



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Troubleshooting session for CTIS (Organisation Management Services)

Session 3

Presented by Débora Martins Braga in October 2022
Master Data Manager – I-CS-RDM

An agency of the European Union



- Questions raised for today
- Housekeeping rules
- Questions previously raised
- Supporting documentation





Questions raised for today

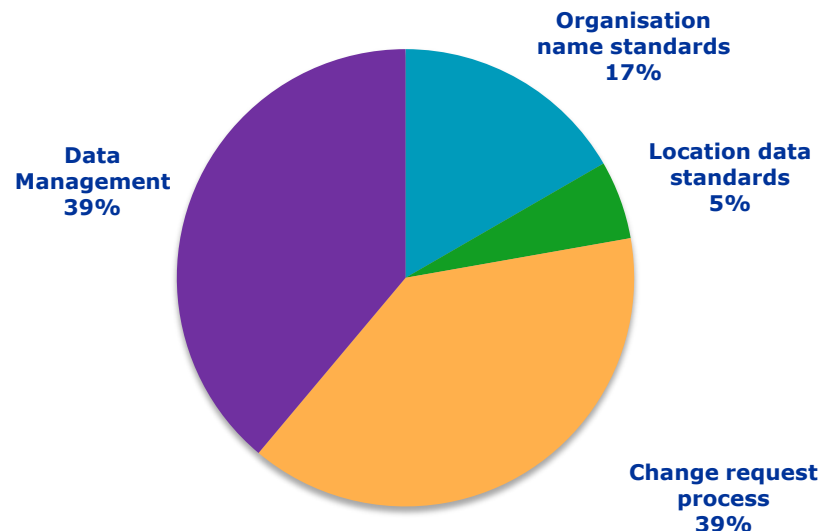


Troubleshooting questions

session 3

Objective: clarify OMS related questions

- 2 questions on Data management





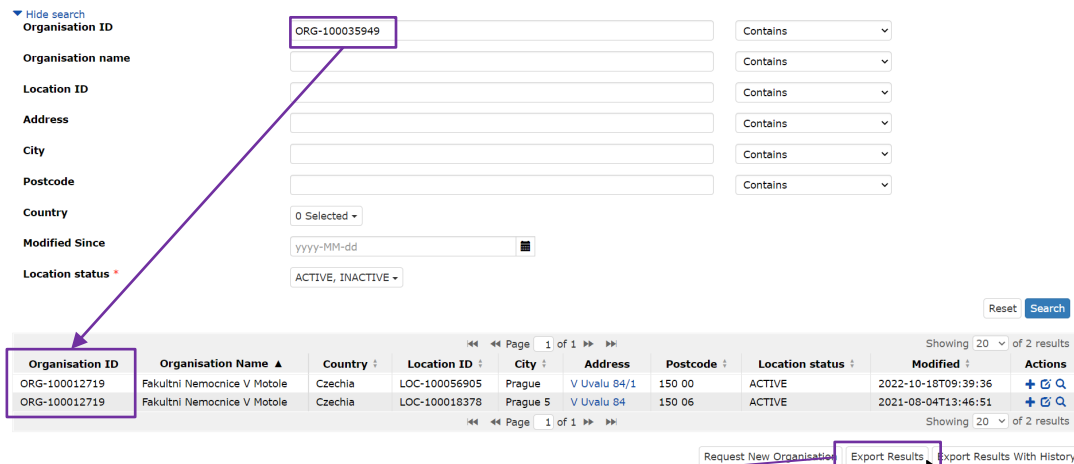
Our organisation is twice registered in the OMS system ORG-100012719 and ORG-100035949?



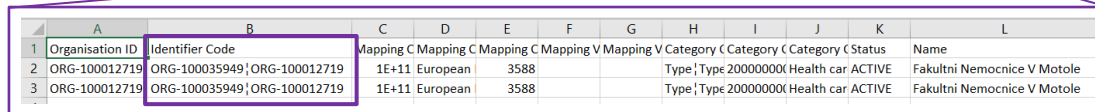
Data management

OMS is a master data management system that:


- Never delete any information – if no longer relevant or wrongly created the record it will be inactivated
- Retains historical data such as historical/previously recorded names and other system identifiers
- Have the merge capability, where in case of a merge (business merge or deduplication) all identifier are valid and mapped to the golden record



Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100012719	Fakultni Nemocnice V Motole	Czechia	LOC-100056905	Prague	V Uvalu 84/1	150 00	ACTIVE	2022-10-18T09:39:36	+ +
ORG-100012719	Fakultni Nemocnice V Motole	Czechia	LOC-100018378	Prague 5	V Uvalu 84	150 06	ACTIVE	2021-08-04T13:46:51	+ +



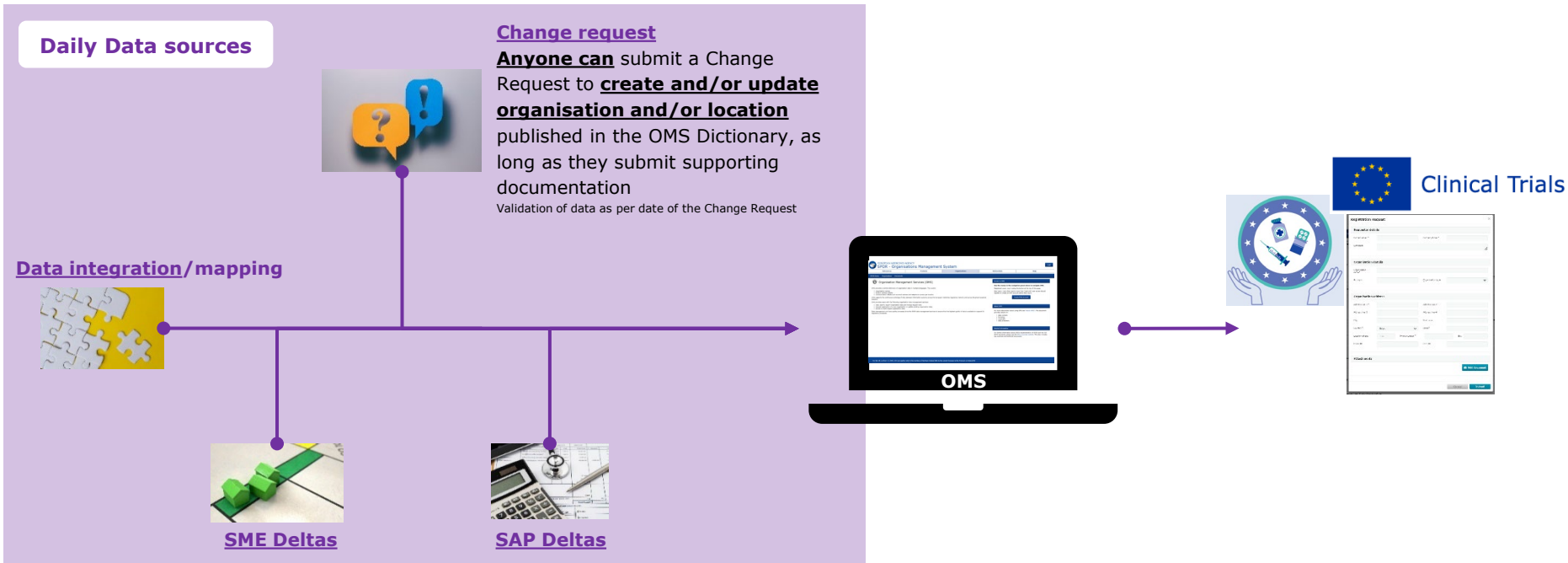
A	B	C	D	E	F	G	H	I	J	K	L	
1	Organisation ID	Identifier Code	Mapping C	Mapping C	Mapping C	Mapping V	Mapping V	Category C	Category C	Category C	Status	Name
2	ORG-100012719	ORG-100035949;ORG-100012719	1E+11	European	3588			Type;Type 20000000(Health car	ACTIVE	Fakultni Nemocnice V Motole	
3	ORG-100012719	ORG-100035949;ORG-100012719	1E+11	European	3588			Type;Type 20000000(Health car	ACTIVE	Fakultni Nemocnice V Motole	




