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1

Join via **QR code** or **slido.com**



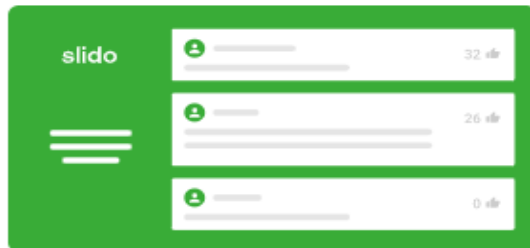
2

Send or upvote the questions
you want to hear answered



3

Questions will be shown on the screen
and **managed live in the Q&A session**



4

Questions not addressed
during this session may be
addressed in **subsequent**
webinars and/or in **FAQ** document
in SPOR Portal



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH





Organisation Management Service (OMS)

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












Increase Awareness of OMS activities



Share planned activities



Show how OMS is addressing customer feedback

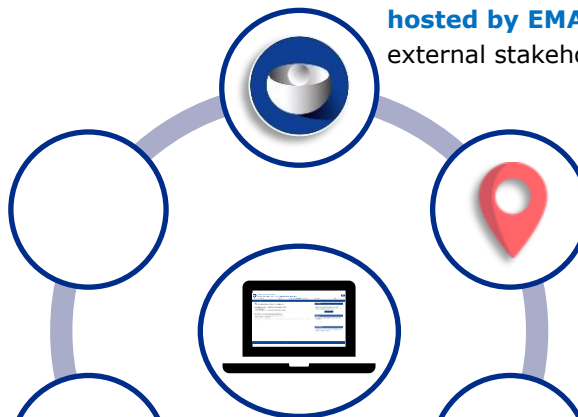
1	Welcome 14:00 – 14:05		7	OMS Documentation & Help	
2	Introduction to OMS		8	OMS in Projects/Systems	
3	OMS processes		9	Planned OMS Activities	
4	OMS Change request process		10	Key takeaways & Conclusions	
5	OMS Data Quality Management		11	Q&A Session 15:45 – 16:00	
6	OMS Statistics				





Introduction to OMS

OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



An **organisation**, as a legal entity, groups all its physical locations within a **country** **Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation ID	Organisation Name ▲	Country ▼	Location ID ▼	City ▼	Address	Postcode ▼	Location status
ORG-100013412	European Medicines Agency	Netherlands	LOC-100020264	Amsterdam	Domenico Scarlattilaan 6	1083 HS	ACTIVE
ORG-100013412	European Medicines Agency	Netherlands	LOC-100020260	Amsterdam	P.O. Box 71010	1008 BA	ACTIVE
ORG-100013412	European Medicines Agency	Netherlands	LOC-100018793	Amsterdam	Orlyplein 24	1043 DP	INACTIVE
ORG-100006175	European Medicines Agency	United Kingdom	LOC-100010800	London	30 Churchill Place	E14 5EU	INACTIVE

Organisation ID: ORG-100032140

Organisation Name: Opella Healthcare Belgium

Alternative Name:

- EN - N.V. Opella Healthcare Belgium S.A.
- EN - Opella Healthcare Belgium Trading As Sanofi Belgium
- FR - Opella Healthcare Belgium S.A.
- NL - Opella Healthcare Belgium N.V.

OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders

An **organisation**, as a legal entity, groups all its physical locations within a **country** **Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

Organisation Details

Organisation ID:	ORG-100000546
Organisation Name:	Sandoz GmbH
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

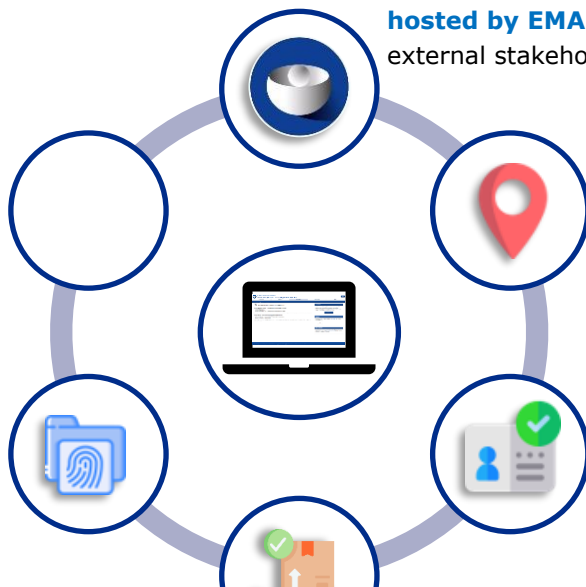
Location ID:	LOC-100000450
Address:	Biochemiestrasse 10 Kundl Tirol 6250 Austria
xEVMPD Code:	ORG1431
EudraGMDP Number:	6236, 6506, 6513, 6536, 6618, 7357, 5296, 5298, 9027, 9400, 9530, 16284, 18205
Last Modified Date:	2021-05-20T15:58:30
Status:	ACTIVE

	A	B	D	F	G	H	I	J
1	Name	missing information in OMS and needed for certificates	Status	Straße	Hausnummer	PLZ	Ort	Staat
2	Sandoz GmbH	/ Site ComOps Wien	GA - aktiv	Stella-Klein-Löw-W	17	1020	Wien	Österreich
3	Sandoz GmbH		GA - aktiv	Jakov-Lind-Straße	5.Top 3.05	1020	Wien	Österreich
4	Sandoz GmbH	/ Site ComOps Wien - Außenlager SCHACHINGER pharmalogistik GmbH	GA - aktiv	Schemmerlstraße	72	1110	Wien	Österreich
5	Sandoz GmbH	/ Site ComOps Wien - Außenlager SCHACHINGER pharmalogistik GmbH	GA - aktiv	Logistikzentrum W	10-18	2201	Hagenbrunn	Österreich
6	Sandoz GmbH	- Außenlager Gebrüder Weiss GmbH	GA - aktiv	Löffelweg	35	6060	Hall	Österreich
7	Sandoz GmbH	- Organisationseinheit LOG	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
8	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Anti Infectives & Chemical Operations FDF Kundl (AICO FDF Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
9	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Sandoz Development Center Kundl (SDC Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
10	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Anti-Infectives & Chemical Operations API Kundl (AICO API Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
11	Sandoz GmbH		GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
12	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Aseptics Drug Product Schaffensau / Kundl (Aseptics DPS Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
13	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Drug Substance Kundl (DSK)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
14	Sandoz GmbH	- Außenlager Gebrüder Weiss GmbH	GA - aktiv	Gewerbepark	9	6300	Wörgl	Österreich
15	Sandoz GmbH	- Außenlager Schenker & Co AG	GA - aktiv	Gewerbepark	2	6300	Wörgl	Österreich
16	Sandoz GmbH	- Außenlager Schenker & Co AG	GA - aktiv	Gewerbepark Süd	8	6330	Kufstein	Österreich

OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders

An **organisation**, as a legal entity, groups all its physical locations within a **country** **Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)



The **Location_ID** will be unique and will **not change**

ORG-100000789	Sanofi-Aventis Groupe	France	LOC-100001368	Paris	54 Rue La Boetie	75008	ACTIVE	2019-08-28T17:37:51	+ 🔗 🔍
ORG-100026749	Sanofi	France	LOC-100014428	Paris	54 Rue La Boetie	75008	ACTIVE	2020-08-21T14:56:22	+ 🔗 🔍
ORG-100010027	Sanofi Pharma Bristol-Myers Squibb SNC	France	LOC-100014368	Paris	54 Rue La Boetie	75008	INACTIVE	2020-03-03T14:09:38	+ 🔗 🔍
ORG-100001962	Sanofi Clir S.N.C.	France	LOC-100005474	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-11T11:57:00	+ 🔗 🔍
ORG-100014407	Sanofi Mature Ip	France	LOC-100020362	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-03T15:28:54	+ 🔗 🔍

OMS **does not have individuals**. If individuals are required in a certain regulatory procedure, this needs to be dealt directly by each system.

OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders

An **organisation**, as a legal entity, groups all its physical locations within a **country Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

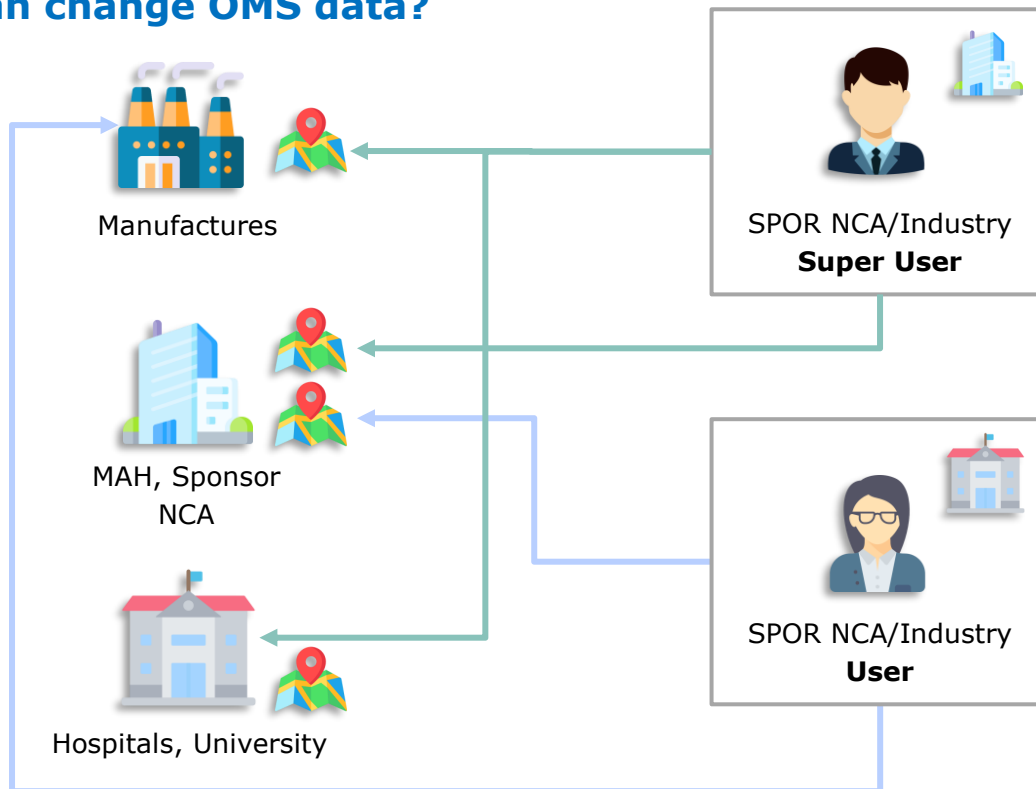
Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

OMS publish the **latest information** available and maintain all **versions** in a date format (version timestamp)



The **Location_ID** will be unique and will **not change**

Who can change OMS data?



