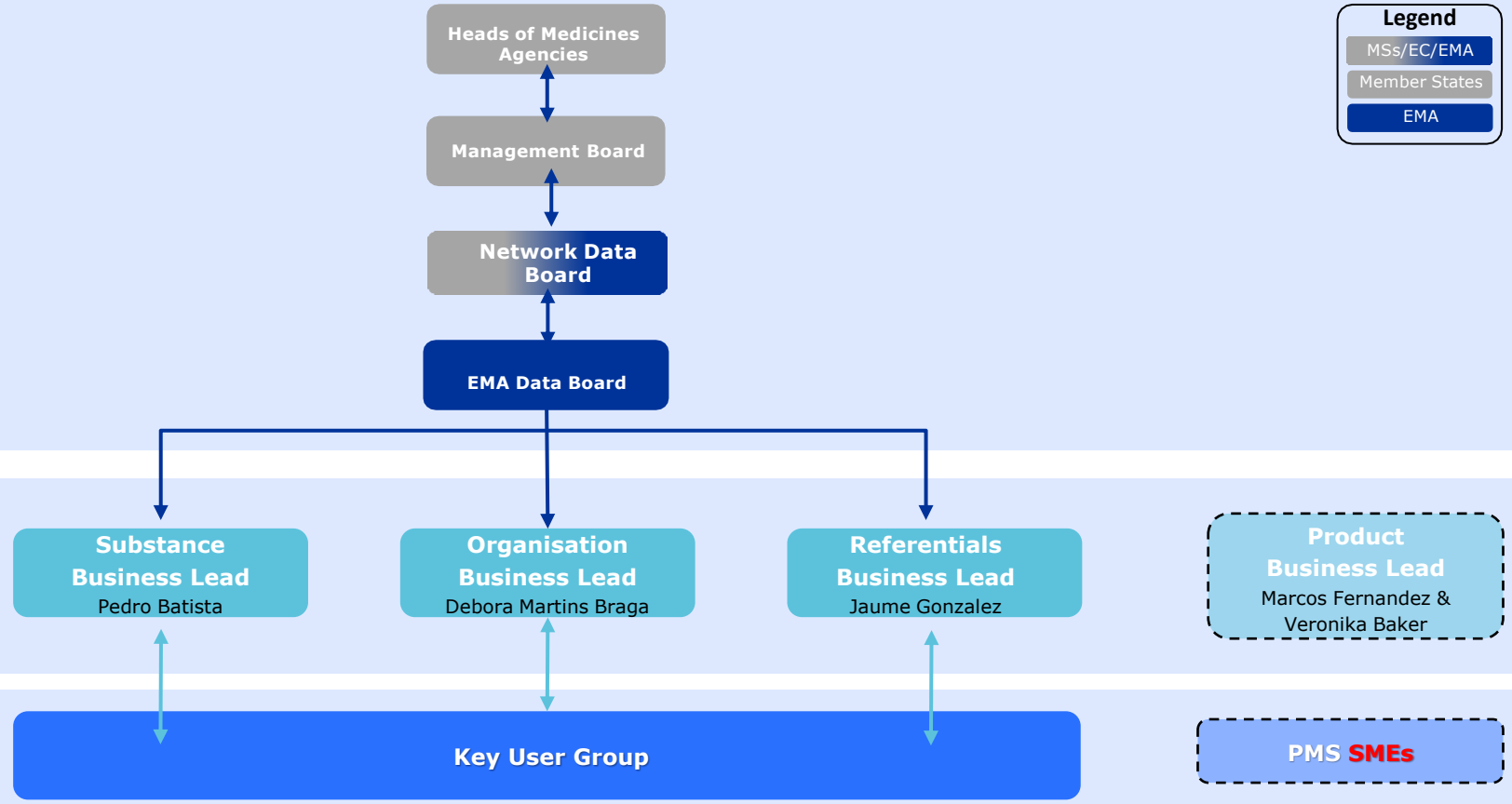
Data Governance

How SPOR data is managed and 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 groups ensures stakeholder views are considered



Notes:

- xEVMPD is being managed as per rules defined by Art 57 Implementation Working Group (IWG).
- PMS will replace xEVMPD and is being governed by Agile Governance and supported by POs and SMEs.
- When PMS is in operation it will be governed under SPOR governance (KUG & NDB)

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Governing how SPOR data is managed

EUROPEAN MEDICINES AGENCY

EMA Data Stewards execute day to day data mgmt and collect issues via Service Desk/Change Requests

1

How can I **capture Large volume receiver** addresses in OMS?

