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SCIENCE MEDICINES HEALTH

Introduction to SPOR data services

SPOR data services: Delivering quality data services on Substances, Products, Organisations and Referentials to power EU regulatory activities

4 August 2016
SPOR data services project team

An agency of the European Union

Contents

Objectives

1. To provide Industry stakeholders with a base understanding of SPOR data services: why we need them, resulting changes and benefits, implementation approach

2. To signpost key reference material that will support Industry stakeholders in their planning to implement changes due to SPOR

3. To ensure Industry stakeholders are aware of how EMA plan to support them through engagement, communications and training activities

The case for SPOR data services

The issue: lack of standardisation

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Lack of standardisation…

- Different controlled vocabularies* are used across different organisations
- Names used for organisations differ between, and sometimes across different departments within, NCAs and Industry
- Different names for substances are used across different regions in Europe and globally
- Data is often entered manually

Results in…

- Inconsistent data quality and duplication
- Inefficiencies relating to correcting data and investigating data discrepancies
- Manual intervention required to resolve data issues
- Slower decision-making
- Decision-making based on inaccurate information

**Controlled vocabularies (aka Referentials) are lists of terms that refer to attributes of medicinal and pharmaceutical products e.g. dosage form, route of administration, unit of measurement*

Why do we need standardisation?

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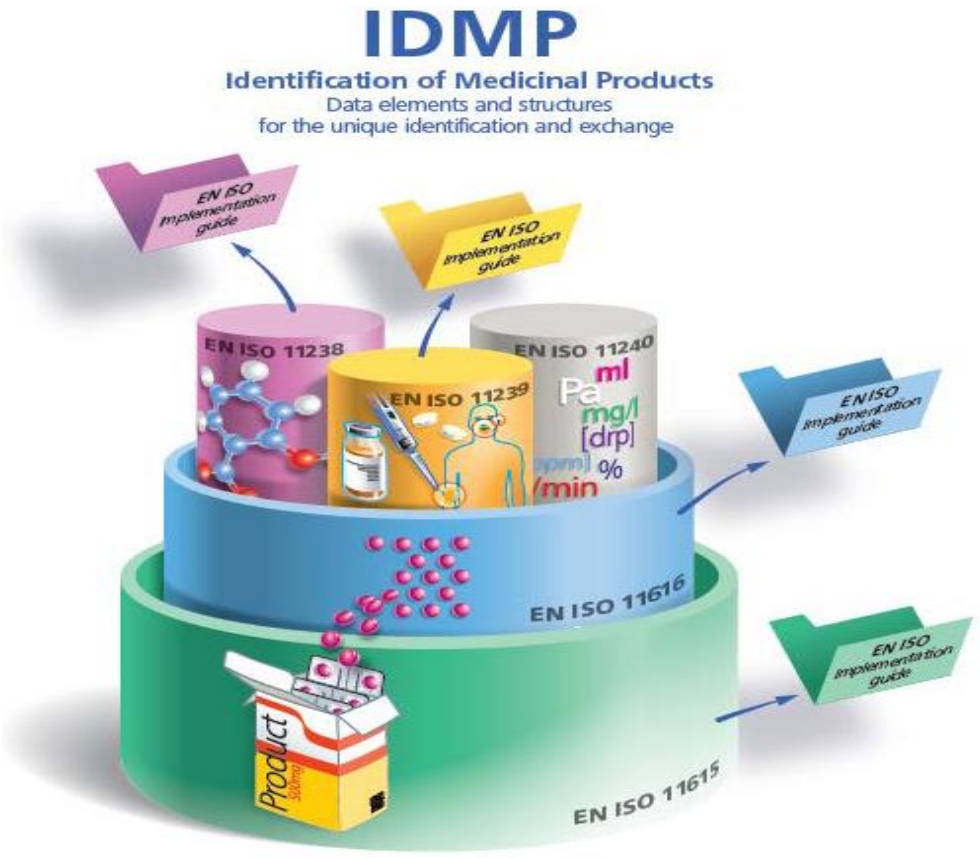
Standardised data will…

Pharmacovigilance	**…improve signal detection and speed of response for authorised products, thus improving protection of public health in EU**
ePrescription	**…support cross-border electronic prescriptions of medicines in EU** enabling **patients to obtain the right products when outside their home country based on standardised data**
Falsified medicines	…**support the mechanism for controlling authenticity of medicines**
Shortages	**…allow substances and products to be identified across countries enabling faster response to address shortages**
Batch recalls	**…allow substances and products to be identified across countries enabling faster identification and withdrawal**
Inspections	…**improve the link between the Supply Chain and the regulatory dossier** since inspectors will have better records available to support their findings on Manufacturing sites
Regulatory activities	…**facilitate process efficiencies in regulatory activities** e.g. submission of regulatory application forms and Variations

ISO IDMP will introduce standardisation

There is a legal obligation for Industry to make use of the terminologies defined in ISO IDMP standards: Regulation (EU) No 520/12012 (art. 25 & 26)

> *"The use of internationally agreed terminology, format and standards should facilitate the interoperability of systems used for the performance of pharmacovigilance activities and avoids the duplication of encoding activities concerning the same information. It should also allow for an easier information exchange between regulatory authorities on an international level"*
> *Commission Implementing Regulation (EU) No 520/2012*



The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships. This enables the the unique identification of:

- Medicinal product information (MPID/PCID) - ISO 11615
- Pharmaceutical product information (PhPID) - ISO 11616
- Substances (Substance ID/Specified Substance ID) - ISO 11238
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
- Units of measurement (UCUM) - ISO 11240

ISO IDMP standards apply to both authorised and investigational medicinal products for Human use

The solution: master data management

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The identification, compilation and central management of pharmaceutical master data will support compliance with ISO standards and respond to the need for standardisation

The 5 new ISO IDMP standards are all about **master data**

Master data is any non-transactional information that is considered to play a key role in the core operation of a business and is re-used for multiple purposes

Types of data:

Unstructured - data found in e-mail, white papers, magazine articles, corporate intranet portals, product specifications, marketing collateral, and PDF files. (e.g. data in: product dossier, summary of product characteristics)

Transactional – data related to sales, deliveries, invoices and other monetary and non-monetary interactions. (e.g. application submission and approval dates)

Metadata - data about other data which may reside in XML documents, report definitions, column descriptions in a database, log files, configuration files

