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SCIENCE MEDICINES HEALTH

RMS & OMS – Industry on-boarding to SPOR

20 October 2017

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RMS & OMS related milestones

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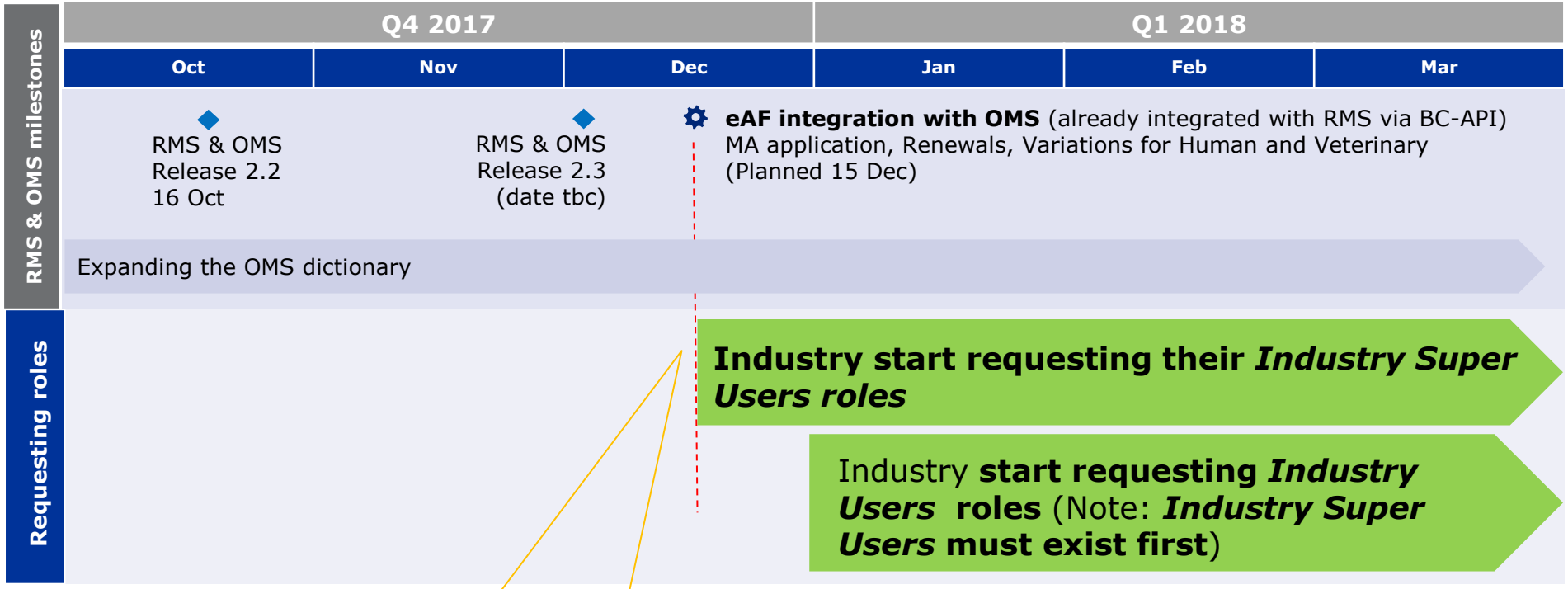

Industry on-boarding to SPOR aligned with eAF / OMS integration

RMS & OMS Related Milestones

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- EMA Data Stewards continue working to expand the content of the OMS dictionary *(OMS dictionary – list of organisations with associated locations)*
- OMS & RMS release **2.2 is live**; scope includes **functionality enhancements** and **bug fixes**:
  - RMS: EDQM deltas, improved subscriptions
  - OMS: Web portal functionality (CRs, improved export) & Data management
- Final **OMS & RMS release 2.3** planned for early **December**, which addresses the September OMS UAT
- **Process** to provide SPOR Application Programming Interface (**API)** to support your API development will be communicated in coming weeks
- **eAF integration with OMS** is planned for **15 December** 2017
  - RMS is integrated already with eAF via the Backward Compatible API
- EMA will invite industry to begin registering their Super Users and Users in December and commence use of both RMS and OMS
  - This aligns with eAF release v1.22.0.0 going live on 15 December 2017

