EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR webinar: Using OMS & RMS data in eAF

28 November 2017

Draft Agenda

EUROPEAN MEDICINES AGENCY

1.	Case for SPOR (why, how, what)	*Agnieszka Laka, SPOR Business Change Lead*
2.	RMS in summary	*Jaume Gonzalez, RMS Business Lead*
3.	OMS in summary	*Kepa Amutxastegi, OMS Business Lead*
4.	Using RMS in eAF	*Jaume Gonzalez*
5.	Using OMS in eAF	*Kepa Amutxastegi*
6.	Demonstration & case study	*Kristiina Puusaari, eSubmissions Business Lead*
7.	Requesting Substances via EMA Service Desk	*Pedro Batista, SPOR Data Steward*
8.	SPOR user registration process	*Gabriel Boronat, SPOR Business Change*
9.	Key messages	*Agnieszka Laka & Gabriel Boronat*
10.	Additional information & relevant documents	*Gabriel Boronat*

Case for SPOR

EUROPEAN MEDICINES AGENCY

Issues → **Centralise SPOR data** → **Enter once, reuse often** → **Benefits**

- Data is at the centre of organisations
- We are collecting more data then ever
- Data is scattered across organisations, applications, databases.
- Consequence is data that is not consistent and/or not integrated
- **The result? Inconsistent data cannot be reused**

We are **centralising management of data** in four domains of pharmaceutical & regulatory data:

- **Substances**
- **Products**
- **Organisations**
- **Referentials**

Integrate SPOR master data with business processes so that **data** is **entered once** and **reused across different business processes**

- Process optimisation
- Decision making
- Public health
- Compliance
- Transparency

Benefits will be realised overtime.

How will SPOR be delivered

EUROPEAN MEDICINES AGENCY

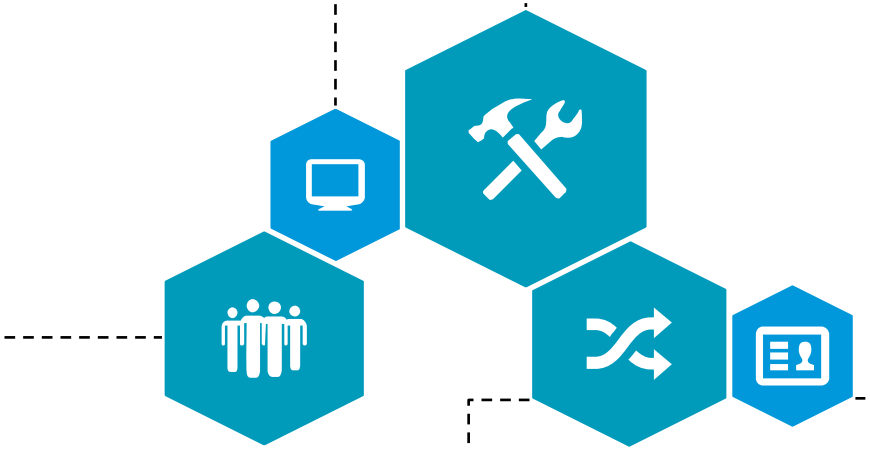
- **ISO IDMP standards** (five standards) define the rules that uniquely identify medicinal product and the relevant elements to identify them.
- Commission Implementing Regulation (EU) No 520/2012 (art. 25 & 26) obliges EU Member States, marketing authorisation holders, and EMA to **make use of the ISO IDMP standards.**
- **SPOR projects** implement ISO IDMP standards and the processes to **manage** four domains of data (**master data**) in pharmaceutical/regulatory industry:
  - **S**ubstance Management Services (SMS) – ISO 11238
  - **P**roduct Management Services (PMS) – ISO 11615, 11616
  - **O**rganisation Management Services (OMS)
  - **R**eferentials Management Services (RMS) – ISO 11239, 11240
- **Delivery of SPOR is phased**
  - RMS and OMS services delivered first (June 2017)
  - Delivery of PMS and SMS will follow (iterative)
- **SPOR applies to both Human & Veterinary domains**

What will SPOR deliver

EUROPEAN MEDICINES AGENCY

Lists of organisations, (OMS dictionary), **referentials, terms,** and **substances** for stakeholders to use in EU regulatory activities

SPOR data accessible via the SPOR web portal and SPOR API (application programming interface)



A specialised team of **EMA data stewards** will manage SPOR data and provide support to stakeholders

New process for industry and NCAs to **register/update** SPOR data before submitting regulatory applications.
Data entered once and reused in different processes

New **data management** approaches for industry, NCAs, and EMA:

- On-going data synchronisation.
- Possible need for data transformation/enrichment

Integration of RMS and OMS with eAF

ISO IDMP compliant **RMS** & **OMS services live** in June 2017.
No impact on regulatory submissions at go live.
RMS and OMS projects concludes in December 2017.

Use of RMS mandated as of July 2018

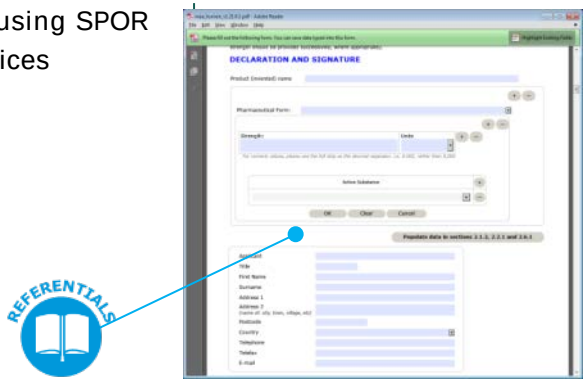
Start using RMS services

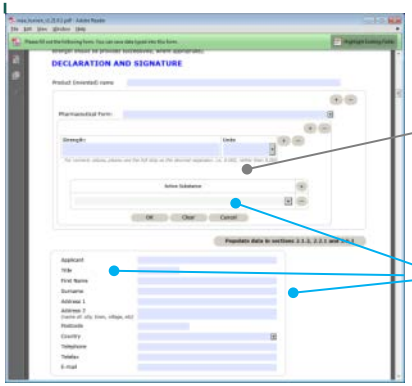
Use of OMS in eAF mandated

Start using OMS services in eAF

2017 **2018**

Consultations with stakeholders on the benefits of using SPOR services





Q3/Q4 2018 CESSP planned to go live (*)

June 2017:
RMS replaces EUTCT,
RMS integrated with eAF
(consumes RMS data)

15 Dec 2017:
eAF integration with OMS
(MA application, Renewals, Variations for Human and Veterinary)

(*) – subject to planning

Integration of RMS and OMS with eAF

EUROPEAN MEDICINES AGENCY

- The launch of RMS and OMS services (June 2017) did not immediately change any regulatory submission processes.
- EMA has been consulting stakeholders on the benefits of using SPOR data (data entered once, reused often).
- Consultation with the eAF Group resulted in plan to integrate of eAF with OMS - scheduled for December 2017.
  - RMS is already integrated with eAF
- In future SPOR master data is expected to support regulatory submissions in Telematics systems such as the electronic application forms (eAF) and the Common European Single Submission Portal (CESSP).
- A minimum period of 6 months will be allowed before the use of RMS and OMS will be mandated in any given regulatory procedure.

Referentials Management Services (RMS) – summary

About RMS 1/2

EUROPEAN MEDICINES AGENCY

- **RMS replaces EUTCT** (EU Telematics Controlled Terms) **as the central repository** and provider of Referentials data for the EU medicines regulatory network (EMRN).
- EMA will act as data broker (one-stop shop) and liaise with maintenance organisations and data owners to consolidate **Referentials Lists** into a single place and in a **common format.**
- **RMS includes the following lists of controlled terms:**
  - Lists migrated from EUTCT;
  - EDQM lists and Units of Measurement (UoM) lists (*these are ISO IDMP standard lists*);
  - EudraVigilance lists;
  - New lists required for OMS.
- **Substance-related lists remain in EUTCT until** the Substance Management Services (SMS) is delivered.
  - EUTCT should be used only for browsing and downloading the Substances-related lists.

About RMS 2/2

EUROPEAN MEDICINES AGENCY

- Users can access the data via the RMS web portal, or programmatically via the application programming interface (API).
- There is a **common process** for Industry and other parties to submit change requests for the **registration of new terms** or **update of existing terms in** the **RMS** **portal, prior to submitting regulatory applications**. This includes:
  - Creation of a new list/term, or
  - Request updates of already existing lists/terms, or
  - Request deletion of terms.
- The new RMS tool enables these tasks to be performed in a more efficient way as data stewards do not depend on IT colleagues.
- In addition to standard functionality such as browsing or searching RMS allows users to set preferences to personalise their RMS experience:
  - Subscribe to receive notifications of changes to terms and lists;
  - Tag subsets of referential terms;
  - Save frequently used searches.