Our organisation is registered in the OMS system, but the institution did not do the registration and does not know who made the registration




Data management






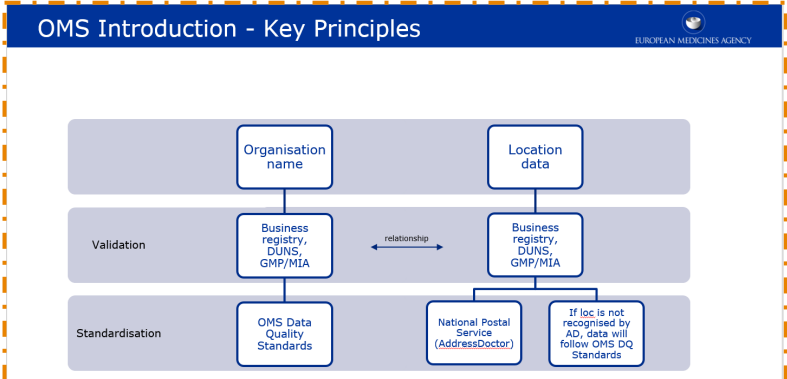
How can we have/register locations that are not available in the National business register?







Change Request process



Source: OMS webinar



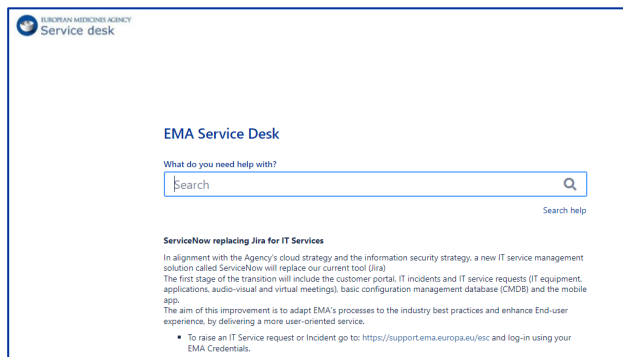
OMS Dictionary can have as many locations as used by an organisation

1. Add Organisation with location details available in the Business registry 
2. Add other locations details required for regulatory procedures
 - If a certain physical address is being used by another ORG, we need to create a **new location** (new relationship) ORG<>LOC 
 - **Location** (LOC ID) can only be **linked to one organisation** 
 - Physical address can be linked to as many organisations as needed 

Change request
Anyone can submit a Change Request to **create and/or update organisation and/or location** published in the OMS Dictionary, as long as they submit **supporting documentation**
Guidance on type of documentation to be submitted per type of change request is available on the OMS portal under E - OMS Change Requests
Validation of data as per date of the Change Request



Housekeeping rules

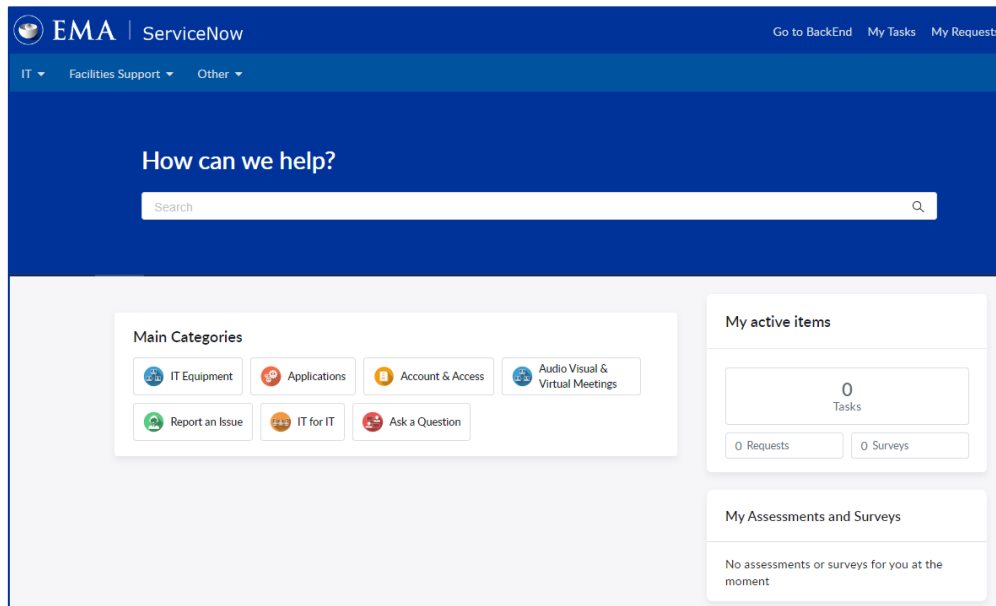


Any tickets opened **BEFORE**
September 12th 2022 will be
addressed via **Service Desk**



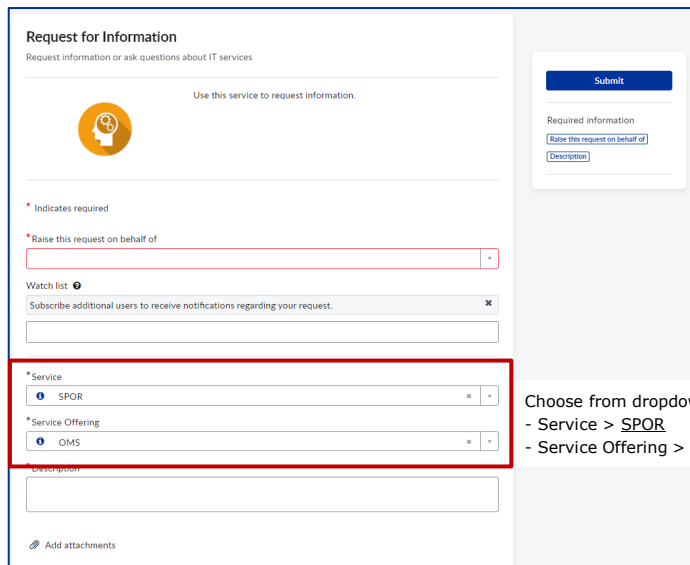
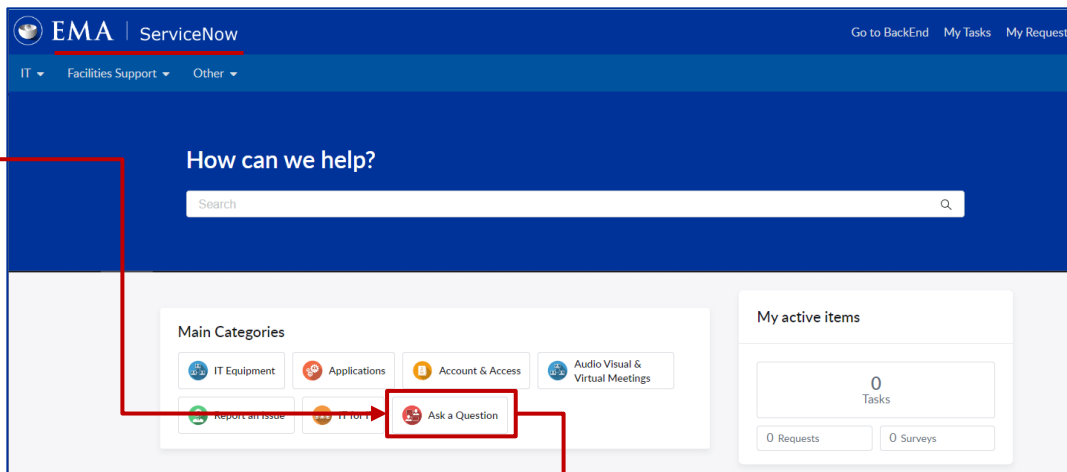
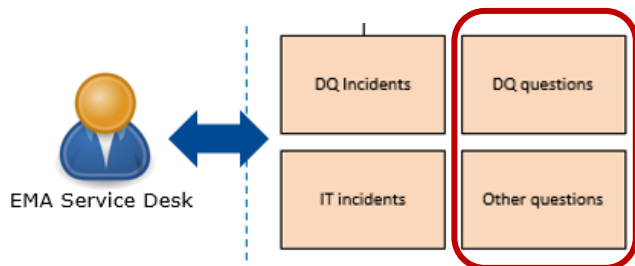
Any tickets opened **AFTER**
September 12th 2022 will be
addressed via **ServiceNow**