OMS Content Plan Q3 2017 – 2018

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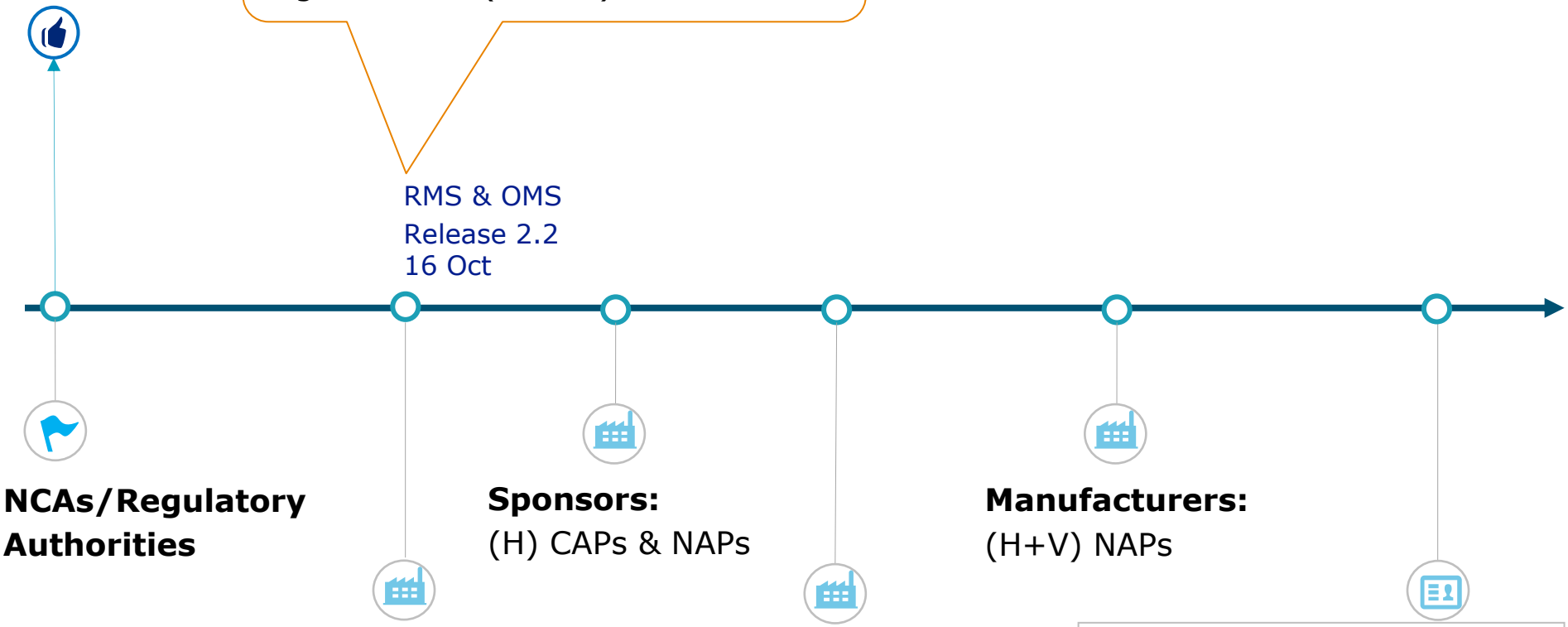
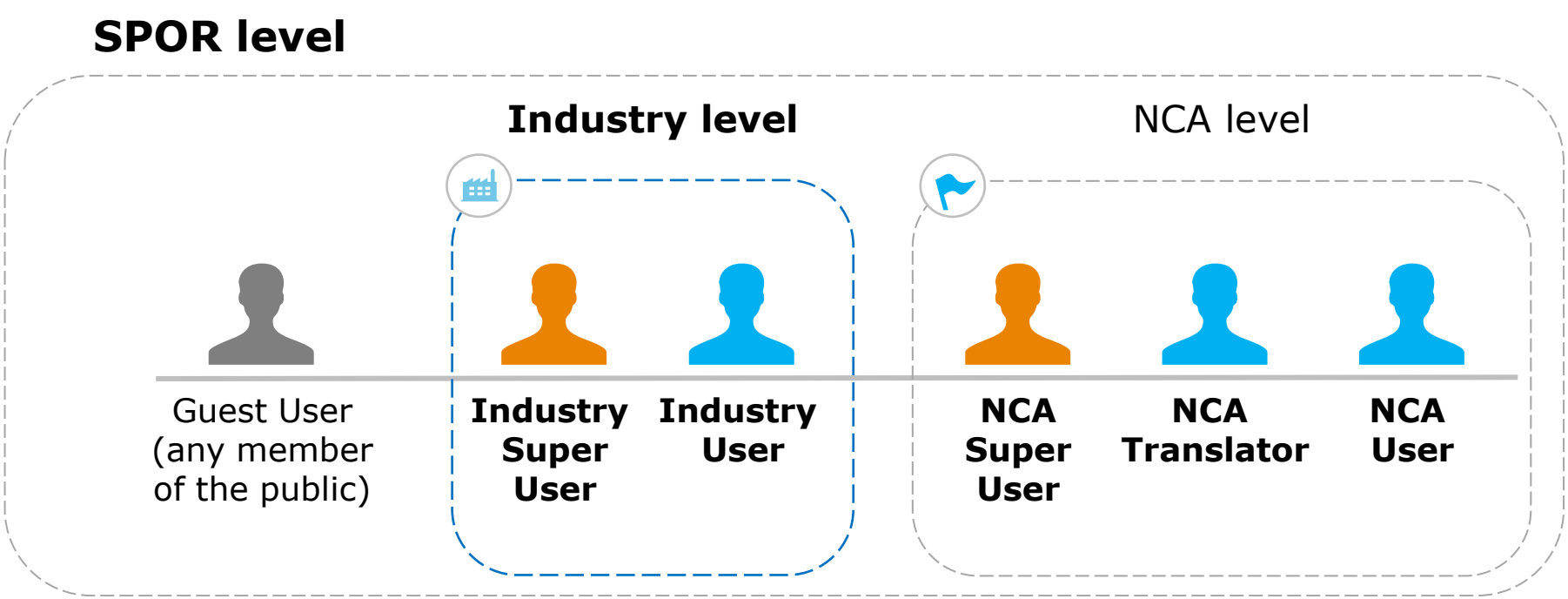
Key