Master – Any non-transactional data that is considered to play a key role in the core operation of a business and is re-used for multiple purposes such as customer, product, site, supplier, vendor. (e.g. Products, Substances, Organisations, Referentials)

Implementing ISO IDMP through SPOR (1 of 2)

In the case of the regulated EU pharmaceutical industry, there are four domains of master data:

Master data is any non-transactional information that is considered to play a key role in the core operation of a business and re-used for multiple purposes

1. **Substances:** Harmonised data and definitions to uniquely identify the ingredients and materials that constitute medicinal product
2. **Products:** Harmonised data and definitions to uniquely identify medicinal product based on regulated information (e.g. marketing authorisation, packaging and medicinal information)
3. **Organisations:** Data that comprises of organisation name and location address data for organisations such as MAH, sponsors, regulatory authority, manufacturers
4. **Referentials:** Lists of terms (controlled vocabularies) used to describe attributes of products e.g. lists of dosage forms, units of measurement, routes of administration

Implementing ISO IDMP through SPOR (2 of 2)

- Four projects have been established to implement services that centralise management of each of the domains of master data
- The four projects are collectively known as **SPOR data services:**

Substance Management Services (SMS)

Organisations Management Services (OMS)

Product Management Services (PMS)

Referentials Management Services (RMS)

- The implementation of the four SPOR projects will be phased
- All proposals relating to implementation of SPOR have been and will continue to be consulted on widely with regulators and industry representatives
- SPOR applies to both domains, **Human and Veterinary**
- In parallel, EMA is implementing the messaging standards developed by Health Level Seven (HL7), which define a format for the electronic exchange of data that is compliant with the ISO IDMP technical specifications.

Use of SPOR in regulatory activities

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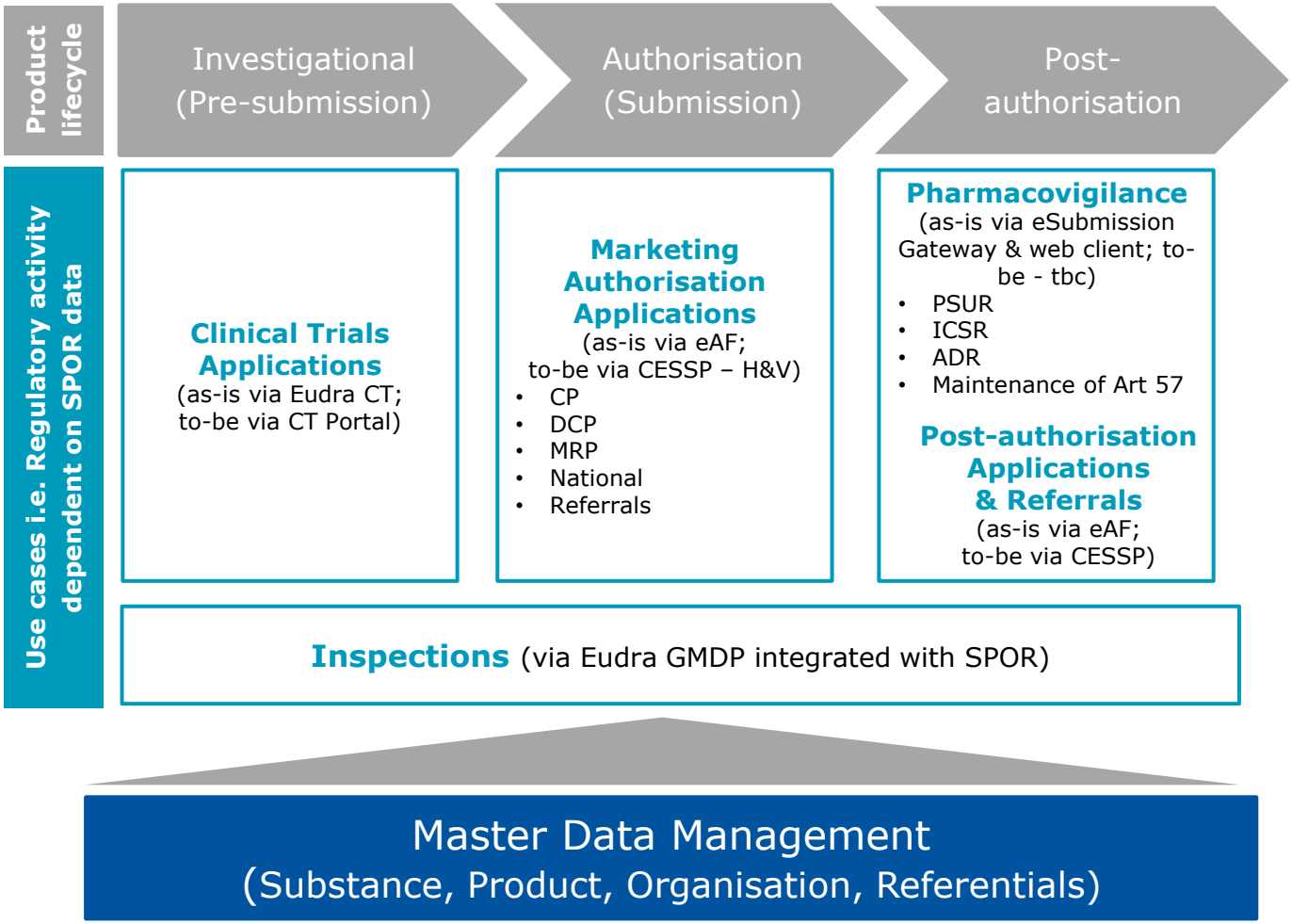
Adoption of SPOR operating models will facilitate the implementation of consistent, centrally-maintained, ISO IDMP-compliant SPOR data, which will feed regulatory activity across the product lifecycle



