Troubleshooting session for CTIS
(Organisation Management Services)

Session 4

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

- OMS Key Principles

- Questions raised for today

- Questions previously raised

- Supporting documentation

OMS Key Principles

OMS Key Principles

Changes to OMS Dictionary happen through change request → **Supporting documentation IS required to create/update OMS data** → **OMS is a standardised list of organisations and locations**

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

Documentation is mandatory* to most of the OMS change requests

OMS manages organisations as legal entities, meaning as they are registered with the local authorities, supporting documentation is critical for the validation process

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

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

*guidance available on the OMS portal under document *E - OMS Change Requests* on correct document to be submitted

Guidance available on the OMS portal under document *C - OMS Data Quality standards* on rules used by OMS team both at organization and location level
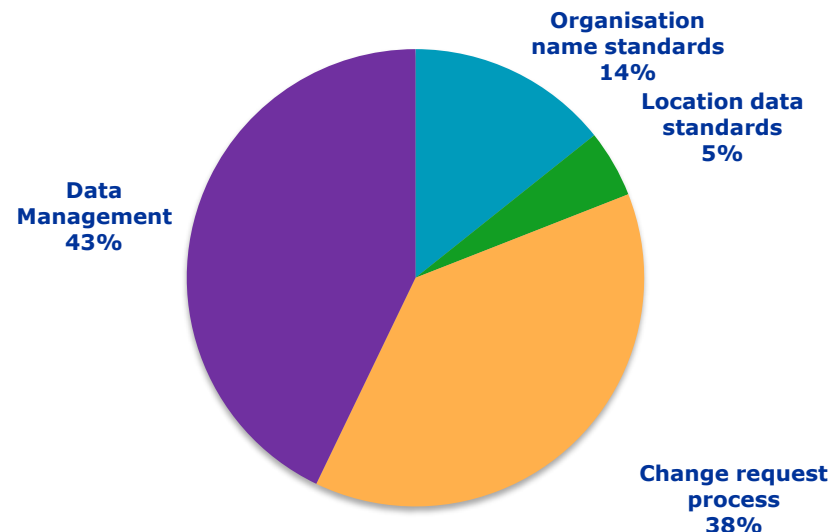
Questions raised for today

Questions raised – summary

Troubleshooting questions

session 4

<u>Objective</u>: clarify OMS related questions

- 2 questions on Data management
- 1 questions on Change request process

Organisation name standards 14%

Location data standards 5%

Data Management 43%

Change request process 38%

Data management

If a private practice has the identical name to another entity that is already registered in OMS?

Source: OMS webinar

OMS Dictionary captures **organisations** as a **legal entity** within a certain country/jurisdiction

If the private practice is already **available** in the OMS Dictionary > use the organisation already available

If the private practice has **AN IDENTICAL** name (but it's not exactly the same) > **create** a new organisation

Questions raised

When will the issues be fixed where OMS connection when searching for sites/vendors in CTIS is not working or data is missing?

How OMS data is **managed** > **OMS team**

OMS

How OMS data is **used** > **CTIS team**

CTIS

euclinicaltrials.eu

OMS team **can help with**:
- Clarification on OMS registration process i.e. access to OMS portal, submission of change requests
- Clarification on OMS standards used
- Error message when using the OMS portal
- Organisation and/or location data missing or data needs to be updated

CTIS team **can help with**:
- Clarification on the use of CTIS i.e. how to register, how to submit/update a procedure
- Error message on CTIS portal i.e. during submission or creation of new organisations using the CTIS portal

EUROPEAN MEDICINES AGENCY

(1/2) NEW registration process for CTIS organisations

Change Request process

3rd November 2022

6th December 2022 - TBC

OMS manages Organisations registered with the National Business registry (sources used by OMS are available on the OMS Data Quality Standards), public entities, hospitals and academia*
To register such organisations and/or locations users need to continue using the standard OMS registration process

Sponsors (that do not fulfil the requirements above*) to use the **NEW CT registration process**

Sites (that do not fulfil the requirements above*) to use the **NEW CT registration process**