Organisation Management Services (OMS) – summary

What OMS delivers

EUROPEAN MEDICINES AGENCY

- **OMS** is a **new service** that EMA is implementing **for** the **EU medicines regulatory network**
- **OMS** will provide a **central source of organisation data** (**OMS dictionary**) that consists of lists of organisations with associated physical locations to be used in support of EU regulatory activities
- **eAF** is the **first** business process **to use OMS** dictionary

Example of organisation search in OMS portal

Page 1 of 2

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status
ORG-100001756	Aventis Pharma Limited	United Kingdom	LOC-100003259	Alnwick	Willowburn Avenue	NE66 2JH	ACTIVE
ORG-100001756	Aventis Pharma Limited	United Kingdom	LOC-100002301	Guildford	One Onslow Street	GU1 4SY	ACTIVE
ORG-100004158	Sanofi - Aventis A.E.B.E	Greece	LOC-100000261	Kallithea	Syngrou Avenue 348	176 74	ACTIVE
ORG-100000970	Sanofi Aventis S.A	Spain	LOC-100001217	Leganes	Poligono Industrial Ciudad Del Automovil	28914	ACTIVE
ORG-100001968	Sanofi S.p.A.	Italy	LOC-100002628	Milan	Viale Luigi Bodio 37/B	20158	ACTIVE
ORG-100001968	Sanofi S.p.A.	Italy	LOC-100002763	Scoppito	Strada Statale 17 Km 22	67019	ACTIVE
ORG-100001968	Sanofi S.p.A.	Italy	LOC-100001330	Brindisi	Via Sant'Angelo 22/26	72100	ACTIVE
ORG-100001968	Sanofi S.p.A.	Italy	LOC-100002755	Anagni	Localita Valcanello 4	03012	ACTIVE
ORG-100000111	Sanofi-Aventis	France	LOC-100003678	Neuville Sur Saone	31 Quai Barbes	69250	ACTIVE
ORG-100000111	Sanofi-Aventis	France	LOC-100003674	Chilly-Mazarin	1 Avenue Pierre Brossolette	91380	ACTIVE

What will OMS deliver

EUROPEAN MEDICINES AGENCY

- The initial content of the OMS dictionary derives from existing systems, *i.e.* xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems.
  - In future new sources may be identified and organisation data incorporated in the OMS dictionary, *e.g.* CESSP, EV Vet, NCA systems, *etc*.
- This source data has been standardised, cleansed and consolidated by EMA Data Stewards.
- Data has been segregated to align with business priority which is based on organisation roles.
- EMA will inform stakeholders once each data set has been included in the OMS dictionary.

Initial OMS content plan 2017/2018

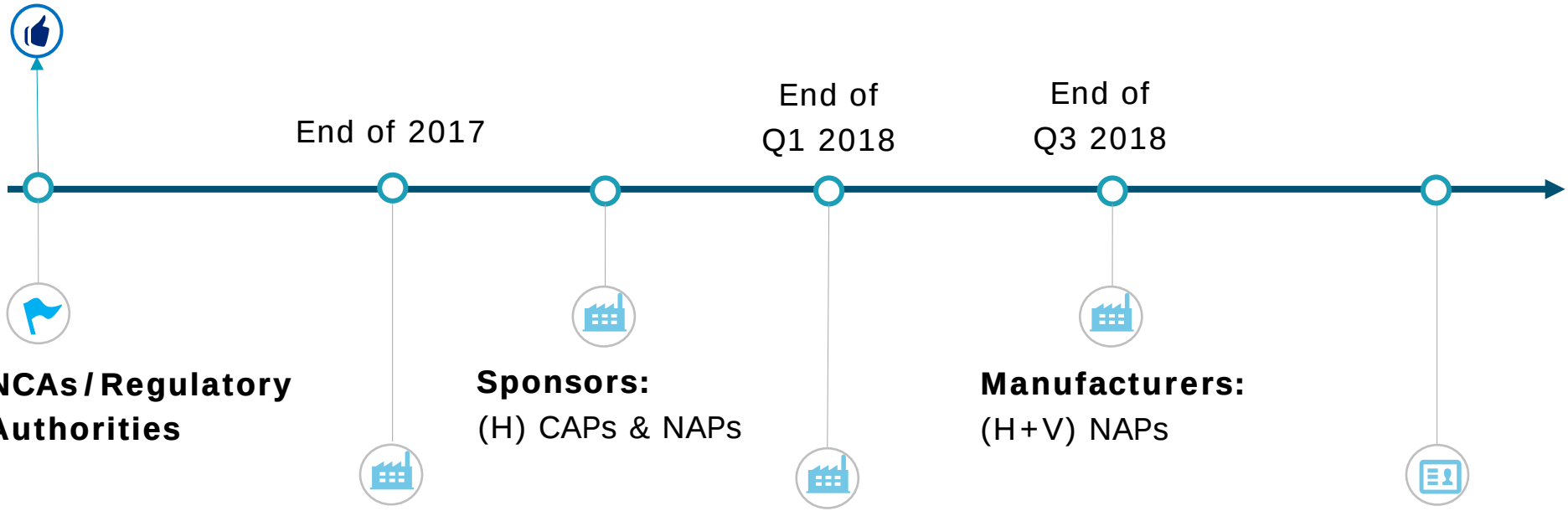
EUROPEAN MEDICINES AGENCY

Key

Points at which new organisation data set is published/completed in OMS. Communication will be provided closer to the publication of the data set.

MAHs - Marketing Authorisation Holders
MAAs - Marketing Authorisation Applicants
CAPs - Centrally Authorised Products
NAPs - Nationally Authorised Products
H, V - Human, Veterinary

OMS go-live
June 2017



NCAs / Regulatory Authorities

Sponsors:
(H) CAPs & NAPs

Manufacturers:
(H+V) NAPs

- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs
- **MRL applicants** (Vet)

Manufacturers:
(H+V) CAPs

Additional Organisation data to be added in future; prioritisation defined at a later stage eg. Vet non CAP MAHs

What will OMS deliver

- Organisation data will be structured with unique IDs (**Organisation_ID and Location_ID**) and mapped to records loaded from source systems, *e.g.* xEVMPD or EudraGMDP organisation IDs
- In the OMS there is **no differentiation between an organisation created in the context of a human medicinal product versus a veterinary medicinal product**
- OMS **will 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 an MAH in the context of one medicinal product but as Sponsor or Manufacturer for another medicinal product
- Organisations are categorised by **type**: 'Industry', 'Regulatory Authority', 'Educational Institution', 'Healthcare', *etc*. or by **size:** SME as 'Micro', 'Small', or 'Medium'

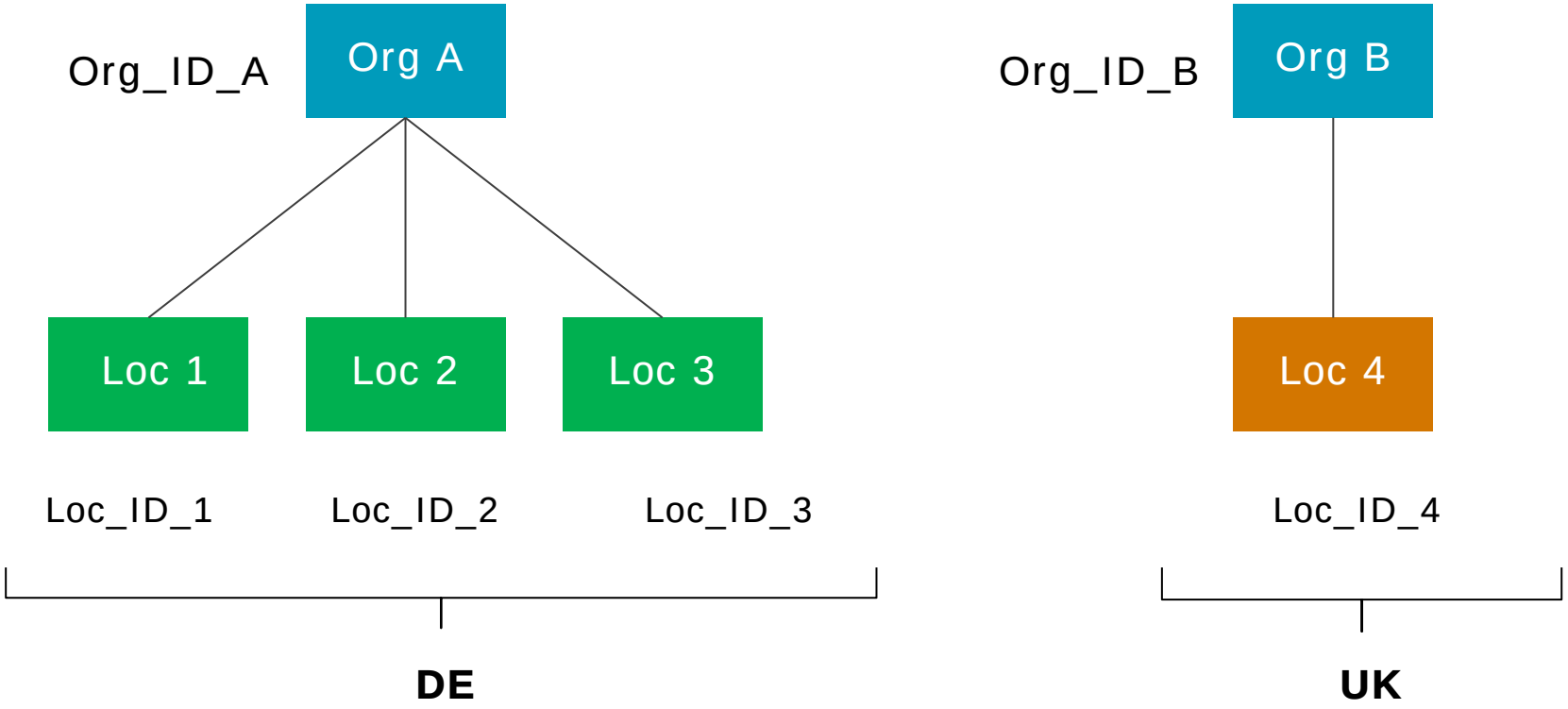
What will OMS deliver

EUROPEAN MEDICINES AGENCY

- OMS data can be accessed directly via the OMS web portal or programmatically via the application programming interface (API).
- Anybody can access the SPOR portal and **view / search OMS data.**
- Users will be able to search for organisations and locations and view details of organisations and locations.
- Search is a starting point for the user to request changes to the organisation data. The following options are available:
  - if the user is not able to find the requested organisation – defined by name in a given country – they can request **creation of a new organisation;**
  - if the organisation is found, but the required location is not found, the requestor needs to submit a request to **add a new location to the existing organisation;**
  - alternatively, a user locates an existing organisation and location, but determines that the **organisation and/or location need to be changed**.

