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SCIENCE MEDICINES HEALTH

Using OMS data in eAF

SPOR webinar, 27 June 2018

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This presentation has been prepared in collaboration with the eAF/CESP group. SPOR team would like to thank this group for the collaboration.

Presenters:

- Georg Neuwirther, Head of IT at Austrian Medicines and Medical Devices Agency (representing eAF/CESP)
- Kepa Amutxastegi, OMS Business Lead / Lead Data Officer / SPOR Service Delivery Manager, EMA
- Agnieszka Laka, EMA SPOR Change Manager

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Agenda

1. About OMS
2. Using OMS in eAF/CESP
3. Submission of OMS Change Requests (CRs)
4. Key messages
5. OMS support & guidance

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1. About OMS

EMA SPOR Team

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About OMS

- OMS operating model at a glance
- What is OMS dictionary
- Organisation_ID versus Location_ID
- Source of initial data for the OMS dictionary
- Expanding the OMS dictionary
- OMS Data Quality
- Manufacturers in OMS

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OMS Operating Model at a glance

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Industry, Regulatory Authorities, EMA

Users & consuming systems of organisation data

Stakeholders use OMS data for regulatory activities, business processes & to submit OMS change requests when required.

EMA is the maintenance organisation & owner of OMS data

OMS is the central repository and provider of organisation data. This data is accessible through the OMS portal and also programmatically through the API, which can also be used to submit change requests. A team of Data Stewards provide support to stakeholders.

Who decides if and when the use of OMS data is mandated?

- Organisation data is available for other systems to use
- Business owner of the process using OMS data decides how/when to use it and mandates its use
- OMS team will work closely with the business process owners regarding the use of OMS data

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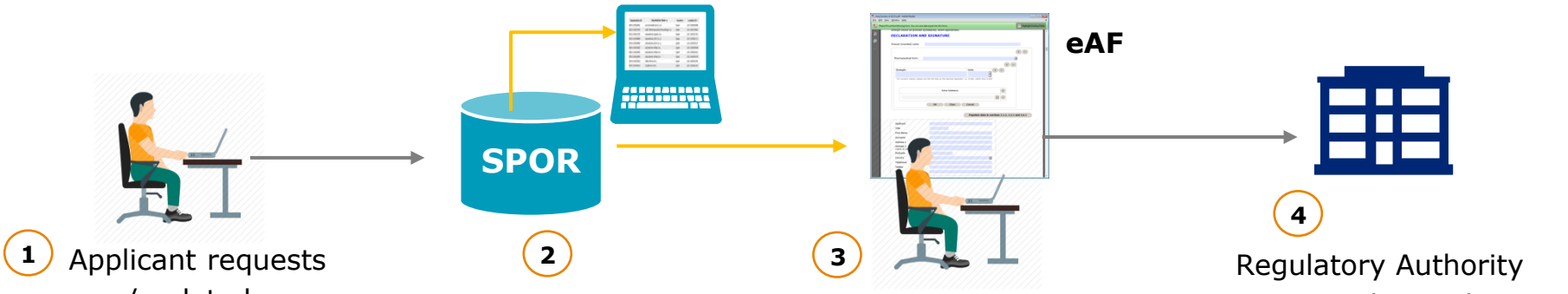
What mandating of OMS means in the context of eAF?

- A drop down list is used to select Org data (no free text field)
- Applicants request new/updated organisations in OMS before submitting eAF



1 Applicant requests new/updated organisation in the OMS.

2 EMA Data Stewards validate & process the requests. Successful validation = Organisation/location is published/updated in OMS & available in eAF for selection. See SPOR SLAs document.

3 Applicant completes & submits eAF.

4 Regulatory Authority receives the application

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What is the OMS Dictionary?

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OMS - **list of organisations** with associated **physical locations** also referred to as the **OMS dictionary**

Example of list of organisations from OMS:

Page 1 of 1

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status
ORG-100003451	Accord Healthcare S.L.U.	Spain	LOC-100002098	Barcelona	Edificio Este Planta 6	08039	ACTIVE
ORG-100007093	ASAC Pharmaceutical Immunology S.A.	Spain	LOC-100010940	Alicante	Calle Capricornio 15	03006	ACTIVE
ORG-100001785	Laboratorios Lestral S.A.	Spain	LOC-100007240	Madrid	Avenida Madronos 33	28043	ACTIVE
ORG-100004809	Laboratorios LETI S.L.U.	Spain	LOC-100006131	Barcelona	De Les Corts Catalanes 184 Planta 7	08038	ACTIVE
ORG-100004809	Laboratorios LETI S.L.U.	Spain	LOC-100000327	Tres Cantos	Calle Sol 5	28760	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100004944	Barcelona	Torrent Vidalet 29	08012	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100002016	Barcelona	Calle Provenca 386, 5º	08025	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100005554	Rubi	Poligono Industrial Can Roses Nave 15	08191	ACTIVE
ORG-100003502	Mabo-Farma S.A.	Spain	LOC-100001926	Alcala De Henares	Carretera M-300 Km. 30,500	28802	ACTIVE
ORG-100004616	Octapharma S.A.	Spain	LOC-100000130	San Fernando De Henares	Avenida de Castilla 2	28830	ACTIVE

Page 1 of 1

- In the OMS there is no difference between an organisation created in the context of a human medicinal product and a veterinary medicinal product
- **OMS does not define** which **role(s)** the organisation perform(s) since it depends on the context in which the data is used.
- An organisation can act as an MAH (Marketing Authorisation Holder) in the context of one medicinal product but also as a Sponsor or Manufacturer for another medicinal product

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Organisation_ID versus Location_ID