OMS is now in **ServiceNow**



Access ServiceNow [here](#)

How to create a Question/Request for information?



Request for Information

Request information or ask questions about IT services

Use this service to request information.

Submit

Required information

Raise this request on behalf of

Description

* Indicates required

* Raise this request on behalf of

Watch list

Subscribe additional users to receive notifications regarding your request.

* Service

- SPOR

* Service Offering

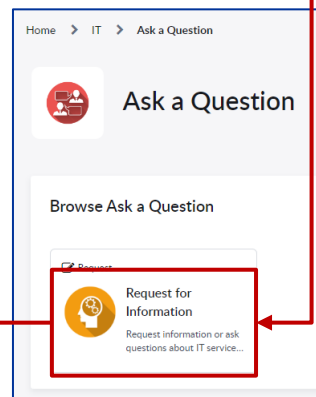
- OMS

Description

Add attachments

Choose from dropdown list:

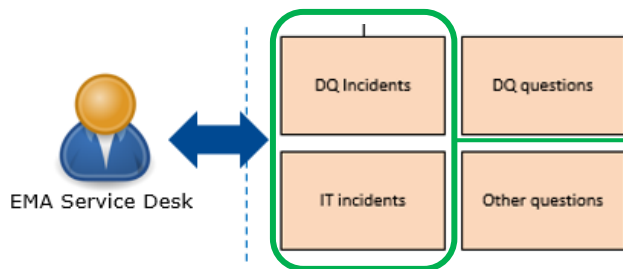
- Service > SPOR
- Service Offering > OMS



Questions/Request for information – SLA 22WD

- Data quality question i.e. further clarification required on the OMS Data Quality Standards, further clarification on change request outcome
- Other questions i.e. questions related with the OMS processes and access, further clarification related with change request submission

How to create an Incident/Issue?



The screenshot shows the EMA ServiceNow portal. At the top, it says 'EMA | ServiceNow' and 'Go to BackEnd My Tasks My Requests'. Below this is a search bar and a 'How can we help?' section. The 'Main Categories' section includes 'IT Equipment', 'Applications', 'Resource & Access', and 'Audio Visual & Virtual Meetings'. The 'Applications' category is highlighted with a green box. Below this, there are buttons for 'Report an Issue', 'IT for IT', and 'Ask a Question'. On the right, there is a 'My active items' section showing '0 Tasks', '0 Requests', and '0 Surveys'.

The screenshot shows the 'Report an issue with OMS' form. It includes a 'Submit' button and a 'Required information' section with fields for 'Subject', 'Description', and 'Urgency'. There are also sections for 'Watch list' and 'Add attachments'.

The screenshot shows the 'Applications topics' section. It includes buttons for 'MMD/Dream', 'SPOR', 'Microsoft Teams', 'IRIS', 'Webex', and 'CTIS'. The 'SPOR' button is highlighted with a green box.

The screenshot shows the 'Browse SPOR' section. It includes a 'Filter by' dropdown and a 'Sort by' dropdown. There are several request cards, including 'Request SMS services', 'Request XEVM/Art.57...', 'Request OMS services', 'Request RMS Service', 'Report an issue with OMS', and 'Report an issue with XEVM/Art.57'. The 'Report an issue with OMS' card is highlighted with a green box.

- Incidents/Issue – SLA 5WD**
- Data quality Incident i.e. data not following OMS Data Quality Standards
 - Technical Incident i.e. error message being displayed by the system

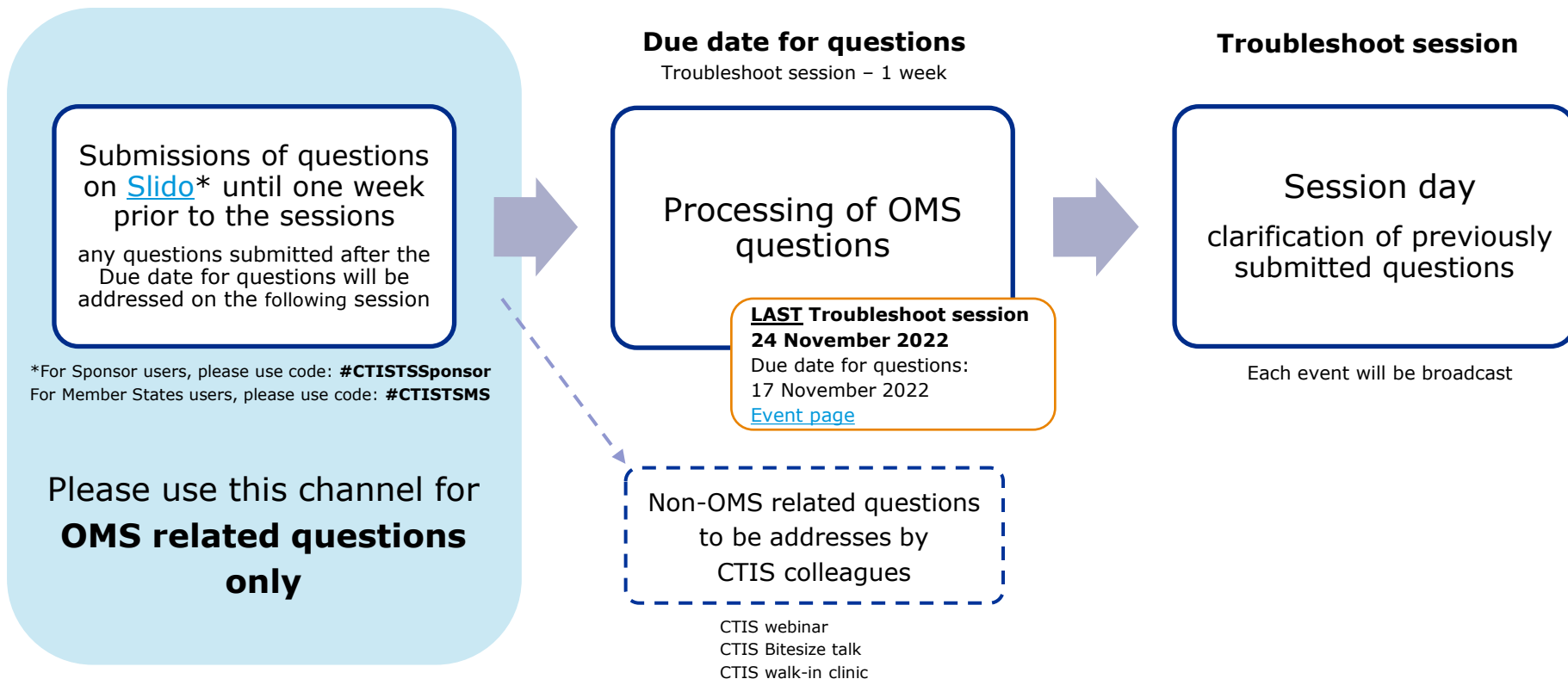
How to create a Request?