Org_ID versus Loc_ID

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



Using RMS in eAF

Integration of RMS data with eAF

EUROPEAN MEDICINES AGENCY

- RMS is already integrated with eAF (RMS data is pulled into eAF automatically).
- **Terms should be registered** before they are required to be used in a regulatory procedure.
- Current process for applicants to request registration of terms is by sending email to mdms@ema.europa.eu (as described in eAF Q&A document).
- From December 2017 applicants are encouraged to start using RMS portal to submit change request to register terms (mdms@ can still be used until end of June 2018).
- From July 2018 only change request submitted via RMS will be accepted.

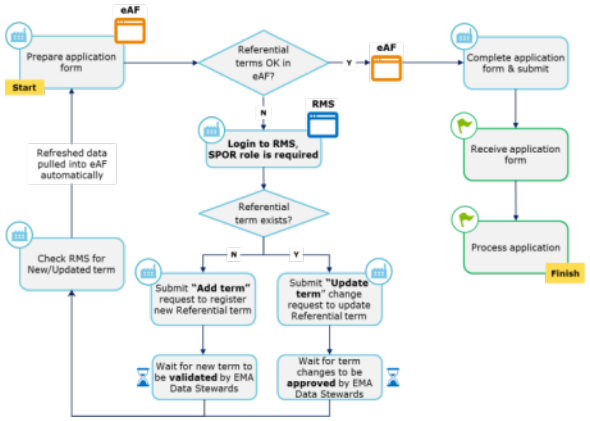
June 2017 RMS services live.
RMS is integrated with eAF. No impact on regulatory submissions at go-live.

15 December 2017 industry stakeholders start using RMS portal instead of mdms@

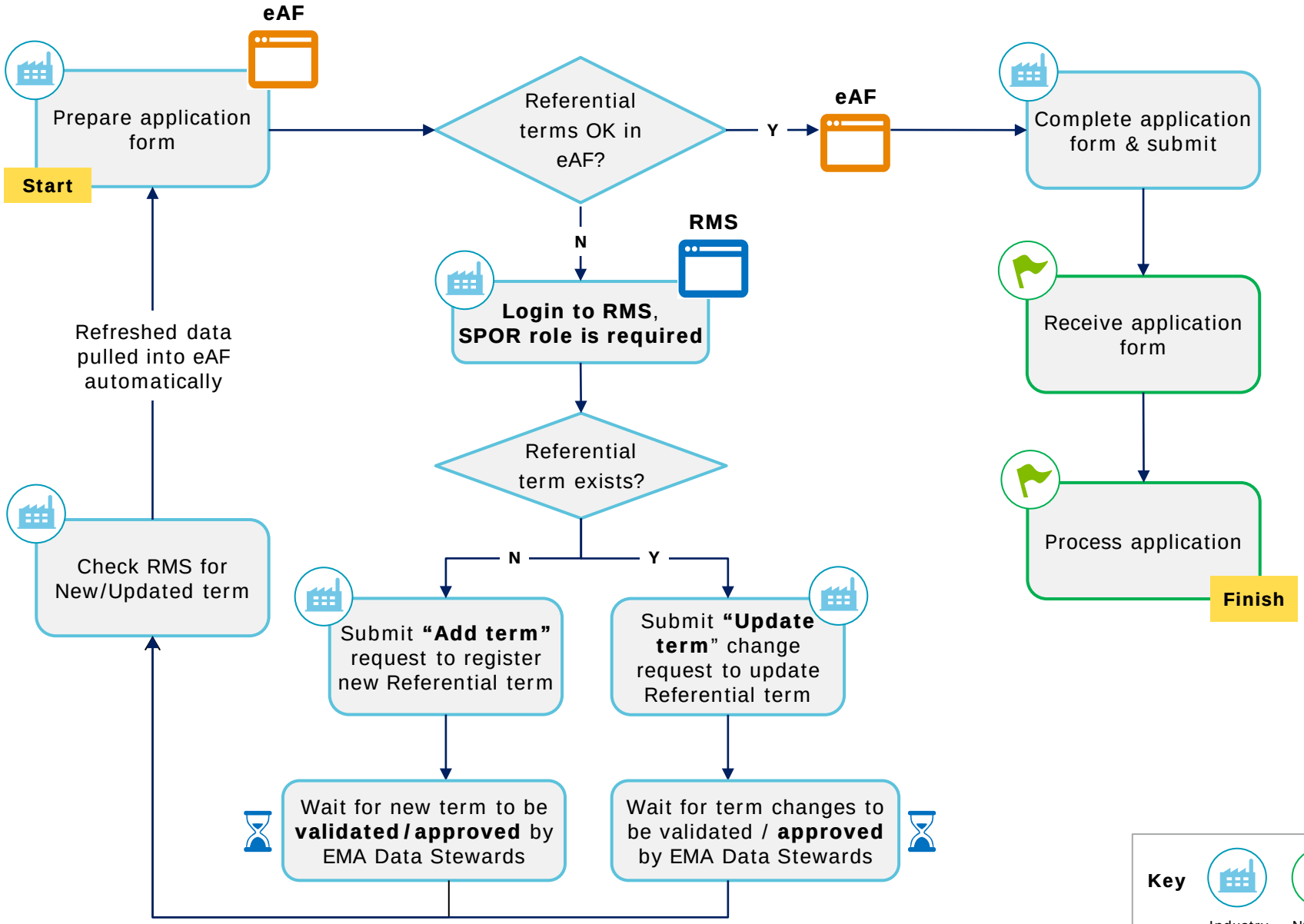
From July 2018 submission of change requests via RMS portal only

2017 | **2018**

Using RMS in eAF process (see slide 19)



RMS in eAF


eAF
Prepare application form
Start
Referential terms OK in eAF?
Y
eAF
Complete application form & submit
N
RMS
Login to RMS, SPOR role is required
Receive application form
Refreshed data pulled into eAF automatically
Referential term exists?
Process application
Finish
Check RMS for New/Updated term
N
Y
Submit "Add term" request to register new Referential term
Submit "Update term" change request to update Referential term
Wait for new term to be validated / approved by EMA Data Stewards
Wait for term changes to be validated / approved by EMA Data Stewards
Key
Industry activity
NCA, EMA activity

RMS in eAF

EUROPEAN MEDICINES AGENCY

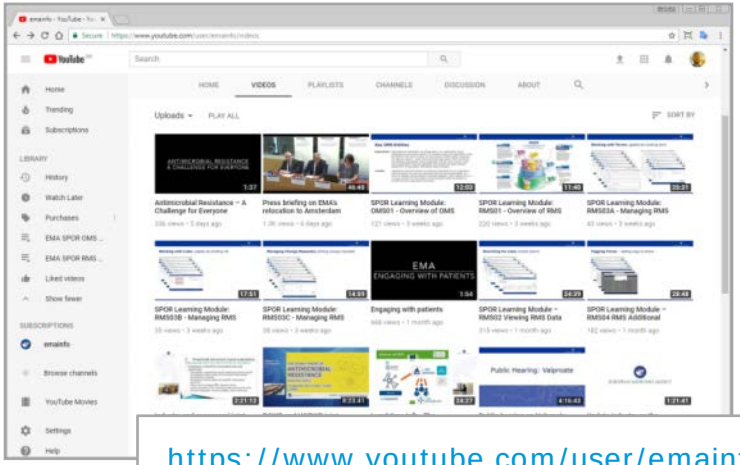
- After submitting "**Add term"** request it will usually take 2-3 working days to be **validated** and get a **provisional** term available for selection in eAF.
  - Data stewards can reject the request at validation level in case is clearly not a valid term. The requestor would have to submit a new term request
  - Data stewards can return the request at validation level in case the request is no complete or if additional information is required. The requestor would have to submit additional information
- Additionally, there is an **approval process** to determine the final term naming conventions. Depending on the List owner it can take from **1 month** to **1 year.**
  - When terms are approved their status becomes **CURRENT** (approved)
  - When terms are rejected their status becomes **NULLIFIED** or **NON-CURRENT** (used but no longer recommended)
    => *use a* ***CURRENT*** *term instead*

RMS in eAF

- After submitting an "**Update term"** request it will usually take 3-5 working days to be validated. After validation no changes will be reflected in the term.
  - EMA Data stewards can reject the request at validation level in case the changes are not acceptable. The requestor would have to submit a new update term request, if needed.
- Additionally, there is an **approval process** that will take up to 2 months.
  - If the "Update term" request is **approved** the requested changes become visible in RMS/eAF;
  - If the "Update term" request is **rejected** the term information remains the same in RMS/eAF.