Anyone can submit a Change Request to **any organisation and/or location** published in the OMS Dictionary, as long as they submit supporting documentation

Validation of data as per date of the Change Request

OMS is a standardised list of Organisations/Locations



OMS uses **Reference sources of information** (Trade registry, DUNS, other documents/sources) to ensure **data correctness/accuracy**



OMS data **reflects reality**:

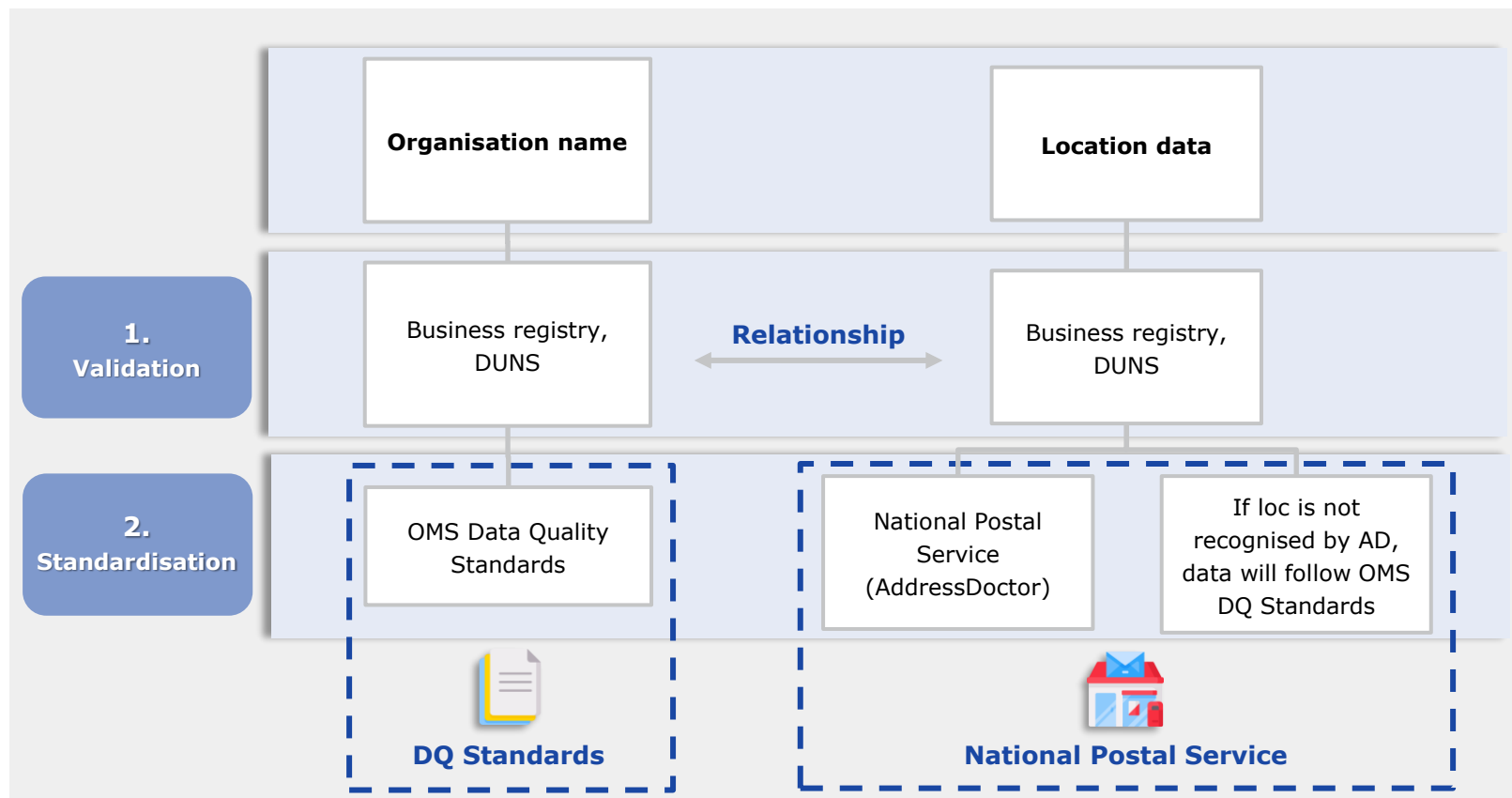
- correct organisation/legal entity
- correct relationship with its address
- correct address



OMS reflects **equivalent** information as the **Trade registry** (or other documents/sources) but it is **not meant to be** the same/“**copy**” of Trade registry (or other documents/sources)



OMS reflects **consistent information** i.e. OMS will apply/standardise the Organisation/address information according to the agreed DQ rules



AddressDoctor is an **address library** used for address validation, correction and standardisation



World-wide & Certified

- AddressDoctor's validation service is delivered in combination with **reference data for more than 240 countries and territories**
- The service combines in one engine **postal certifications** from **all five global postal organisations**



Standardised

- Addresses are **formatted according to local postal standards**
- Validation service can parse, analyse, verify, correct and format addresses according to local postal standards - ensuring that correct elements appear in the appropriate hierarchical alignment



Enriched

- AddressDoctor's validation service allows to **enrich address data with geocodes**



Character set & transliteration

- Address Verification supports **40 different character sets** and **transliterates addresses into Latin characters** from six different writing systems
- When available in the reference files addresses can be automatically transliterated – address localised will be generated