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

As of 16 October OMS have published approximately 26% of organisations (>1500)

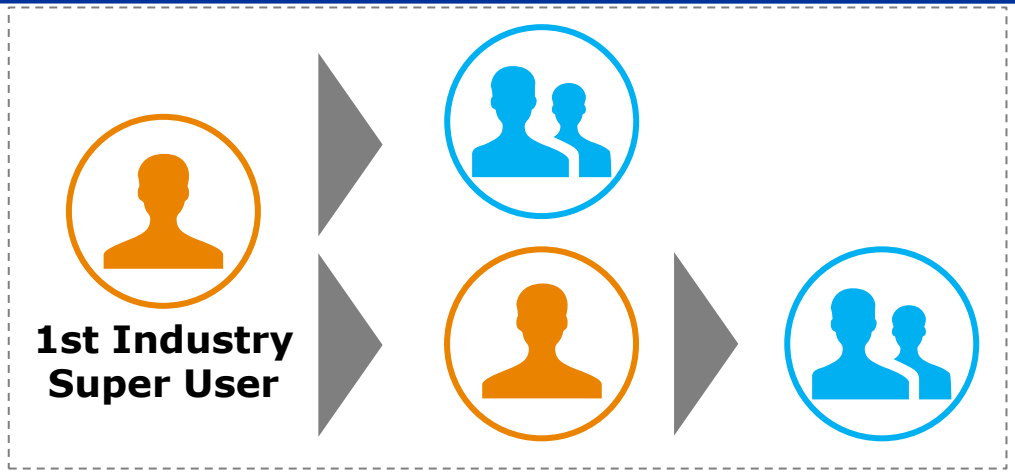


SPOR User Roles 2/2



- **Guest User** (with basic access)
- **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 *(User is affiliated to a specific Industry or NCA organisation)*

Role of the Industry Super User



Key

Industry Super User

Industry 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*)

Managing user populations by a company 1/2

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- In the EMA Account Management portal, an account can have either Industry or NCA user roles, but not both
- Once an account with the EMA is verified, requests for access to SPOR roles (*Industry Super User, Industry User*) can be made for multiple organisations
- Managing multiple organisations as a Super User requires multiple *Industry Super User* roles with the correct organisation affiliations
- Users will need to submit individual access requests for each of their roles
- Each of the *Industry User* access requests will be approved by the respective *Super User* of the organisation for which the role is requested (unless it is the first Super User for this organisation, in which case EMA would approve.)
- Each organisation should have at least two registered *Industry Super Users*. An organisation can also have multiple *Industry Users*