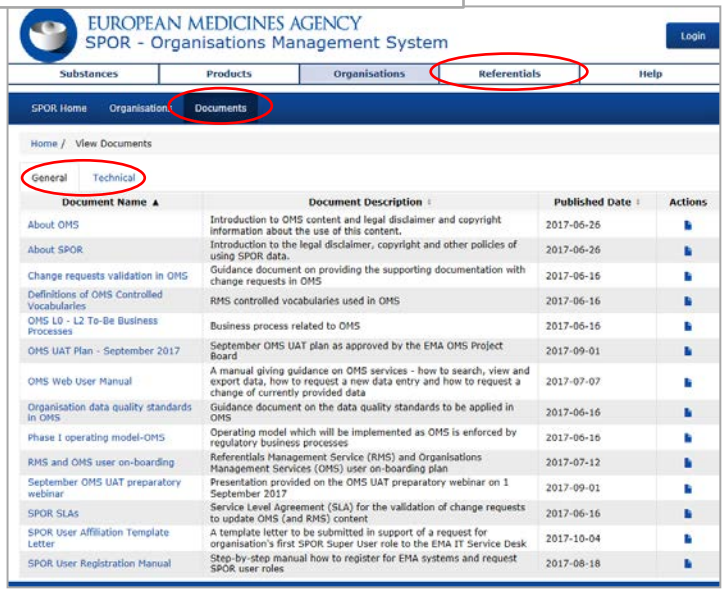
RMS relevant documents

- RMS training videos are published on the @emainfo YouTube channel. They cover core functionality for users of RMS and are available freely.
- RMS web user manual – provides step-by-step guidance for main functionalities available from the RMS web user interface, e.g. searching and browsing data, requesting new data entries, and requesting changes to existing data.
- SPOR Service Level Agreements (SLAs) – service levels for validation of change requests to update RMS data.



https://www.youtube.com/user/emainfo/videos

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

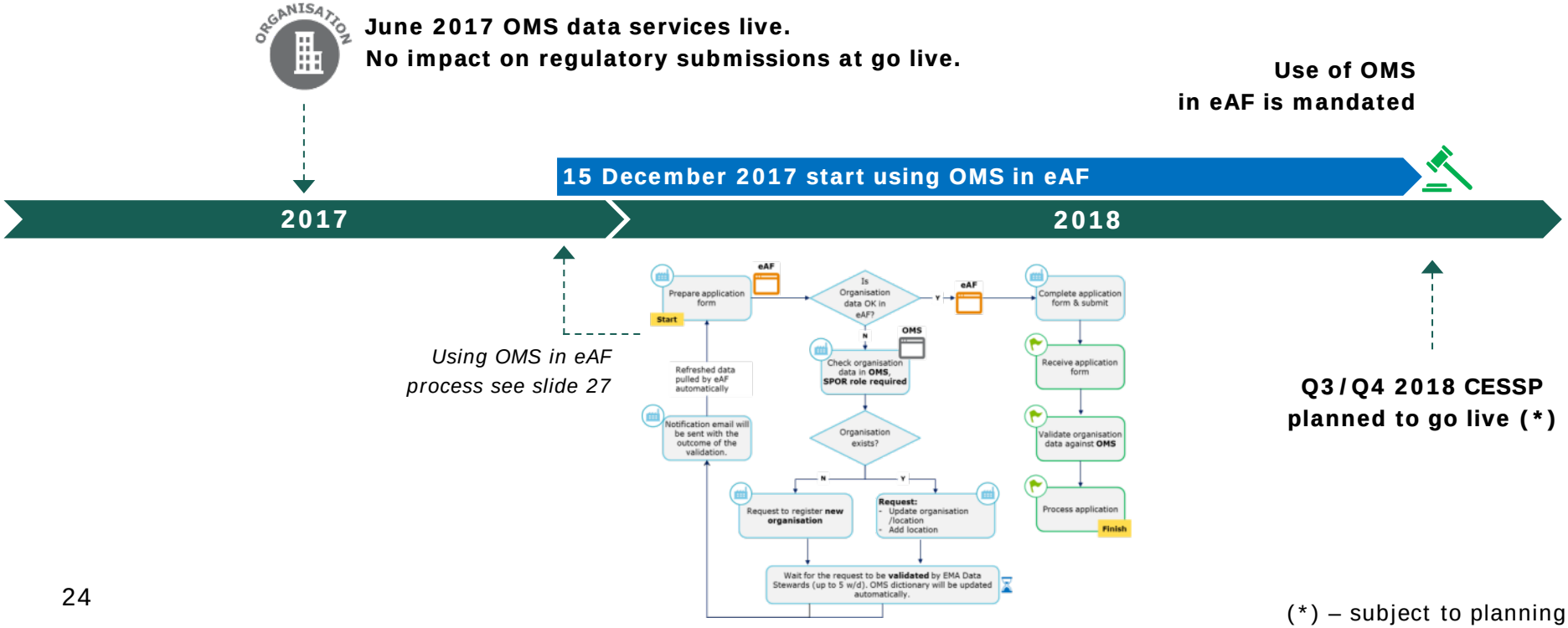


Using OMS data in eAF

Using OMS data in eAF

EUROPEAN MEDICINES AGENCY

- **OMS** will be **integrated in all four** electronic application **forms** for **all address fields** in eAF release v1.22.0.0, planned to go-live on 15 December 2017.
- Use of **OMS in** the **eAF** will **initially** be **optional.**
- **Mandating OMS** planned for **Q3/Q4 2018.**



(*) – subject to planning

Using OMS data in eAF

EUROPEAN MEDICINES AGENCY

Applicants are advised to **perform a search** from within the form to **familiarise** themselves **with the use of OMS** and to ensure that they are familiar with the process **before its use becomes mandatory.**

Two outcomes are possible after searching for an organisation:

1. If the **address/location is not found or is incorrect**, users can enter manually the address details using free text fields, as previously in the eAF. Users are advised to follow the OMS process to submit requests for adding or amending organisation data.
2. If the **address/location is correct**, users may proceed using the OMS-provided data.

Using OMS data in eAF

EUROPEAN MEDICINES AGENCY

Stakeholders can start submitting the relevant OMS change requests

Publication of **Manufacturers** in the **OMS** dictionary is planned to be completed by **Q3 2018**, stakeholders are asked **not to submit OMS change requests for Manufacturer** organisations **until EMA** has **communicated** this data set has been added to the dictionary.

Updates of OMS data to take place during Q1 2018 to align with xEVMPD data

Manufacturers:
(H+V) NAPs

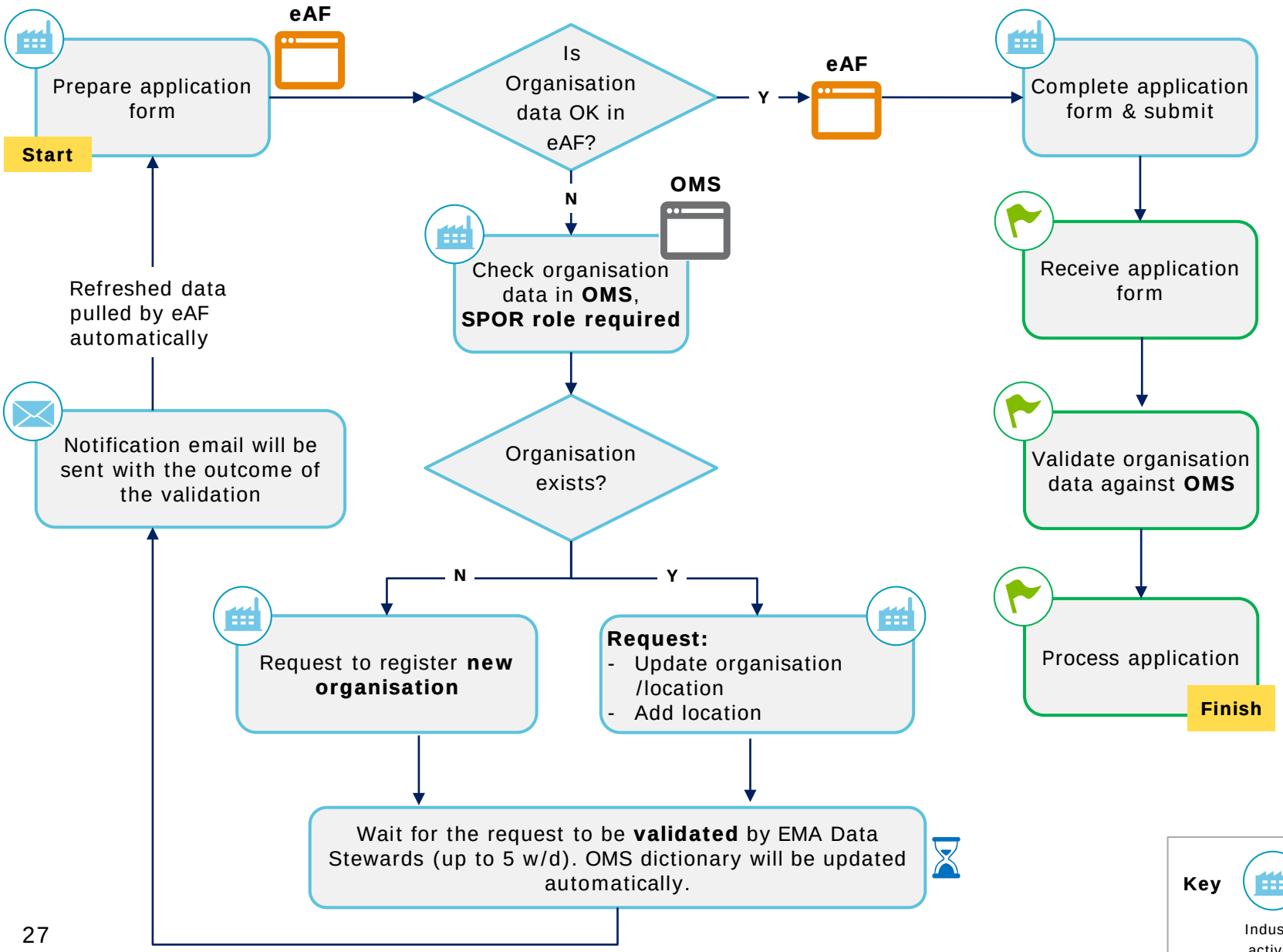
- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs

Manufacturers:
(H+V) CAPs

Additional Organisation data to be added in future; prioritisation defined at a later stage eg. Vet non CAP MAHs

Key
Points at which new organisation data set is published/completed in OMS.
Communication will be provided closer to the publication of the data set

OMS in eAF


Prepare application form
eAF
Start
Is Organisation data OK in eAF?
Y
eAF
Complete application form & submit
N
OMS
Check organisation data in **OMS**, **SPOR role required**
Receive application form
Refreshed data pulled by eAF automatically
Notification email will be sent with the outcome of the validation
Organisation exists?
Validate organisation data against **OMS**
N
Y
Request to register **new organisation**
Request:
- Update organisation /location
- Add location
Process application
Finish
Wait for the request to be **validated** by EMA Data Stewards (up to 5 w/d). OMS dictionary will be updated automatically.
Key
Industry activity
NCA, EMA activity