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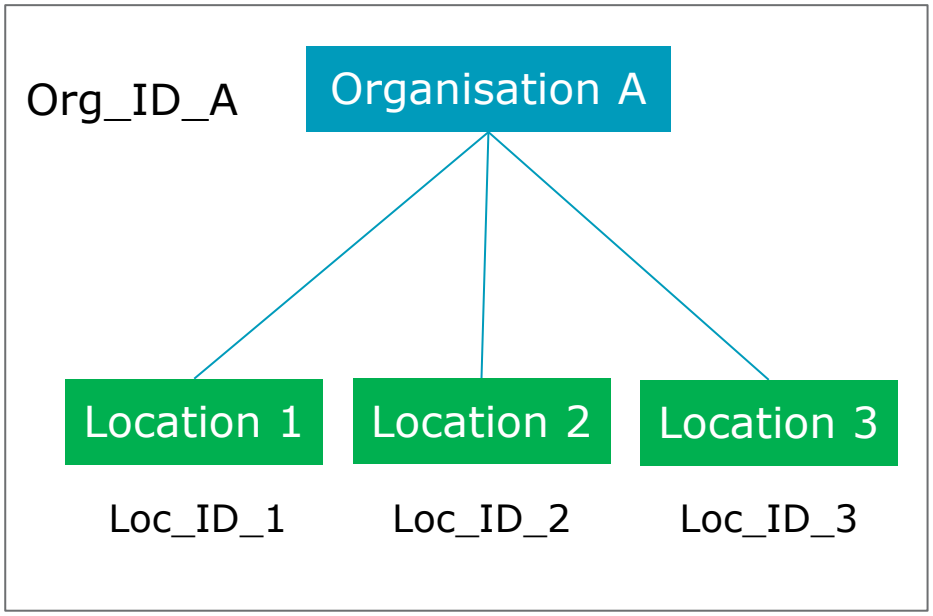
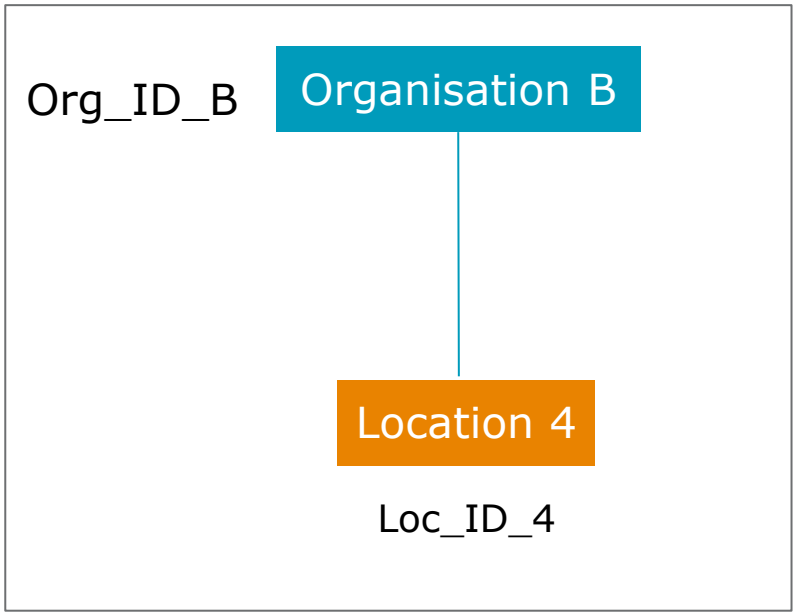
Note: Organisation A name can be the same as Organisation B name





- Organisation name is unique in a given jurisdiction but not across different jurisdictions. Two organisations with the same name in different jurisdictions will have different Organisation_ID
- Organisation to be published in OMS must be associated to at least one ACTIVE or INACTIVE Location
- The Location_ID is kept when the Location is moved to another Organisation
- An address can be used in multiple locations under different organisations but a location can only be linked to one organisation at one point in time

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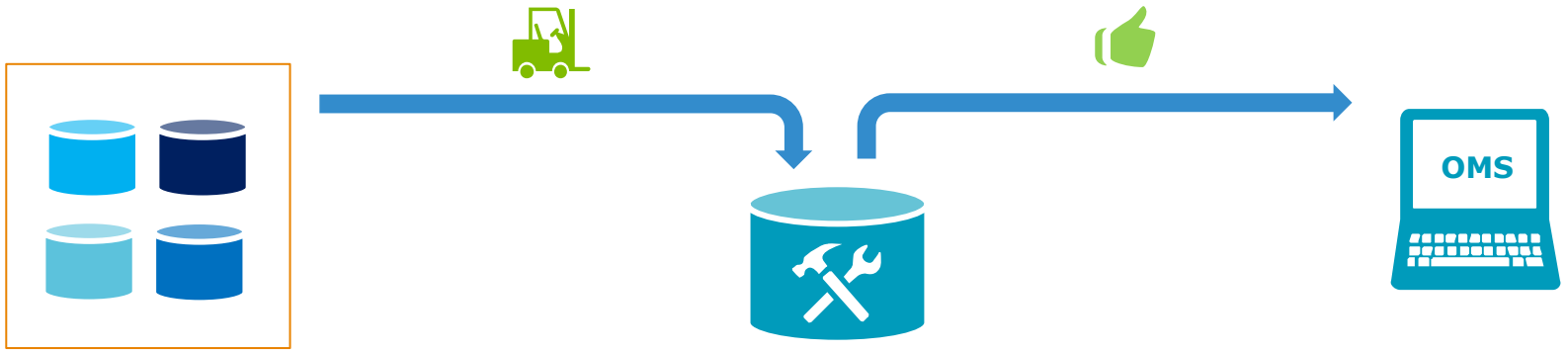
Source of initial data for the OMS dictionary



The initial content of the OMS dictionary originates from the Telematics systems, *i.e.* **xEVMPD[1] – Article 57, EudraGMDP, and 3 other EMA corporate systems**. MAHs for Veterinary CAPs were mainly sourced from an EMA corporate repository that is used for the management of centralised procedure. The data was taken from these systems in Q4 2016.

Data mastering process in OMS:

- **cleansing**
- **standardisation**
- **consolidation**

Mastered organisation **data** published **in** the **OMS dictionary**.

[1]xEVMPD contains MAHs and Sponsors

In January 2018 EMA started updating OMS data, based on the latest changes in xEVMPD – Article 57. This means that the relevant changes to the data in xEVMPD content will be reflected in the OMS. This activity will take place on an ongoing basis.