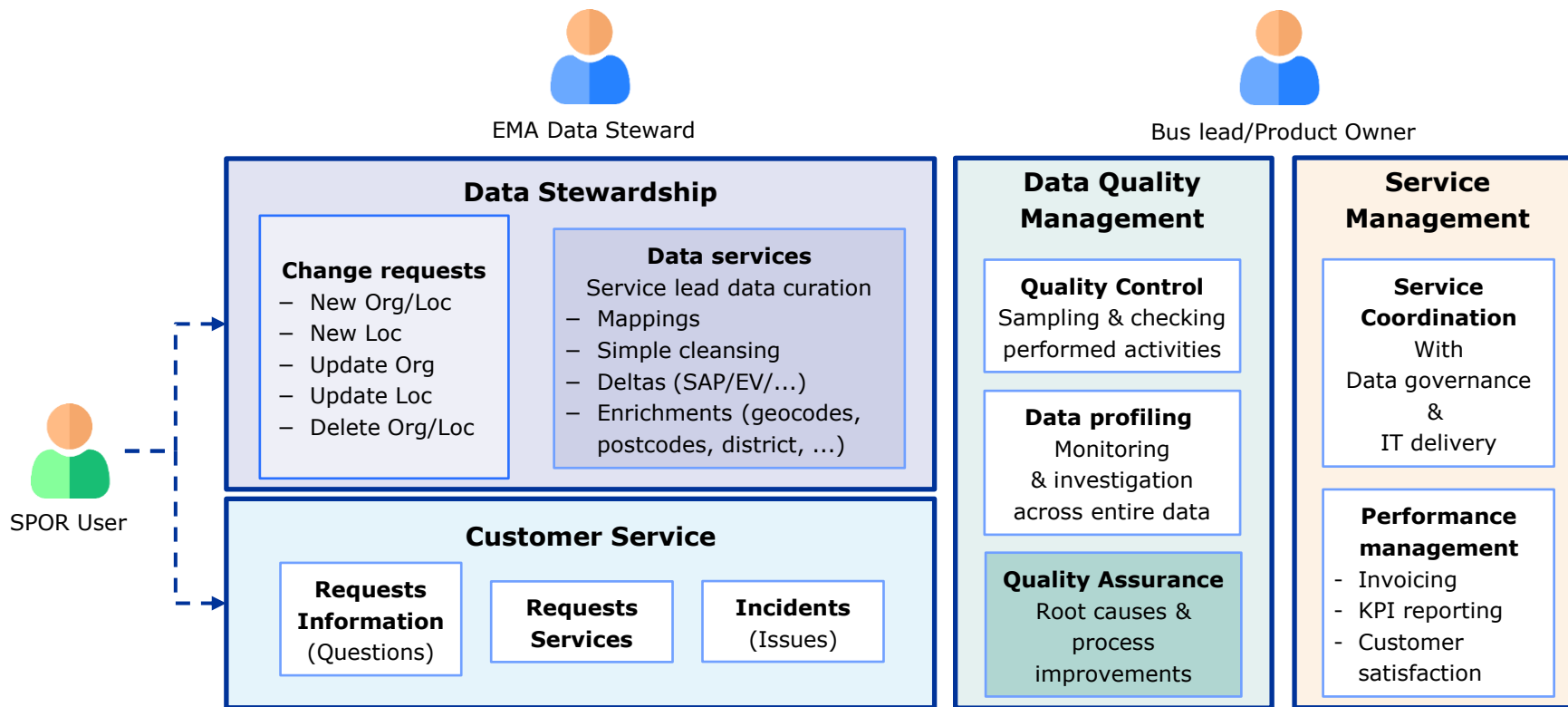


Up-to-date

- The reference database is **updated throughout the year**



OMS processes: Data Stewardship

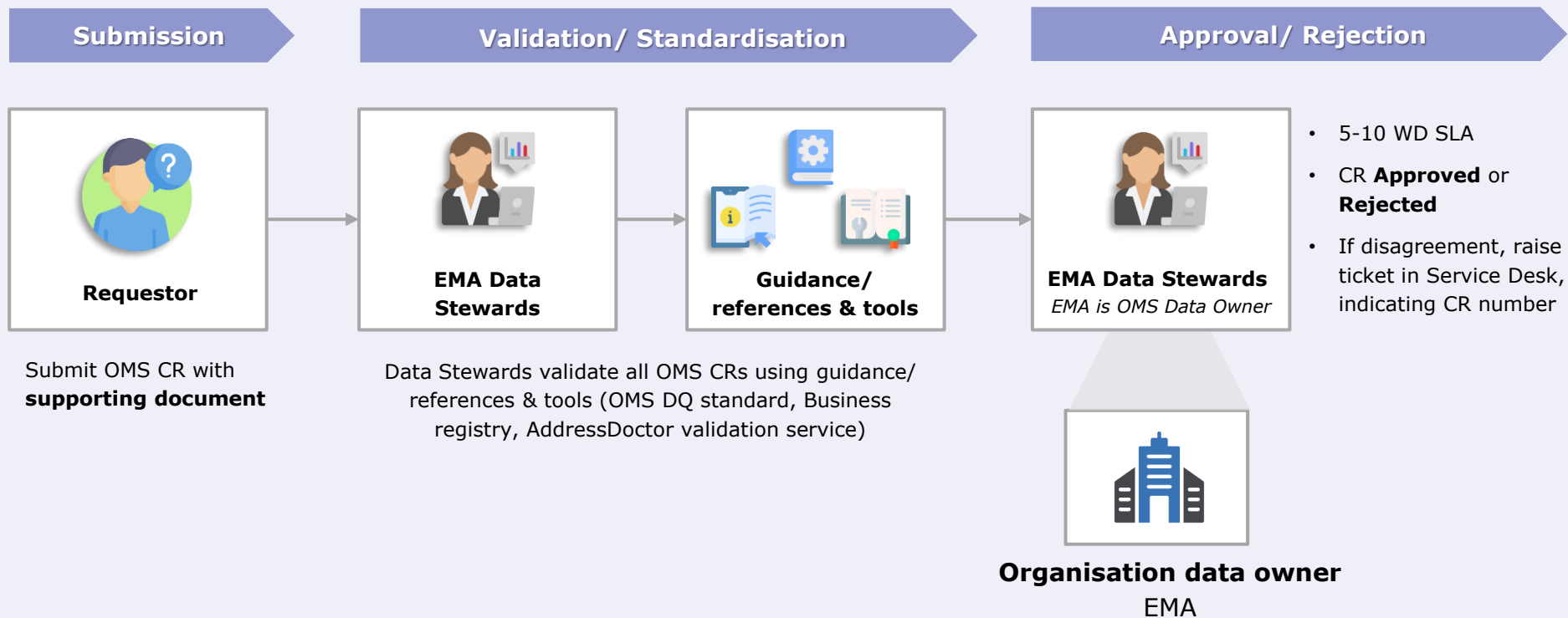


Data management processes are defined, operational and are monitored/reported on
details for each SPOR domain elaborated in individual webinars this week



OMS Change Request process

OMS Change Request process at a glance





OMS data services team aims to answer to the majority of requests within the defined timeframes **depending on the operation requested:**

- New organisation
- New location
- Update or Deactivate organisation and/or location

**Service-level
agreement (SLA)**

Type of request	75% of requests	90% of requests	Expected outcome
Add Organisation/ Location	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation/Location is available for use if the request is approved.
Add Location(s)	Resolved within 5 working days.	Resolved within 10 working days.	The Location is available for use if the request is approved.
Update Organisation	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation is updated if the request is approved.
Update Location	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation is updated if the request is approved.
Deactivate Organisation/ Location	Resolved within 10 working days.	Resolved within 15 working days.	The Organisation is not physically deleted rather its status is updated to "Inactive" if the request is approved.
Update Organisation & Location	Resolved within 10 working days.	Resolved within 15 working days.	The Organisation and Location is available for use if the request is approved.
Returned requests	N/A	N/A	The requestor has two weeks to reply back with additional information required, after which point the request is rejected.

Requestor



Change Requests Submission (1/2)




EUROPEAN MEDICINES AGENCY

New Request

Requestor



**EUROPEAN MEDICINES AGENCY**
SPOR - Organisations Management System

[Substances](#) | [Products](#) | [Organisations](#) | [Referentials](#) | [Help](#)

[SPOR Home](#) | [Organisations](#) | [View Requests](#) | [Documents](#)

[Home](#) / [Search Organisations](#) / [New Organisation Request](#)

▼ CR Information

CR Type

Request Reason*

Justification

Requestor

Contact email*

Contact Phone

▼ Organisation Details

Organisation Name*

Acronym

Organisation Type*

▼ Location Details

Address*

City

Postcode

County

Country*

Location Email ⁽¹⁾

Location Phone ⁽¹⁾

DUNS ID

GS1 ID

☐ ⁽¹⁾ Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields.
If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ▼	Comment ▼
No data available in table		


[Cancel](#) [Submit](#)

Change Requests Submission (2/2)

Update Request

Requestor



 EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

SubstancesProductsOrganisationsReferentialsHelp

SPOR HomeOrganisationsView RequestsDocuments

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type
Update Organisation and Location

Request Reason*
[Dropdown]

Justification
[Text Area]

Requestor
[Text Field]

Contact email*
[Text Field]

Contact Phone
[Text Field]

Organisation Details

Organisation ID
ORG-100000011

Organisation Name*
Bayer AG

Acronym
[Text Field]

Organisation Type*
Industry

Location Details

Location ID
LOC-100023192

Address*
[Text Field]
[Text Field]
[Text Field]

City
Berlin

Postcode
10589

Country
e.g. London

Country*
Germany

Location Email (1)
e.g. john.doe@ema.europa.eu

Location Phone (1)
Int'l Code: e.g. +44 e.g. 02036606000 Ext: [Text Field]

DUNS ID
e.g. 01-234-5678

GSI ID
e.g. 0-00-12345-67890-5

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ↓	Comment ↓
No data available in table		

☐ (1) Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OHS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields. If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

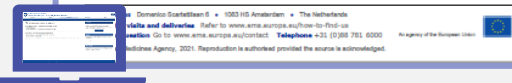
CancelSubmit



29 June 2021
EMA/412467/2020
Information Management Division

Guidance on supporting documentation/information to be
provided with OMS change requests

For OMS users



EEA organisation



1. Extract from the National Business Registry

Hospital, University & Public entities



1. Headed letter with organisation and location details – signed and dated
2. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data

Non-EEA organisation



1. Document stating the DUNS or GS1 identifier number
2. Extract from the National Business Registry
3. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data
4. Headed letter with organisation and location details – signed and dated



▼ Organisation

ⓘ This entity is in a pending state

Organisation Name
Status
Comments

Organisation Translation

▼ Organisation Category ⓘ

Party Category Code ▼

Industry

Party Category

Organisation Mappings ⓘ

Organisation Identifiers


▼ Organisation Location ⓘ

Status ▼ Address Line 1 ▼

PROVISIONAL Oddfellows House

Midatech Ltd
PROVISIONAL
↓
Midatech Limited

Validation



**CERTIFICATE OF INCORPORATION
OF A PRIVATE LIMITED COMPANY**

Company No. [REDACTED]


The Registrar of Companies for England and Wales hereby certifies that
MIDATECH LTD

is this day incorporated under the Companies Act 1985 as a private company and that the company is limited.

Given at Companies House, Cardiff, the 27th October 2000

[REDACTED]

[REDACTED]



COMPANIES HOUSE

HC0078

Standardisation



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 June 2017
EMA/740982/2016
Information Management Division

Organisation data quality standards in OMS
Data quality principles

Country	Reference	Legal Entity naming in organisation names (in EN and National languages)
SE	Swedish Companies Registration Office	AB, AB (publ), EEIG,
SI	Slovenian Business Register	d.o.o., EGIZ, d.d.
SK	Slovakian Business Register	a.s., k.s., s.r.o. = spol. s r.o., v.o.s., EZHZ,
UK	Companies House	Limited, Public, EEIG,

Organisation Location

This entity is in a pending state

Address Line 1	c/o TheVIT AS	Address Line 2	Gunnar Randers' vei 24	Address Line 3	
Address Line 4		Street Number		Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	
GPS Longitude		Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor		To Date	
Comments					

Record 4 of 4

Brønnøysundregistrene

Validation

Firmaattest

Organisasjonsnummer:

Organisasjonsform:

Stiftelsesdato:

Registrert i Foretaksregisteret:

Foretaksnavn:

Forretningsadresse:

Kommune:

Land:

Under avvikling

c/o TheVIT AS
Gunnar Randers' vei 24
2007 KJELLER
3030 LILLESTRØM
Norge

Organisation Location

This entity is in a pending state

Standardisation

Address Line 1	Gunnar Randers' Vei 24	Address Line 2		Address Line 3	
Address Line 4		Street Number	24	Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	59.974546
GPS Longitude	11.047364	Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor	No	To Date	
Comments	3-Good/ Local Address -> Line1:Gunnar Randers' Vei 24 City:Kjeller Country:Norge Lang:NO				

Record 4 of 4



Rejected change requests:

- *Reject Reason code*
- Comment providing the user with justification and further guidance



OMS does not have change request return option:

If the user did not **submit supporting documentation** or **forgot to update the relevant data**, a **new change request** needs to be created in the system

- For new ORG/LOC – create new change request
- For updates – 1 change at a time – the first change request needs to be rejected, only after the user will be able to submit the new change request



EMA Data Steward

Approves change request



Ensures the data is available
on SPOR and is showing the
correct information



Check the organisation and location
record on the OMS web portal -
<https://spor.ema.europa.eu/omswi/#/>