OMS in eAF

EUROPEAN MEDICINES AGENCY

EMA is the maintenance organisation of 'O' data

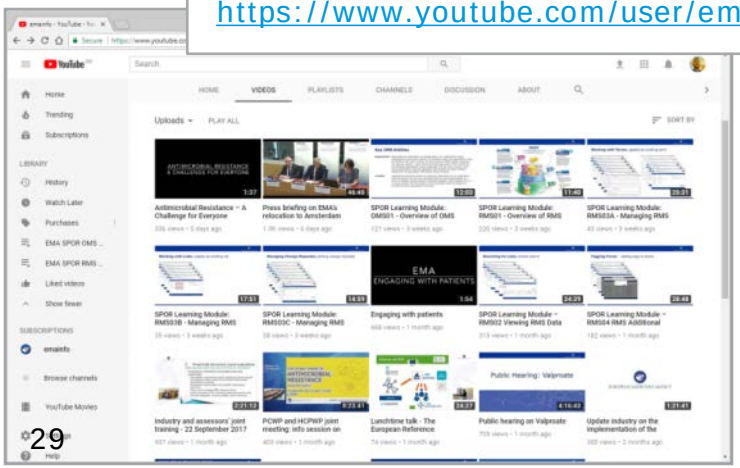
- EMA will generate and maintain Organisation IDs.
- When NCAs receive applications they will need to validate against OMS data. If the data does not exist in OMS, or is not accurate, then they will need ask Industry to submit via OMS a new organisation registration or an update.
- This user process will not become applicable for Veterinary-only NCAs until Manufacturers-related data is available in a later release of the OMS dictionary.

Checking Organisation data will help ensure **completeness** of the OMS dictionary which will be paramount to support future business cases in the context of EU regulatory activities

OMS relevant documents

- OMS training videos are published on the @emainfo YouTube channel. They cover core functionality for users of RMS and OMS and are available freely.
- OMS web user manual – provides guidance on OMS services, e.g. searching and viewing data, exporting data, requesting new data entries, and requesting changes to existing data.
- Organisation data quality standards – guidance on the data quality standards applicable to OMS.
- SPOR Service Level Agreements (SLAs) – service levels are indicative and will be reviewed in future. SLAs will be discussed with stakeholders and adjusted as SPOR data is consumed by additional systems.

https://www.youtube.com/user/emainfo/videos



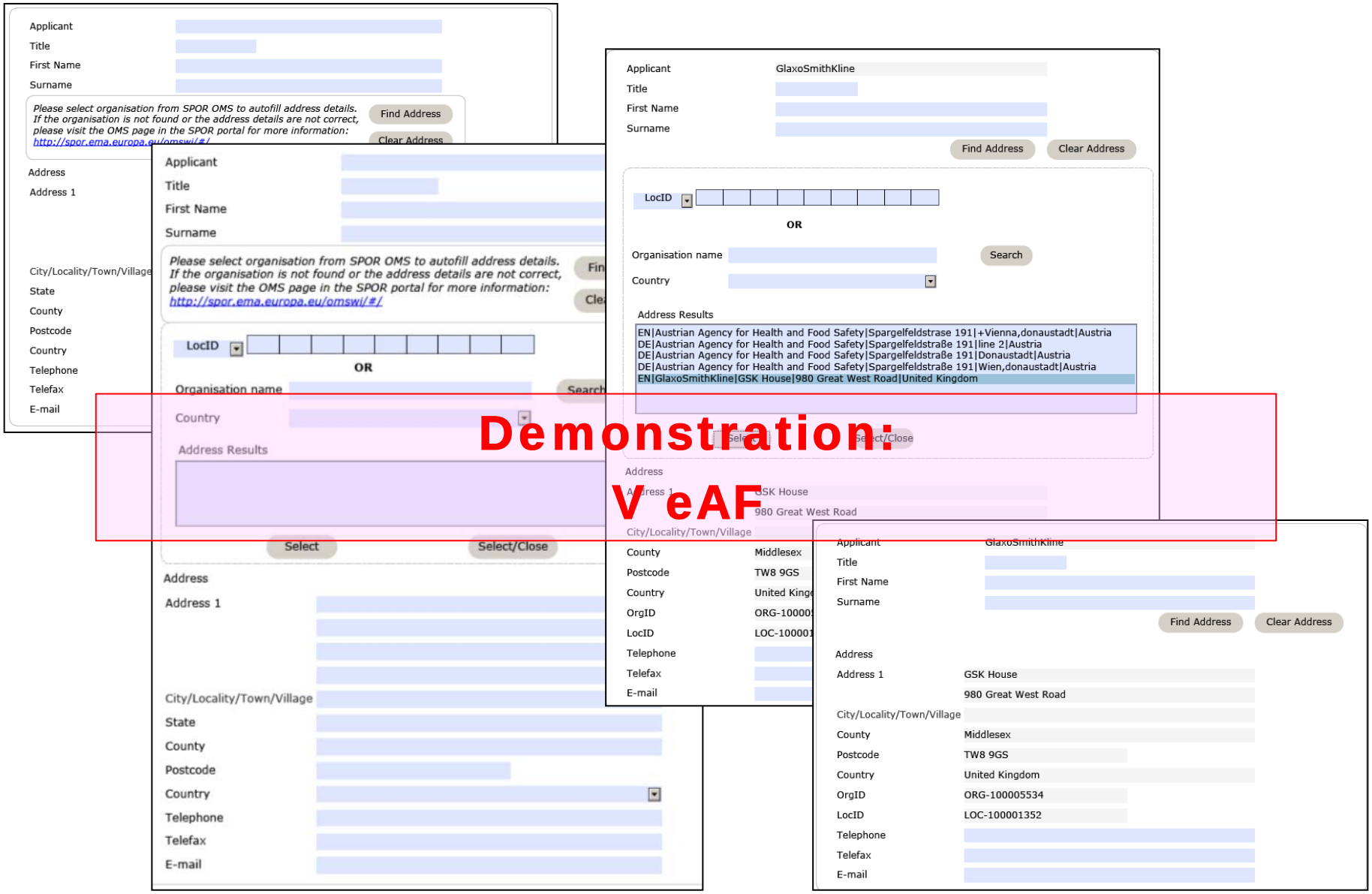
http://spor.ema.europa.eu/sporwi/

eAF-OMS – example form

EUROPEAN MEDICINES AGENCY

eAF-OMS – example form

EUROPEAN MEDICINES AGENCY



Demonstration: eAF

Requesting Substance – using EMA Service Desk instead of mdms@ email

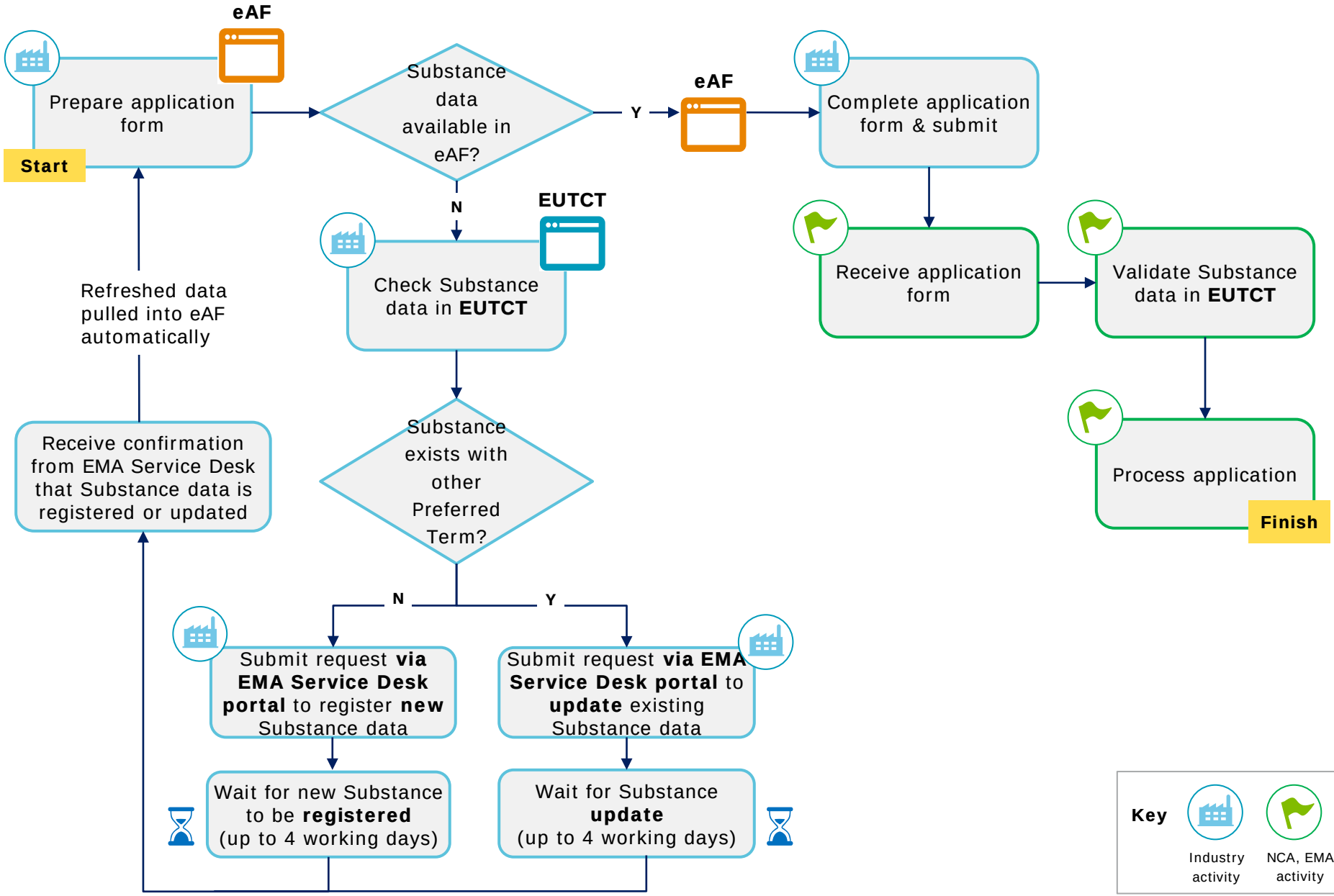
Substances in eAF submissions 1/2

EUROPEAN MEDICINES AGENCY

- **Substance-related lists remain in EUTCT until** the Substance Management Services (SMS) is delivered.
  - EUTCT should be used only for browsing and downloading the Substances-related lists.
- Substance data remains in EUTCT until the Substance Management Services (SMS) is delivered.
- As of January 2018 new substance requests and updates should be submitted via requests made to the **EMA Service Desk portal.**
- When submitting a substance request to the EMA Service Desk please provide supporting documentation for the substance (e.g. product SmPC or substance specifications).
- mdms@ema.europa.eu email address will be discontinued in Q1 2018.