Sites (that do not fulfil the requirements above*) will be **registered/maintained directly in CTIS**
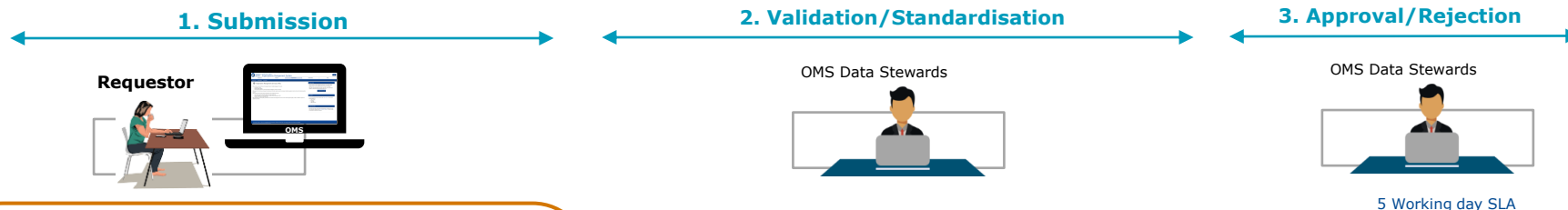
8   OMS – Organisation Management Services

(1/2) NEW registration process for CTIS organisations

Change Request process

To be used by **Organisations THAT ARE NOT** registered with the National Business registry (sources used by OMS are available on the OMS Data Quality Standards), public entities, hospitals or academia

1. Submission

Requestor

2. Validation/Standardisation

OMS Data Stewards

3. Approval/Rejection

OMS Data Stewards

5 Working day SLA

Submit a change request using the OMS portal:
- Login OMS portal
- Search for the organisation using the organisation name field – the system should return zero results
- Click Request New Organisation button
- Populate the change request form with the organisation details
- Attach CT registration Headed letter filled with all mandatory information – template available on OMS portal as J - CT registration Headed letter template

Data Stewards validate all OMS CRs using guidance/references & tools:
- Validation if CT registration Headed letter filled with all mandatory information
- Organisation name will be created as submitted by user
- Location details will be created as per local national postal service - standardised/formatted and/or enrich data in English and in local languages

OMS CR approved = data published/updated in the OMS dictionary and available in CTIS portal

-----

OMS CR rejected = reasons explained to requestor via email
If disagreement, raise ticket in ServiceNow, identifying the relevant CR number

Survey

We now invite you to fill out a short feedback survey

For **Sponsor** users, please use code

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

CTIS Training Environment update

The CTIS Training environment survey (Survey 4.0) is reopened:

https://ec.europa.eu/eusurvey/runner/2abb5ba8-0ec4-9979-b692-0c63f4508b9b

This survey collects expressions of interest in accessing the CTIS training environment ('CTIS Sandbox'), information and contact details of representative individuals, the organisations that they represent and the planning for use of CTIS of these organisations is reopened.

All details will serve to proactively identify the needs and intention of use of CTIS and grant access accordingly.

Any questions?

Further information

Contact us through [ServiceNow](#) for any 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
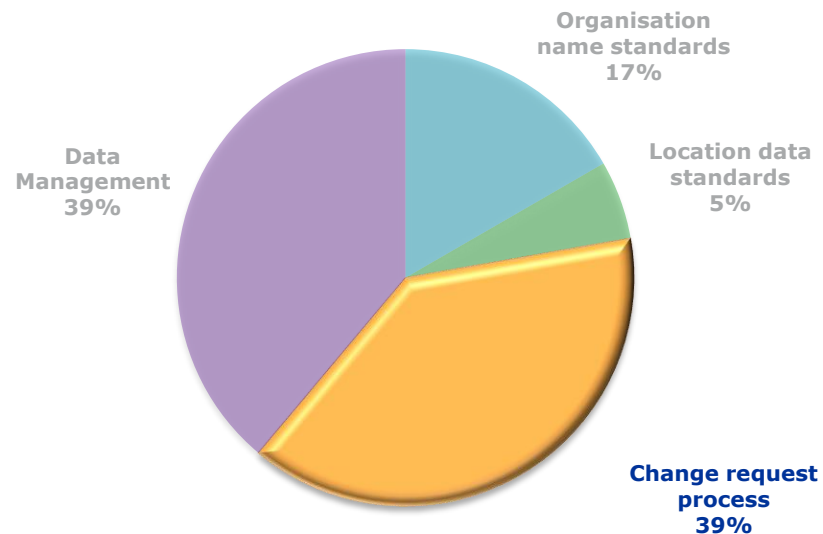
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Questions previously raised

Troubleshooting question type

Objective: clarify data related questions

Change Request process

Organisation name standards
17%

Location data standards
5%

Data Management
39%

Change request process
39%

Who can change OMS data?