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Expanding the OMS dictionary with data sets

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Data set 1 published in the OMS:
- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs

Data set 2 by Q2 2018:
- EudraVigilance organisations to support EV user management

Data set 3 by Q2 2018:
- Orphan Designation organisations (supporting IRIS portal)

Data set 4 by Q3:
- Sponsors (H) CAPs and NAPs

Additional Organisation data to be added in future. Its prioritisation will be communicated Q1 2019.

Data set 5 by end of Q2 2019
- Manufacturers: (H+V) CAPs & NAPs

As of January 2018 Registered SPOR users can start submitting OMS change requests (**CRs**) for **Data set 1** to request changes or additions to OMS data:
- **Add Organisation**
- **Update Organisation**
- **Add Location**
- **Update Location**
- **Update Organisation & Location**

Data set 6: Veterinary MAHs & MAAs for NAPs
As of Sep 2018 stakeholders can start submitting OMS change requests for data set 6

EMA will communicate when each data set is added to the OMS dictionary. Until communicated please do not submit the OMS CRs.

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OMS Data Quality approach

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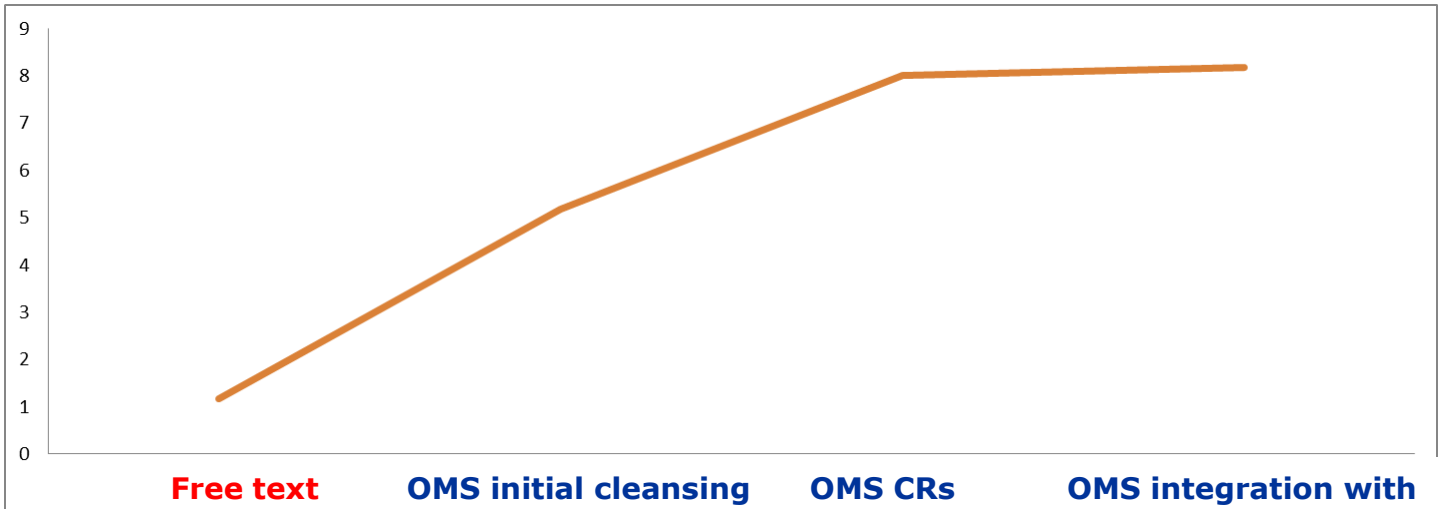
OMS Data Quality is expected to improve over time



- **OMS improves organisation data quality compared to previously unstructured data (free text)**
- **OMS initial data cleansing/ mastering stage**
  - Focus is on **producing consolidated and standardised content** to be able to support EU regulatory procedures. Data is consolidated and standardised (i.e. standardisation) according to pre-defined business rules
  - **Further improvements are planned in subsequent stages**
- **OMS maintenance and submission of change requests (CRs)**
  - In the OMS creation/updates of organisation data is based on documents provided by requestors thereby improving its accuracy
- **Integration of OMS with business processes**
  - **Integration** with business processes will lead to **quality improvements & further standardisation** of the data

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OMS Data Quality – how you can contribute

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- OMS provides a **centralised data source** of organisation data which enables us to move **from free text** approach to a **structured & standardised data** ready to be used across different regulatory processes including Marketing Authorisations
- Using/Mapping to OMS data will help you:
  - Understand what additional data you might need to support your procedures
  - Address any data quality issues relevant to the regulatory submissions
  - Prepare for when the use of OMS data will be mandated, thus improving the efficiency of your future submissions
- Data in OMS is traceable so no mapping effort is lost (xEVMPD and EudraGMDP ID mappings are kept and published)

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Manufacturers in OMS (**as-is**)

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Manufacturer

Manufacturers liaise with NCAs for their Manufacturing Import Autorisations (MIA)

Applicants/MAHs

Applicant select Org/Loc in the relevant section of the application form. Finalise & submit.

Responsible for registration/updating org data in OMS before MA application submissions (e.g. Initial MAA, Var, Ren.)

Application referring to a manufacturer that has not yet been inspected

NCAs

MIA
- New/updated Manufacturers (H&V) in EU
- *May not contain: Luxembourg data*

API registrations
- All API manufacturers (H only!) in EU
- *May not contain: data from France, Liechtenstein; Norway; Romania*

GMP certificates
- Inspections carried out to all EU manufacturers (H&V)
- Inspections carried out to some non-EU manufacturers (H&V)
- *May not contain: Luxembourg data*

OMS supplies data to eAF

OMS Change Requests for:
- Manufacturers in Luxembourg
- Vet API manufacturers
- H API manufacturers in France, Liechtenstein; Norway; Romania
- New/updated Manufacturers in non-EU countries (if not yet inspected)

Data loaded to OMS in Q4 2016 (going through cleansing/consolidation currently)

More data loads may happen in the future (to add new organisations/Locations, known as DELTA load)

EudraGMDP

OMS

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Manufacturers in OMS (**proposed to be**)

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To be further discussed & agreed with the Network in the future

Applicants/MAHs

Manufacturer

Applicant select Org/Loc in the relevant section of the application form. Finalise & submit.