Substances in eAF submissions 2/2

EUROPEAN MEDICINES AGENCY



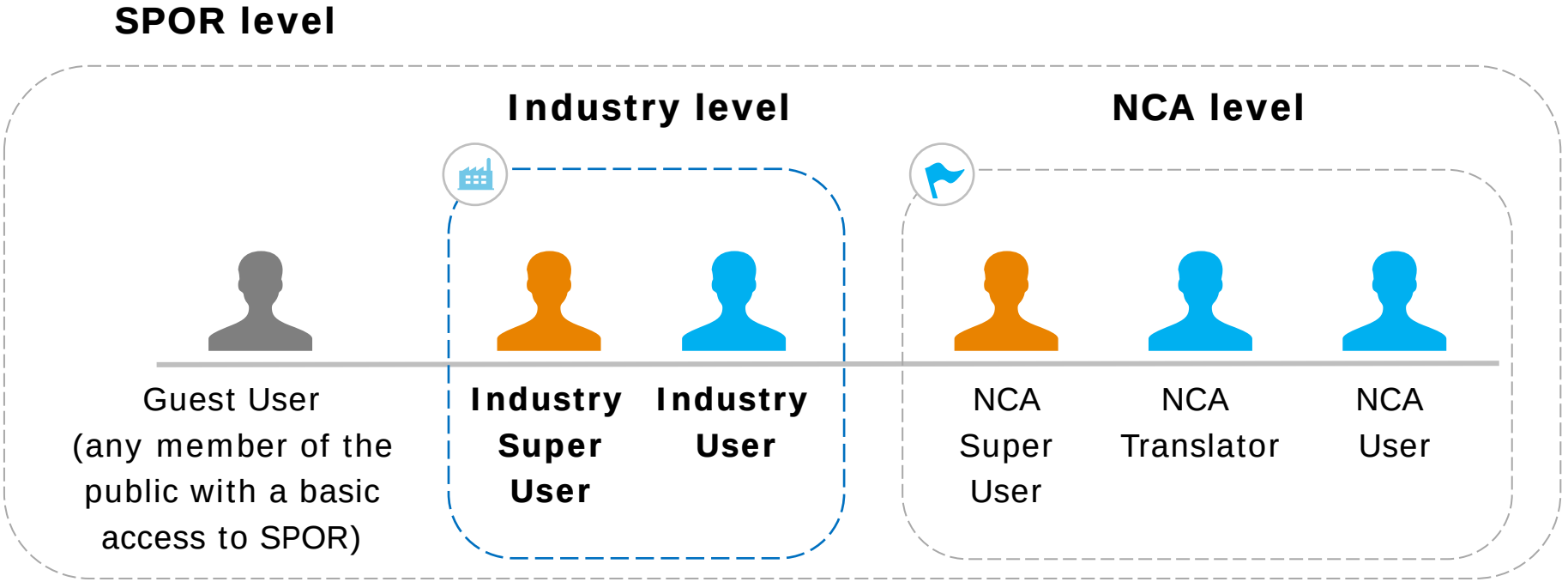
Requesting SPOR roles

SPOR User Roles 1/2

EUROPEAN MEDICINES AGENCY

- **Referential** and **Organisation data** is **accessible** via the **SPOR web portal.**
- **Anybody** (registered or not) **can** go to the SPOR web portal to **view** and **search publically-available data**:
  - RMS: public lists;
  - OMS: all content.
- SPOR also provides users with services that enable them to **request changes** and **updates** to existing **organisation** or **referential data.**
- To request changes and updates to organisation and referential data users must:
  1. be **registered** with the **EMA Account Management** portal.
  2. have a **SPOR** user **role** and be **affiliated** to a **specific industry organisation.**

SPOR User Roles 2/2



- **Guest User** - a user who does not require login credentials (username and password) to access the SPOR portal. They can view and search publically available data (RMS public lists; OMS all content).
- **Super Users** and **Users** are **roles** that **are organisation–specific**, *i.e.* these users are granted their access rights on behalf of a specific organisation. Industry *User is affiliated to a specific industry organisation.*

Overview of SPOR user roles & functionality

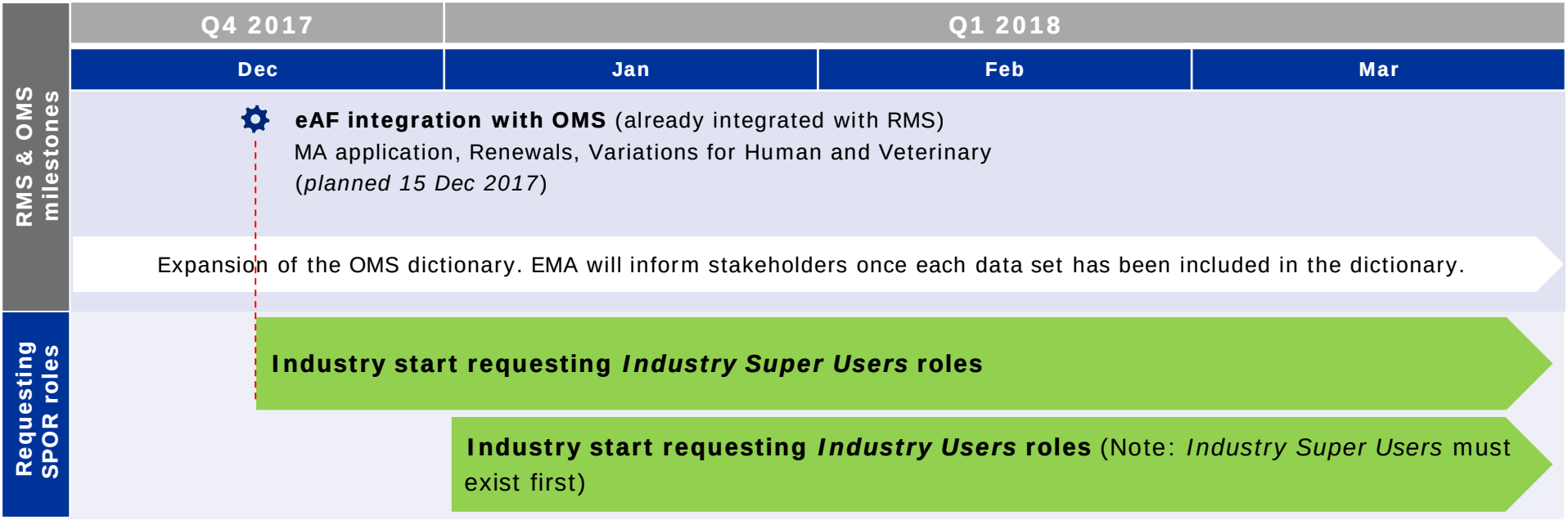
EUROPEAN MEDICINES AGENCY

	Guest User	Industry Super User	Industry User
Login	Not required	Login required	Login required
View Public data	Yes	Yes	Yes
Search data	Yes	Yes	Yes
Download data	No	Yes	Yes
Request changes and updates to data (submit change request)	No	Yes	Yes
Permission to authorise users	No	Yes - Can authorise Industry Users	No

Permission to authorise SPOR users is the only difference between Super User and User

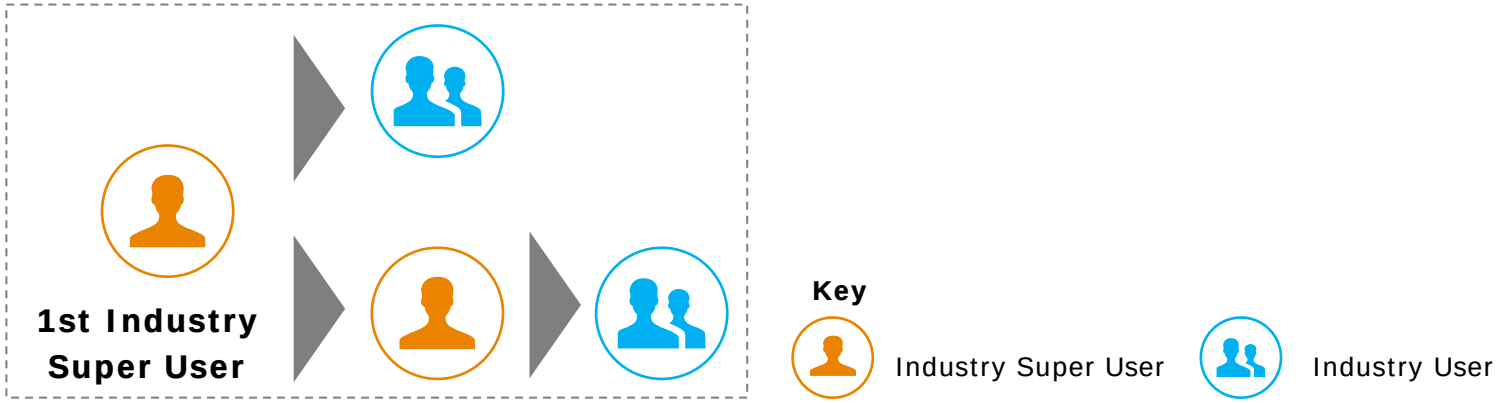
Requesting SPOR user role

EUROPEAN MEDICINES AGENCY



- 15 December – industry stakeholders can start requesting *Industry Super Users* roles.
- From January 2018 - industry stakeholders start requesting *Industry Users* roles (Note: *Industry Super Users* must exist first).