Change Request process

Clinical Trials

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

SPOR NCA/Industry **Super User**

SPOR NCA/Industry **User**
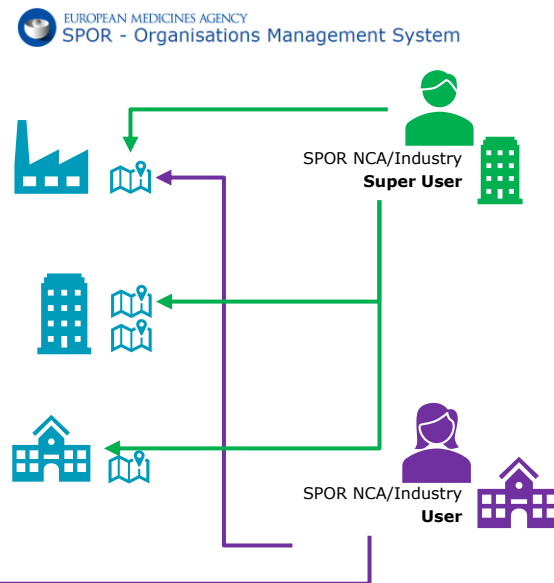
Questions raised

How to add/update OMS data?

Change Request process

Clinical Trials

Add organisations

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SPOR - Organisations Management System

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

Using **Change Request** functionality available through:
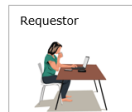
- **CTIS** to **add organisations**

- **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

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 EudraGMDP will use OMS data

Hospital, University & Public entities
1. Headed letter – signed and dated
2. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data

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

Questions raised

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

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

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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**

*Further information available on the OMS portal
under A4 - OMS Introduction - Webinar 10 March 2022

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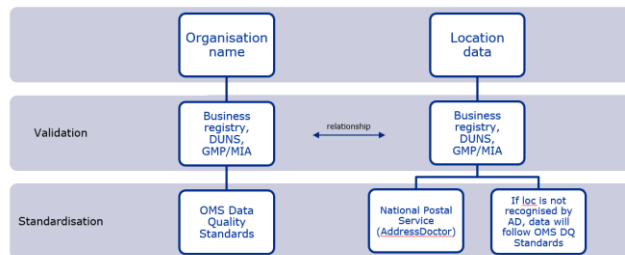
Change Request process

Source: OMS webinar

OMS Introduction - Key Principles

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Organisation name — Location data

Validation: Business registry, DUNS, GMP/MIA — relationship — Business registry, DUNS, GMP/MIA

Standardisation: OMS Data Quality Standards — National Postal Service (AddressDoctor) — If loc is not recognised by AD, data will follow OMS DQ Standards

10   OMS – Organisation Managem...

- 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

2. Add other locations details required for regulatory procedures

   - If a certain <u>physical address</u> 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**

   - <u>Physical address</u> can be linked to as many organisations as needed

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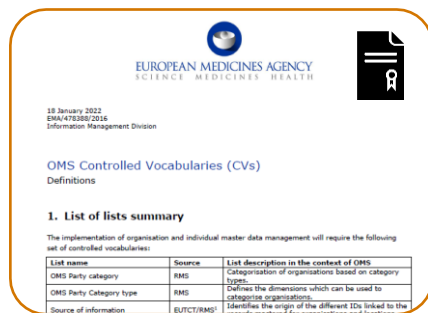
Change Request process

List name	Source	List description in the context of OMS
OMS Party category	RMS	Categorisation of organisations based on category types.
OMS Party Category type	RMS	Defines the dimensions which can be used to categorise organisations.
Source of information	EUTCT/RMS¹	Identifies the origin of the different IDs linked to the

*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.