Organisation Details

Organisation ID:	ORG-100000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details

Location ID:	LOC-100005386
Address:	EN Avenue Einstein 12 Wavre Brabant Wallon 1300 Belgium
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE

Organisation Details

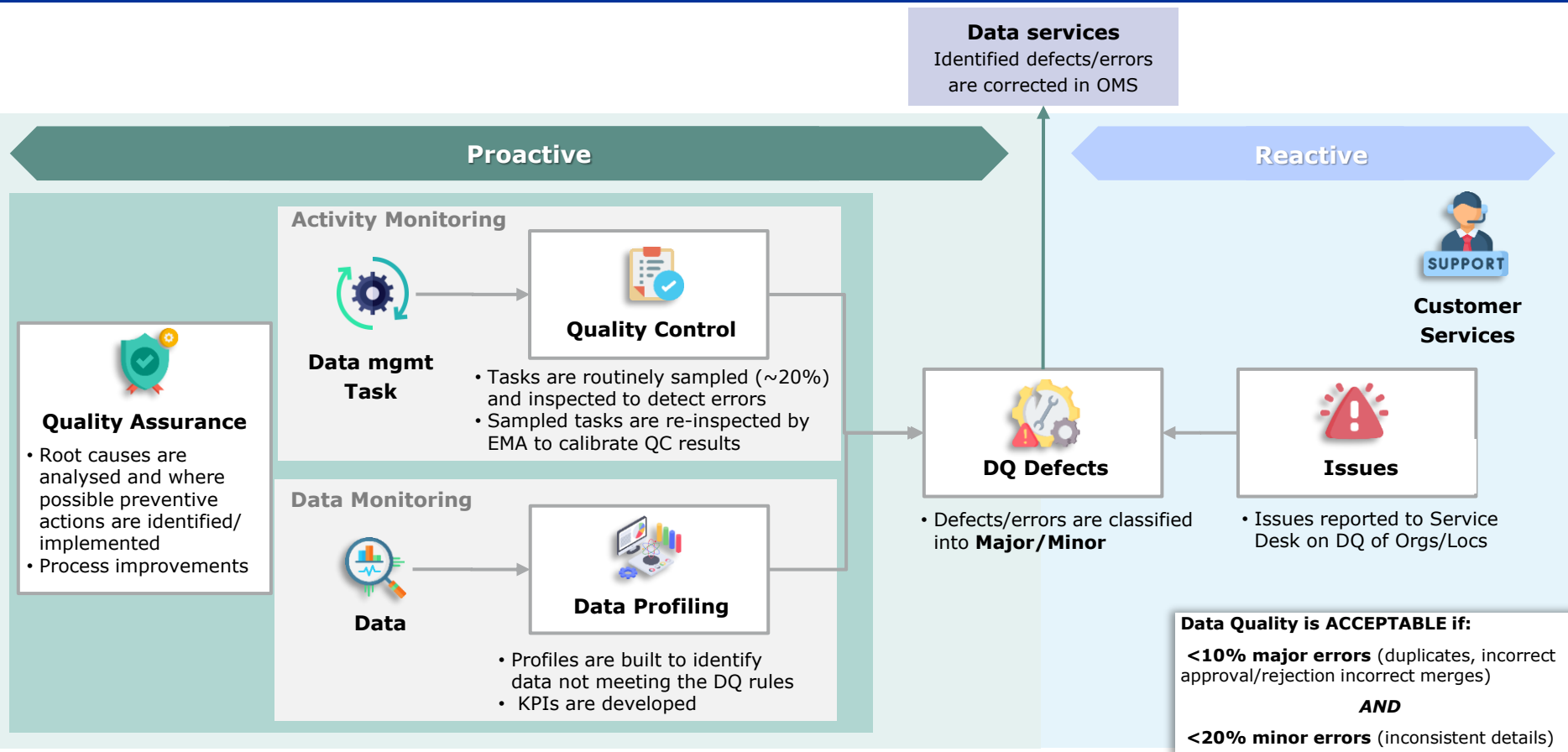
Organisation ID:	ORG-100000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details

Location ID:	LOC-100005386
Address:	FR Avenue Einstein 12 EN Wavre FR Brabant Wallon 1300 Belgique
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE



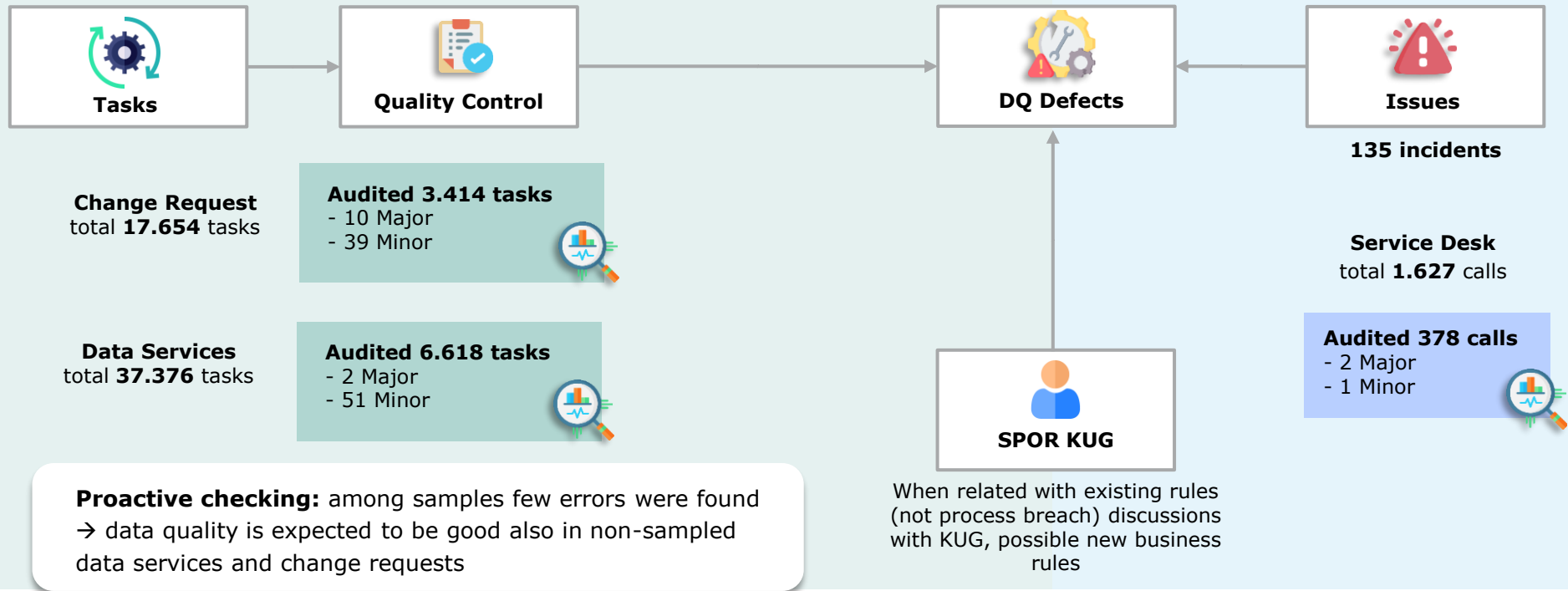
OMS Data Quality Management



Proactive

Reactive

Activity Based Monitoring





Data Quality Errors

Minor

- Update inconsistent with DQ Standards
- Deduplication not performed

Major

- Incorrect merge
- Duplicate created
- Incorrect legal entity
- Deduplication not performed of ACTIVE records



Processing Errors

Minor

- Process breached
- Task not performed

Major

- Incorrectly rejected task

Minor

- Update inconsistent with DQ Standards
- Deduplication not performed

Major

- Incorrect merge
- Duplicate created
- Incorrect legal entity
- Deduplication not performed of ACTIVE records

Minor

- Process breached
- Task not performed

Major

- Incorrectly rejected/approved
- Incomplete rejection/approval

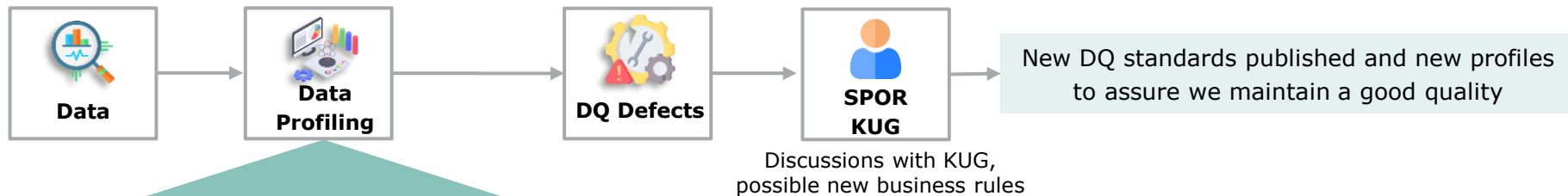
Data services



Change request



Data Based monitoring



- Profiles are built (data vs business rules) to identify data that does not follow the DQ requirements
- Constant monitoring and development
- Priority given following color indicators and type of error (major vs minor):

1. **Red** – outside acceptable thresholds
2. **Yellow**
3. **Green** – close to acceptable threshold, non-100% scores

OMS_LOCATION_DQ				
Scorecard		Properties		
OMS_LOCATION_DQ - metrics				
Name	Total Rows	Invalid Rows	Score	Score Trend
▼ Conformity			98.27	<div></div> ➔
Postcode_Format_UK	11219	2	99.98	<div></div> ➔
Postcode_Format_US	4685	188	95.99	<div></div> ➔
Postcode_Format_NL	2305	1	99.96	<div></div> ➔
Postcode_Format_IT	2603	0	100	<div></div> ➔
Postcode_Format_IE	1762	7	99.6	<div></div> ➔
Postcode_Format_ES	2957	1	99.97	<div></div> ➔
Postcode_Format_CZ	2274	0	100	<div></div> ➔
Postcode_Format_BE	1751	0	100	<div></div> ➔

Scorecard_Org_Dedup

Scorecard

Properties

Scorecard_Org_Dedup - metrics

Name	Total Rows	Invalid Rows	Score	Score Trend
▼ Default			99.99	<div></div> →
ORG_COUNT	41295	1	99.99	<div></div> →



OMS_ORGANISATION_DQ

Scorecard

Properties

OMS_ORGANISATION_DQ - metrics

Name	T..	▲	Score	Score Trend
Accuracy	-			-
▶ Duplications	99.99		<div></div>	→
▶ Conformity	90.49		<div></div>	↗
▶ Consistency	99.99		<div></div>	→
Completeness	-			-

Data Quality attributes

Accuracy

Reflects reality?