Any Request that **cannot** be submitted through **OMS Portal** using the **available Change Request** functionality

Requests – SLA 5WD

- Any Request that is cannot be submitted through OMS Portal using the available Change Request functionality i.e. delete existing contact details, delete Alternative Name, add/update National business registry number available on the export and API





We now invite you to fill out a short feedback survey

For **Sponsor** users, please use
code



For **Member States** users, please
use code:





Any questions?

Next OMS
Troubleshoot
session

24 November
2022

Please submit questions prior to the next session via Slido (www.sli.do) **by 17 November 2022**

For sponsor users, please use code: **#CTISTSSponsor** and for Member States users, please use code: **#CTISTSMS**.

Further information

Contact us through ServiceNow for any Urgent clarification

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 <https://support.ema.europa.eu/esc> **Telephone** +31 (0)88 781 6000

Follow us on  **@EMA_News**

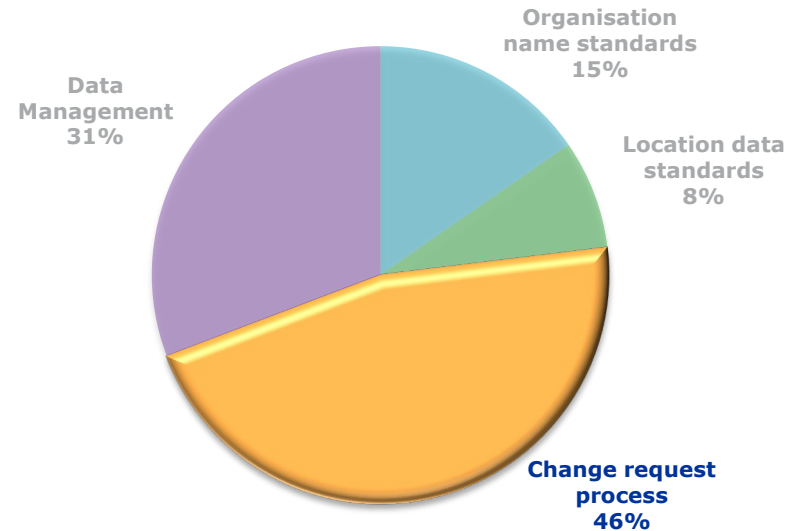


Questions previously raised

Troubleshooting question type

Objective: clarify data related questions

Change Request process



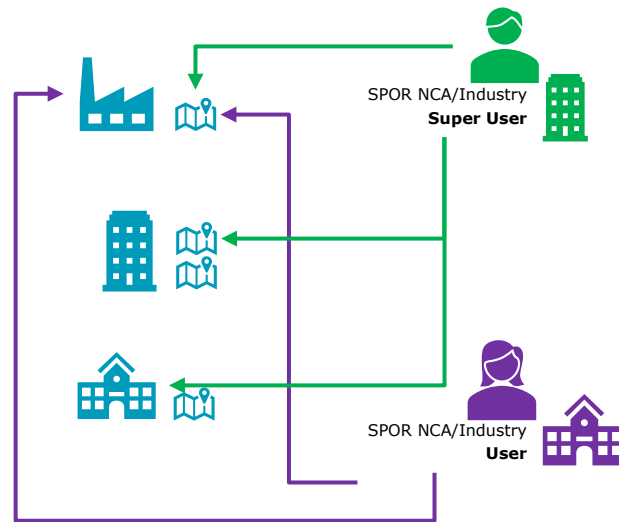


Who can change OMS data?




Change Request
process

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System



Anyone can change OMS data:

- Using **CTIS** anyone can submit a **Change Request to create organisation** in the OMS Dictionary
- Using **OMS** anyone can submit a **Change Request to create and/or update 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

Questions raised



How to add/update OMS data?

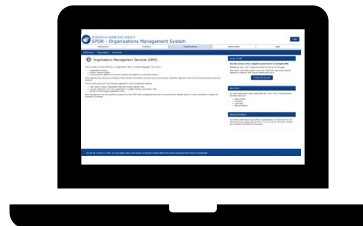


Change Request process

 Clinical Trials

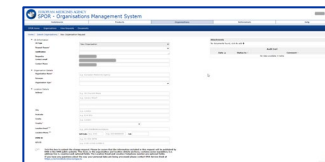


Add organisations



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

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System



Using **Change Request** functionality available through:

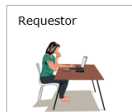
- **CTIS** to **add organisations**
- **OMS** to **add/update any organisation/location data**
- As long as **submit supporting documentation** is submitted

Validation of data as per date of the Change Request

1. Submission

2. Validation/Standardisation

3. Approval/Rejection



Requestor



EMA Data Stewards

Guidance/references & tools

- OMS DQ standard
- Business registry
- AddressDoctor validation service



EMA Data Stewards

5 - 10 Working day SLA



*document available on the [OMS portal](#)

EEA organisation


1. Extract from the National Business Registry


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 EudraGMPD will use OMS data

Hospital, University & Public entities

1. Headed letter – signed and dated
2. GMP certificates until January 28th 2022 – hereafter EudraGMPD will use OMS data


 Currently it is ~~not~~ possible for Sponsor to registry several sites in OMS in parallel. Is it possible to add this function in OMS?

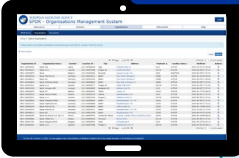

Change Request process

With the right access, **multiple change requests can be created in parallel:**


- ✓ Via **CTIS** multiple change requests to **add new organisations** can be submitted while preparing an application > please consult Handbook for further information on CTIS access
- ✓ Via **OMS** multiple change requests to **add/update multiple records** – limited to 1 pending change per record > user needs to have SPOR Super User or SPOR User access

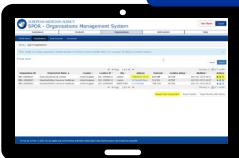


Guest 



- Search
- Content view

Unaffiliated 



- Automatic with new EMA accounts created
- Export information
- **ONLY** Request **New organisation**
- 1 request at a time

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



Our investigational site is registered twice in OMS under different names same addresses. How can we merge this 2 entries?



Change Request process

OMS Data Quality attributes*

Accuracy
Reflects reality?

Uniqueness
Only instance?

Conformity
Data standardised?


Consistency
Conflicting information?

Completeness
Details missing?


When **potential duplicated records** are identified by user

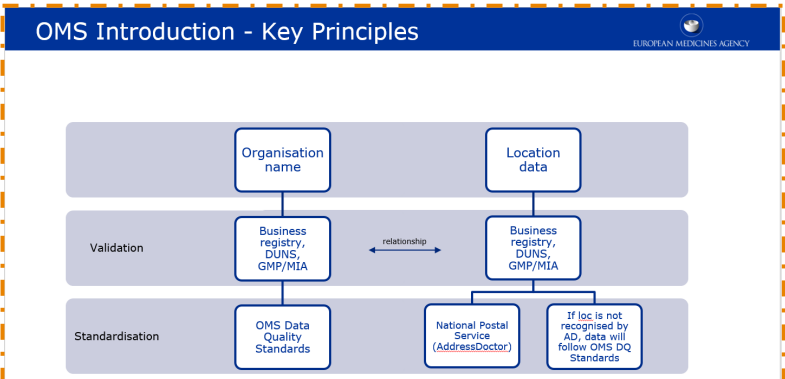
Submit a **Change request** via **OMS** portal to one of the records and use the **justification field to add a brief comment, including the ORG-ID of the potential duplicate**

Help us assure high level of **Data Quality**

 How can we have/register locations that are not available in the National business register?