Requestor

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
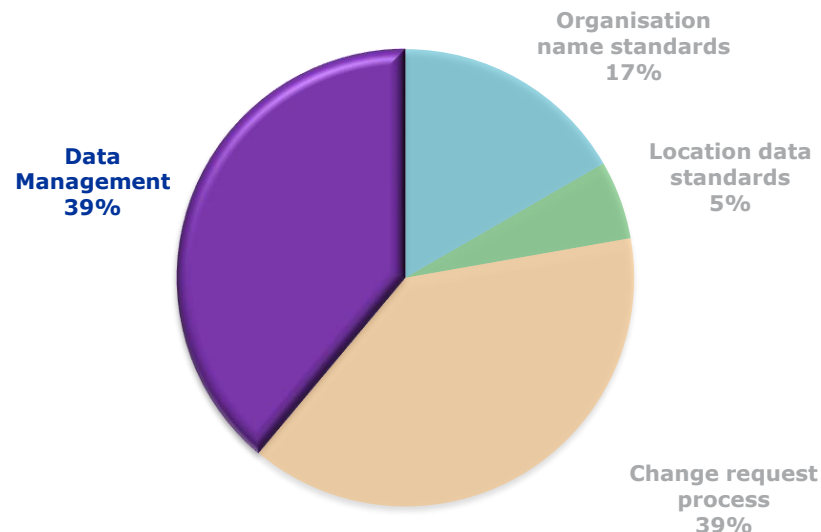- No validation process – anyone can add/delete details

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

Data Management 39%

Organisation name standards 17%

Location data standards 5%

Change request process 39%

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Data management

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

OMS

Source: OMS webinar

OMS Introduction - Key Principles

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

"Big" organisations e.g. Hospital/U... by one organisation and one or... **Departments are not managed** i...
manag...

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

OMS does **not have individuals.** If... sponsors, this needs to be dea... ...system. If an individual is reg... business registry, then it's conside... hence EMA can register the...

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

(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

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

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

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Data management

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

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

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

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 structured 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

Classified as internal/staff & contractors by the European Medicines Agency

Questions raised

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

Source: OMS webinar

OMS Introduction - Key Principles

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11   OMS – Organisation Management Services

Classified as internal/staff & contractors by the European Medicines Agency

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

Data management

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?

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

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Data management

? What kind of organisations are part of the OMS?

OMS

Source: OMS webinar

OMS Introduction - Key Principles

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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

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Organisation data structured with unique IDs

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

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

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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

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Data management

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

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

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

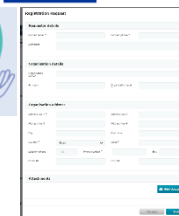**Daily Data sources**

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
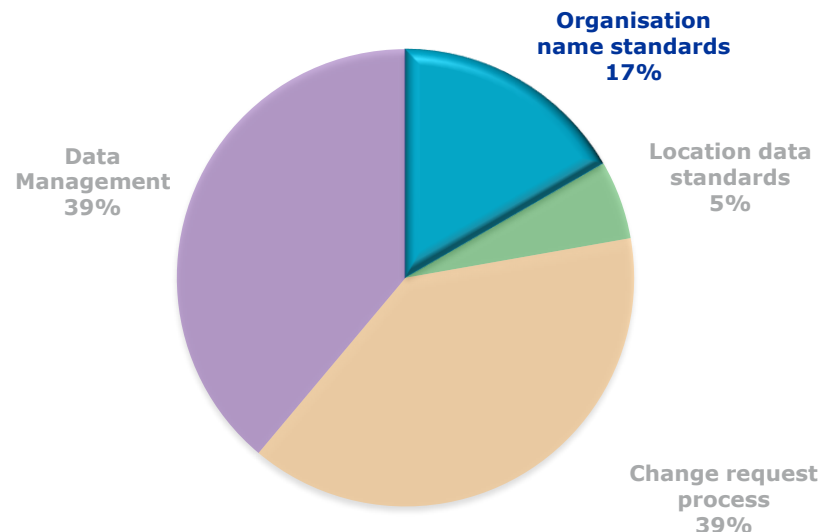Validation of data as per date of the Change Request

Data integration/mapping

SME Deltas

SAP Deltas

OMS

Clinical Trials

Troubleshooting question type

Objective: clarify data related questions

Organisation name standards

Organisation name standards 17%

Location data standards 5%

Change request process 39%

Data Management 39%

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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?