Uniqueness

Only instance?

Conformity

Data standardised?

Consistency

Conflicting information?

Completeness

Details missing?



OMS_LOCATION_DQ

Scorecard


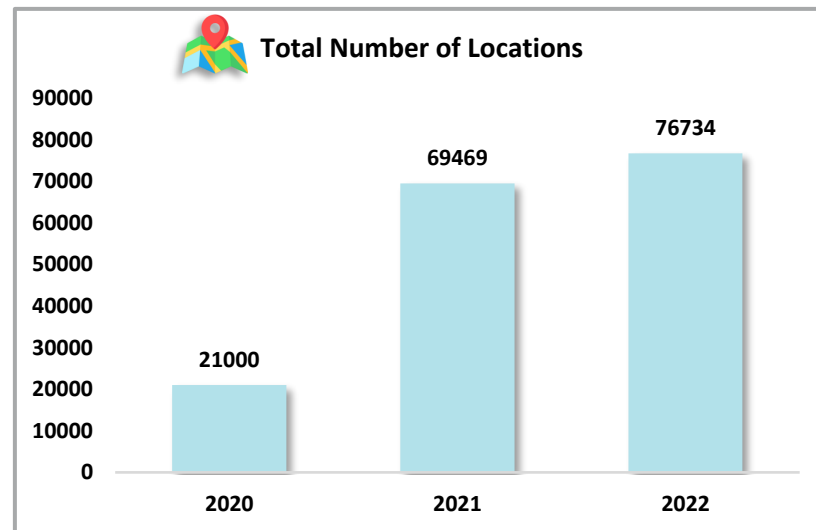
Properties

OMS_LOCATION_DQ - metrics


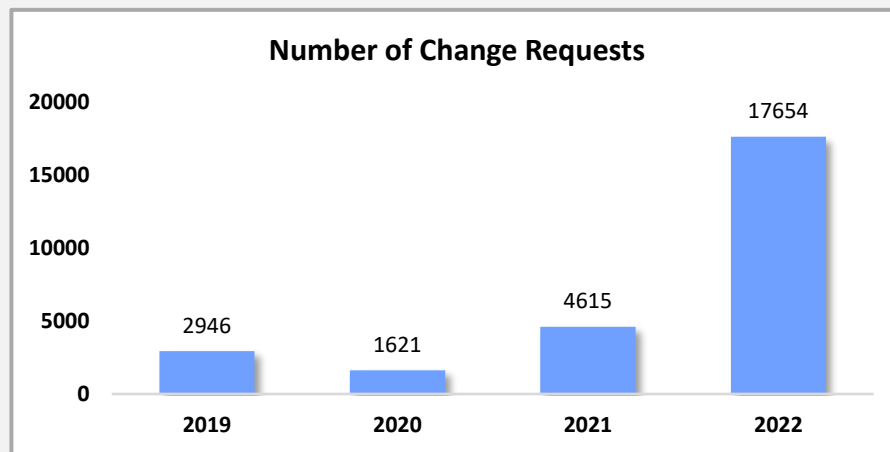
Name	T..	I..	Score	Score Trend
▶ Accuracy			89.92	<div></div> →
▶ Duplications			100	<div></div> →
▶ Conformity			98.27	<div></div> →
Consistency			-	-
▶ Completeness			98.98	<div></div> →



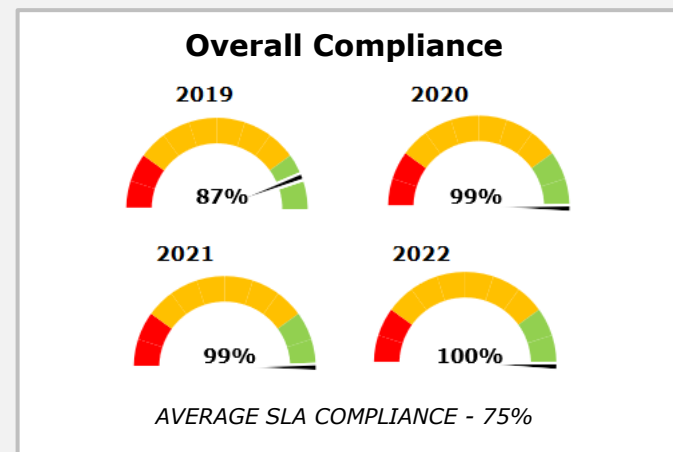
OMS Statistics




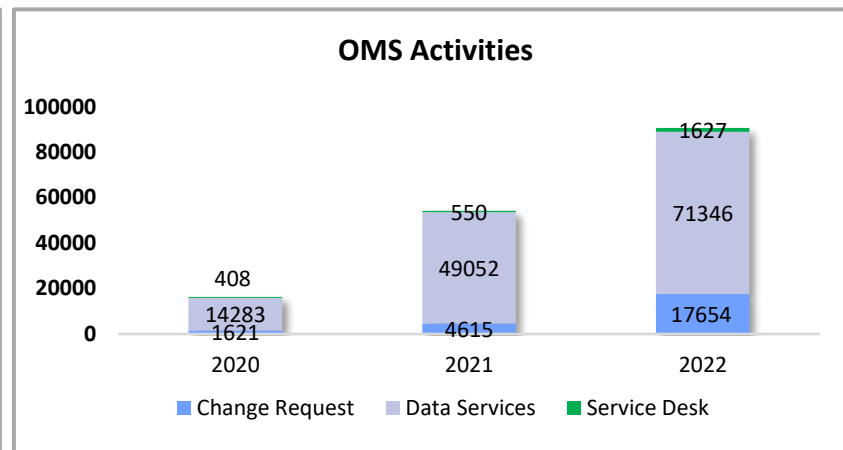
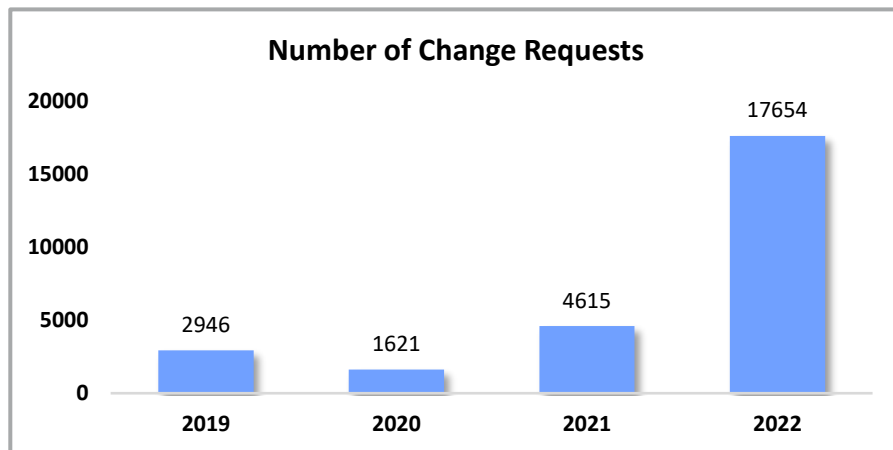
The **increase in organisations (>5k)** and **locations (>7k)** in 2022 was mainly due to the mandatory use of OMS in **UPD, EudraGMDP** and **CTIS**



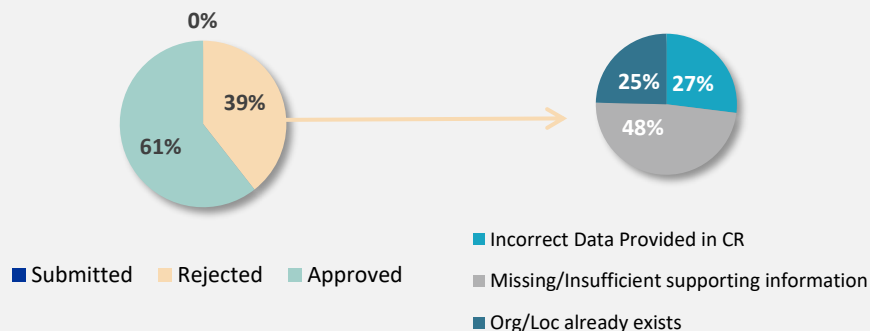
In **2022 change requests** increase of **295% (nearly 4 times more)** due to mandatory use of OMS for UPD, CTIS and EudraGMDP



- 
- In **2022 ~100%** of CRs were resolved **within SLA**
 - Despite the significant increase, we were able to address requests within the agreed deadline