Change Request process

 Source: OMS webinar



- OMS should reflect **data that reflects reality***:
 - *correct organisation/legal entity
 - *correct relationship with its address
 - *correct address

OMS Dictionary can have as many locations as used by an organisation

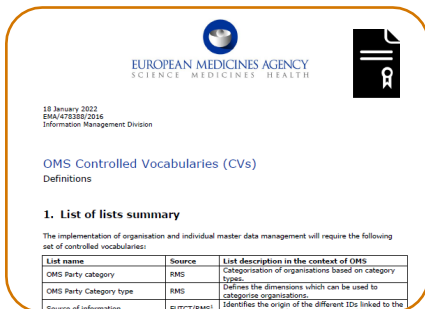
1. Add Organisation with location details available in the Business registry 
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 - If a certain physical address is being used by another ORG, we need to create a **new location** (new relationship) ORG<>LOC 
 - **Location** (LOC ID) can only be **linked to one organisation** 
 - Physical address can be linked to as many organisations as needed 



Which organisation type should be entered when creating an Ethic Committee (e.g. health care or Regulatory Authority)?



Change Request process



*document available on the [OMS portal](#)

All category values are available on OMS Controlled Vocabulary

Value Level 1	Value Level 2	Party Category Type	Description
1. Educational Institution		Type	Examples: Academia which can participate in the Clinical Trial or MA regulatory activities.
2. Health care		Type	
	2.1. Hospital/Clinic/Other health care facility	Type	In the context of Clinical trials, when a hospital is within an educational institution, it is expected that the hospital exists as a separate legal entity and therefore recorded in OMS as a 'Health care.' If the hospital/clinic is a private business i.e. commercial or non-commercial, this value will still apply. Organisation will not be categorised as pharmaceutical company. The Clinical trial application process will define whether the hospital/clinic is a commercial or non-commercial organisation.



Submission

Request to add an organisation - use Level 1 category when populating the form

4. Regulatory Authority



e.g. create an Ethic Committee

Validation

EMA adds Level 2 category

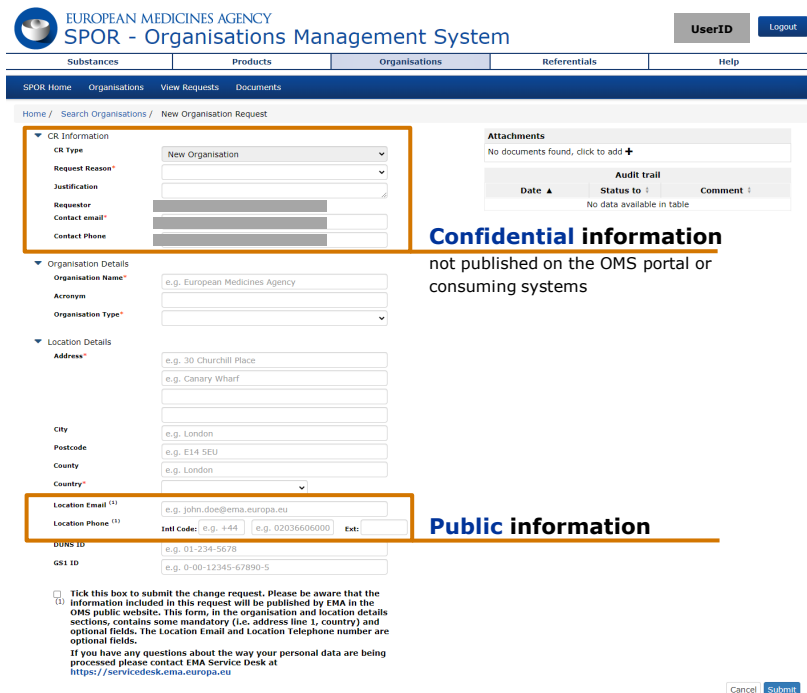
4.2. Ethics Committee



Our vendors have provided personal email addresses as OMS registration.
Does every vendor need to create a general inbox?



Change Request
process



Confidential information
not published on the OMS portal or consuming systems

Public information

Communication details in OMS:

- Are not mandatory
- Change request required to add/update details
- Captured at location level - 1 phone number & 1 email address per locations
- Are publicly available
- No validation process – anyone can add/delete details

OMS recommendation is to provide a
functional phone number and email address

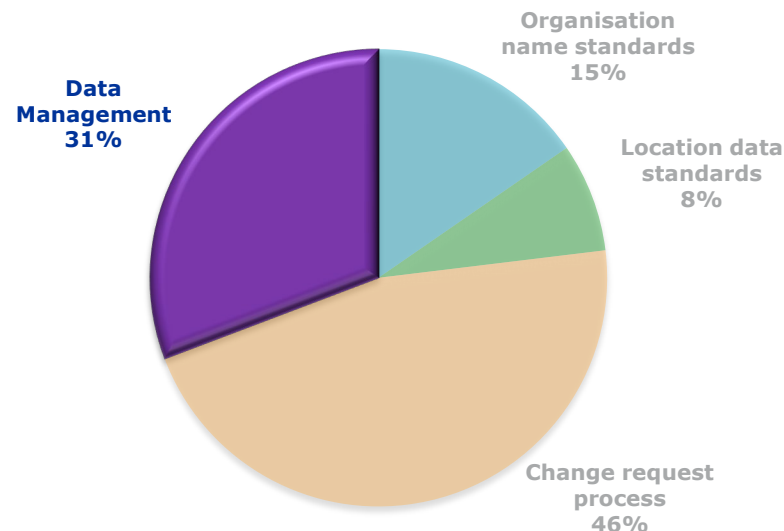
Further communication details should be maintained directly in CTIS



Troubleshooting question type

Objective: clarify data related questions

Data Management





When providing information on the registration/update OMS differentiate among the following groups: Pharmaceutical companies, CROs, Academia.
How should sites be recorded?



Data management



Source: OMS webinar

OMS Introduction - Key Principles



OMS data is hosted by EMA, accessible to and used throughout EMA

"Big" organisations e.g. Hospitals/Universities are managed by one organisation and one or more departments. **Departments are not managed** in OMS

OMS does **not have individuals**. If you are a sponsor, this needs to be dealt with in your system. If an individual is registered in a business registry, then it's considered a legal entity hence EMA can register the individual

OMS **does not define which role(s) the organisation performs** since this depends on the context in which the data will be used, e.g. in theory an organisation can act as a MAH in the context of one medicinal product but as a sponsor or manufacturer for another medicinal product

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(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** even after moving the location under another organisation

In the OMS there is **no differentiation between an organisation** created in the context of a **human** medicinal product versus a **veterinary** medicinal product

Regulatory roles, such as sponsors and sites are **NOT** maintained in OMS

OMS categorise organisations for the type of activities

Category	Consuming system	OMS
Hospital X	Site or Manufacture	L1 Health care L2 Hospital/Clinic/Other health care facility
University Y	Sponsor or Site or MAH	L1 Educational Institution
Company Z	Sponsor or MAH or Manufacture	L1 Industry L2 Pharmaceutical company
Company W	CRO or Sponsor or MAH	L1 Industry L2 Pharmaceutical company

Should the PI (name and surname and title) be registered in OMS or only the site where he/she works?