eHealth

Falsified Medicines

Future EU initiatives that will depend on SPOR data

Benefits of implementing SPOR

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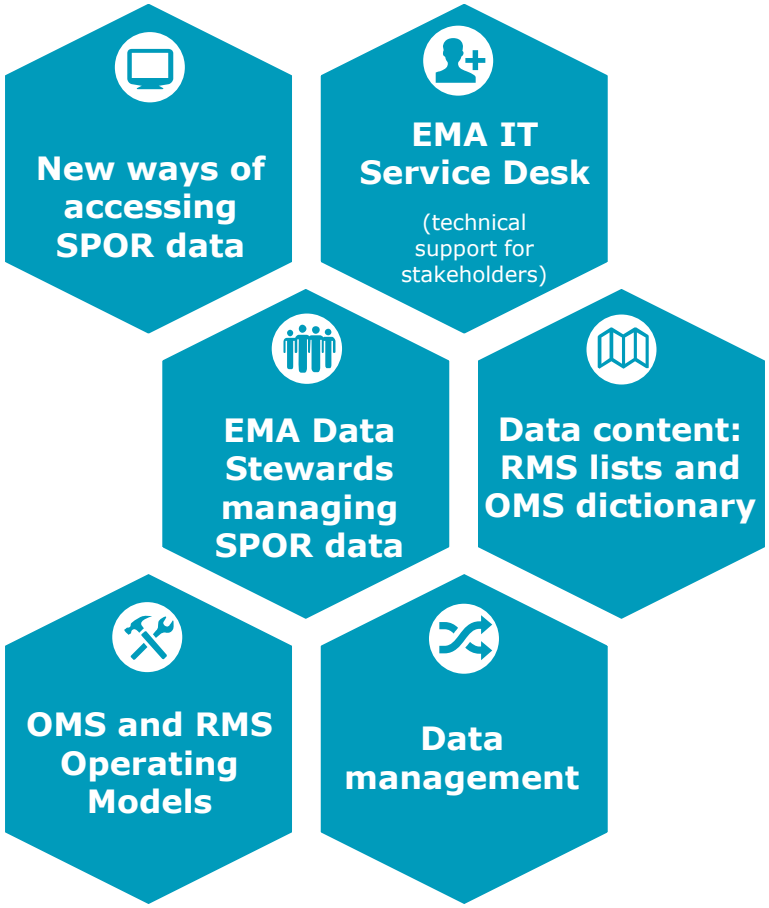
Standardised data alone is not sufficient to achieve benefits. The benefits of SPOR will be realised incrementally:

- As all phases of SPOR are completed; and
- Provided other opportunities for integration are implemented via EU Telematics Programmes such as CESSP, Clinical Trials EU Portal

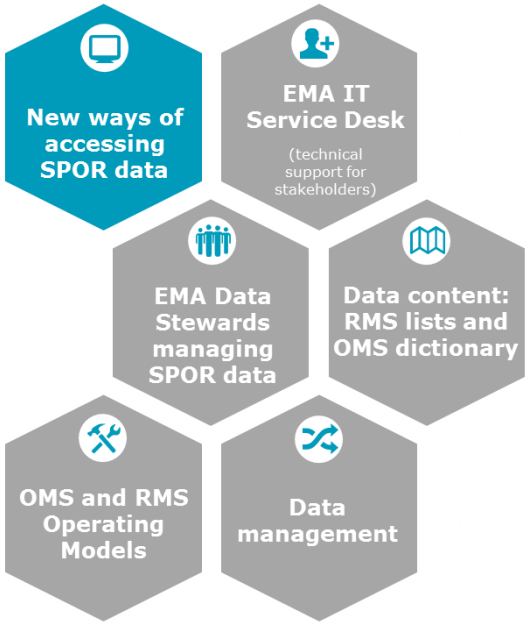
Benefits	*Enabled by*
Positive impact on public health and safety E.g. product recalls, safety information and assessment	**Faster, more efficient regulatory action and decision-making**
Better decisions, faster regulatory action	Improved **data integrity and reliability** through centrally-held SPOR data
Increase in data quality, simplification of data management practices	**Data reviewed, assessed and approved** as part of the new data operating model
Fulfil regulatory requirements more effectively	**Reducing silos** and **improving interoperability** across EU systems
Operational savings and efficiencies	**Data entered only once and reused** across different procedures and regulators

Implementation of SPOR data services

Key changes as a result of SPOR



Key changes as a result of SPOR

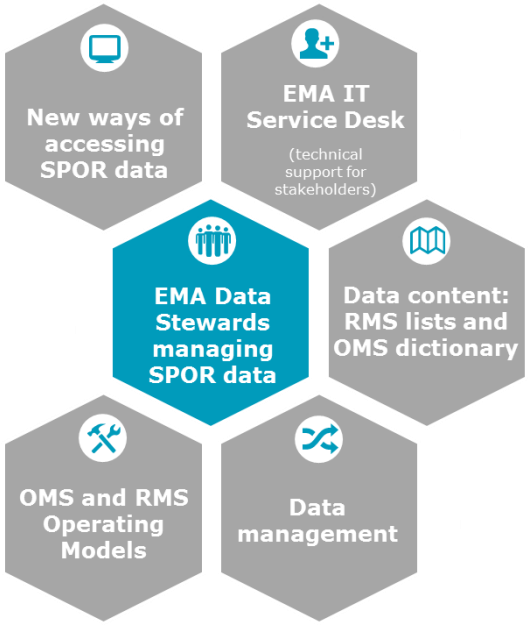


New ways of accessing SPOR data

- SPOR web interface
- SPOR APIs* (Application Programming Interface)
- Draft API specifications have been shared with SPOR Task Force; final API specifications are expected to be published in August
- For RMS, backward compatibility will be maintained with EUTCT for NCAs who use EUTCT

**An API is a mechanism to allow your IT systems to exchange information automatically with RMS and OMS*

Key changes as a result of SPOR

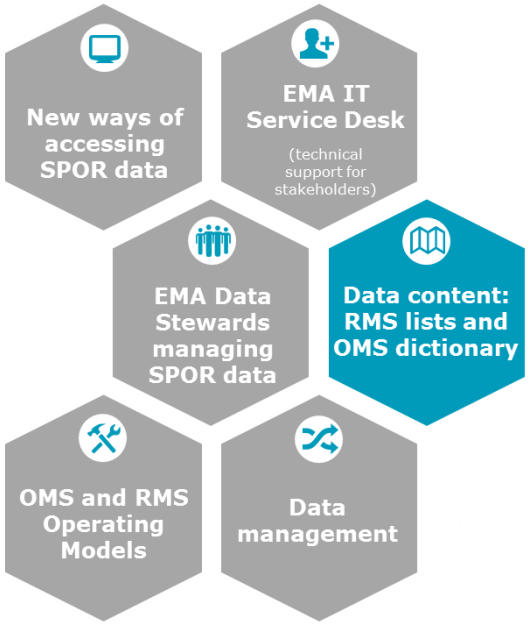


EMA Data Stewards

- A specialised team of EMA staff that will manage data on behalf of stakeholders and provide user support*
- Validate access requests to SPOR services
- Directly involved in maintaining the quality of the data:
  - Profiling the data (assessing quality of data)
  - Various data anomalies (different formats of the data e.g. telephone number) can be identified / monitored and data correction can be initiated
  - Reports generated using this cleansed data will be more reliable
- Take action on change requests for new/amended Referential Lists/Terms and Organisation data