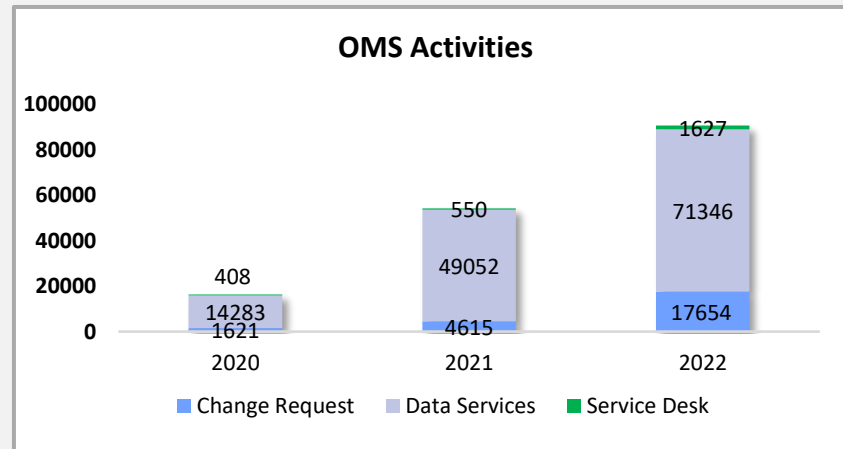
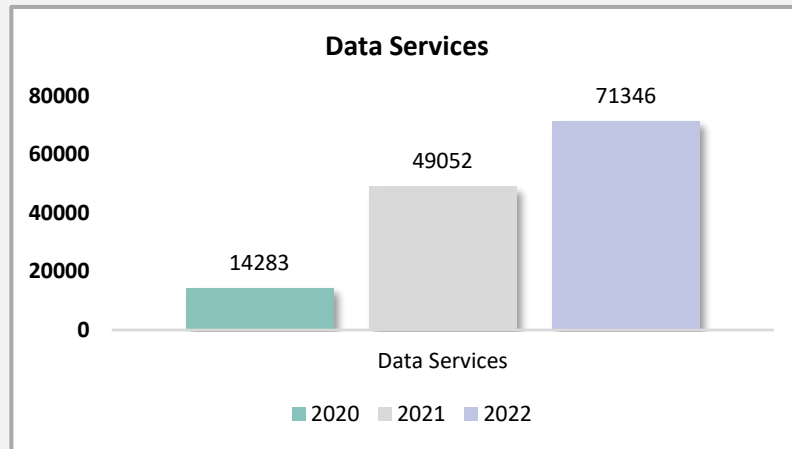


CRs by status 2022



Despite CRs increase of nearly 4 times, rejections decreased by 6%

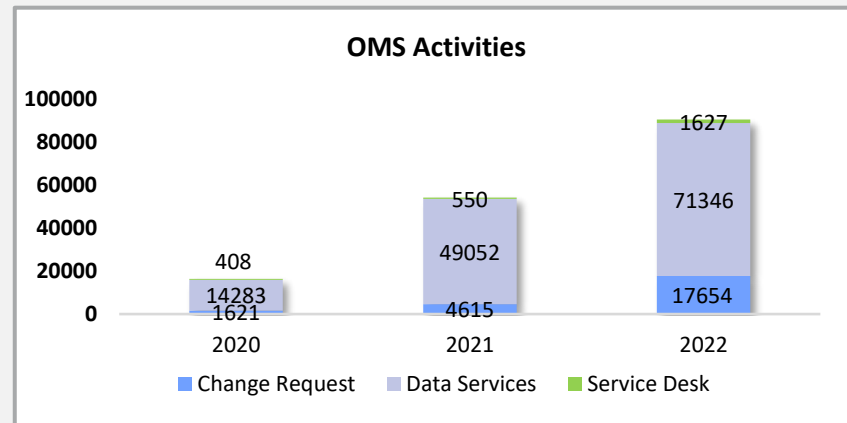
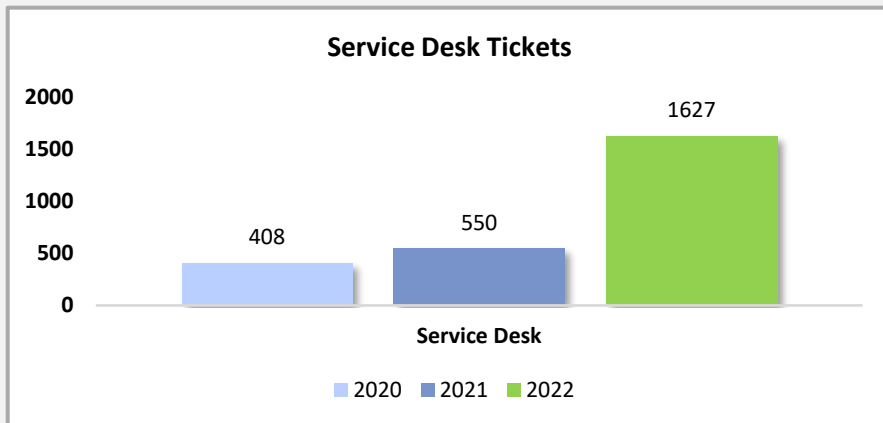
- Most common reason for rejection continues to be Missing/Insufficient information (48%)
- Rejections decreased 6% compared to 2021 due to implementation of a warning message whenever a CR is submitted without any supporting documentation
- To further reduce rejections, we plan to have a return CR functionality, instead of rejecting CRs



In **2022 Data Services** increase of **45% (nearly 2 times more)**:

- Conclusion of EudraGMDP integration – ~63.000 records cleansed in 7 months throughout 2021-2022
- Daily SME and SAP integration
- Currency check (organisations not updated over the past 2 years) – 24.000 records checked, resulting in Deactivation of 22% of the records
- Data profiling - reviewing data and standardising it as per latest DQ rules



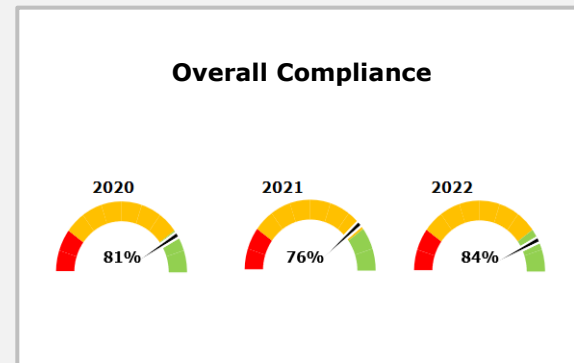


In **2022 Service Desk** increase of **196% (nearly 3 times more)**:

- Mandatory use of OMS for UPD, CTIS and EudraGMDP
- *For Q3&Q4 ~40% where wrongly created in ServiceNow and therefore appear twice in statistics*
- *Significant increase of Data Quality questions (nearly 4x) and Operational/system related questions (nearly 3x)*

In **2022 ~84%** of Service desk tickets were resolved **within SLA**:

- This is 8% improvement when compared to 2021
- The SLA compliance was impacted by the number of IT incidents which required investigation and prevented the team from quick resolution. This affects less than 1336 total of tickets and represents only 2% of the 90k records in OMS



User Perspective

Customer Satisfaction Survey

0,11% Incidents/volume

0,91% Incidents/users

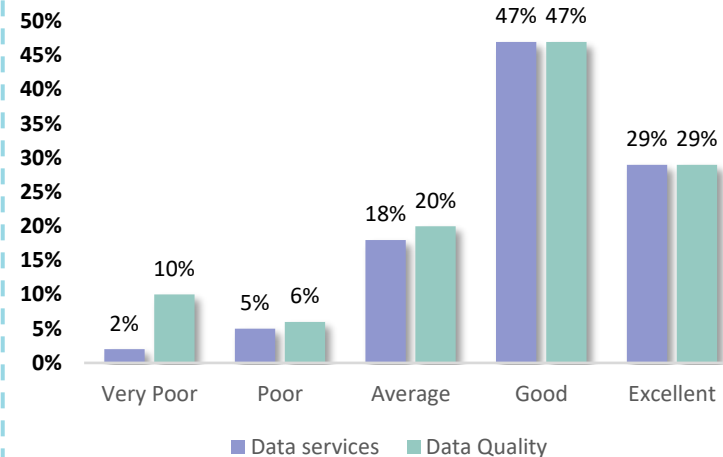
135 Data Quality Incident

14 809 Users

45 304 Organisations

76 734 Locations

Customer Satisfaction



Data Services and **Data Quality** in OMS were positively rated overall by users with over **76%** as "Good" or "Excellent"



OMS Documentation & help

SPOR portal

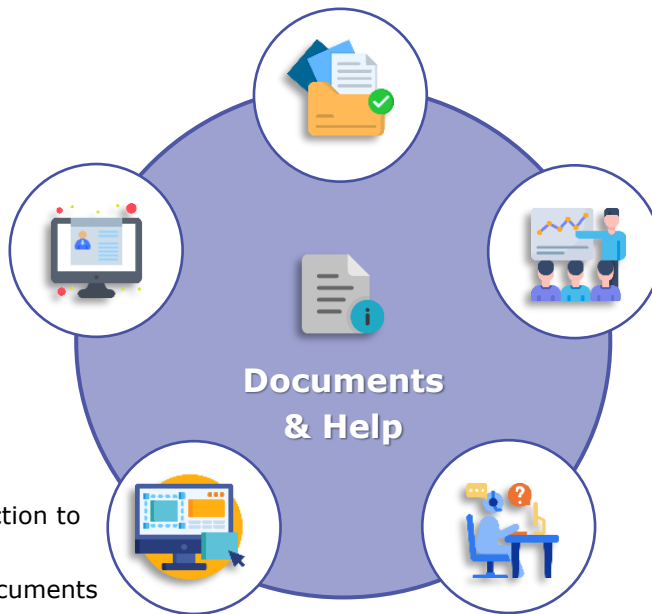
- OMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- Change Request Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)
- OMS FAQs

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



Training opportunities

- [@emainfo channel](#) contains Videos of SPOR webinars with tips/tricks and questions raised from users