Responsible for registration/updating org data in OMS before MA application submissions (e.g. Initial MAA, Var, Ren.)

Responsible for registration/updating org data in OMS for application for e.g. MIA

NCAs

Application referring to a manufacturer that has not yet been inspected

MIA
- New/updated Manufacturers (H&V) in EU
- *May not contain: Luxembourg data*

API registrations
- All API manufacturers (H only!) in EU
- *May not contain: data from France, Liechtenstein; Norway; Romania*

GMP certificates
- Inspections carried out to all EU manufacturers (H&V)
- Inspections carried out to some non-EU manufacturers (H&V)
- *May not contain: Luxembourg data*

OMS Change Requests for:
- New/updated Applicant/MAH in EU

OMS supplies data to eAF

OMS Change Requests for:
- New/updated Manufacturers (H&V) in EU
- New/updated Manufacturers in non-EU countries

EudraGMDP

OMS supplies data to EudraGMPD

OMS

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Manufacturer in OMS (**proposed to be**)

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Changes in the manufacturers lifecycle management depend on:

- Agreement of the new process and business rules with NCAs
- Consultation and communication plan with manufacturers
- Changes to EudraGMDP system
- Responsibility of Inspectors' Working Group (IWG) to prepare the business case for this project

New EudraGMDP project

Not yet prioritised/planned

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2. Using OMS in eAF

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Using OMS in eAF

- Summary of milestones & impacts
- eAF/CESP releases
- Using OMS data in eAF - DEMO
- Mandatory use of OMS in eAF
- eAF/CESP releases vs OMS data

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Summary of milestones & impacts

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June 2017 new OMS data services live.
No impact on regulatory submissions at go live.

Free text removed in Q3 2019

OMS dictionary being expanded with additional data

2017 | **2018** | **2019**

Dec 2017
OMS & v.1.22 eAF integration - OMS starts supplying organisation master data to eAF (MAA, Variation, Renewal (vet/human).
Use of OMS is initially optional.

Jul 2018
v.1.23 eAF integration - OMS Location (address) versions available in eAF for Variation forms (vet/human).
Use of OMS is still optional.

Q1/2019 (tbc):
CESP & OMS integration go live for Human & Vet MAAs

Q3 planned for CESP to mandate use of OMS data. Selection from OMS only for MAH, MA Applicant, Manufacturer for Initial MA Applications.
eAF Initial MAAs removed. (tbc).

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eAF/CESP releases

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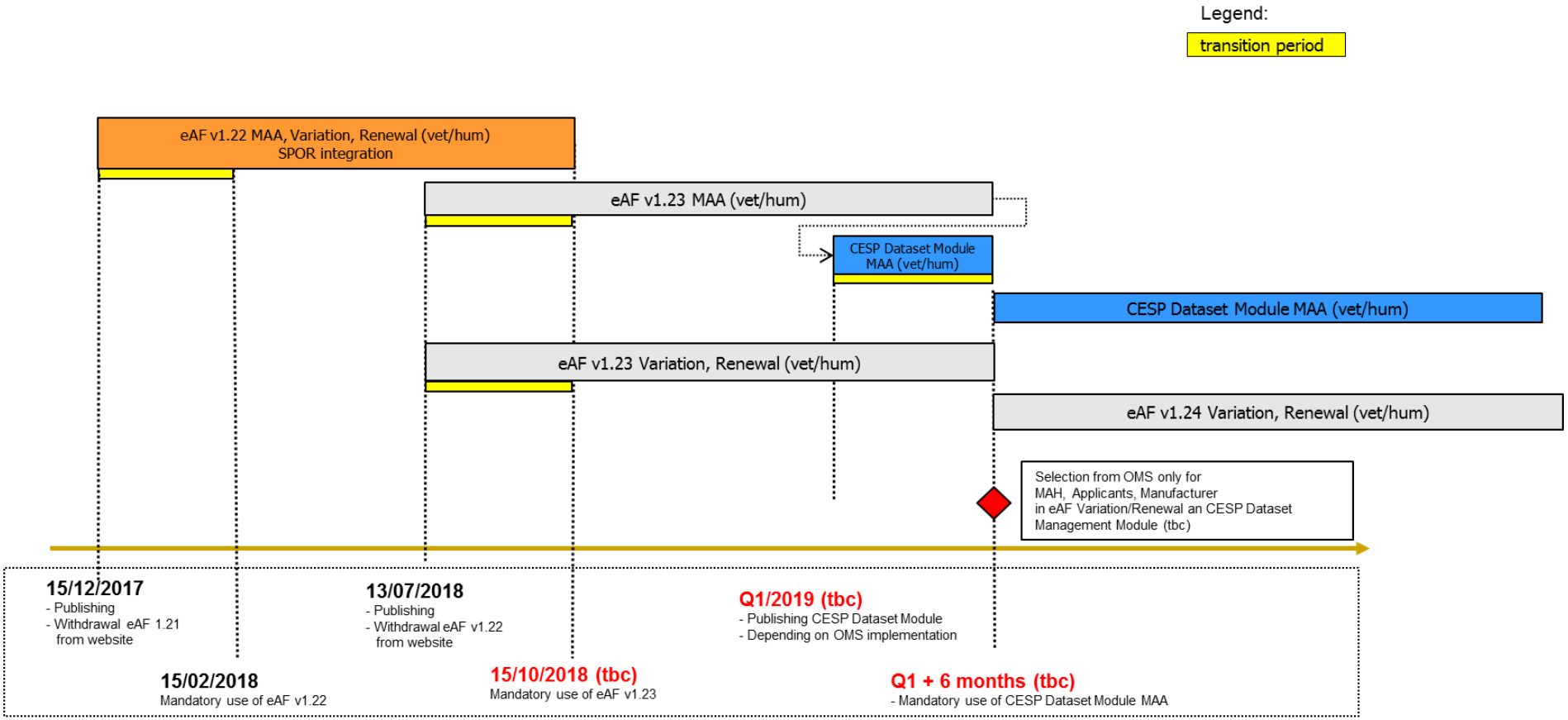
in discussion...