** PMS and SMS: the level of support that will be provided is still under discussion*

Key changes as a result of SPOR



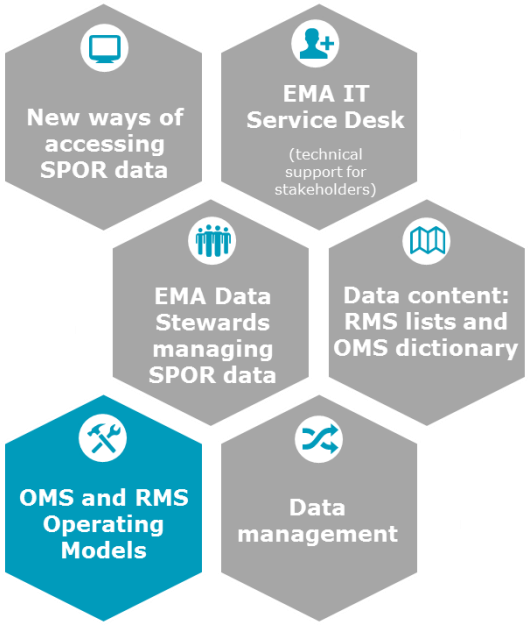
Data content

- RMS lists at go-live:
  - Lists from EUTCT (apart from Substance list)
  - Lists to support OMS
  - Lists for ISO 11239 (Pharmaceutical dose forms, units of presentation, routes of administration and packaging) and ISO 11240 (Units of measurement)
  - Some lists to support PMS project (e.g. Material)

- Content of the OMS dictionary at go live:
  - MAHs: (H+V) CAPs & (H) NAPs
  - MAAs: (H+V) CAPs
  - MRL applicants (Vet)
  - MA & MRL contacts: (H+V) CAPs

- RMS lists and content of the OMS dictionary will gradually be expanded. *Please see data release plans on slides 36 and 38*

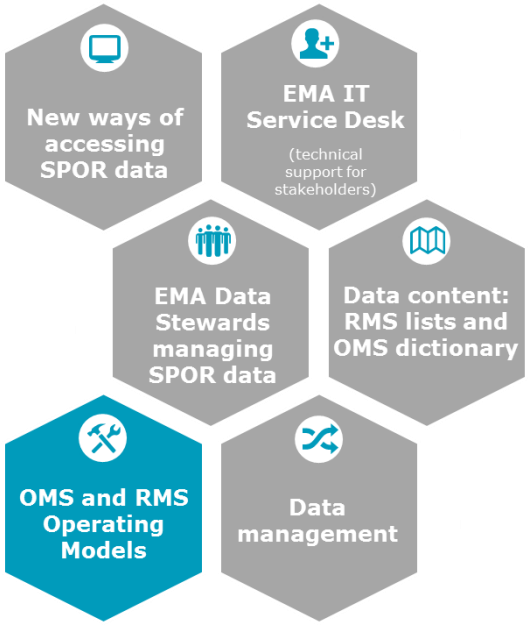
Key changes as a result of SPOR



OMS Operating Model

- Establishes a centralised dictionary of Organisations data to be used as a reference and in support of EU regulatory activities
- EMA will host the Organisations master data and will provide access to all stakeholders
- Common process which requires Industry to request organisation registration (or update) with EMA before regulatory submission
- NCAs will also be able to submit change requests (pre-register) to OMS
- Organisation data will be validated by the EMA Data Stewards and available in a structured format
- *Please see slide 36 for OMS operating model*

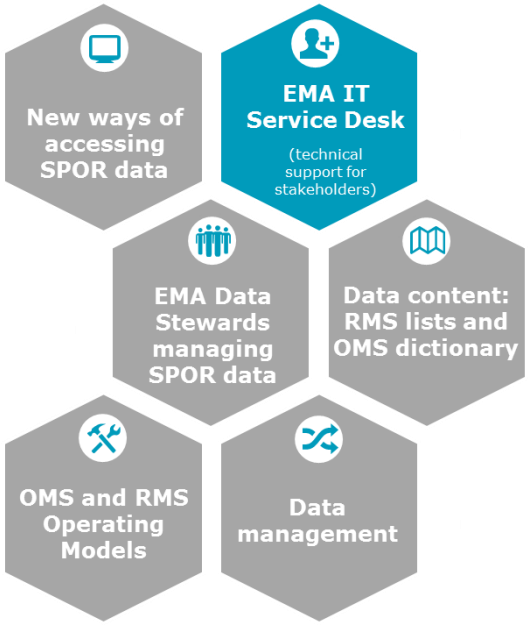
Key changes as a result of SPOR



RMS Operating Model

- EMA will act as the broker and it will provide Referentials data services to the EU network
  - Referentials data maintained by EMA Data Stewards and available in structured format
- EMA will host reference lists from different maintenance organisations (WHO, EDQM, MSSO, BfArM, etc)
  - EDQM: maintenance organisation for ISO IDMP 11239 (ph. forms, units of presentation, routes of administration, packaging)
  - BfArM: maintenance organisation for ISO IDMP 11240 (units of measurement)
- EMA will be a maintenance organisation for new lists where no maintenance organisation exists
- Common process which requires industry and other parties to request registration of Terms before regulatory submission
- Translations done by NCAs
- All organisations need to register legacy & specific terms with EMA
- *Please see slide 34 for RMS operating model*