Escalation to **Business Lead** who understands issue and requirements, explores options and prepares to consult Key User Group

2

Key User Group advises on changes

to SPOR data mgmt

3

This is a problem in Germany → Local SMEs are consulted → Advice is provided

Business lead decides/implements changes that have no significant impact to SPOR data mgmt

4

- OMS Data Quality rules doc is updated with new large volume receiver rules and published;
- New rules are implemented for new/updated orgs/locs

EMA/Network Data Board advises/decides changes that have significant impact to SPOR data mgmt

5

E.g. dealing with Multiple/combined locations

Stakeholders are informed via SPOR Portal, dedicated communication or via SPOR webinars

For Questions: www.slido.com code: #2213087

** These aspects are still under discussion*

Classified as public by the European Medicines Agency

Governing how SPOR data is used

EUROPEAN MEDICINES AGENCY

Feedback is collected from users by Key User Group or EMA Data Stewards

1

How is OMS becoming mandatory for CP? What are the impacts?

Escalation to **Business lead** who consults **Network Data Board**

2

Understands issue and user concerns, explores options

Network Data Board advises process owners on best data mgmt practices across business areas

3

- Stakeholder readiness
- Information needed for users
- Detailed rules/instructions (Applications should not be rejected; Dossier does not need to be aligned)
- ...

The **process owner** decides how to implement SPOR in its business area

4

- H-div considers advice but ultimately defines the timelines and rules of how this will be implemented
- Timelines extended & FAQ prepared

Business lead steers any needed changes and data stewards implement them

5

- Business lead contributes to FAQ
- FAQ is published and advertised by KUG

Stakeholders are informed **by Process Owners.**

SPOR team may contribute to the elaboration of information such as FAQ or dedicated webinars.

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

IT Delivery Structure

EUROPEAN MEDICINES AGENCY

IT Delivery

New/changed IT capabilities to manage/ govern SPOR data

Governance Bodies provide strategic direction and govern major investments

Agile Governance Bodies

Click here for further information

Value Streams (VS) align delivery with expected business value, provide tactical/strategic focus

Technology lifecycle mgmt information security VS	Managing the Agency VS	Research and development VS	Product Lifecycle Management VS	Monitoring VS
VSO: Leonidas Tertipis **VSM:** Pedro Rodriguez	**VSO:** Mireia Castillon **VSM:** Rob Hopping	**VSO:** Steven Le Meur **VSM:** Nektaria Varela	**VSO:** Karl Hamilton **VSM:** Melanie Loveday/ Hannes Kulovits	**VSO:** Pedro Pina Ferreira **VSM:** Pedro Oliveira

Product teams deliver the product/solutions

OMS PO
Debora Martins

RMS PO
Jaume Gonzales

SMS PO
Pedro Batista

PMS PO
Marcos F. Gomez &
Veronica L. Di Paola
Dino Soumpasis (Network)

XEVMPD PO
Marcos F. Gomez &
Veronika Baker

SPOR Epic Owner – Isabel Chicharo

VSO: *Value Stream Owner*
VSM: *Value Stream Manager*
PO: *Product Owner*

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Governing how SPOR IT capabilities are delivered

EUROPEAN MEDICINES AGENCY

Demand/needs/feedback from users is collected from different sources

1

Escalation to **Business lead/Product Owner** who liaises with Value Stream Owner & Epic owners for defining the Epic (IT capabilities)

2

Agile Governance Bodies provide strategic direction and govern major investments

3

Network Data Board may advise on priority/ importance of new data mgmt capabilities

4

Product teams deliver the product/solutions

5

- KUG collects feedback from users on data mgt tools – changes & improvements.
- EMA Data Stewards collects Data Quality/process input via EMA Service Desk/Change Requests.
- Process owners can provide data requirements on how to use SPOR data in its business process/context

- Prioritisation is done by **Portfolio Board** and **Network Portfolio Advisory Group**