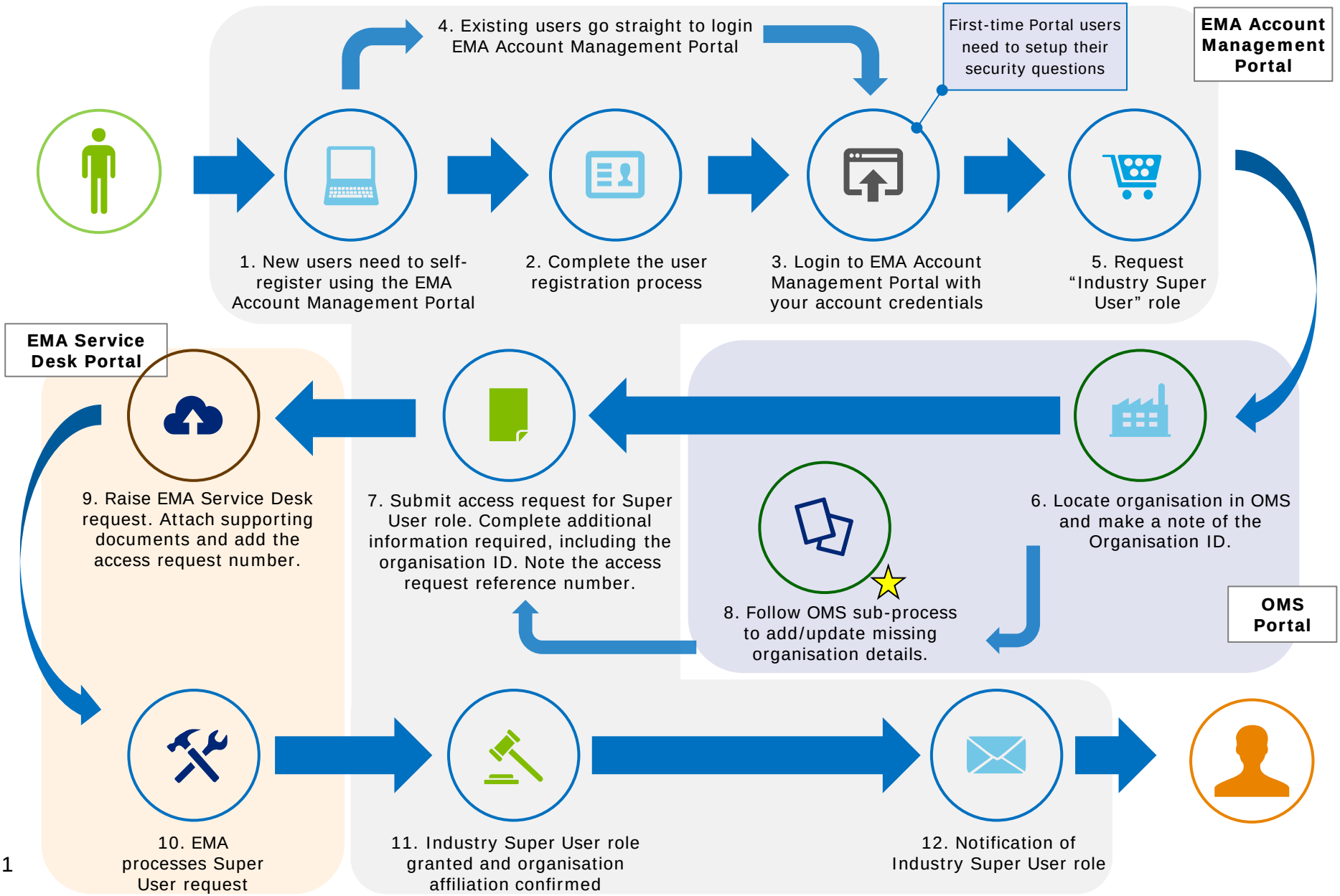
Role of the Industry Super User



- For each industry organisation, **EMA** will **approve the first Super Industry User.**
- Any **subsequent Super User** or **User** access requests will be **approved by** the **Super User of the requestor's organisation.**
- Super Users are accountable on behalf of their organisations for approving roles. EMA will not check.
- **Super User accountabilities** are:
  - Approve and verify access for the Users in their organisation
  - Confirm that the Users indeed belong to the organisation before granting them access
  - Ensure there are a sufficient number of SPOR Super Users and Users per organisation
  - [Inactivate leavers etc.] Once the Super User or User leaves the organisation, the Super User needs to inactivate their access in the EMA Account Management Portal (*process to be confirmed*)