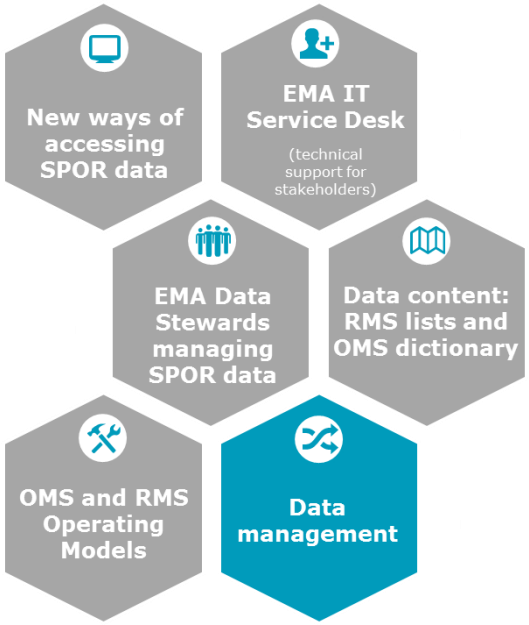
Key changes as a result of SPOR



EMA IT Service Desk

- EMA IT Service Desk will provide technical support for SPOR data services for all stakeholders
- More details on this will follow nearer go-live

Key changes as a result of SPOR



Data Management

- Industry will need to synchronise data in their local systems with RMS and OMS on an **ongoing basis**
- In order to reflect changes/updates in SPOR data in their local systems, Industry may need to transform their local data to align with ISO/EU data formats within RMS and OMS:
  - Data transformation – change the data structure e.g. split data fields
  - Data enrichment – complete the set of data e.g. add a new field such as post code

SPOR Task Force

Together, ISO IDMP and SPOR Master Data (aka SPOR data services) constitute one of the Telematics programmes known as the Data Integration Programme

EMA has established a **SPOR Task Force** (aka ISO IDMP Task Force) made up of representatives from the EU Regulatory Network, members nominated by Industry Associations and other interested parties

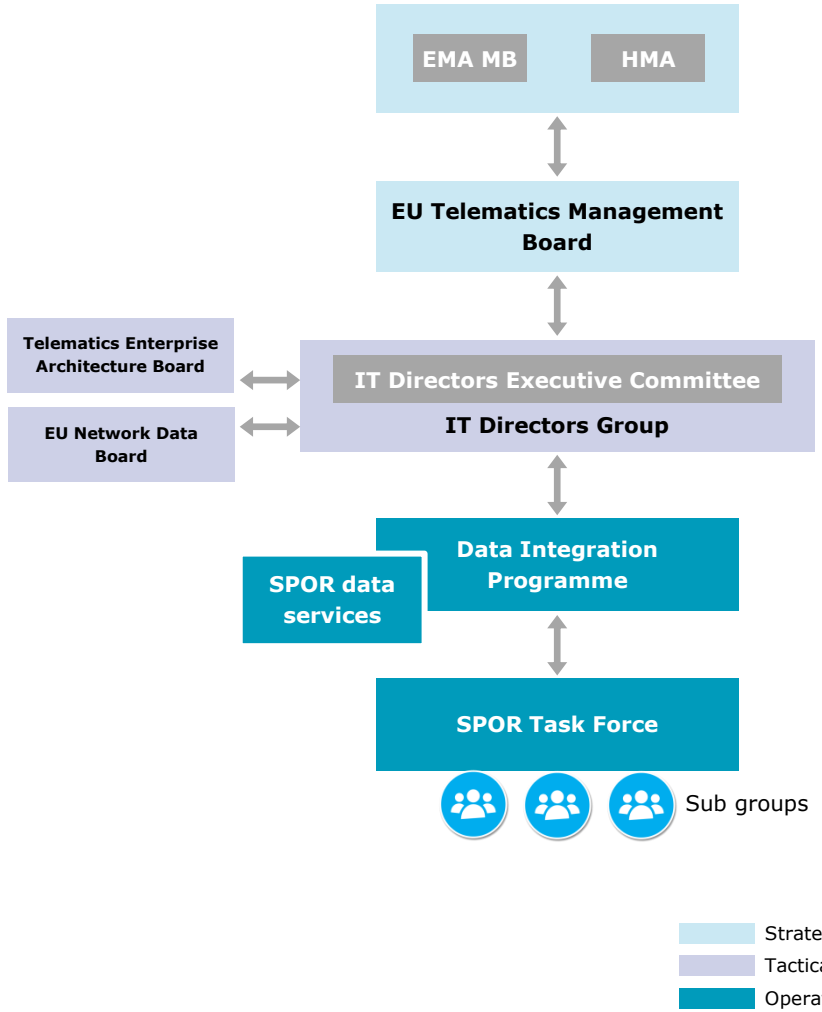
SPOR Task Force:

- Responsible for advising on aspects related to planning, development, implementation and maintenance of the ISO IDMP standards in the EU
- Deliver recommendations on the implementation strategy
- The group will also act as a communication channel to all external stakeholders affected by the implementation of the ISO IDMP standards in the EU

Sub groups:

- Small working groups of topic experts have been assigned to support project activities. They present findings and recommendations back to the SPOR Task Force for review and final adoption.