Managing user populations by a company 2/2

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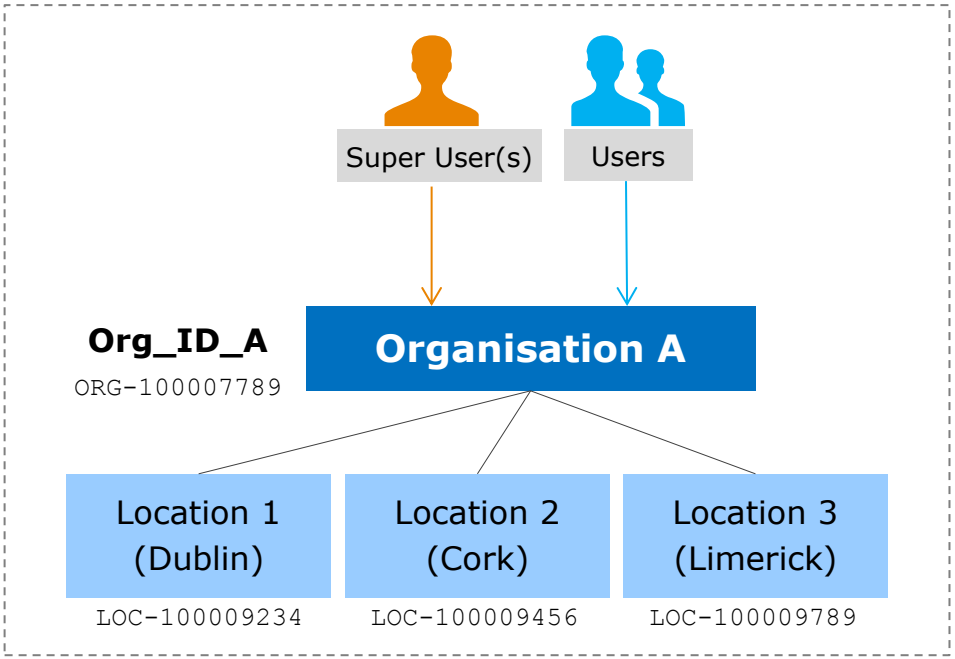
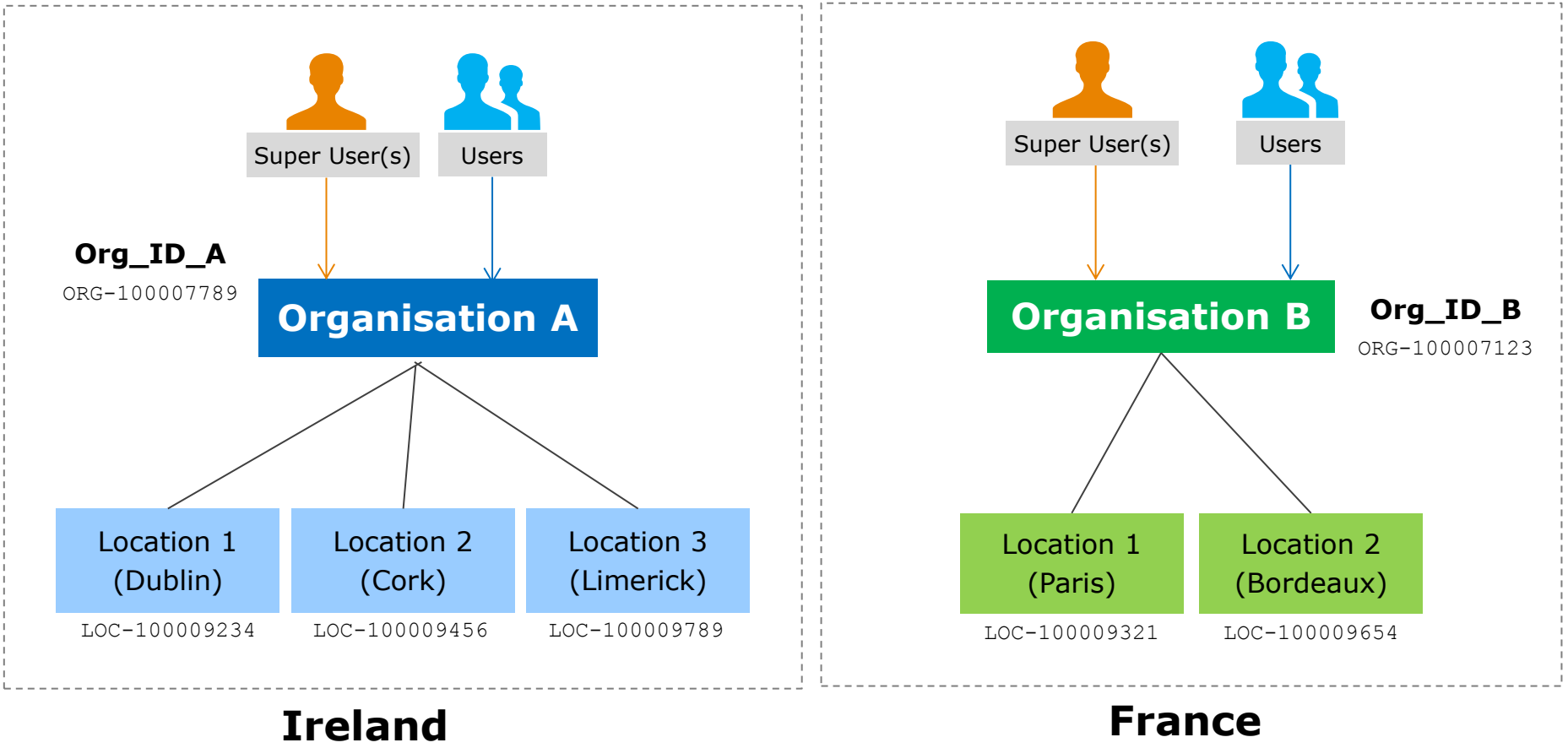
- An industry company may have different subsidiary organisations, each with its own organisation ID
- Company structures and hierarchies are not defined in OMS – for example, there is no recognition of HQ or Affiliates
- The population of SPOR Industry Users and Industry Super Users for an organisation is driven by several factors:
  - Business needs
  - Processes and policies with regard to granting access
  - Overall number of products
  - Some companies may outsource regulatory affairs to third party service providers
- **Each organisation must decide on the numbers of SPOR roles that have access to SPOR on their behalf**
  - There can be different approaches (see slides 9 – 12)