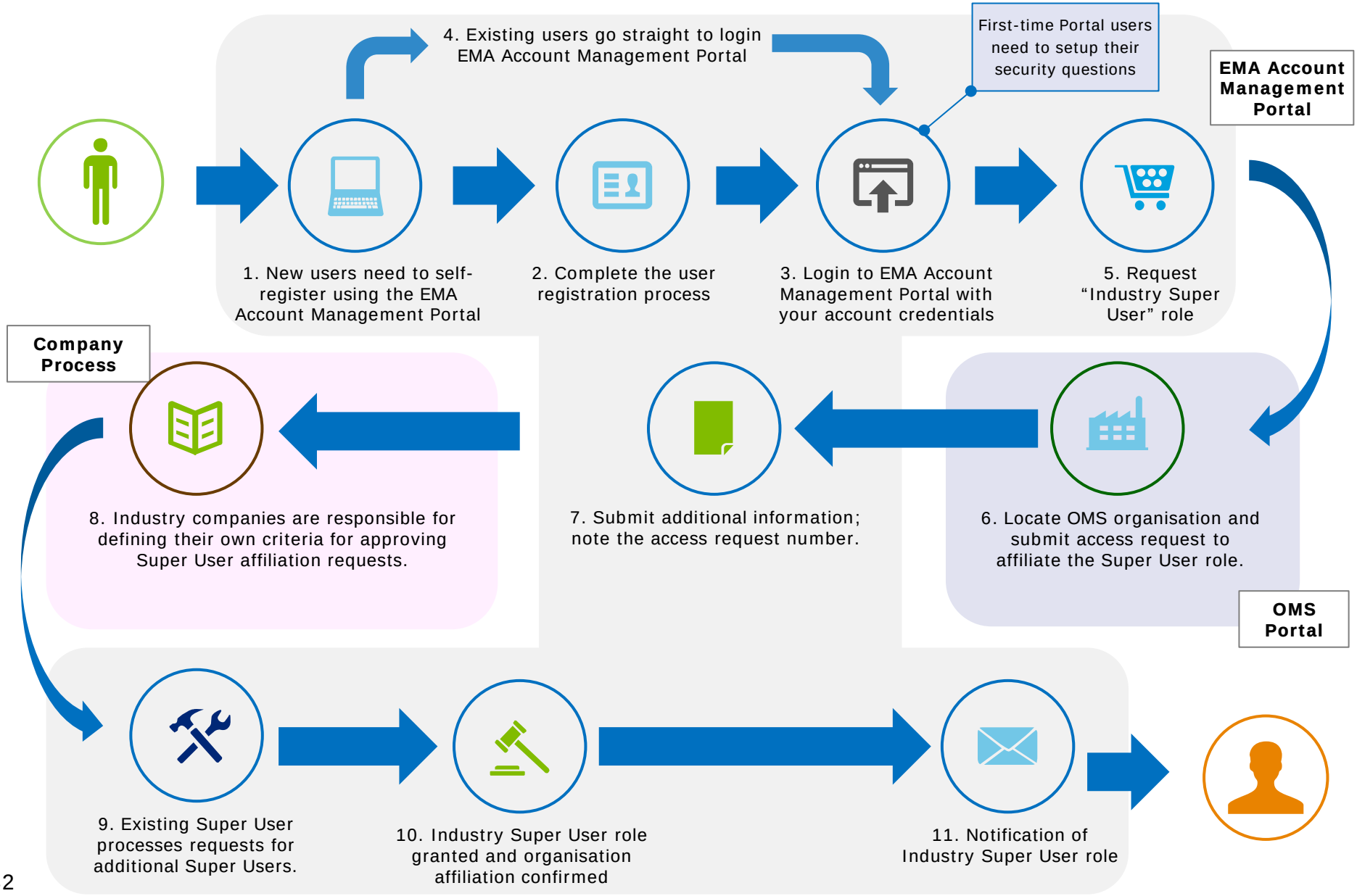
Registering 1st Industry Super User

EUROPEAN MEDICINES AGENCY



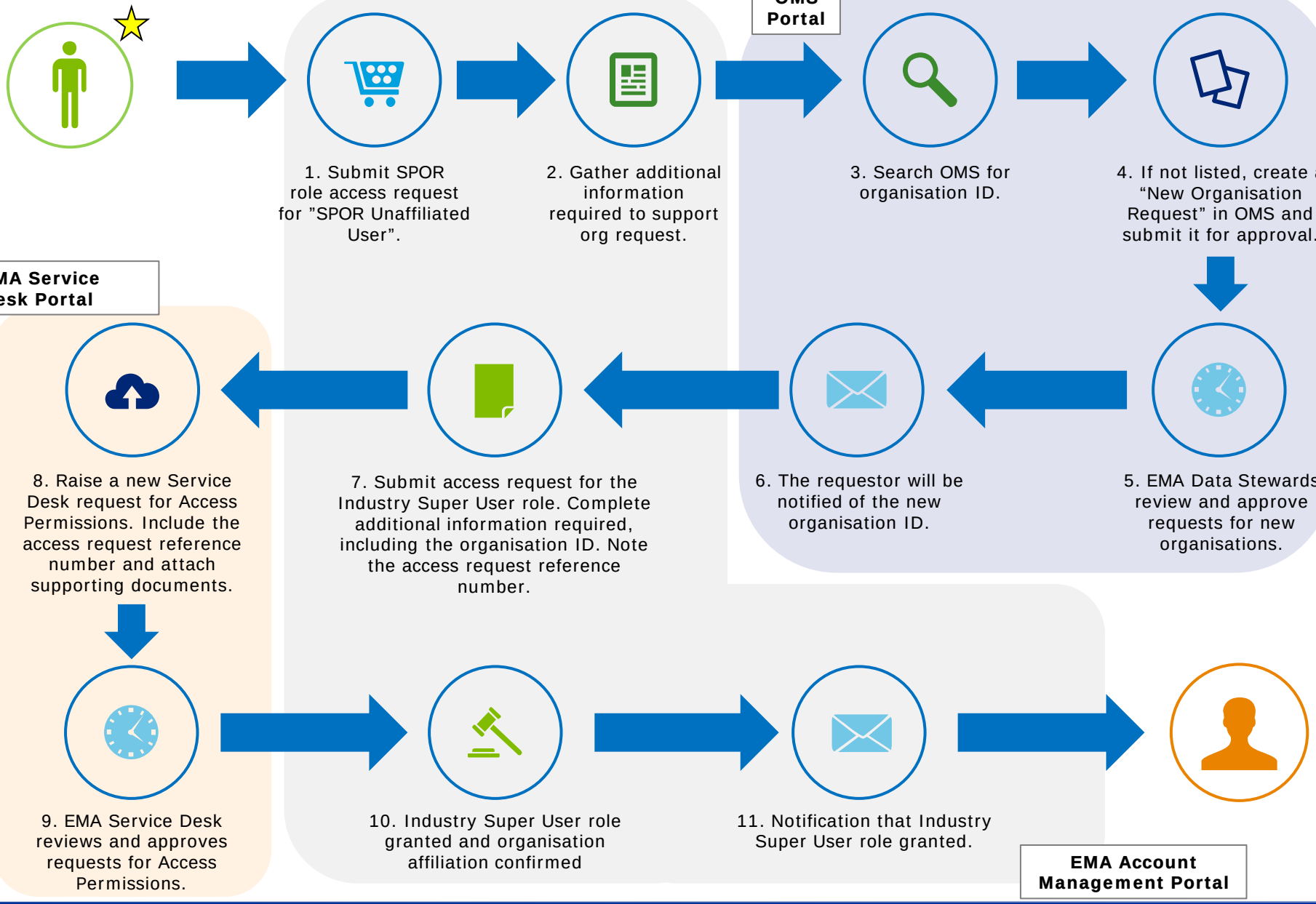
Registering Additional Industry Super Users

EUROPEAN MEDICINES AGENCY



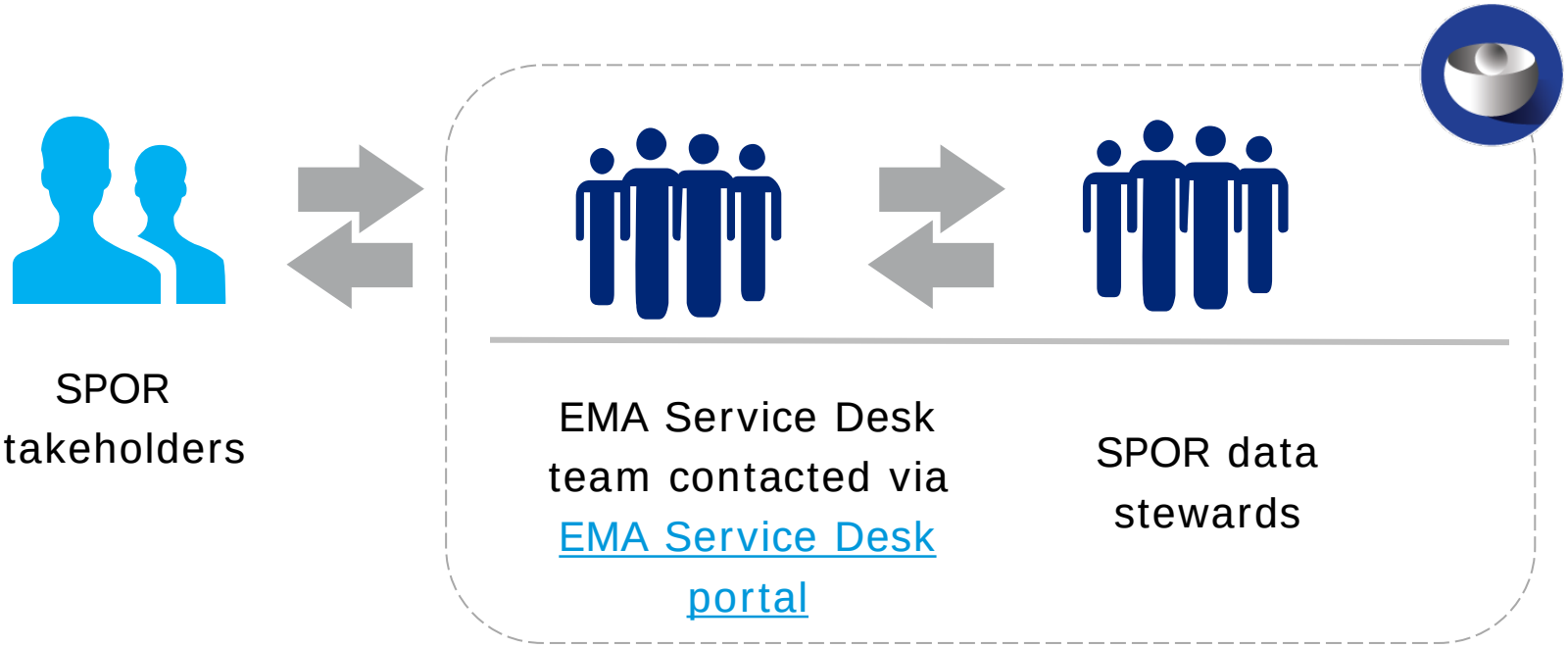
Requesting Organisations in OMS

EUROPEAN MEDICINES AGENCY



SPOR Help & Support

EUROPEAN MEDICINES AGENCY



SPOR Help & Support

EUROPEAN MEDICINES AGENCY

Tools / self service	When
EMA Account Management portal https://register.ema.europa.eu/	• To create a new EMA account in order to obtain access to EMA systems • To request SPOR user role
EMA Service Desk portal. The online EMA Service Desk for IT systems	• For technical support • Also used when registering 1st industry super user - Raise EMA Service Desk request. Attach supporting documents and add the access request number

Key Messages & Actions

Key Messages & Actions

EUROPEAN MEDICINES AGENCY

1. Raise awareness of SPOR amongst your colleagues, especially those involved with regulatory submissions and reference data management. Training material is available that covers key functionality of OMS and RMS.
2. Review the EMA Account Registration rules and the SPOR documentation to understand how they apply to your own organisations.
3. Consider how you will appoint Industry Super Users and Industry Users – the scenarios provided above may help you to consider the best options for your own organisations.
4. Consult with colleagues, perhaps from related organisations within your own company, to agree how you will authorise and maintain SPOR user roles.
5. Requests for updates and additions to the data stored in OMS and RMS will require users to have a registered SPOR account.
6. Industry stakeholders should be ready to start registering their first Industry Super User roles from **15 December 2017**. Organisations will need at least one registered Super User before they can register additional Users.

Key Messages & Actions

EUROPEAN MEDICINES AGENCY

Using OMS in eAF

- The EU electronic application forms (eAF) are now integrated with SPOR master data services for Referentials (RMS). Updated versions of eAF scheduled to be released 15 December 2017 it will be integrated with OMS.
- Use of OMS in the eAF will initially be optional.
- As of January 2018 Stakeholders can start submitting the OMS change requests for:
  - MAH (H+V) CAPs & (H) NAPs
  - MAAs:(H+V) CAPs
- Publication of Manufacturers in the OMS dictionary is planned to be completed by Q3 2018, stakeholders please do not submit OMS change requests for Manufacturer organisations .
  - EMA will communicate when you can start submitting OMS change requests for Manufacturers.
  - Mandating of OMS planned for Q3/Q4 2018.

Key Messages & Actions

EUROPEAN MEDICINES AGENCY

Using RMS

- The EU electronic application forms (eAF) are now integrated with SPOR master data services for referentials (RMS).
- **Terms should be registered** before they are required to be used in a regulatory procedure.
- Current process for applicants to request registration of terms is by sending email to mdms@ema.europa.eu.
- From December 2017 applicants are encouraged to start using RMS portal to submit change request to register terms (mdms@ema.europa.eu can still be used until end of June 2018).
- **From July 2018 only change request submitted via RMS will be accepted.**

Using OMS & RMS data in eAF

EUROPEAN MEDICINES AGENCY

Upcoming events

Topic: SPOR Q&A

When: 7 December 2017, 14.00 – 16.00 London Time

Format: webinar

Audience: SPOR change liaisons, regulatory (users of eAF)

DRAFT agenda:

SPOR user registration – Q&A

Using OMS, RMS data in eAF – Q&A

Topic: Hands on – how to submit change request for RMS and OMS

When: 2nd half of Jan 2018 date/time tbc.

Format: webinar

Audience: SPOR change liaisons, users of eAF, SPOR users

DRAFT agenda:

How, what, Dos and don'ts, basic rules on data quality aspects.

To register please e-mail SPOR-Change-Liaisons@ema.europa.eu

We have limited number of places (registration first come first served).

Thank you!

Disclaimer