Stakeholders are informed via Agile ceremonies and events – advertised on EMA Website

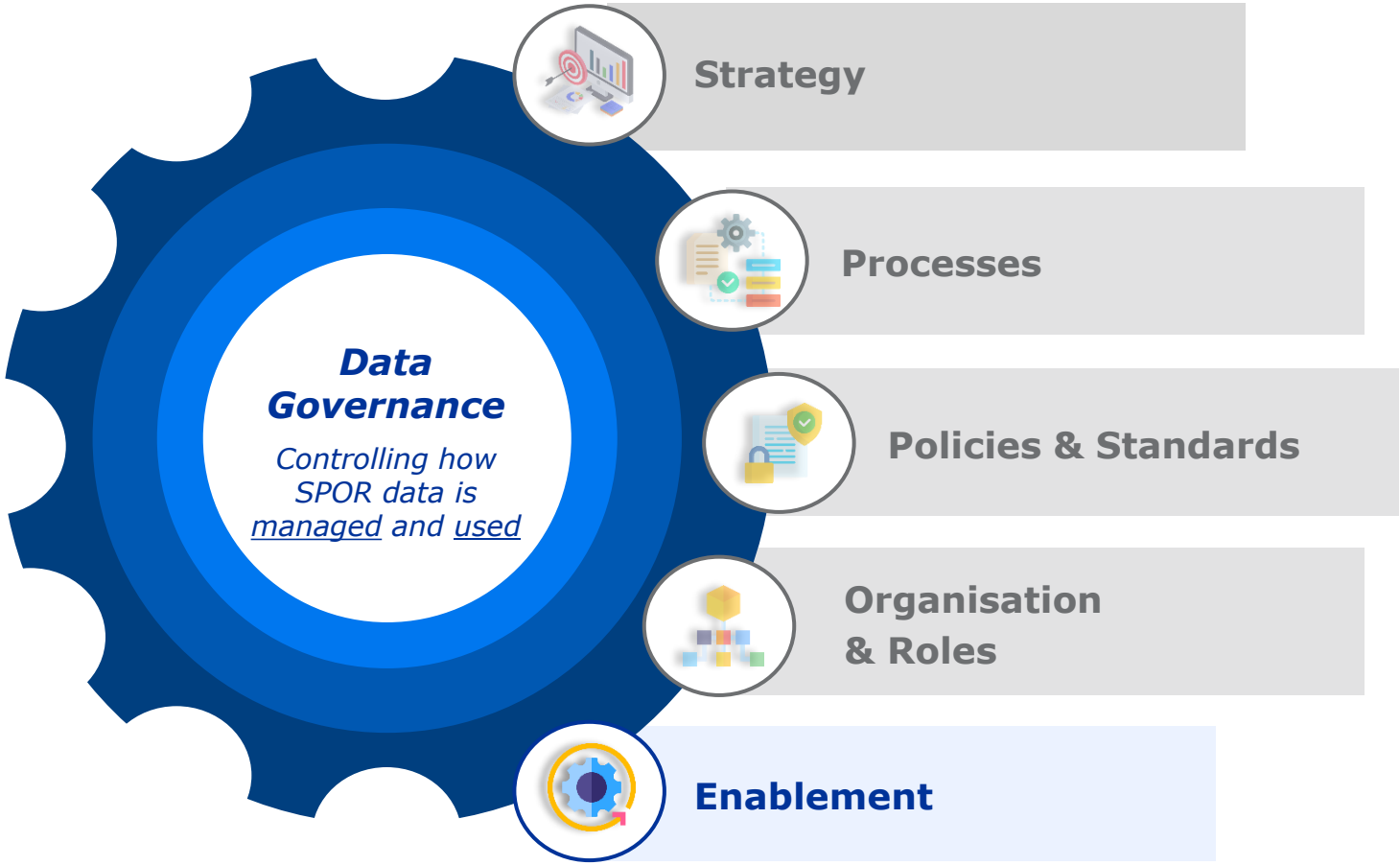
Anybody can provide **feedback** via the **quarterly system demos** which are open to the public

For Questions: www.slido.com code: #2213087

** These aspects are still under discussion*

Classified as public by the European Medicines Agency

Enablement



For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Enablement

EUROPEAN MEDICINES AGENCY

Continuous improvement

Key Performance Indicators (KPIs) defined on:

- **Volumetrics** - what data is managed, growth rates, update rates
- **Data mgmt** - types of activities (Change Requests, data services, customer services), SLA compliance
- **Service quality** – Data Quality errors detected & overall level of Data Quality/activity
- **Data quality** – Data Quality 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

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

What data do we manage?