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

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SCIENCE MEDICINES HEALTH

07 June 2017
EMA/740982/2016
Information Management Division

Organisation data quality standards in OMS
Data quality principles

Organisation name

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

Legal entity

- Country specific
- Apply standardisation

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(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?

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 |

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

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?📊

Organisation name standards

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?

Example

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 stablished 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)

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Organisation name standards

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.

OMS

▼ Hide search	
Organisation ID	
Organisation name	Medac Gesellschaft Für Klinische Spezialpräparate
Location ID	
Address	
City	
Postcode	
Country	
Modified Since	
Location status *	

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

CTIS

OMS consuming systems will display:
- Organisation <u>Name</u>
- <u>Address</u> data

For further details please refer to the OMS Dictionary

|◄◄ ◄◄ Page 1 of 1 ►► ►►|

| Organisation ID	Organisation Name ▲	Country ⇕	Location ID ⇕	City ⇕
ORG-100000774	Medac Gesellschaft Fur Klinische Spezialpraeparate mbH	Germany	LOC-100001503	Tornesch
ORG-100000774	Medac Gesellschaft Fur Klinische Spezialpraeparate mbH	Germany	LOC-100006936	Hamburg
ORG-100000774	Medac Gesellschaft Fur Klinische Spezialpraeparate mbH	Germany	LOC-100068469	Elmshorn
ORG-100000774	Medac Gesellschaft Fur Klinische Spezialpraeparate mbH	Germany	LOC-100008802	Wedel
ORG-100005514	Medac Gesellschaft Fur Klinische Spezialpraparate GmbH Tyskland Filial	Sweden	LOC-100006442	Varberg
ORG-100005514	Medac Gesellschaft Fur Klinische Spezialpraparate GmbH Tyskland Filial	Sweden	LOC-100058937	Malmo
ORG-100005514	Medac Gesellschaft Fur Klinische Spezialpraparate GmbH Tyskland Filial	Sweden	LOC-100012592	Varberg
ORG-100042691	Medac Gesellschaft fur Klinische Spezialpraparate mbH Sucursal Em Portugal	Portugal	LOC-100070775	Rio De Mouro
ORG-100042691	Medac Gesellschaft fur Klinische Spezialpraparate mbH Sucursal Em Portugal	Portugal	LOC-100070572	Alges
ORG-100042691	Medac Gesellschaft fur Klinische Spezialpraparate mbH Sucursal Em Portugal	Portugal	LOC-100071001	Sintra

Organisation Details

Organisation ID:	ORG-100005514
Organisation Name:	Medac Gesellschaft Fur Klinische Spezialpraparate 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
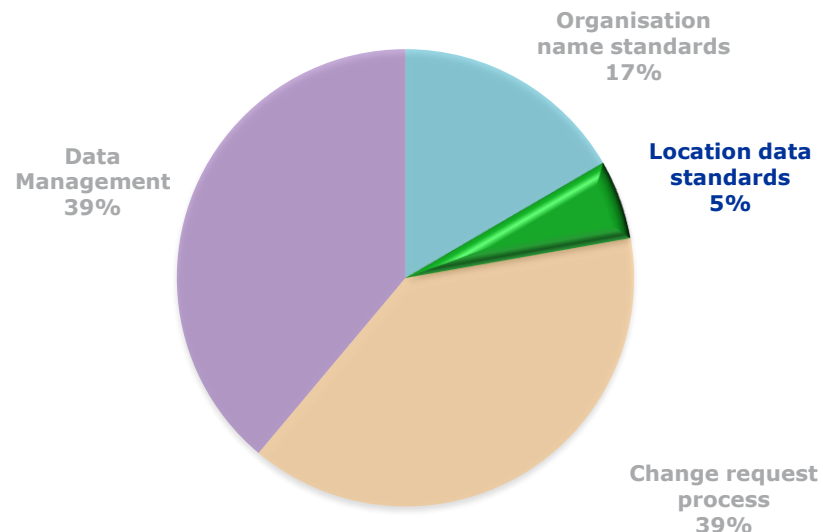
Data Management 39%