User registration – Scenario 1



Ireland

User registration – Scenario 2



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

User registration – Scenario 3

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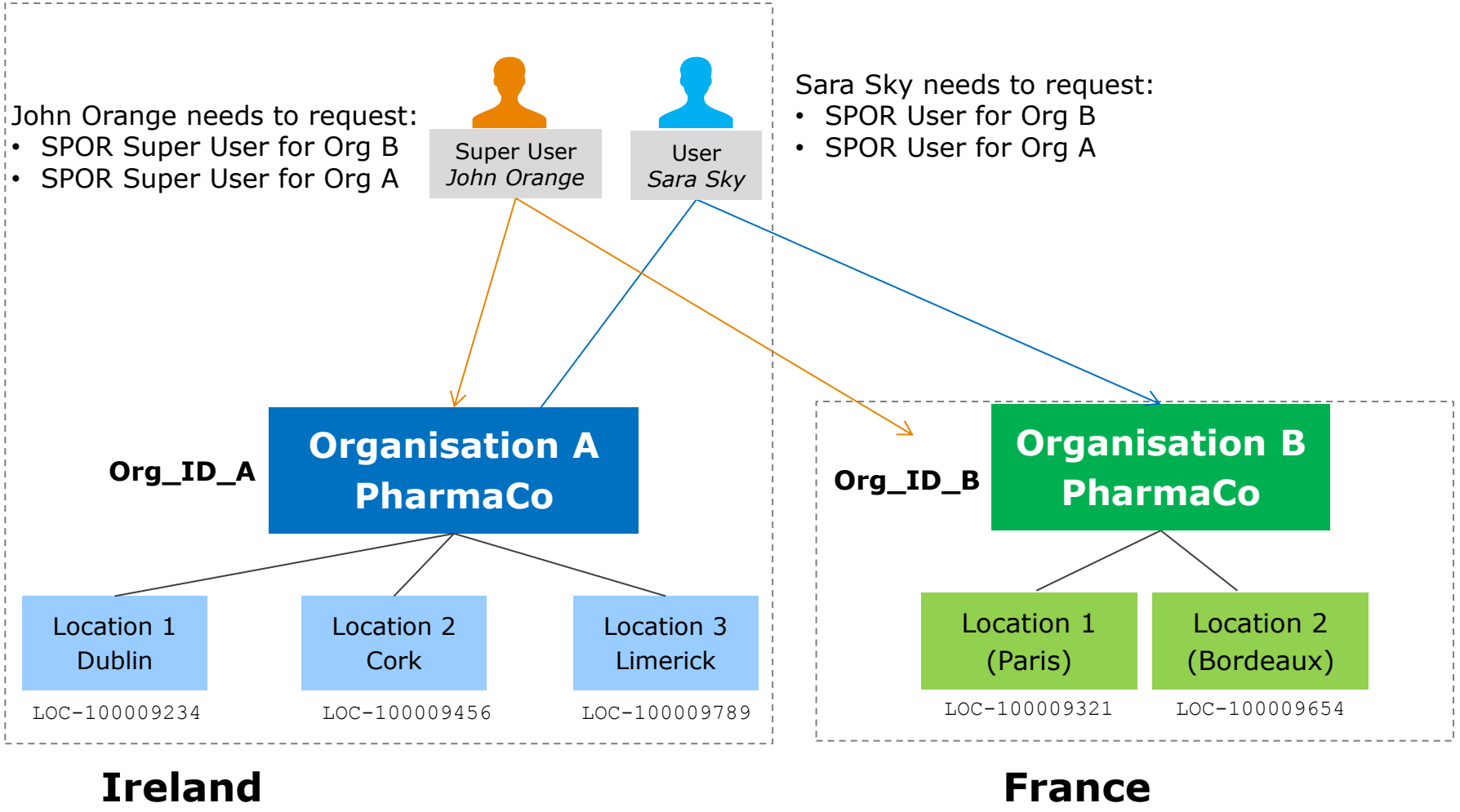
Shared Industry Users and Super Users for Multinational Companies



Note: *the name of Organisation_A* ***is*** *be the same as the name of Organisation_B.*