SPOR within the Telematics Governance



High level programme timeline

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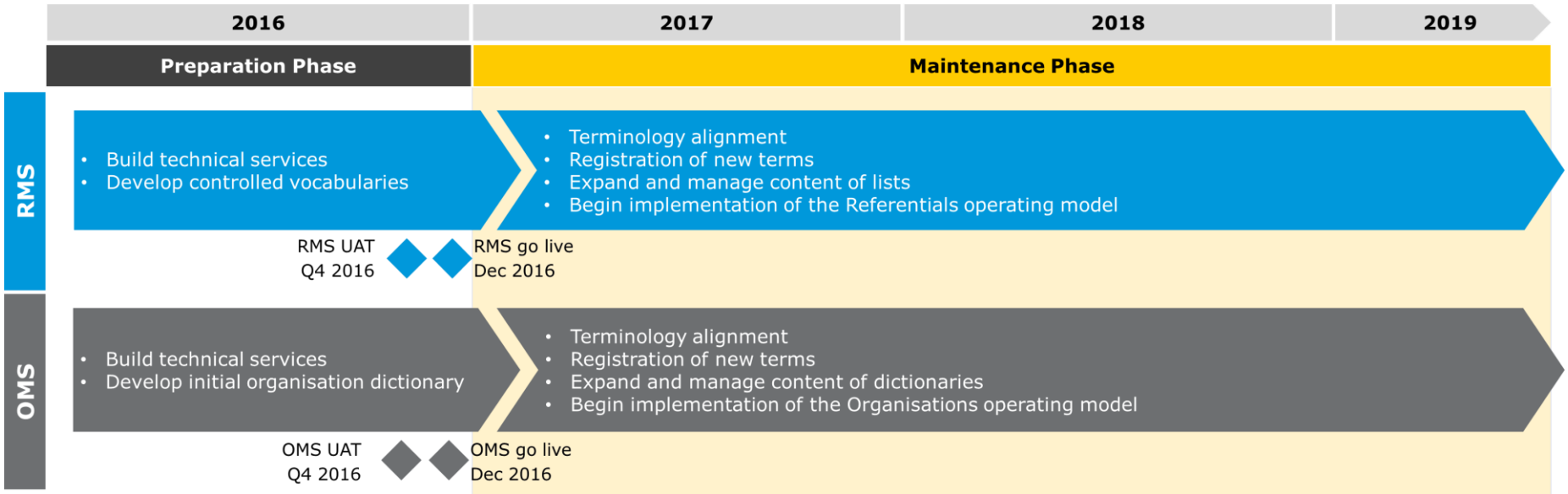
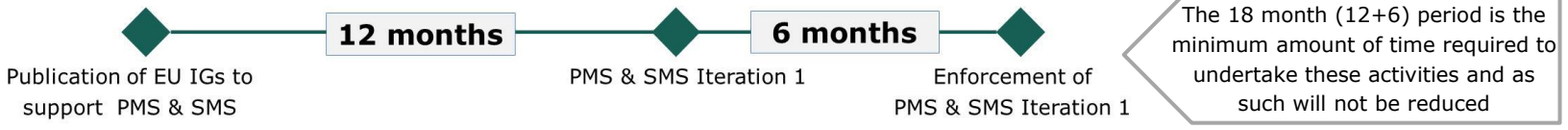


- The focus for 2016 is on the first phase of implementation of SPOR through RMS and OMS
- These two services will lay the data foundations for delivery of PMS and SMS
- PMS and SMS projects are on hold in order to focus resources on implementing RMS and OMS and while the ISO standards are being finalised. They are expected to resume towards the end of 2016
- In the meantime, the PMS and SMS Sub-Group continues to carry out its business-related preparatory work
- The plan for PMS and SMS will be shared at a later stage. The high level timeline for PMS and SMS Iteration 1 is outlined below



Key activities for Industry

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- The focus of activity in 2016 relates to preparing for RMS and OMS go-live
- Industry own their plans to design, implement, test and deploy changes in alignment with SPOR delivery timelines
- Industry should undertake the following activities in order to provide a better foundation for PMS and for enforcement of use of RMS and OMS in 2017

1 **Programme participation**	• Engage with programme via Industry Change Liaisons and existing forums eg. SPOR Task Force, Sub Groups • Engage with change management activities e.g. communications and training
2 **Follow through on priorities**	• Undertake the activities below in order to be ready to actively use RMS and OMS post go-live • Follow the agreed RMS and OMS operating models post RMS and OMS go-live, which include pre-registration and ongoing maintenance of SPOR data
3 **Data mapping**	• No OMS mapping is required by Industry prior to OMS go-live • No RMS mapping is required by Industry prior to RMS go-live. • Post go-live, Industry should map against new Referentials lists and new OMS dictionary content as it is published • Post go-live, Industry should synchronise their local Organisation data against the OMS dictionary and their local Referentials data against existing RMS lists
4 **Data pre-registration**	• At OMS go-live, Industry should send requests for new/updated Organisation data relating to MAHs only. As the dictionary is expanded with other types of Organisation data, Industry will be invited to pre-register data relating to these new Organisations. • Post RMS go-live, Industry should send requests for new/updated Referentials prior to submitting an application
5 **Process change**	• Identify all data management processes that will need to be adapted in order to align local data and synchronise it with RMS and OMS on an ongoing basis
6 **Systems change**	• Identify all impacted systems and architecture that will need to be adapted in order to support the process changes identified above

Focus on Industry data activities

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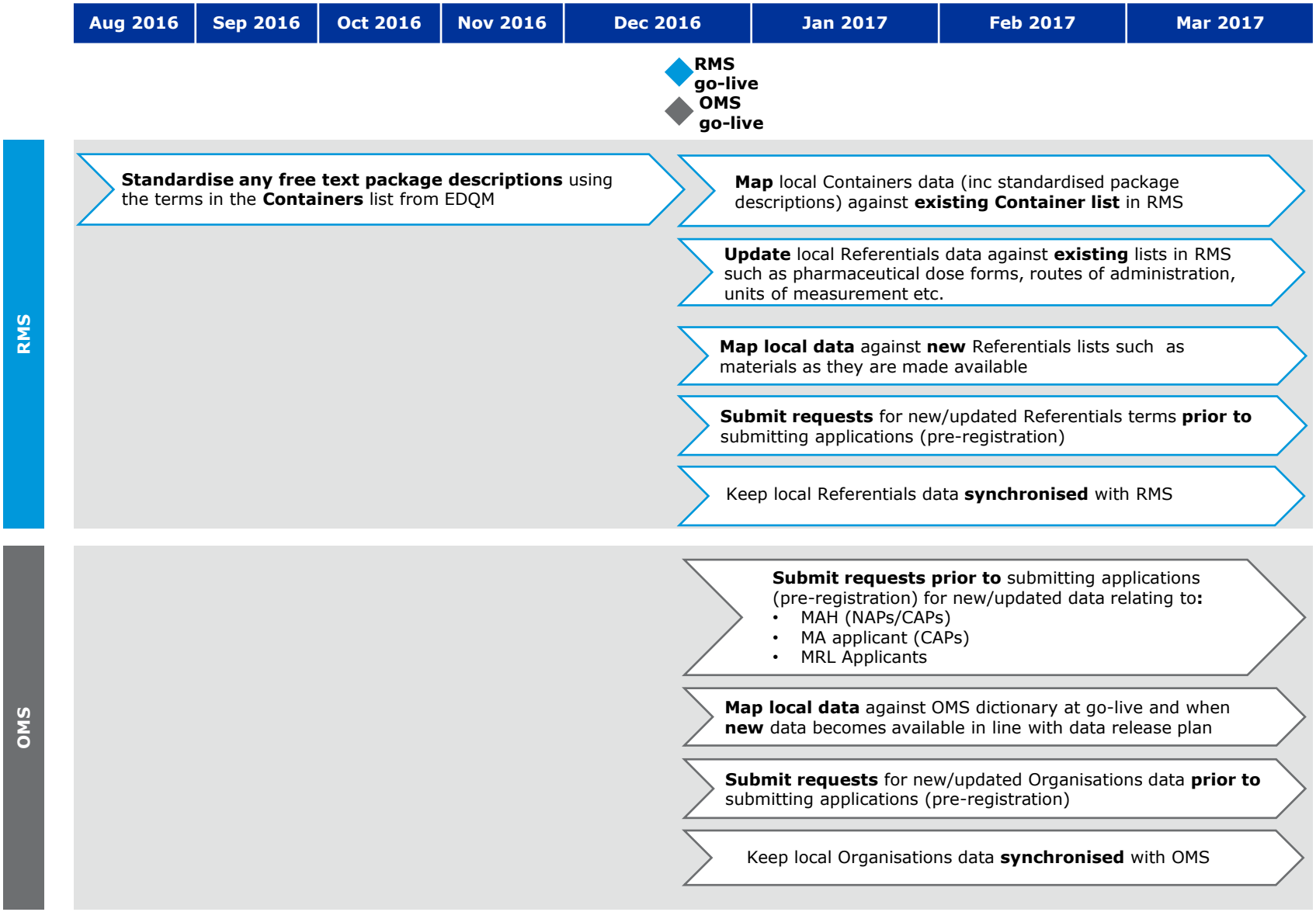

