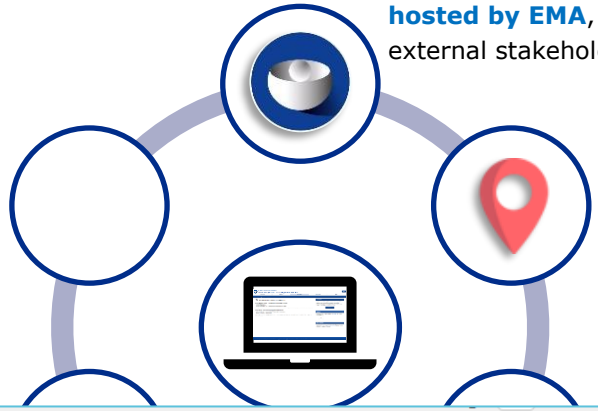
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Organisation Management Services (OMS)

Presented by Débora Martins Braga on 9 February 2024
Master Data Manager – I-CS-RDM

OMS Introduction - Key Principles (1/4)

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.

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OMS Introduction - Key Principles (2/4)

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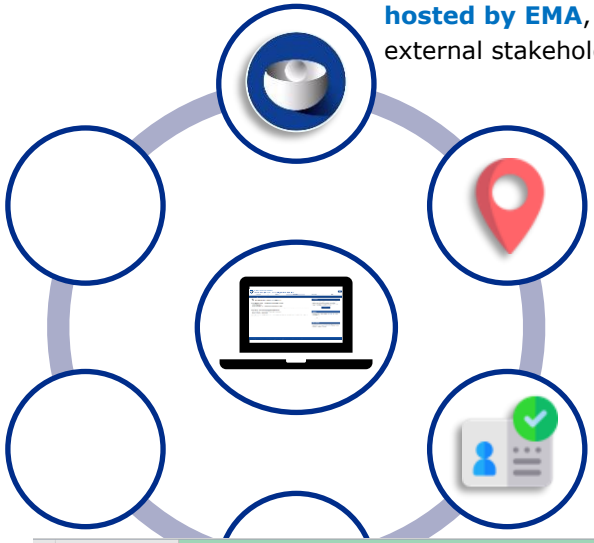
OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



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 WI	10-18	2201	Hagenbrunn	Österreich
6	Sandoz GmbH	- Außenlager Gebrüder Weiss GmbH	GA - aktiv	Löfflerweg	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 Schaftenau / 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

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OMS Introduction - Key Principles (3/4)

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

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OMS Introduction - Key Principles (4/4)

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

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

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**

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

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**

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OMS Introduction – Data vs Reference Sources

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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 Data Quality rules

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OMS Change Request process

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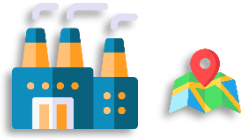
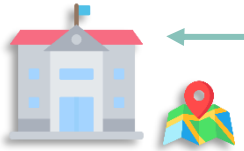
OMS Change request process – Who can change OMS data?



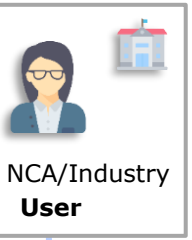
Manufactures

MAH, Sponsor
NCA

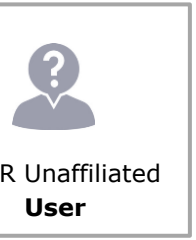


Hospitals, University

SPOR NCA/Industry
Super User



SPOR NCA/Industry
User



SPOR Unaffiliated
User

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

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OMS Change Request process at a glance

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Submission

Requestor

Submit OMS CR with **supporting document**

Validation/Standardisation

EMA Data Stewards

Guidance/ references & tools

Data Stewards validate all OMS CRs using guidance/ references & tools:

- **Validation**: Supporting documentation and/or National Business registry
- **Standardisation**: OMS Data Quality standards and/or AddressDoctor validation service

Approval/Rejection

EMA Data Stewards
EMA is OMS Data Owner

- 5-10 WD SLA
- CR **Approved** or **Rejected**
- If disagreement, raise ticket in Service Desk, indicating CR number

Organisation data owner
EMA

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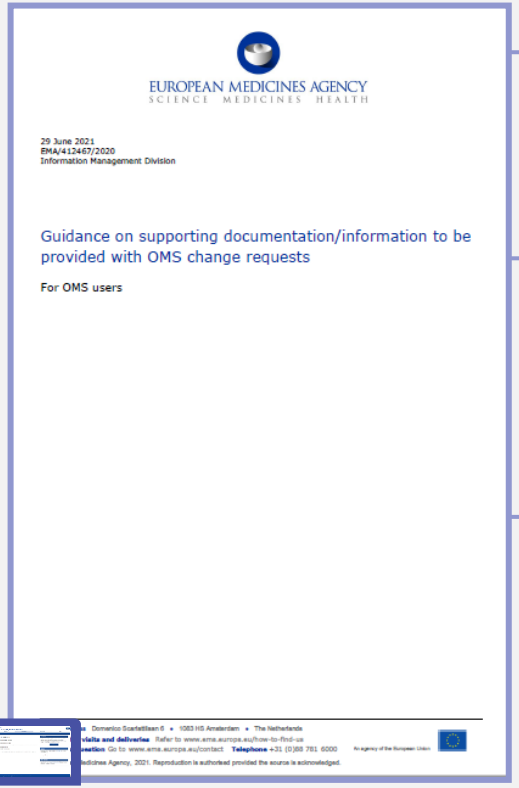
Supporting documentation for Change Requests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SCIENCE MEDICINES HEALTH