User registration – Scenario 4

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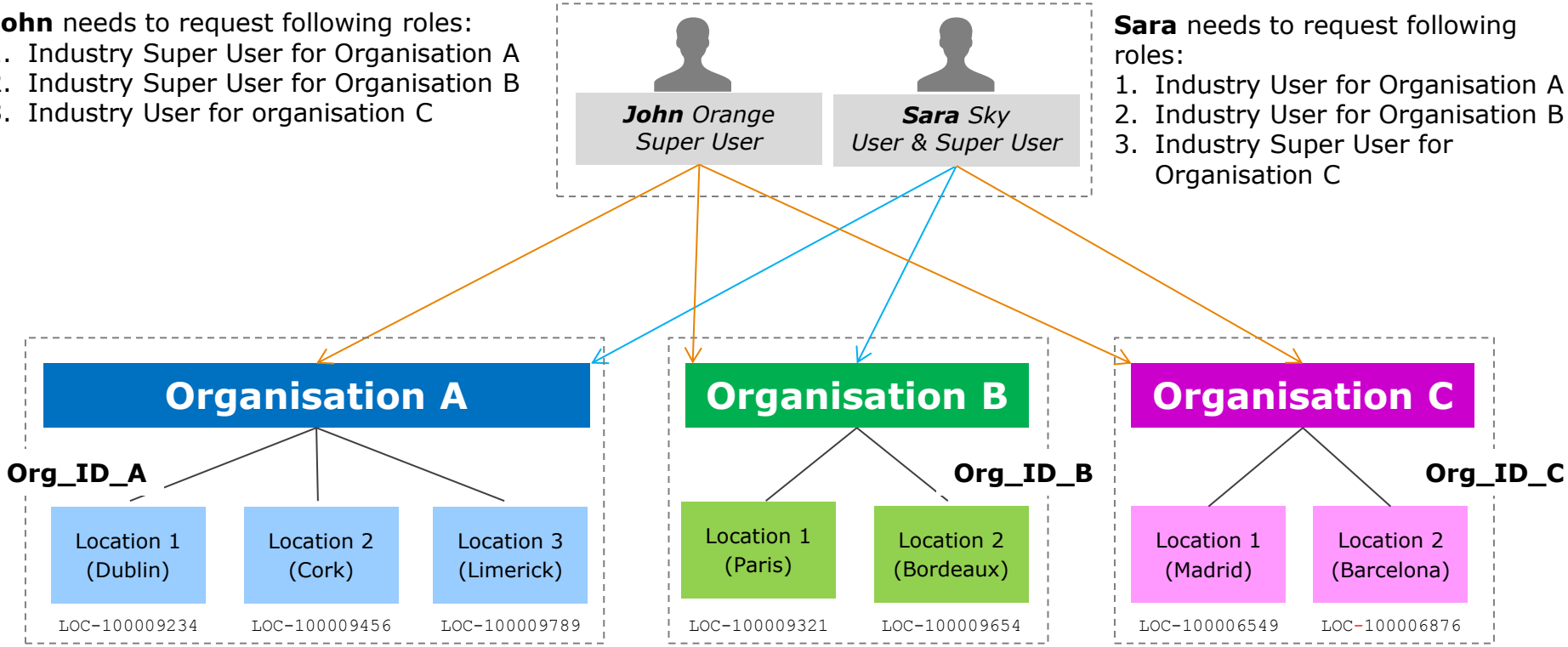
Third Party/Service Provider/Consultancy

John needs to request following roles:
1. Industry Super User for Organisation A
2. Industry Super User for Organisation B
3. Industry User for organisation C

Sara needs to request following roles:
1. Industry User for Organisation A
2. Industry User for Organisation B
3. Industry Super User for Organisation C



Note: the name of Organisation A could be the same as the name of Organisation B or Organisation C

Service Levels for SPOR Data Stewards

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- Indicative RMS and OMS SLAs
- RMS requests aimed to be validated within 2-5 working days and approved within 1-2 months
- OMS standard requests aimed to be approved within 5 working days (target)
- **In future the SLAs will be reviewed as these are new services where the workload still need to be verified**
- **SLAs will be discussed with stakeholders and adjusted as SPOR data is consumed by additional systems**