Organisation name standards 17%

Location data standards 5%
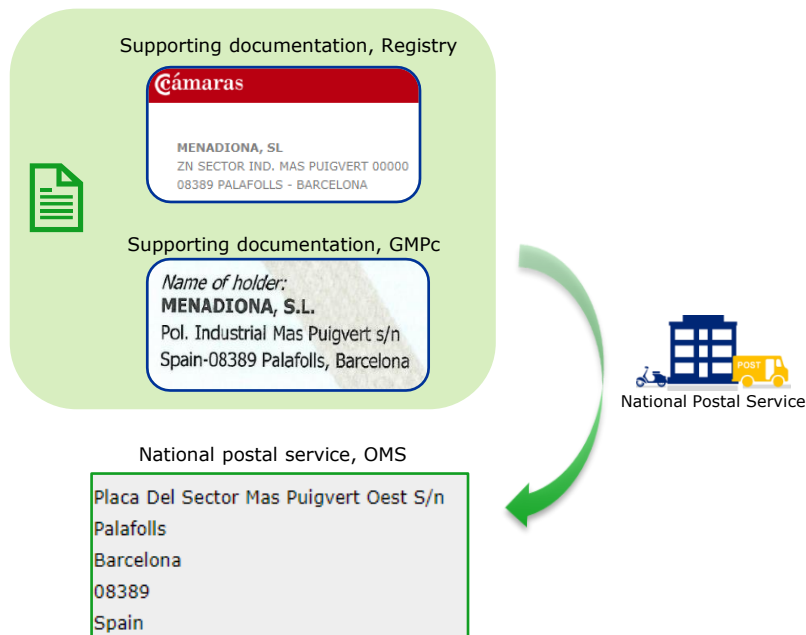
Change request process 39%

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?

Supporting documentation, Registry

Cámaras

MENADIONA, SL
ZN SECTOR IND. MAS PUIGVERT 00000
08389 PALAFOLLS - BARCELONA

Supporting documentation, GMPc

Name of holder:
MENADIONA, S.L.
Pol. Industrial Mas Puigvert s/n
Spain-08389 Palafolls, Barcelona

National Postal Service

National postal service, OMS

Placa Del Sector Mas Puigvert Oest S/n
Palafolls
Barcelona
08389
Spain

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
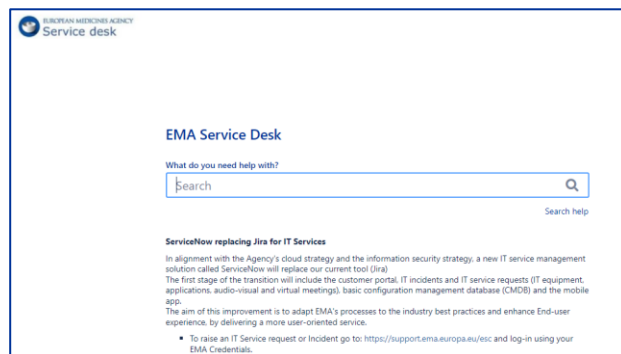**Standardise** and **enrich** location data

Housekeeping rules

OMS – Organisation Management Services

EUROPEAN MEDICINES AGENCY

EMA Service Desk

What do you need help with?

Search help

ServiceNow replacing Jira for IT Services

In alignment with the Agency's cloud strategy and the information security strategy, a new IT service management solution called ServiceNow will replace our current tool (Jira)

The first stage of the transition will include the customer portal, IT incidents and IT service requests (IT equipment, applications, audio-visual and virtual meetings), basic configuration management database (CMDB) and the mobile app.

The aim of this improvement is to adapt EMA's processes to the industry best practices and enhance End-user experience, by delivering a more user-oriented service.

- To raise an IT Service request or Incident go to: https://support.ema.europa.eu/esc and log-in using your EMA Credentials.