Impact on existing submission processes

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- Future phases of SPOR will deliver beyond 2017 to allow technical and business process integration of SPOR data with systems developed within other EU Telematics Programmes

- RMS and OMS operating models can only be **fully** enforced once all phases of SPOR have completed and once other programmes dependent on SPOR data are implemented and integrated

- **At go-live**, submission processes will continue as before and there will be no immediate process changes for Industry stakeholders
  - Some changes in the current submission processes are being explored in relation to Article 57 (xEVMPD) and Initial MAH application submission

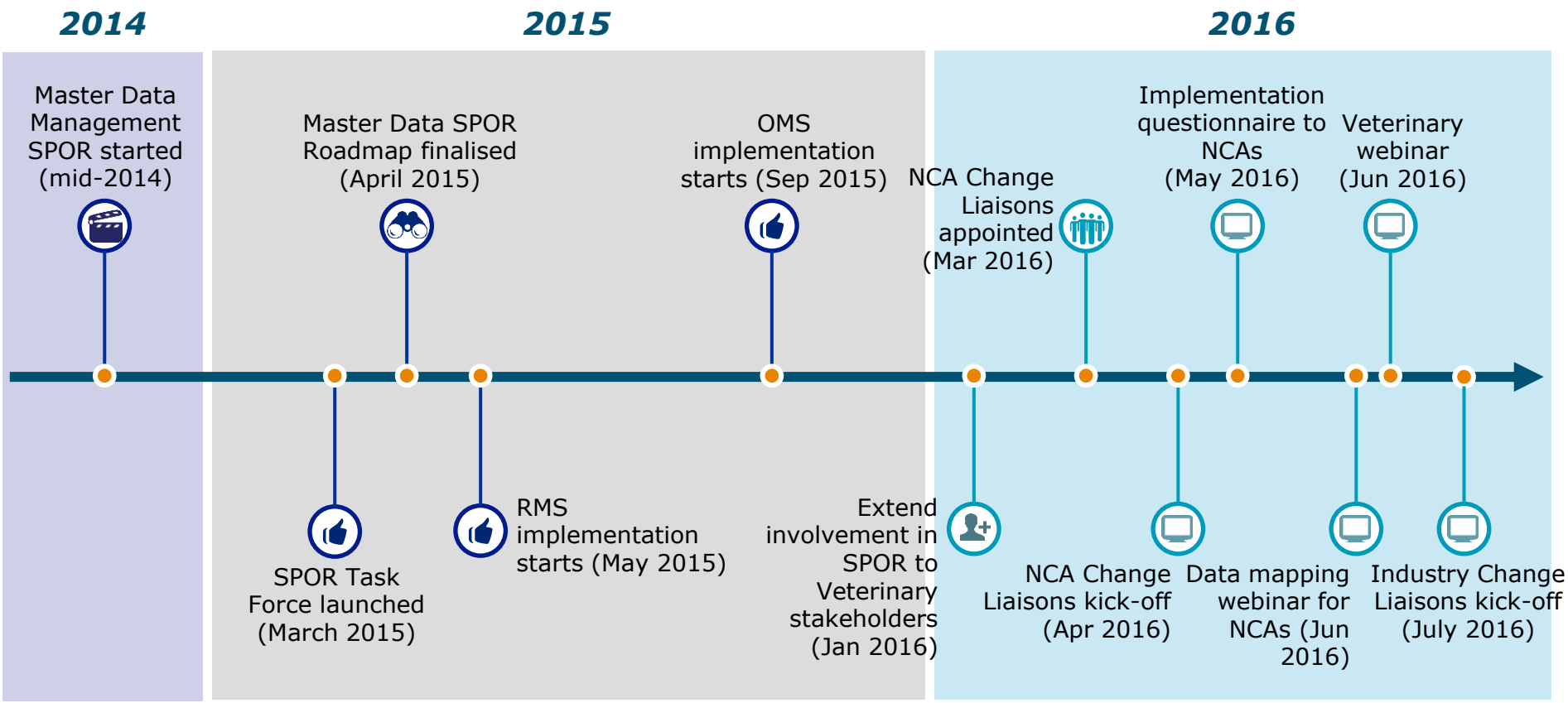
- **During Q1 2017**, it is in the interests of Industry to familiarise themselves with using RMS and OMS operating models and systems in order to better position themselves for when their use becomes enforced later in 2017 and for when PMS goes live in 2018

- More information will be released in the Autumn to explain any applicable process changes and timings

SPOR engagement activity

The SPOR story so far…

While the impacts of SPOR on Industry stakeholders are not yet being felt, there is plenty of activity taking place in the background to establish the environment for uptake of RMS and OMS by Industry post go-live:



SPOR Change Network

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We have established a Change Network to help us broaden the reach of the EMA in communicating about SPOR. It comprises the following key roles:

Industry Change Liaisons

Members

SPOR Task Force members representing **EU Industry Associations** (Industry Association Change Liaisons) and Vendors (Vendor Change Liaisons)