SPOR Help & Support 1/2

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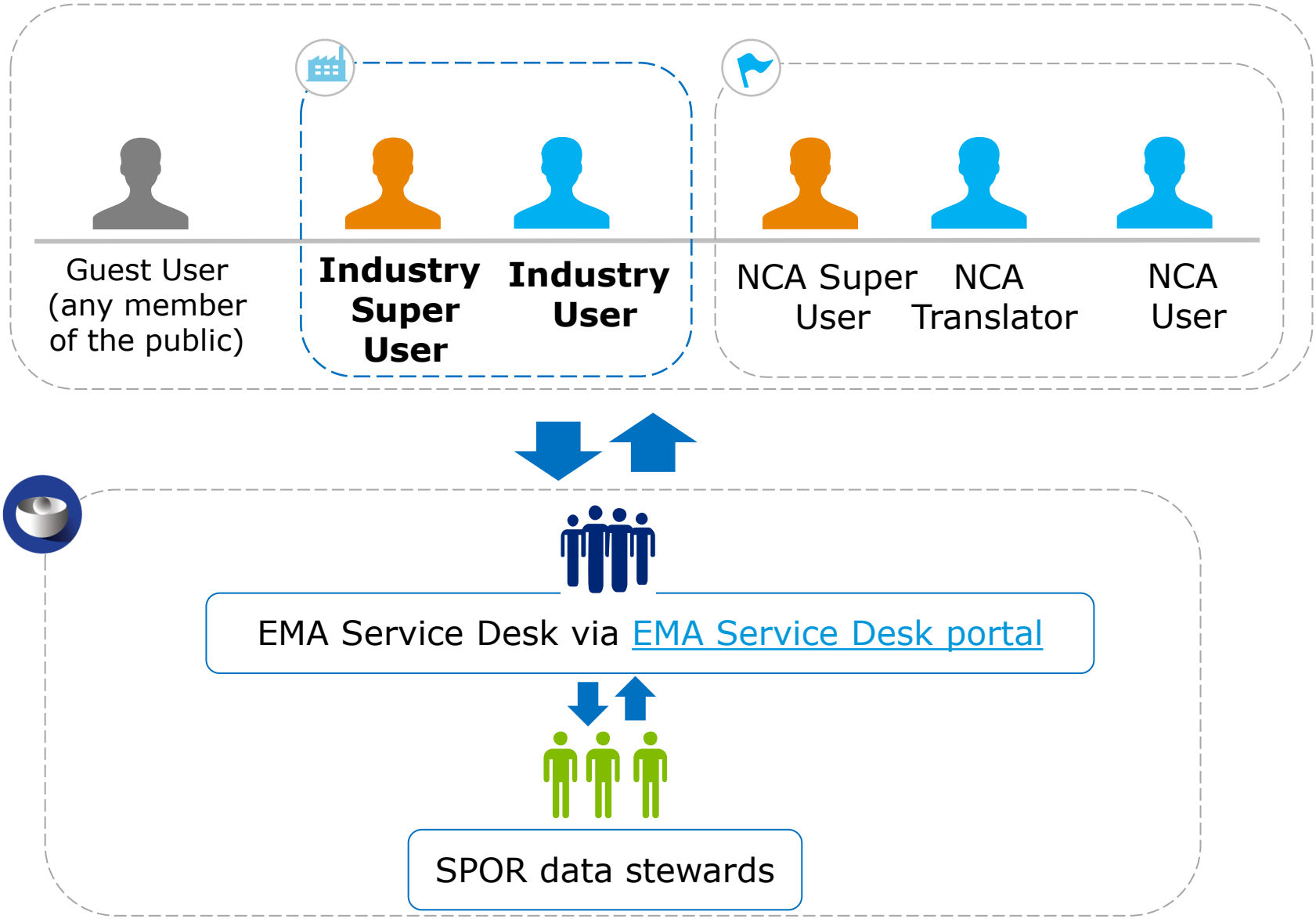
SPOR stakeholders



SPOR Help & Support 2/2

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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

E-mails	When
mdms@ema.europa.eu	• For SPOR master data content related questions • In December 2017 we will replace the mdms@ema.europa.eu email address with the EMA Service Desk portal for requesting Substance
SPOR-Change-Liaisons@ema.europa.eu	For SPOR project related questions such as; how SPOR is being implemented? what activities are in the pipeline?