Data management

Source: OMS webinar

OMS Introduction - Key Principles

EUROPEAN MEDICINES AGENCY

OMS data is hosted by EMA, accessible to and used throughout EMA and by external stakeholders

"Big" organisations e.g. Hospitals/Universities are represented by one organisation and one or more locations - details of **Departments are not managed in OMS** and will have to be managed directly by each system

OMS provides a central source of organisation data (**OMS Dictionary**) which consists on a list of **organisations** with associated **physical locations** to be used as a reference and in support of EU regulatory activities

OMS does **not have individuals**. If individuals act as sponsors, this needs to be dealt directly by each system. If an individual is registered within the business registry, then it's considered a company and hence EMA can register the individual in OMS

An **organisation**, as a legal entity, groups all its physical locations within a **jurisdiction/country**

Organisation data structure with unique IDs


OMS does **not have individuals**. If individuals act as sponsors, this needs to be dealt directly by each system. If an individual is registered within the business registry, then it's considered a company and hence EMA can register the individual in OMS

11 OMS – Organisation Management Services
Classified as internal/staff & contractors by the European Medicines Agency

Individuals are NOT maintained in OMS

Individuals or PI details will need to be capture at consuming system level

Clinical Trials



What is the extent of information entered for each clinical trial site (e.g. Hospital details only, or also Department details, Investigator details)?



Data management



Source: OMS webinar

OMS Introduction - Key Principles



EUROPEAN MEDICINES AGENCY

"Big" organisations e.g. Hospitals/Universities are represented by one organisation and one or more locations - details of **Departments are not managed in OMS** and will have to be managed directly by each system



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"Big" organisations e.g. Hospitals/Universities are represented by one organisation and one or more locations - details of **Departments are not managed in OMS** and will have to be managed directly by each system



Public entities not available on the National business registry, such as **Hospital/University/Institutes** will be created and **maintained in OMS as a legal entity**, OMS will **NOT capture**:

- Department details
- Units/Specialities information
- Investigator details



An organisation (i.e. Ethic Committee) registered in OMS may be changing the legal name or legal entity identification. Can data be modified retaining the Original ORG-ID or should a new organisation be registered?



Data management

OMS manages **organisations as legal entities**, we will maintain the data according to the information available in the National business registry

Assessment need to be case by case



Changes available in the National business registry?

or valid source - applicable to entities not registered with the National business registry

Yes

No

Same ORG ID

Name change, Business merge, Business acquisitions

New ORG ID



What kind of organisations are part of the OMS?



Data management



Source: OMS webinar

OMS Introduction - Key Principles



"Big" organisations e.g. Hospitals/Universities are represented by one organisation and one or more locations - details of **Departments are not managed in OMS** and will have to be managed directly by each system

OMS does **not have individuals**. If individuals act as sponsors, this needs to be dealt directly by each system. If an individual is registered within the business registry, then it's considered a company and hence EMA can register the individual in OMS

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OMS data is hosted by EMA, accessible to and used throughout EMA and by external stakeholders

OMS provides a central source of organisation data (**OMS Dictionary**) which consists on a list of **organisations** with associated **physical locations** to be used as a reference and in support of EU regulatory activities

An **organisation**, as a legal entity, groups all its physical locations within a **jurisdiction/country**

Organisation data structured with unique IDs



An **organisation**, as a legal entity, groups all its physical locations within a **jurisdiction/country**

OMS Dictionary captures **organisations** as a **legal entity** within a certain country/jurisdiction - to validate the data we use each the official National business registry, with the exception of:

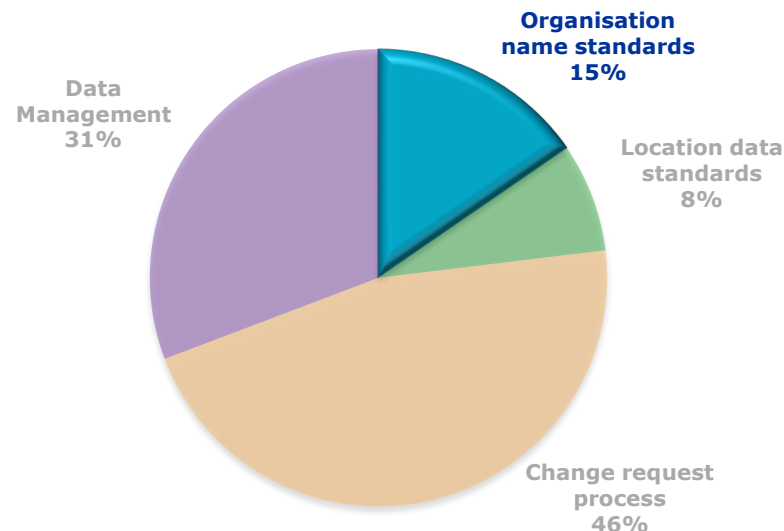
- Public entities i.e. Ministry of health
- Hospitals
- Universities
- Clinics – on-going validation process under discussion to be able to include them

*to any of the above, department/units details will not be captured in OMS

Troubleshooting question type

Objective: clarify data related questions

Organisation name standards





(1/2) We're still having difficulty getting OMS values amended to the registered name (national registry is incorrect), will these issues be re-examined/addressed?



Organisation name standards

The OMS provides a **single source of validated organisation/location data** that can be used as a reference to support EU regulatory activities

OMS reflects equivalent information as the Business registry, it is not meant to be the same/"copy" of Business registry



Organisation name

- Title case, except EEA organisations where a case sensitive format exist



Legal entity

- Country specific
- Apply standardisation



(2/2) We're still having difficulty getting OMS values amended to the registered name (national registry is incorrect), will these issues be re-examined/addressed?



Organisation name standards


Example

19MPP046HPT01	56681	GMPC	AUROBINDO PHARMA LIMITED	Unit - XI, Survey No. 61-66, I.D.A., Ranasthalam Mandal, Srikakulam District	Pydibhimavaram Village, Andhra Pradesh	532 409	India	2019-05-23
MT/018HM/2019	53908	GMPC	Aurobindo Pharma Limited, Formulation Unit -XV	Plot No. 17A, E Bonangi (Village), Parawada (Mandal)	Visakhapatnam District	531 021	India	2019-02-03
FT064/MH/001/2020	93823	GMPC	Aurobindo Pharma Limited - Unit X	Plot No. 16, APIIC, Multi Product Special Economic Zone, Menakuru Village, Naidupeta Mandal, SPSR Nellore District	Andhra Pradesh	524421	India	2018-10-26



ORG-100011510	Aurobindo Pharma Limited	India	LOC-100049448	Nellore	Plot No 16 Unit-X	524421
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According to Indian Ministry of Corporate Affairs (National Business registry), only **AUROBINDO PHARMA LIMITED** is registered, hence we can't create a separate ORG ID for each Manufacture Unit



OMS values to the registered name (the ES national registry is being incorrectly interpreted by the EMA change control analysts). Specifically, S.L vs S.L.U?



Organisation name standards

Example



Sociedad	NIF	Registro	Estado de la sociedad
TEVA PHARMA SL	B83959379	MADRID	Vigente

Indice

Denominación :	TEVA PHARMA SL
Inicio de Operaciones :	01/04/2004
Domicilio Social :	C/ ANABEL SEGURA 11 - EDIFICIO ALBATROS B 1ª PLANTAALCOBENDAS28-MADRID
Duración :	Indefinida
N.I.F. :	B83959379
Datos Registrales :	Hoja M-352166 Tomo 19969 Folio 81
Objeto Social:	LA FABRICACION, TRATAMIENTO, Y COMERCIALIZACION, INCLUYENDOSE ACTIVIDADES DE IMPORTACION Y EXPORTACION, DE PRODUCTOS QUIMICOS Y FARMACEUTICOS.
Estructura del órgano:	Consejo de administración
Unipersonalidad:	La sociedad de esta hoja es unipersonal , siendo su socio único PHARMA ESPANA INC, con N.I.F. 2883369

What is happening?