Publication after consultaton of focus group and industry



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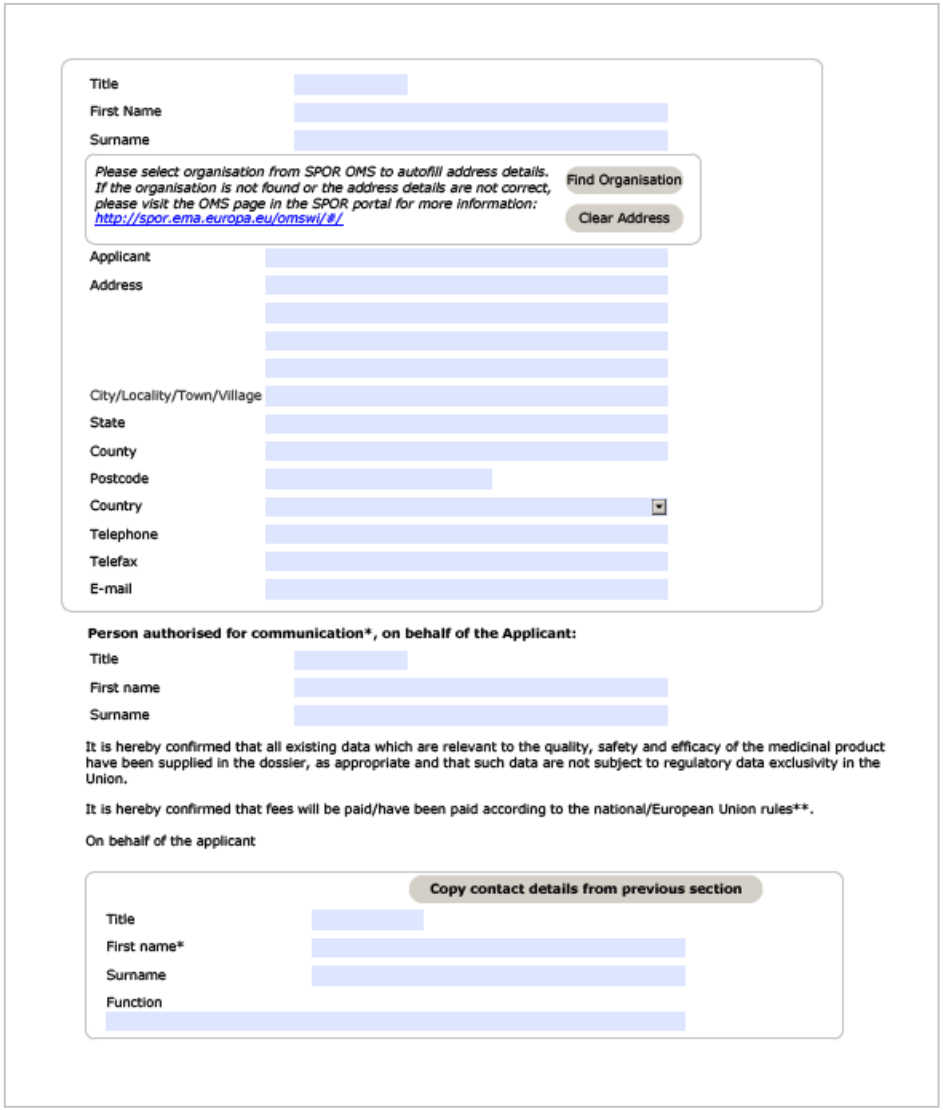
Using OMS data in eAF - demo



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Using OMS data in eAF

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- **Using the Drop down list available to select Org data**
  - Applicants are advised to **familiarise** themselves **with the use of OMS data** and to ensure that they are familiar with the process **before the use of OMS data becomes mandatory.**
  - Applicants are advised to **perform a search** from within the form
  - **What OMS data can be searched on in eAF?**
    - IDs: **Organisation_ID** and **Location_ID**
    - Name: **Organisation name** (Main name and alternative names)
    - **Country**
      - eAF v1.22 Forms allow search only on current version (no historical/previous versions)
      - A change will be implemented in eAF variations form (v1.23), in the present/proposed section, to also allow searching for historical/previous versions in the present section (but not on proposed)
  - **What happens after searching for an organisation?**
    - If the **Organisation name and/or address/location is not found or is incorrect**, users are advised to follow the OMS process to submit requests for adding or amending organisation data before the eAF submission for the following data,
      - Now….
        - MAHs for Human medicinal products CAPs & NAPs, and MAHs for Veterinary CAPs
        - MA Applicants for Human and Veterinary CAPs
      - In addition, from September 2018….
        - MA Applicants and MAHs for Veterinary NAPs
    - If the **Organisation name and address/location are correct**, users may proceed with using the OMS-provided data.

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What IS mandatory by when?

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"Role"		Content available in OMS	OMS CR submitted from	Mandatory in CESP (only for initial MA application)
Applicants	H CAP	Yes	As off January 2018 - stakeholders can start submitting the relevant OMS change requests.	
	H Non-CAP (MRP, DCP, National)	No plans, we expect many will fall within data set 4 (Sponsors target end Q3 2018)	**As off Q3 2019**	
	V CAP	Yes	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V Non-CAP (MRP, DCP, National)	Content populated via submission of OMS CRs	**As of September 2018** - stakeholders can start submitting the relevant OMS change requests.	
MAH	H CAP	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	6 Month after CESP goes live. (eAF forms will be removed)
	H Non-CAP (MRP, DCP, National)	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V CAP	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V Non-CAP (MRP, DCP, National)	Content populated via CRs	**As of September 2018** - stakeholders can start submitting the relevant OMS change requests	
Manufacturers	H CAP	By end of Q2 2019	**As off Q3 2019**	
	V CAP	By end of Q2 2019	**As off Q3 2019**	
	H Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As off Q3 2019**	
	V Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As off Q3 2019**	
Other	Eg. CROs, Billing Orgs., Contact people Organisations, etc	Not planned yet.		