EMA Service Desk

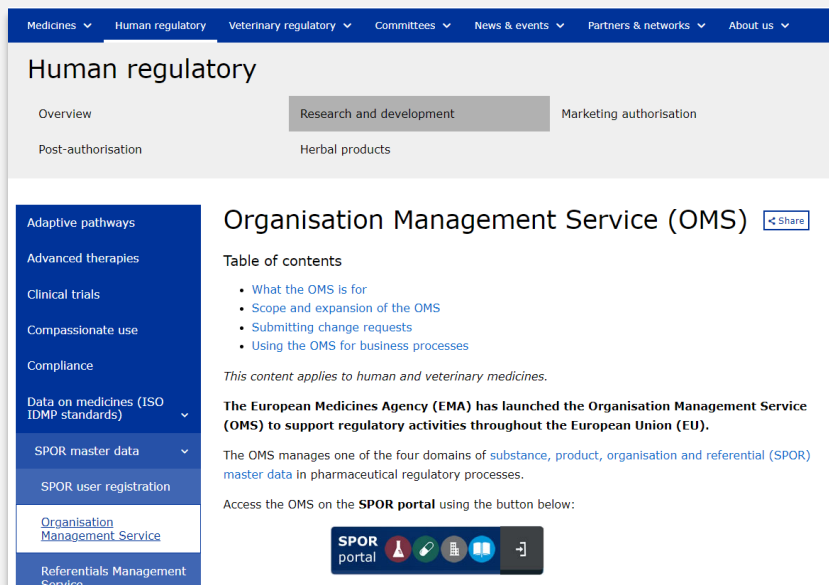
- For any help needed and not found in docs e.g
- Service requests, issues, requests for technical support can be submitted through the [ServiceNow Portal](#)

EMA Corporate website – OMS info



What:

- Background information
- Info on SPOR projects
- OMS vision & OMS project



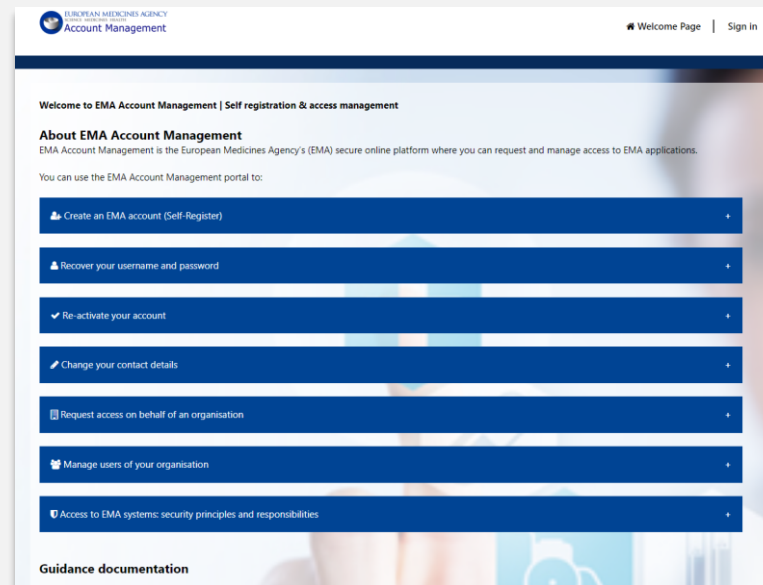
The screenshot shows the EMA Corporate website with the 'Human regulatory' section selected. The 'Organisation Management Service (OMS)' page is displayed, featuring a table of contents and a description of the service. The table of contents includes links to 'What the OMS is for', 'Scope and expansion of the OMS', 'Submitting change requests', and 'Using the OMS for business processes'. The description states that the EMA has launched the OMS to support regulatory activities throughout the EU, and it manages one of the four domains of substance, product, organisation and referential (SPOR) master data. A button for the 'SPOR portal' is visible at the bottom.

EMA Account Management



What:

- General guidance on how to register users and use IAM tool
- Detailed instructions for OMS are in a ppt in SPOR portal and in videos on YouTube



The screenshot shows the EMA Account Management portal. The header includes the EMA logo and the text 'Account Management'. The main content area is titled 'Welcome to EMA Account Management | Self registration & access management'. It provides information about the EMA Account Management platform and lists several options for users to manage their accounts, including 'Create an EMA account (Self-register)', 'Recover your username and password', 'Re-activate your account', 'Change your contact details', 'Request access on behalf of an organisation', 'Manage users of your organisation', and 'Access to EMA systemic security principles and responsibilities'. A 'Guidance documentation' section is also visible at the bottom.



[OMS Web UI \(europa.eu\)](https://europa.eu)

OMS portal Documents:

- Link access to export the document
- Short description of document content
- Last update date

OMS service & Statistics & quick initiation guidance

Process guidance: Operating Model; DQ standards used, system/ CR guidance

OMS in consuming systems

Performance: customer satisfaction surveys & SLAs

Registration process & templates

API access

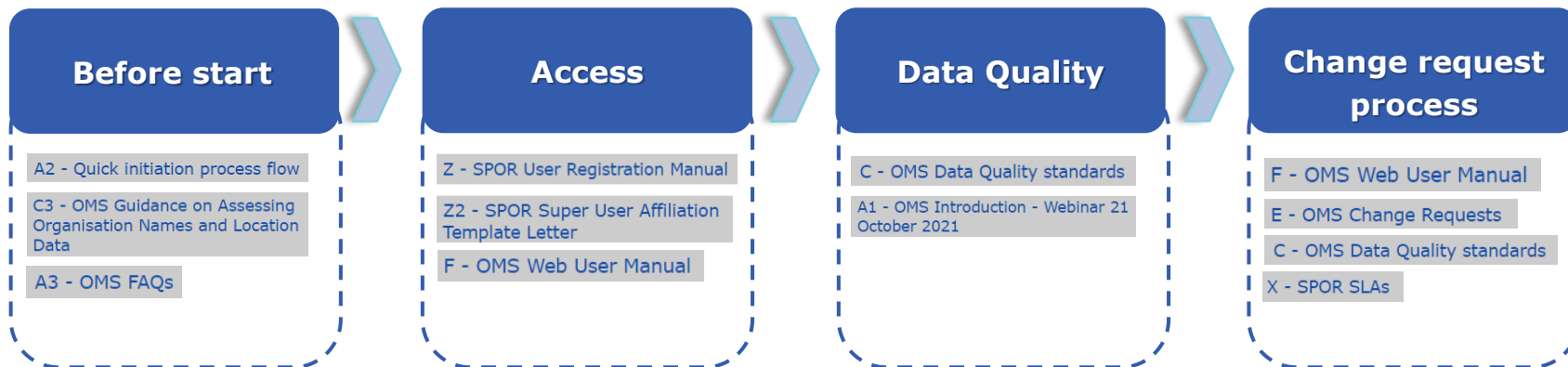
General	Technical	
Document Name ▲	Document Description ↓	Published Date ↓
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.	2017-06-26
A1 - OMS Introduction - Webinar 21 October 2021	Webinar - OMS Key principles, services and activities - 21 October 2021	2021-02-04
A2 - Quick initiation process flow	Guidance - Quick reference guidance for first time users: introduction, access and add/update records	2022-02-03
A3 - OMS FAQs	Guidance - OMS Frequently Asked Questions	2023-02-13
A4 - OMS Introduction - Webinar 10 March 2022	Webinar - OMS services, activities and statistics - 10 March 2022	2022-03-14
A5 - OMS News Items	NEWS - Recent changes implemented, open discussions, future discussions and upcoming functionalities	2023-02-23
A6 - OMS Introduction - Webinar 15 September 2022	Webinar - OMS services, activities and statistics - 15 September 2022	2022-09-20
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.	2018-05-25
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS	2023-03-09
C1 - OMS DQ - Webinar 25 September 2018	Webinar - Key principles and rules covered in OMS Data Quality standards - 25 September 2018	2018-11-19
C2 - OMS DQ - Webinar 26 February 2019	Webinar - OMS Data Quality Issues - 26 February 2019	2019-08-16
C3 - OMS Guidance on Assessing Organisation Names and Location Data	Guidance - When minor differences between organisation names and location data are acceptable	2021-02-16
C4 - OMS Mapping Guidance	Guidance - Process for mapping and when to create an OMS change request	2021-06-02
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	2017-06-16
E - OMS Change Requests	Guidance - Rules and Supporting documentation required by change request type	2023-01-23
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.	2018-04-17
G - Using OMS data in eAF - Webinar 27 June 2018	Webinar - OMS landscape and its use in eAF and in CESP in the future - 27 June 2018	2018-06-27
G1 - Q&A on eAF Mandatory use of OMS	Process - OMS mandatory for CAPs from November 1st onwards - Questions and Answers	2021-10-06
H - Manufacturer organisations in the OMS dictionary	Process - Manufacturer organisation data lifecycle in the context of regulatory activities and who is responsible for registration/updating organisation data about manufacturers in the OMS.	2018-12-18
I - Impacts of OMS merge on EMA systems	Guidance - Validation of OMS consuming system data after the merge takes place in OMS	2021-04-28
J - CT registration Headed letter template	Template - For requesting the creation of sponsors and/or clinical trial sites	2023-01-23
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.	2017-06-26
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, Industry on-boarding, and eAF integration.	2018-02-12
V1 - RDM Customer Satisfaction Survey 2021	SPOR Customer Satisfaction Survey November 2021	2022-01-31
V2 - RDM Customer Satisfaction Survey 2022	SPOR Customer Satisfaction Survey October 2022	2023-02-13
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.	2021-02-17
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.	2023-02-14
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 October 2017	2020-07-15
Z2 - SPOR Super User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.	2020-09-20
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers	2017-12-06
Z4 - SPOR API Access - Webinar 10 November 2021	SPOR API Access - Webinar 10 November 2021	2021-11-11
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use	2021-06-29
Z6 - SPOR API Access Request Form	SPOR API Access Request Form	2021-11-08
Z7 - SPOR API Access and Usage - Webinar 18 March 2022	Webinar - API Registration process and OMS/RMS API usage demo and tips	2022-04-04



[OMS Web UI \(europa.eu\)](http://europa.eu)



A5 - OMS News Items





EMA YouTube Channel



What:

- Videos of webinars, related PPTs can be found in SPOR portal

The screenshot shows the EMA YouTube channel page. The channel name is "European Medicines Agency" with the handle "@ema.info" and 17.6K subscribers. The navigation bar includes links for HOME, VIDEOS, LIVE, PLAYLISTS, COMMUNITY, CHANNELS, and ABOUT. A search bar contains the text "rms". The video list includes:

- SPOR Learning Module: RMS01 - Overview of RMS** (European Medicines Agency • 1.8K views • 5 years ago) - 11:40
- Introduction to Referential Management Service (RMS): Industry Webinar** (European Medicines Agency • 175 views • 3 months ago) - 1:29:35
- EMA SPOR RMS training** (European Medicines Agency) - Includes "SPOR Learning Module: RMS01 - Overview of RMS • 11:40" and "SPOR Learning Module - RMS02 Viewing RMS Data • 24:39". A "VIEW FULL PLAYLIST" link is available.
- Industry Webinar - Introduction to RMS services and activities** (European Medicines Agency • 3.3K views • 1 year ago) - 36:34

Service Now - SPOR Dashboard



What:

- For any help needed and not found in documentation
- Request support with an OMS CR that cannot be submitted via the OMS Portal
- Report a technical issue with the use of the OMS Portal

The screenshot shows the ServiceNow SPOR dashboard. The header includes the EMA logo, "ServiceNow", a search bar, and a "Go to BackEnd" link. The navigation bar shows "IT" > "Facilities Support" > "Emabym.Eartha...". The main content area is titled "SPOR" and includes a "Browse SPOR" section with filters and sorting options. The dashboard displays a grid of request cards:



- Request SMS services** (Request assistance with the management of substance...)
- Request XEVMPD/ArL57...** (Request assistance with the management of product...)
- Request OMS services** (Request assistance with the management of...)
- Request RMS Service** (Request assistance with the management of referential...)
- Report an Issue with SMS** (Report an issue with the Substance Management...)
- Report an Issue with XEVMPD/ArL57** (Report an issue with the extended EudraG licence...)
- Report an Issue with OMS** (Report an issue with the Organisation Management...)
- Report an issue with RMS** (Report an issue with the Referential Management...)
- Request SPOR API Services** (Questions and access request to the SPOR API...)
- Report an Issue with SPOR API** (Report an issue with the SPOR API access or conte...)
- Report an Issue with PMS** (Report an issue with the Product Management...)



OMS in Projects/Systems



System	Domain	Process
EMA Account Management & EV registration	H&V	User registration, identity and access management
EudraCT & CTIS	H	Phase 1-4 Trials
IRIS	H&V – CAPs only	Scientific Advice + Orphan Designation + ITF + Marketing Status + Inspections + Parallel Distribution
eAF & DADI*	H&V	Submission MAA, Variations, Renewal
SIAMED via ECD	H&V – CAPs only	Review, Approval
UPD	V	Approval
EudraGMDP	H&V	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation
XEVMPD & EV vet	H&V	Safety reporting

Legend	
	Implemented
	Planned
	Not planned yet



IRIS

Applicants, MAHs and manufactures must be available in the OMS Dictionary before any submission



EudraGMDP

Manufactures and WS distributors – all sites and holders must be available in the OMS Dictionary so that NCAs can issue a certificate



CTIS

Sponsors and CT sites must be available in the OMS Dictionary before any submission



eAF for CAPs

MAH and manufactures must be available in the OMS Dictionary before any submission



UPD

MAH and manufactures must be available in the OMS Dictionary before any submission

Mandatory use of Organisations and Locations details from OMS

Data will not be a copy of supporting documentation, data used in each system will follow OMS standards e.g. manufacturing lines and/or department information will have to be maintained at consuming system level



How OMS data is used in these processes/systems is the BIGGEST challenge!

OMS & KUG are collecting relevant questions from users to prepare **FAQs for each process** in the hope to create clarity and also some standardisation - we have started with OMS mandatory in CAPs and its FAQs



Planned OMS activities

Q1 2023

Q2 2023

Q3 2023

Q4 2023



Deliver efficient and effective regulatory data services

OMS – Customer Services

Process improvement – Simplify Incident mgt

Increase QC/QA

Review Serv Desk Q&A

OMS – Data Management (Change requests & Data services)

OMS Data protection notice

Implementation – EV Deltas to OMS

Process improvement – SAP (Manual) Deltas

OMS – Data Quality

Enrichments

- NBRn
- DUNS?
- Notified Bodies +

Mapping

- EV Backlog to support iSPOC

Cleansing

- Big plots/Multiple doors review?

1

EV Currency check- MAH

Currency check

2

Revise DQ targets

New/updated DQ profiles

OMS – Documentation

OMS in CP – eCPP and others extension

(New) How to read our docs

Review & condense OMS docs

ServiceNow experience > collect user histories and how can we improve based on the same

(New) Data management (to include merges)

OMS – Awareness & visibility

SPOR webinars

SPOR webinars

SPOR Customer Satisfaction survey



Improve customer satisfaction and success



Modernise Data & Information Management

Information Management Modernisation initiatives

Infrastructure/technical improvements

OMS planned improvements – Bug fixes, Return CR functionality, New flag to identify HQ locations, Display NBRn in WebUI/OMS portal and allow its maintenance through CR

3

Upgrade Unaffiliated role

Prioritised Epics (eAF, IRIS, ePI, shortages and other)



2022



Organisation currency
~24k*
22% Deactivated

*records not updated for the last 2 years



2023

Organisation currency
~12k*
on-going...



We encourage companies to **perform a currency** check not only at organisation level but mainly at **locations level** – *most of the locations are not available in the national business registry and EMA needs the support from companies to ensure all locations available in OMS Dictionary are still being owned/used by organisations*



WHY

- Ensure information in OMS is current
- Prevent Inactive Organisations of being incorrectly used in applications/regulatory processes
- Simplify processes that rely on current information, such as fee collection



HOW & WHEN

- Review any record not updated for more than 2 years - Still Active?



IMPACT to users

Help us ensure that OMS has current data using change request functionality:

- Deactivate an organisation if it ceased to exist as legal entity in the National Business registry – no changes necessary if no longer used in a given context
- Deactivate a Location if the address does not "belong" i.e. is no longer owned by the organisation



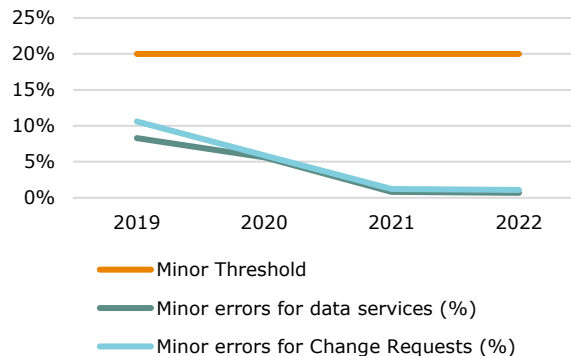
Background

Data Quality is **ACCEPTABLE** if:

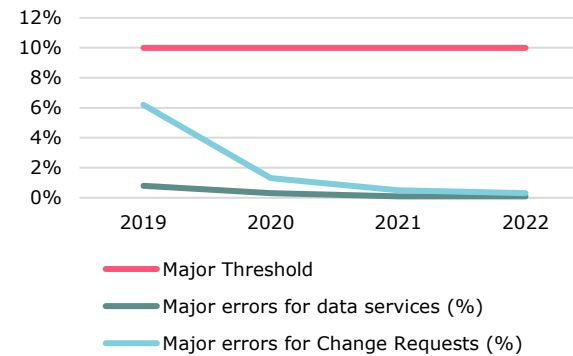
- **<10% major errors** (duplicates, incorrect approval/rejection incorrect merges)
- **<20% minor errors** (inconsistent details)

OMS Services
over time

Overall Quality: Minor Errors



Overall Quality: Major Errors



Conclusions

For the past 4 years we have been performing **consistently under** the defined **thresholds**

Next steps

We are **halving major and minor targets**

Data Quality is **ACCEPTABLE** if:

- **<5% major errors** (duplicates, incorrect approval/rejection incorrect merges)
- **<10% minor errors** (inconsistent details)



Guest

- Search
- Content view



SPOR Unaffiliated

- Automatically assigned to every EMA account
- Export information
- **Create/Update ANY record** – no need to be affiliated to that same company



SPOR Industry/NCA User

- Require to request role in EMA AM
- Approved by Super User
- Export information
- Create/Update **ANY** record – no need to be affiliated to that same company



SPOR Industry/NCA Super User

- Require to request role in EMA AM
- Approved by EMA – affiliation letter needed
- At least 2 Super Users per organisation
- Export information
- Create/Update **ANY** record – no need to be affiliated to that same company

For the first Super User the requester's e-mail should be a work e-mail from the same organisation on behalf of which the user is requesting the user access



WHY

- Simplify access requirements to **new OMS users**
- SPOR Unaffiliated users had limited access to change request functionality – limited to 1 pending Created Organisation CR at a time and unable to update any record



HOW & WHEN

- Any OMS user that has an EMA account has the **SPOR Unaffiliated** role assigned automatically and can **create/updated any of the OMS records**
- No changes to other roles – Guest, SPOR Super user or SPOR User



IMPACT to users

- In OMS SPOR Unaffiliated role now has the same permissions i.e. can perform the same activities as SPOR User role
- SPOR Super User role is still required to manage users of a certain organisation



Key takeaways and conclusions



Increase Awareness of OMS activities

- *Provided background information: introduction to OMS, OMS processes (CR, DQ)*
- *Provided key updates: revised statistics, integration in business processes*



Share planned activities

- *EV to OMS Deltas*
- *Revised and shortened data quality targets*
- *Planned user experience improvements (UI and API) and data quality*
- *First 2 quarters of 2023 dedicated to Infrastructure/technical improvements*



Show how OMS is addressing customer feedback




- *Continue to improve OMS Documentation e.g. (new) News Items*
- *Change OMS access – upgrade Unaffiliated role*



Any questions on the webinar?



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



Further information

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

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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