We have a placeholder in KUG for further assessment – discussion will need to take place between KUG members, Spanish NCA and legal teams

Until further discussions, we will continue using established rules/standards

- ✓ Spanish **Business registry** does **NOT** recognise **Unipersonal as a valid** Spanish **legal entity type**
- ✓ Certain organisations have a unipersonal “status/classification” when accessing extract from Spanish Business registry
- ✓ OMS uses the Spanish **Business registry** as **reference** source while mastering the data
- ✓ OMS cannot “translate” between i.e. S.L. vs S.L.U. as they have different meanings (not the same legal entity type)



It is not possible to search for organisations whose name includes the letters å, ä and ö. This is quite inconvenient as many organisations in Sweden have these letters in their names.




Organisation name standards

OMS

Organisation name will be maintained using **English characters**, local characters will be maintained as Alternative name

OMS portal search uses both fields, if an alternative name exist with the local characters, the mastered record will be displayed



OMS consuming systems will display:

- Organisation Name
- Address data

For further details please refer to the OMS Dictionary

Organisation ID	Organisation Name ▲	Country †	Location ID †	City †
ORG-10000774	Medac Gesellschaft Für Klinische Spezialpräparate mbH	Germany	LOC-100001503	Tornesch
ORG-10000774	Medac Gesellschaft Für Klinische Spezialpräparate mbH	Germany	LOC-100006936	Hamburg
ORG-10000774	Medac Gesellschaft Für Klinische Spezialpräparate mbH	Germany	LOC-100008469	Elmshorn
ORG-10000774	Medac Gesellschaft Für Klinische Spezialpräparate mbH	Germany	LOC-100008802	Wedel
ORG-100005514	Medac Gesellschaft Für Klinische Spezialpräparate GmbH Tyskland Filial	Sweden	LOC-100006442	Varberg
ORG-100005514	Medac Gesellschaft Für Klinische Spezialpräparate GmbH Tyskland Filial	Sweden	LOC-100008937	Malmö
ORG-100005514	Medac Gesellschaft Für Klinische Spezialpräparate GmbH Tyskland Filial	Sweden	LOC-100012592	Varberg
ORG-100042691	Medac Gesellschaft für Klinische Spezialpräparate mbH Sucursal Em Portugal	Portugal	LOC-100070775	Rio De Mouro
ORG-100042691	Medac Gesellschaft für Klinische Spezialpräparate mbH Sucursal Em Portugal	Portugal	LOC-100070572	Alges
ORG-100042691	Medac Gesellschaft für Klinische Spezialpräparate mbH Sucursal Em Portugal	Portugal	LOC-100071001	Sintra

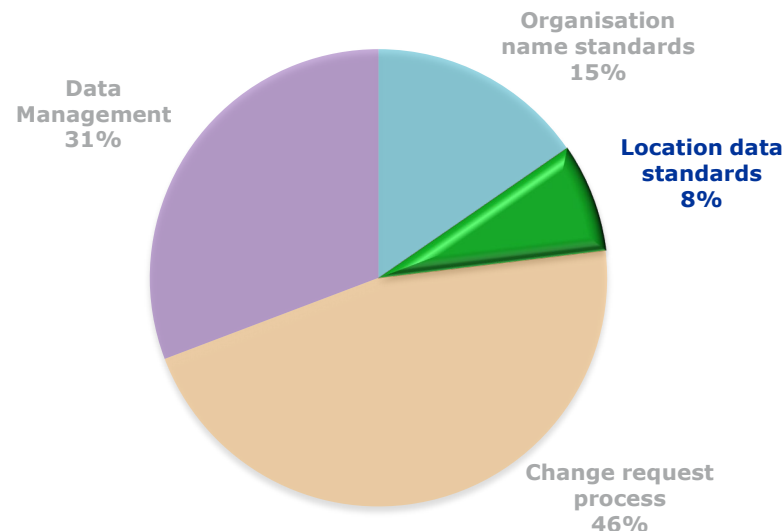
Organisation Details

Organisation ID:	ORG-100005514
Organisation Name:	Medac Gesellschaft Für Klinische Spezialpräparate GmbH Tyskland Filial
Alternative Name:	SV - Medac Gesellschaft Für Klinische Spezialpräparate GmbH Tyskland Filial
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Troubleshooting question type

Objective: clarify data related questions

Location data standards

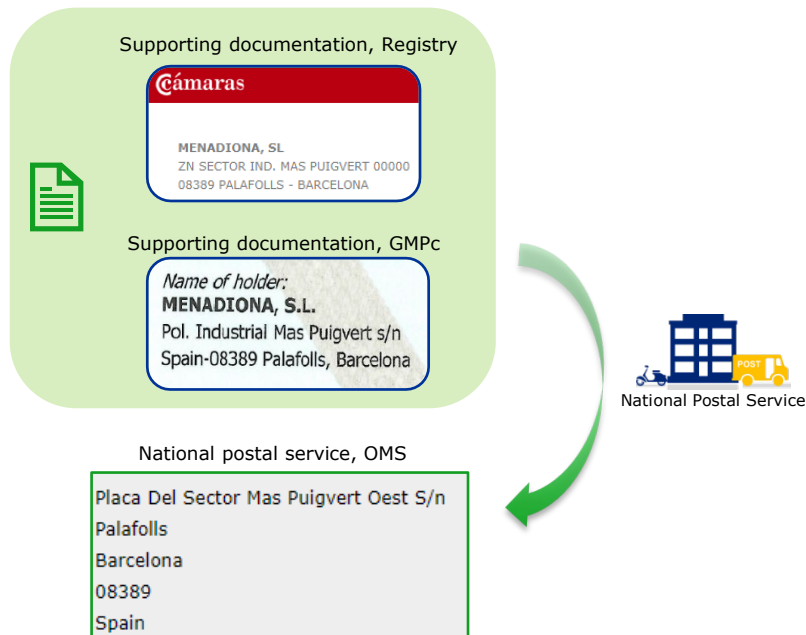




We're still having difficulty getting OMS values amended to the registered name (national registry is incorrect), will these issues be re-examined?



Location data standards



The OMS provides a **single source of validated organisation/location data** that can be used as a reference to support EU regulatory activities

OMS reflects equivalent information as the Business registry, it is not meant to be the same/"copy" of Business registry

OMS/AddressDoctor – populated with National Postal Service details
Standardise and **enrich** location data





Supporting documentaiton

1. Reference documents accessible from the [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

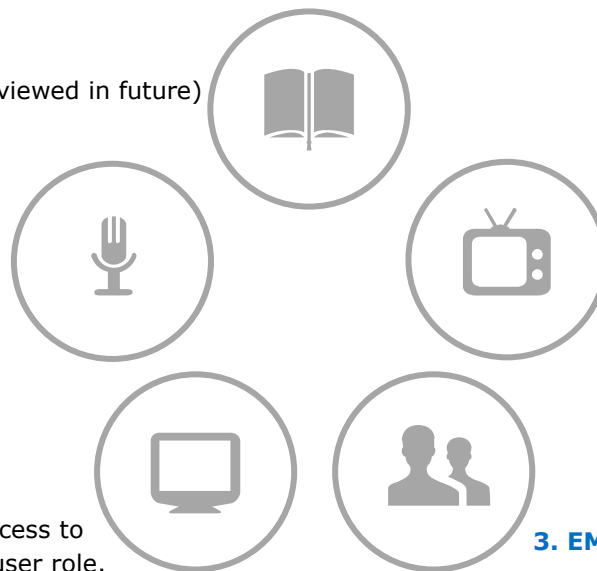
5. SPOR related information & documents on EMA corporate [website](#)