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3. Submission of OMS Change Requests (CRs)

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Submission of OMS Change Requests (CRs)

- OMS CR stages
  - Submission - Who can submit an OMS CR
  - Validation
  - Approval

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OMS Change Request (CR) stages

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1

Submit OMS Change Request (CR):
- Add Organisation
- Update Organisation
- Add Location
- Update Location
- Update Organisation & Location

Any registered SPOR user can submit a CR for his organisation or any other organisation.
CR should include relevant documentation/ information.
See slide 17.

2 **Validation:** EMA data stewards validate the request (SLA 5 w/d - indicative).
Except for very minor (administrative e.g. spelling mistakes) changes, documentation must be provided in the change request.

If validation criteria are not met:

a) CR On hold – SPOR Data Stewards requested clarification / information.

b) CR rejected – E.g. Organisation/Location already exists, not enough information to validate the request, provided data is not acceptable, etc. See 'OMS Controlled Vocabularies (CVs)' document in OMS portal.

3 **Approved**: Validation criteria were met (relevant info and/or document(s) were provided). Following the approval OMS dictionary will be updated automatically and data will be published.

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OMS Change Request (CR) stages - Validation

OMS users please consult "Organisation data quality standards in OMS" guidance when requesting additions and/or updates of organisations/locations in the OMS. Available on the OMS Portal.

http://spor.ema.europa.eu/sporwi/

- **OMS supports** the data management and quality management **mainly** for information in **Latin characters** although data in **BG & GR** characters will be **stored too**
- Organisation names are maintained manually incl. Acronym, Alternative names
- **Location addresses** are **validated**, **standardised** and **enriched** by an **address validator tool** which can also generate the address in local languages
- Communication details (**Email & Telephone**) are only **maintained for Locations**
- The selection for a reason for the request is mandatory
- The **lack of documentation** supporting the request can lead to **CR**'s **rejection**

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OMS Change Request (CR) stages - Validation

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1. Organisation names:

- Organisation name should be in "**Title Case**". However, acronyms in the name can be all in capitals e.g. **AstraZeneca Limited UK**
- **Symbols** should be **avoided** unless they are part of the registered name
- Legal entity may or may not need to be part of the organisation name. It can be different in each country.
- **Organisation names can be stored in multiple languages**:
  - When available, English name will be the preferred name
  - Alternative names can be recorded in other languages as well
  - Unlike for addresses OMS tool does not validate or suggest changes
- Acronyms can be provided but will not be validated by EMA
- In OMS , the non-trading name will be stored as the preferred name and the trading name can be stored as an alternative name in the same language as the preferred name e.g.

Martindale Pharmaceutical Limited - preferred name
Martindale Pharmaceutical Limited Trading as Martindale Pharma - EN alternative name

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OMS Change Request (CR) stages - Validation

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2. Legal entity types in organisation names

- There should be no comma before the legal entity type acronym in the name
- Unless specified otherwise, entity types should be at the end of the organisation names
- The should be no spaces between the letters and/or dots within the legal entity

Note: some types of organisations do not need to be registered with the Trade register

For more information, refer to 'Organisation data quality standards in OMS' document.

Country	Reference	Legal Entity naming in organisation names (in EN and National languages)
EU	European Justice Business Registers	Provides links to EEA national business register websites (when available).
AT	Austrian Business Register	Ges.m.b.H., mbH but only if word before this abbreviation includes the string "gesellschaft" like in "Entwicklungsgesellschaft mbH", GmbH, AG, EWIV, e.U. Austrian commercial register "Firmenbuchdatenbank" does not provide free access, however some basic information is published at the website of the following private data provider: https://www.kompany.at.
BE	Belgian Business register	B.V., N.V., S.A., GEIE, B.V.B.A., Organisation name in the register has no legal entity type as the preferred name. Translation names can contain the legal entity type. To include both N.V. & S.A., create a translation as 'English' with organisation name starting with N.V. and end the name with S.A. Leave the preferred name without the entity type.
BG	Ministry of Justice Registry Agency	Ltd.,
CH	Swiss Business Register	d.o.o., AG,
CY	Cypriot Registrar of Companies	Limited,
CZ	Czech Business Register EN / CZ	a.s., k.s., s.r.o. = spol. s r.o., v.o.s., EHZS, Basic search – landing page: enter company name and click "hledat". Advanced search – click on the magnifying glass with title "rozšířené vyhledávání": enter the company name in 'Název subjektu' and select 'Vyhledat'.
DE	German company register	AG, GmbH, mbH but only if word before this abbreviation includes the string "gesellschaft" like in "Entwicklungsgesellschaft mbH", KG, AöR, GmbH & Co. KG, EWIV, SE, KGaA,
DK	Danish Company Register	A/S, I/S, K/S, ApS, EØFG,
EE	Estonian Business Register	OÜ, EMHG, AS, AS is usually placed before the actual company name, i.e.: AS Kevelt
EL	Greek Business Registry	S.A., M.E.P.E., A.E., L.P. L.P. = Limited Partnership Enter the name of the company at the field: 'Επωνυμία' (the middle one at the first line)
ES	Spanish chamber of Commerce	S.L., S.A., AEIE,

Legal entity naming in organisation names (in EN and national languages)

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3. Standards on location address

Location will be Title Case except post code and PO Box

Location address represents the physical location.

Address line 1 and country are mandatory data attributes for a location to be created. When the is no address line data, PO Box should be provided in the Address line 1 instead.

Address Doctor (AD) can enrich the provided address[1] with additional address data (e.g. district/su-blocality, County/State, etc.) and Geo coordinates (Longitude and Latitude). If required, data steward may choose to ignore the data transformation/enrichment by AD.