EUROPEAN MEDICINES AGENCY

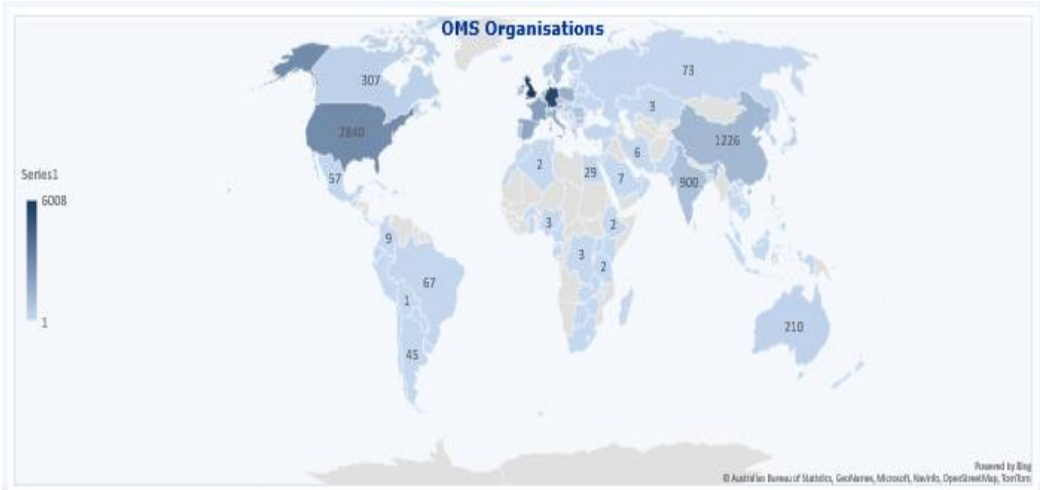
Data volume as of January 2023

Substances
63.948
Substances

Products
1.456.103
Products

Organisations
47.403 Organisations
80.674 Locations

Referentials
212 Lists
129.774 Terms



Change rate in 2023

Growth rate

Substances
0,92% New Substances
1,84% New Names

Products
0,84% Products

Organisations
0,98% New Organisation
0,77% New Locations

Referentials
4,48% New Lists
0,65% New Terms

Update rate

Substances
22,81% Updated Substances

Products
0,75% Updated Products

Organisations
91,50% Updated Organisations
92,38% Updated Locations

Referentials
20,28% Updated Lists
2,21% Updated Terms

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Enablement

EUROPEAN MEDICINES AGENCY

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!

Start: Mon 30th Oct

End: Fri 10th Nov!

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

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

How to stay connected to work on SPOR & XEVMPD

EUROPEAN MEDICINES AGENCY

Data Governance/ Operations

S, P, O & R Webinars H1 2024

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

Mar-Apr 2024

Announced via EMA's Website Events Pages

S, P, O & R Webinars H2 2024

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

Sep-Oct 2024

Announced via EMA's Website Events Pages

SPOR customer satisfaction survey

Feedback from users

Oct-Nov 2024

Announced via SPOR webinars & email

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Key takeaways and conclusions

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Key takeaways

EUROPEAN MEDICINES AGENCY

Data Governance

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.

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Conclusions

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.

Classified as public by the European Medicines Agency

Quiz Time

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Any questions on the webinar?

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #2213087

Classified as public by the European Medicines Agency

Further information

Contact us through ServiceNow @ https://support.ema.europa.eu/

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**

Classified as public by the European Medicines Agency

Glossary

Classified as public by the European Medicines Agency

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

Classified as public by the European Medicines Agency

Glossary (2/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream

Classified as public by the European Medicines Agency

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream

Classified as public by the European Medicines Agency

Glossary (4/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

Classified as public by the European Medicines Agency