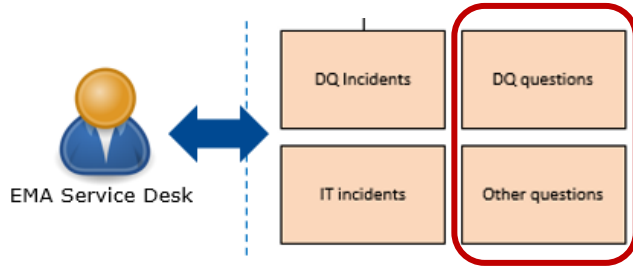Any tickets opened **BEFORE** September 12th 2022 will be addressed via **Service Desk**

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

OMS is now in **ServiceNow**
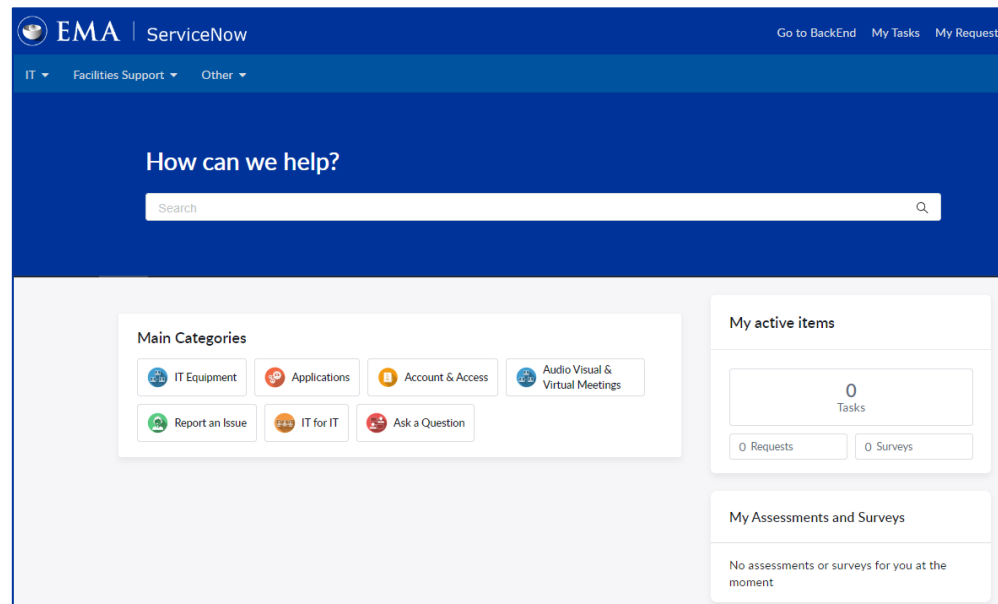
Access ServiceNow here

How to create a Question/Request for information?
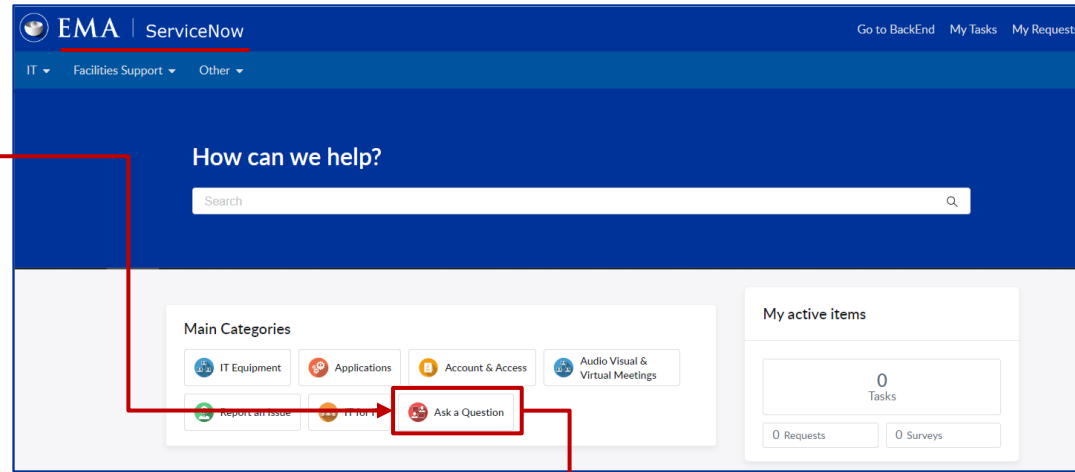
Questions/Request for information – SLA 22WD
- Data quality question i.e. further clarification required on the OMS Data Quality Standards, further clarification on change request outcome
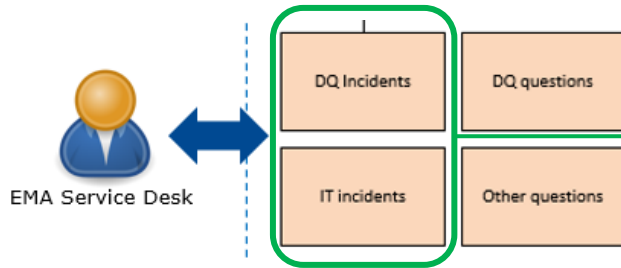- Other questions i.e. questions related with the OMS processes and access, further clarification related with change request submission