[1]As provided by the national postal services

Organisation Details

Organisation ID:	ORG-100000823
Organisation Name:	Bristol-Myers Squibb / Pfizer EEIG
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

Location ID:	LOC-100000481
Address:	Bristol-Myers Squibb House Uxbridge Business Park Sanderson Road Uxbridge Middlesex UB8 1DH United Kingdom
GPS Location:	51.55535, -0.47864
xEVMPD Code:	ORG5340
Last Modified Date:	2017-10-17T15:45:28
Status:	ACTIVE

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4. Address localised

- Address localised is automatically generated by the Address Doctor if the address is verified as with 'Good' quality
- The data generated is derived against the reference address files as provided by the main postal service of that country or jurisdiction
- Although OMS supports the Latin Extended Character set, some postal services may provide the address with letters without the diacritical marks e.g. without accents etc. Example: France
- Each address localised will need to have the language associated to it. There can be multiple address localised created

Users can update address localised through Update Change Request

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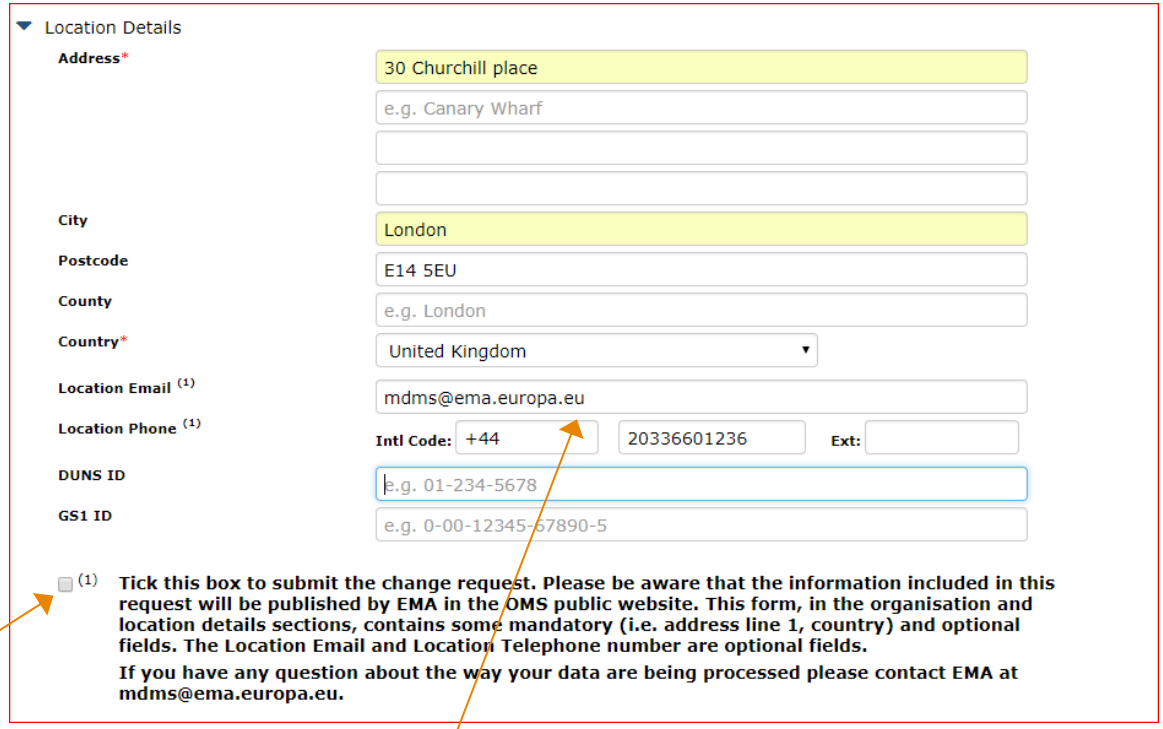
5. Communication Details



GDPR requirements:
The Change request can only be submitted if this box is ticked.

Telephone and Email only apply to the Location.
These are optional data.
If provided, this information will be published in OMS dictionary.
Provide 'mailbox' email address as much as possible.

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OMS Change Requests (CR) & Data Quality

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- **How does the OMS change request process contribute to the Organisation data quality i.e. is data validated in OMS?**
  - The change request must be supported by relevant documentation
    - OMS doesn't force registration in DUNS/GS1 but we accept DUNS/GS1 registration proof
  - EMA Data Steward checks:
    - **Supporting documentation**
    - Justification for the data change
    - **Reference sources of information** (e.g. Business Register/commerce chamber websites)
    - Address verification by **Informatica's address doctor** tool

    Notes:

    – Particularly for Manufacturers not registered in DUNS we assume:
      - manufacturer has manufacturing authorisation
      - MAH has audited the manufacturer before it is registered in OMS.

    – An Organisation is inactivated only when it ceases to operate as a legal entity i.e. it can never be used again in regulatory procedure NOT that it is not used for a given product/procedure
  - EMA **standardises the data** (i.e. it can look different from the document provided)
  - Outcome: a **new Org/Loc created** or a new **Org/Loc VERSION created** (All versions are kept)

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4. Key messages

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Key messages

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- **OMS dictionary** (list of organisations with associated physical locations) can be used to **support regulatory business processes**
- OMS content is growing and **data quality** is expected to **improve over time**
- Business owner of the process using OMS data decides how/when to use it and mandates its use. OMS team will work closely with the business process owners
- **eAF will not mandate** the use of **OMS** data, **free text will still be available**
- **CESP will mandate the use of OMS data in the form**. Organisation data will have to be pre-registered in OMS and can be selected in CESP. This is not planned before Q3-2019 for initial MA Applications
- Applicants are advised to **familiarise** themselves **with the use of OMS data** and with the process **before the use of OMS data will be mandated**
- **Applicants and MAHs** are responsible to **register/update organisation data in OMS** before regulatory submissions (e.g. Initial MAA, Var, Renewal)
- **Submission of OMS Change Requests for Veterinary MAH & MAAs for NAPs starts from September 2018**

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Key messages

- **Key User Group** is planed to be set up in Q4 2018 – this will be a **forum** to discuss **OMS operational issues**
- Use of OMS data in eAF **-** **a focus group** is in operation for eAF/CESP. This group is composed of representatives from CMDx, regulatory EMA (H+V) and NCAs
- **Informing manufacturers in & outside EEA about OMS implementation**
  - Applicants/MAHs are responsible to ensure manufacturers data needed for the regulatory applications is in OMS

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OMS support / guidance

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1. Reference documents accessible from the SPOR portal

- OMS web user manual – guidance on OMS 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 (CR) Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)

http://spor.ema.europa.eu/sporwi/

3. EMA corporate website includes SPOR related information, documents and material from webinars.

2. Training videos
OMS training videos available to view on the @emainfo channel.

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.