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. Extract from the National Business Registry
2. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data
3. Headed letter with organisation and location details – signed and dated

*The numbering indicates the order of documentation preference for each organisation/jurisdiction

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Example - CR Process Organisation validation & standardisation

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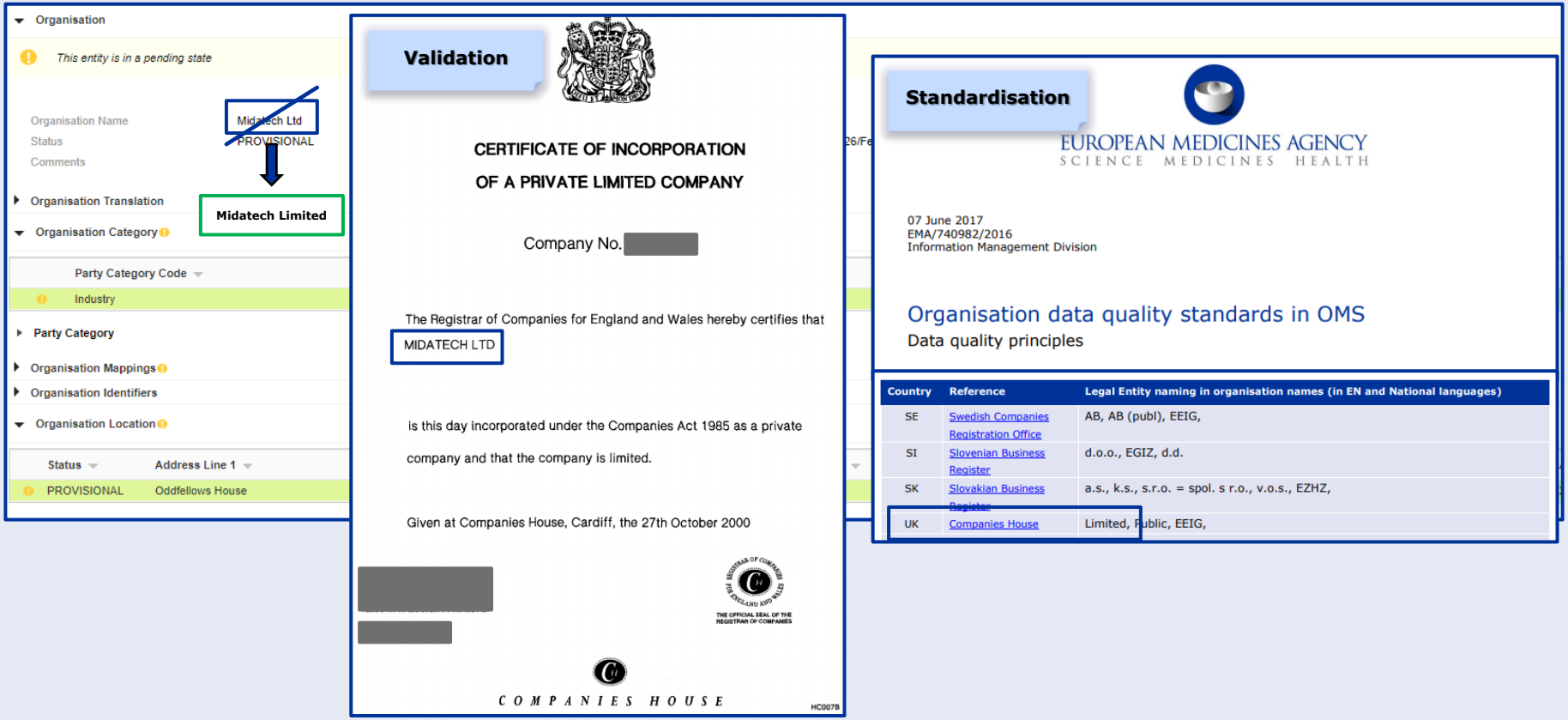

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Example - CR Process Location validation & standardisation

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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

Validation

Brønnøysundregistrene — Firmaattest

Organisasjonsnummer: [redacted]
Organisasjonsform: [redacted] — Under avvikling
Stiftelsesdato: [redacted]
Registrert i Foretaksregisteret: [redacted]
Foretaksnavn: [redacted]

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

Kommune:
Land:

Standardisation

Organisation Location

This entity is in a pending state

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

National Postal Service

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Change request process – add/update OMS data

CTIS portal vs OMS portal

CTIS Portal

- **Add organisations**
- **Add Location**

OMS Portal

- **Add organisations**
- Update Organisation
- **Add Location**
- Update Location
- Update Organisation & Location

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SPOR - Organisations Management System

Change Request process

Change Request will be **REJECTED**, to:

- Legal entities **NOT** present in the National Business Registry (OMS Data Quality Standards defines respective official registry per county – i.e. private clinics, entrepreneurs…

Organisations and locations need to be created/maintained directly in **CTIS local repositorium**

Change Request will be **APPROVED**, to:

- Legal entities present in the National Business Registry (OMS Data Quality Standards defines respective official registry per county)
- Public entities (i.e. Ministry of health, ethics committee, hospital, university…)
- Sponsors (dedicated registration process for sponsors where the above doesn't apply)

Organisations and locations will be published and maintained in the **OMS Dictionary**

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OMS Documentation & help

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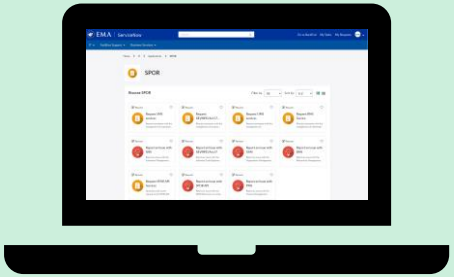
How to reach OMS team?

OMS portal

Change Request functionality to update/add organisation locations to OMS Dictionary

OMS Web UI (europa.eu)



ServiceNow

Questions (data or system related), report an incident or follow-up on Change request

Employee Topic - Employee Center (europa.eu)

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OMS Documentation & Help (I)

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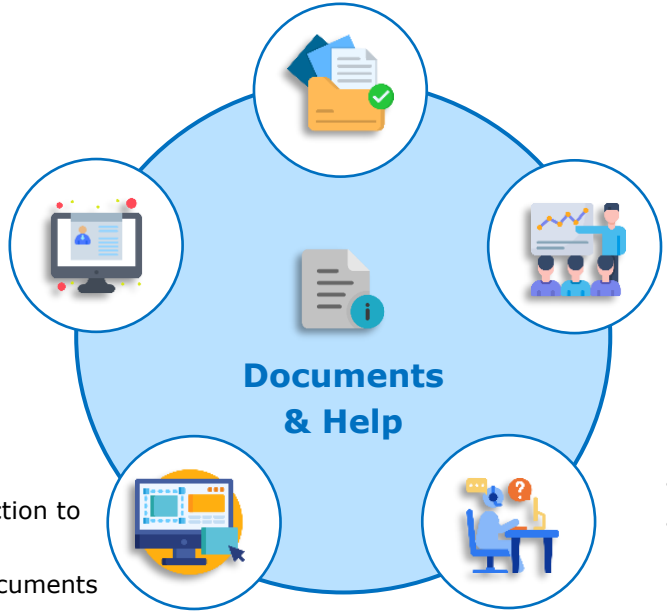
SPOR portal

- 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



Training opportunities

- @emainfo channel contains Videos of SPOR webinars with tips/tricks and questions raised from users

EMA corporate website

- SPOR vision and general introduction to SPOR projects
- SPOR related information and documents

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

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OMS Documentation & Help (II)

OMS Web UI (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
A2 - Quick initiation process flow	Guidance - Quick reference guidance for first time users: introduction, access and add/update records	2023-07-13
A3 - OMS FAQs	Guidance - OMS Frequently Asked Questions	2023-05-31
A5 - OMS News Items	NEWS - Recent changes implemented, open discussions, future discussions and upcoming functionalities	2023-02-23
A7 – OMS Webinar – SPOR Week 18 April 2023	Webinar - OMS services, activities and statistics - 18 April 2023	2023-04-27
A8 – SPOR Data Governance – SPOR Week 17 April 2023	Webinar - SPOR Data Governance	2023-04-27
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	2023-07-13
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
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
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
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
Z8 – Access to SPOR API – SPOR Week 20 April 2023	Webinar - API Registration process and OMS/RMS API usage demo and tips	2023-04-27

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OMS Documentation & Help (III)

OMS Web UI (europa.eu)

A5 - OMS News Items

Before start

- A2 - Quick initiation process flow
- C3 - OMS Guidance on Assessing Organisation Names and Location Data
- A3 - OMS FAQs

Access

- Z - SPOR User Registration Manual
- Z2 - SPOR Super User Affiliation Template Letter
- F - OMS Web User Manual

Data Quality

- C - OMS Data Quality standards
- A1 - OMS Introduction - Webinar 21 October 2021

Change request process

- F - OMS Web User Manual
- E - OMS Change Requests
- C - OMS Data Quality standards
- X - SPOR SLAs

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Any questions?

Further information

Employee Topic - Employee Center (europa.eu)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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