Choose from dropdown list:
- Service > SPOR
- Service Offering > OMS

How to create an Incident/Issue?

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

Supporting documentaiton

SPOR documents & help

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
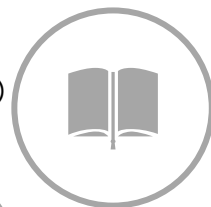
5. SPOR related information & documents on EMA corporate website

2. Training videos
OMS training videos available to view on the @emainfo channel
Previous webinar -
https://youtu.be/bqOZEJ8AvW4

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

3. EMA Service Desk Portal
Service requests, issues, requests for technical support shall be submitted through the
Service Desk Portal.

OMS mapping exercise

Information	Reference Sources	Data in OMS	Impact/Process for mappings & CRs
Organisation name	Information from: 1. Trade registry 2. DUNS 3. Official docs (e.g. GMP certificates)	• OMS reflects an <u>equivalent</u> **Organisation name and legal entity** as the Trade registry (or other documents/sources) which has been *Standardised according to <u>OMS DQ rules</u>*	**Q1**. Is the **Org name/legal entity** in OMS **the same** as to Trade registry? • Yes - map • No – see next question **Q2.** Is the **Org name/legal entity** in OMS **equivalent** to Trade registry i.e. same meaning but standardised according to OMS DQ rules? • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach TR copy
Location/ Address details	National Postal services via AddressDoctor	• OMS should reflect an <u>equivalent legal address</u> as the Trade registry (or other documents/sources) which has been *Standardised according to <u>National Postal Services</u>* • 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	**Q1.** Is the **location/address** in OMS **the same** as to Trade registry? • Yes - map • No – see next question **Q2**. Is the **location/address** in OMS **equivalent** to Trade registry i.e. same meaning but standardised according to OMS DQ rules (AddressDoctor)? • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach TR copy **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)? • Yes – map – if a CR is submitted it will be rejected • No – submit CR & attach reference copy

OMS mapping exercise - Organisation name/legal entity

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!) *(see also other examples in equivalent doc!)*
Company A Ltd.	Company A Inc.	**Org name/legal entity** in OMS **NOT equivalent** to Trade registry	**Submit CR** & attach TR copy

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 **And** Rua da Amargura, 23 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, 21-23 2300-286 Lisbon Portugal	Rua da Amargura, 21-23 2300-286 Lisbon Portugal **And** 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

OMS mapping exercise - Location/Address details

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 update location & attach TR copy. Note: address data verified according to information provided by AddressDoctor. *- If not recognised by AD & EU country a new loc will be created* *- If not recognised by AD & Non-Eu country the loc will be updated*
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 update location & attach TR copy. Note: address data verified according to information provided by AddressDoctor. *- If not recognised by AD & EU country a new loc will be created* *- If not recognised by AD & Non-Eu country the loc will be updated*

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 *This applies for the odd numbers*	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) *This applies for the odd numbers*	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) *This applies for the odd numbers*	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) *This applies for the odd numbers*	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 *This applies for opposite scenario*	**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 *This applies for the odd numbers*	**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 *This applies for the odd numbers*	**Submit CR** to <u>update location </u>& attach TR copy. Note: address data verified according to information provided by AddressDoctor. *- If not recognised by AD a new loc will be created*
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 *This applies for the odd numbers*	**Submit CR** to <u>update location </u>& attach TR copy. Note: address data verified according to information provided by AddressDoctor. *- If not recognised by AD a new loc will be created*
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam **1015 CT** Netherlands	**Location/address** in OMS **equivalent**/**NOT equivalent** to Trade registry *This applies for the odd numbers*	**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

> **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