5. EMA Service Desk Portal

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

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Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
SPOR-Change-Liaisons@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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Annex

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Frequently Asked Questions (FAQs)

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Use of OMS in regulatory context

Q1: If another company has updated my manufacturer do I need to use the latest manufacturer details in submissions?

Answer: eAF provides the current version of organisation data for Initial MA and Renewal application forms. In variation application form v1.23, all versions of Organisation/Locations will be selectable.

Q2: If OMS Data Quality standards are different from my docs, will my application be rejected?

Answer: In theory no, however we acknowledge training and awareness is still needed amongst stakeholders. A new focus group will be formed on eAF/CESP, sub-group of the eAF/CESP maintenance group and composed of representatives from CMDx, regulatory EMA (H+V) and NCAs to be the first point of contact for such general regulatory queries, to centralise them.

Contact details

Q3: What data does OMS manage?

Answer: Email/phone details for the Location NOT for Email/phone details for the contact people.

Q4: Do I need to keep my organisations contact details updated?

Answer: Yes, you should.

Q5: Where do I manage/maintain the details of my contact people?

Answer: These are not to be managed in OMS and should be entered manually in each specific application (CT submission, eAF submission, Art 57 submission, etc).

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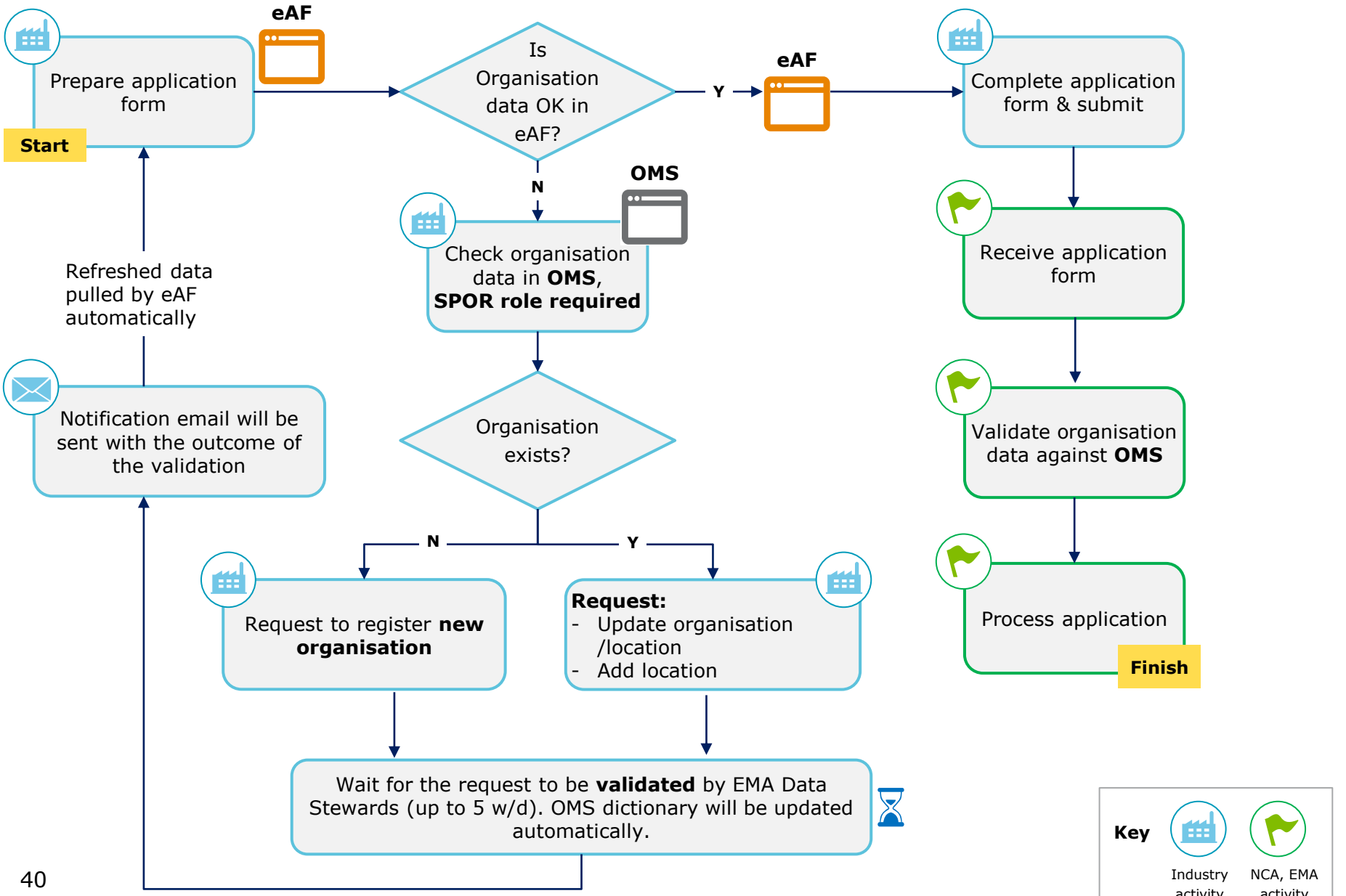
Using OMS data in eAF



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