SPOR-related Documents & Information

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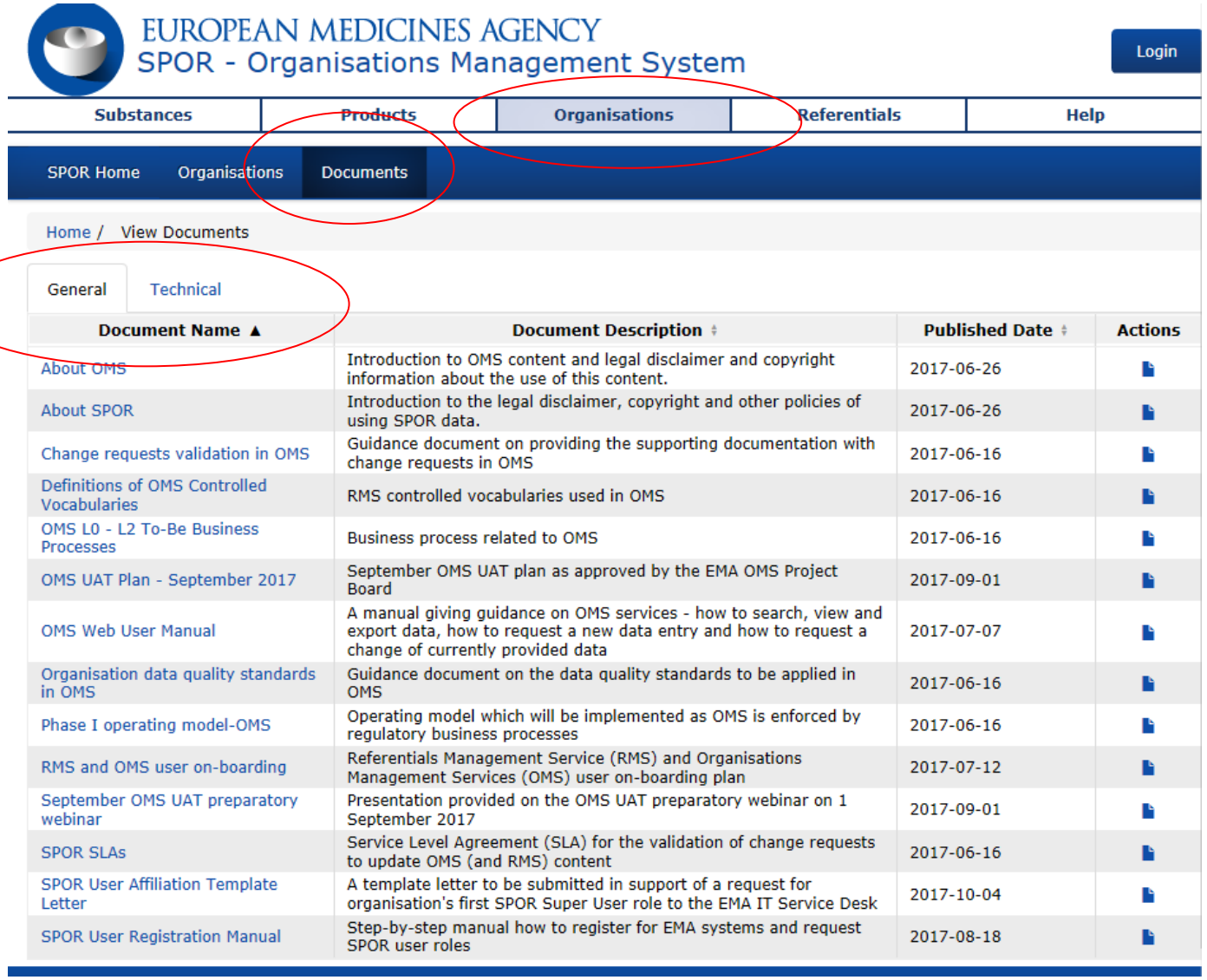

Document Name ▲	Document Description	Published Date	Actions
About OMS	Introduction to OMS content and legal disclaimer and copyright information about the use of this content.	2017-06-26	
About SPOR	Introduction to the legal disclaimer, copyright and other policies of using SPOR data.	2017-06-26	
Change requests validation in OMS	Guidance document on providing the supporting documentation with change requests in OMS	2017-06-16	
Definitions of OMS Controlled Vocabularies	RMS controlled vocabularies used in OMS	2017-06-16	
OMS L0 - L2 To-Be Business Processes	Business process related to OMS	2017-06-16	
OMS UAT Plan - September 2017	September OMS UAT plan as approved by the EMA OMS Project Board	2017-09-01	
OMS Web User Manual	A manual giving guidance on OMS services - how to search, view and export data, how to request a new data entry and how to request a change of currently provided data	2017-07-07	
Organisation data quality standards in OMS	Guidance document on the data quality standards to be applied in OMS	2017-06-16	
Phase I operating model-OMS	Operating model which will be implemented as OMS is enforced by regulatory business processes	2017-06-16	
RMS and OMS user on-boarding	Referentials Management Service (RMS) and Organisations Management Services (OMS) user on-boarding plan	2017-07-12	
September OMS UAT preparatory webinar	Presentation provided on the OMS UAT preparatory webinar on 1 September 2017	2017-09-01	
SPOR SLAs	Service Level Agreement (SLA) for the validation of change requests to update OMS (and RMS) content	2017-06-16	
SPOR User Affiliation Template Letter	A template letter to be submitted in support of a request for organisation's first SPOR Super User role to the EMA IT Service Desk	2017-10-04	
SPOR User Registration Manual	Step-by-step manual how to register for EMA systems and request SPOR user roles	2017-08-18	

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

Key Messages & Actions

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1. Raise awareness of SPOR amongst your colleagues, especially those involved with regulatory submissions and Referentials data management. Training material will be provided that covers key functionality of OMS and RMS.

2. Review the EMA Account Registration rules and the SPOR documentation to understand how they will 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. Industry stakeholders should be ready to start registering their first *Industry Super User* roles from **December 2017**.

Thank You!

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Do you have any questions?

annex

Overview of SPOR user roles & functionality

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	Guest User	Industry Super User	Industry User	NCA User	NCA Translator	NCA Super User
Login	Not required	Login required	Login required	Login required	Login required	Login required
View Public data	Yes	Yes	Yes	Yes	Yes	Yes
View Restricted data	No	No	No	Yes	Yes	Yes
Search data	Yes	Yes	Yes	Yes	Yes	Yes
Download data	No	Yes	Yes	Yes	Yes	Yes
Submit Change Request (CRs)	No	Yes	Yes	Yes	Yes	Yes
Translations	No	N/a	N/a	No	Yes	No
Permission to authorise users	No	Yes - Can authorise all Industry users	No	No	No	Yes - Can authorise all NCA Users

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