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

[Account Management Portal.](#)

*Dedicated webinar in the morning, recording will be made available in due course



2. Training videos

OMS training videos available to view on the [@emainfo](#) channel

Previous webinar -

<https://youtu.be/bqOZEJ8AvW4>

3. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the

[Service Desk Portal.](#)



Information	Reference Sources	Data in OMS	Impact/Process for mappings & CRs
<p>Organisation name</p>	<p>Information from: 1. Trade registry 2. DUNS 3. Official docs (e.g. GMP certificates)</p>	<ul style="list-style-type: none"> • OMS reflects an <u>equivalent Organisation name and legal entity</u> as the Trade registry (or other documents/sources) which has been <i>Standardised according to <u>OMS DQ rules</u></i> 	<p>Q1. Is the Org name/legal entity in OMS the same as to Trade registry?</p> <ul style="list-style-type: none"> • Yes - map • No – see next question <p>Q2. Is the Org name/legal entity in OMS equivalent to Trade registry i.e. same meaning but standardised according to OMS DQ rules?</p> <ul style="list-style-type: none"> • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach TR copy
<p>Location/ Address details</p>	<p>National Postal services via AddressDoctor</p>	<ul style="list-style-type: none"> • OMS should reflect an <u>equivalent legal address</u> as the Trade registry (or other documents/sources) which has been <i>Standardised according to <u>National Postal Services</u></i> • OMS can contain <u>additional addresses</u> for the Organisation not reflected in the Trade Registry but available in other references. These will also be standardised according to National Postal Services 	<p>Q1. Is the location/address in OMS the same as to Trade registry?</p> <ul style="list-style-type: none"> • Yes - map • No – see next question <p>Q2. Is the location/address in OMS equivalent to Trade registry i.e. same meaning but standardised according to OMS DQ rules (AddressDoctor)?</p> <ul style="list-style-type: none"> • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach TR copy <p>Q3. Is the location/address in OMS <u>not listed in Trade registry but in another doc</u> and equivalent to another reference source i.e. same meaning but standardised according to OMS DQ rules (AddressDoctor)?</p> <ul style="list-style-type: none"> • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach reference copy



Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Company A Ltd.	Company A Ltd.	Org name/legal entity in OMS the same as to Trade registry	Map data
Company A Ltd.	Company A Limited	Org name/legal entity in OMS equivalent to Trade registry i.e. <u>same meaning</u> but standardised according to OMS DQ rules	Map data – if a CR is submitted it will be rejected (even if OMS is not a copy/exact match of TR!) <i>(see also other examples in equivalent doc!)</i>
Company A Ltd.	Company A Inc.	Org name/legal entity in OMS NOT equivalent to Trade registry	Submit CR & attach TR copy

OMS mapping exercise - Location/Address details



Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Rua da Amargura, 1 2300-286 Lisbon Portugal	Rua da Amargura, 1 2300-286 Lisbon Portugal	Location/address in OMS the same as to Trade registry	Map data
R. Amargura 1 2300-286 Lisbon Portugal	Rua da Amargura, 1 2300-286 Lisbon Portugal	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>standardised</u> according to OMS DQ rules (AddressDoctor)	Map data – if a CR is submitted it will be rejected
Rua da Amargura, 1 2300-286 Lisbon Portugal	Rua da Amargura, 1 Mouraria 2300-286 Lisbon Portugal	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>enriched</u> according to OMS DQ rules (AddressDoctor)	Map data – if a CR is submitted it will be rejected
Rua da Amargura, 1 2300-286 Lisbon Portugal	Rua da Amargura, 2 2300-286 Lisbon Portugal	Location/address in OMS NOT equivalent to Trade registry i.e. different meaning, different physical place	Submit CR to <u>create new location</u> & attach TR copy Note: Requires verification with National postal service but even if equivalent the TR determines if they are legally different
Rua da Amargura, 1 2300-286 Lisbon Portugal	Rua da Amargura, 1 2300-300 Lisbon Portugal	Location/address in OMS equivalent/NOT equivalent to Trade registry	Submit CR to update location & attach TR copy Note: Requires verification with National Postal Service - If same physical location > we update the postal code - If is a different physical location > we create new location

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Rua da Amargura, 21-23 2300-286 Lisbon Portugal	Rua da Amargura, 21 2300-286 Lisbon Portugal <u>And</u> Rua da Amargura, 23 2300-286 Lisbon Portugal	Location/address in OMS equivalent to Trade registry i.e. same meaning but standardised according to OMS DQ rules (AddressDoctor)	Map data – if a CR is submitted it will be rejected
Rua da Amargura, 21-23 2300-286 Lisbon Portugal	Rua da Amargura, 21-23 2300-286 Lisbon Portugal <u>And</u> Rua da Esperanca, 13 4300-500 Porto Portugal	location/address in OMS equivalent to Trade registry + additional location/address not reflected in the Trade Registry but available in other references	Map data Additional location present in OMS can be added to the NCA/Industry databases for completeness purposes

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Rua da Amargura, 21-23 2300-286 Lisbon Portugal	Rua da Amargura, 21 2300-286 Lisbon Portugal	Location/address in OMS partially equivalent to Trade registry	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD & EU country a new loc will be created</i> <i>- If not recognised by AD & Non-Eu country the loc will be updated</i>
Rua da Amargura, 21-23 2300-286 Lisbon Portugal	Rua da Amargura, 21-25 2300-286 Lisbon Portugal	location/address in OMS equivalent to Trade registry + additional location/address not reflected in the Trade Registry but available in other references	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD & EU country a new loc will be created</i> <i>- If not recognised by AD & Non-Eu country the loc will be updated</i>

Examples on multiple doors addresses - NL

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS the same as to Trade registry <i>This applies for the odd numbers</i>	Map data
Keizersgracht 62/64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>standardised</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
62-64 Keizersgracht Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>standardised</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam Noord-Holland 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>enriched</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 63 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different meaning, different physical place <i>This applies for opposite scenario</i>	Submit CR to <u>create new location</u> & attach TR copy Note: Requires verification with National postal service but even if equivalent the TR determines if they are legally different
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CT Netherlands	Location/address in OMS equivalent/NOT equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to update location & attach TR copy Note: Requires verification with National Postal Service - If same physical location > we update the postal code - If is a different physical location > we create new location

Examples on multiple doors addresses - NL

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 63-65 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different physical place as Addresses contain multiple consecutive odd or even numbers	Submit CR to <u>create new location</u> & attach TR copy
Keizersgracht 61 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different physical place As Addresses contain multiple consecutive odd or even numbers	Submit CR to <u>create new location</u> & attach TR copy
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CS Netherlands	Location/address in OMS partially equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD a new loc will be created</i>
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-66 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry + additional location/address not reflected in the Trade Registry but available in other references <i>This applies for the odd numbers</i>	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD a new loc will be created</i>
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CT Netherlands	Location/address in OMS equivalent/NOT equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to update location & attach TR copy Note: Requires verification with National Postal Service <i>- If same physical location > we update the postal code</i> <i>- If is a different physical location > we create new location</i>

Data Quality Rule in NL:

- Addresses can contain multiple consecutive odd or even doors numbers
- Addresses can not contain multiple non- consecutive doors numbers
- Odd or even doors number is displayed at the end after the street name
- Doors numbers are separated by hyphen with no space
- Postal code has 4 digits and 2 capital letters