Role

- Cascade communications material across Industry in an interactive way
- Promote sharing of best practice
- Feedback on comms and training materials and activities

NCA Change Liaisons

Members

Nominees from NCAs

Role

- Cascade communications material with their own organisation and to their **national trade associations**, translating as needed

Contact points at Industry Associations (via EMA stakeholder office)

Members

EMA's established contact points at **EU Industry Associations**

Role

- Work with Industry Change Liaisons to cascade communications material across Industry

SME stakeholder office

Members

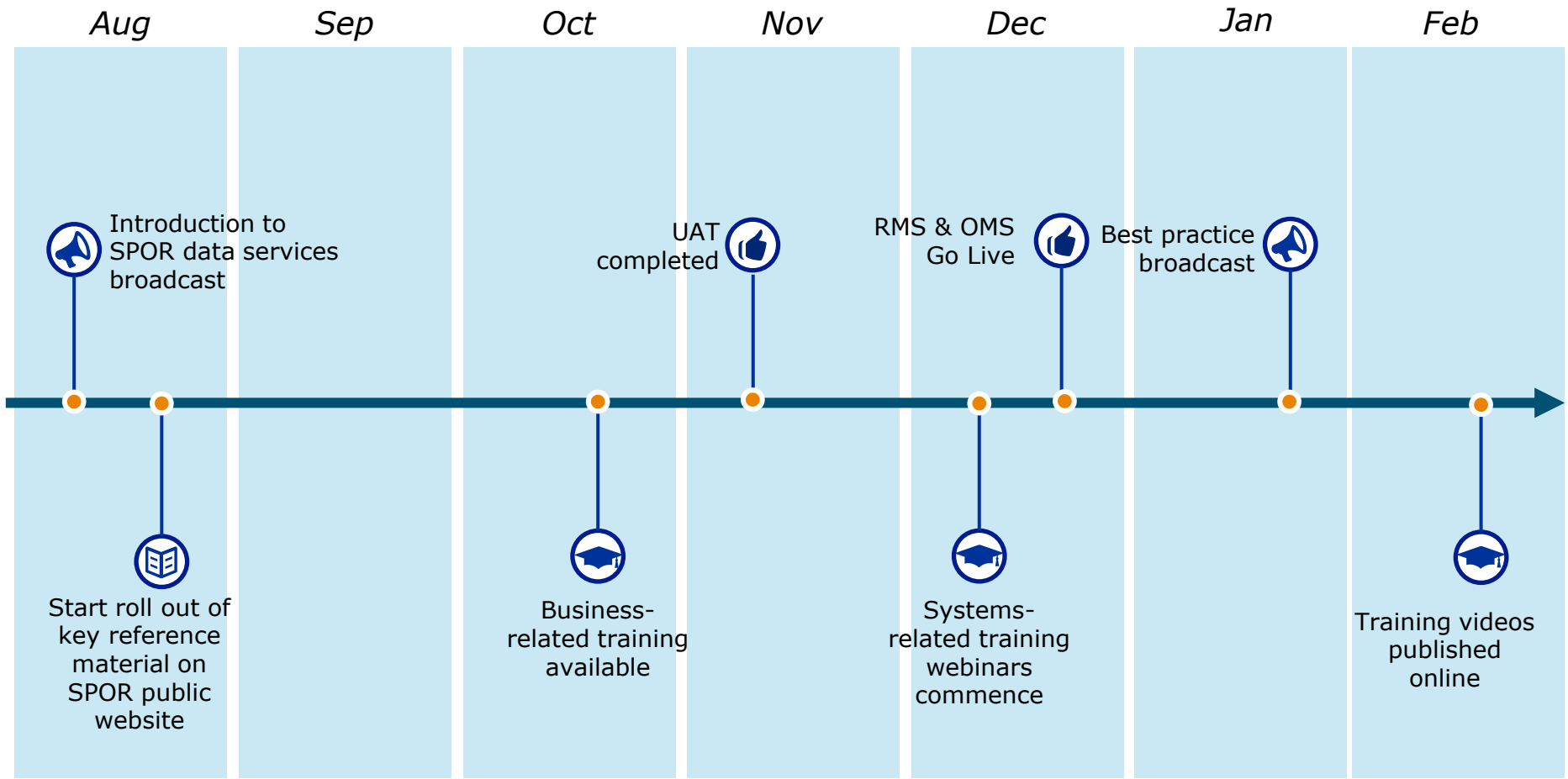
EMA function that supports SME stakeholders

Role

- Cascade communications material directly to **SME stakeholders** that are registered with EMA

Key Industry engagement activities

- Industry Change Liaisons will provide a continuous channel for information and training throughout the year
- In addition, a number of specific events are planned that will be open to all Industry stakeholders



Your routes to find out more

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Industry Change Liaisons

SME stakeholder office

Industry stakeholders should reach out to the appropriate body within the Change Network as the **first port of call** relating to SPOR for:

- Information: central communications and key messages
- Training: signpost training material and reinforce your understanding
- Answering your questions
- Receiving your feedback on communications & training activity and content
- Supporting the exchange of best practice

- We will publish a contact list for Industry Change Liaisons on the SPOR public website
- See *Appendix* for list of Industry Associations represented by Industry Change Liaisons
- If you are a national trade association you may need to contact your NCA

SPOR public website for information on SPOR, reference materials and videos on key topics:
Navigation route: EMA home > Data submission on medicines > Implementation of ISO IDMP standards

Videos to provide bite-size chunks of information on key topics. These are easily digestible snippets of information (unlike recorded webinars which can last up to 3 hrs)

Webinars/Broadcasts to deliver longer duration live communications to a large audience across the EU region in an interactive, engaging way. Also provides a forum for Q&A. Where appropriate, webinars will be recorded and posted online.

SPOR reference material

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Business documentation:

- Roll-out plan for RMS and OMS
- Stakeholder engagement approach
- SPOR high level benefits
- SPOR high level changes
- RMS and OMS operating model guidance
- Expansion timelines of RMS lists and OMS dictionary

Technical documentation:

- Data mapping guidance for Referentials and Organisations
- RMS and OMS data models
- RMS and OMS APIs specifications

Some of the topics covered in this presentation will be expanded and shared in August
Links will be provided to reference material from the ISO IDMP/SPOR landing page on the EMA public website
Navigation route: www.ema.europa.eu>Data submission for medicines>Implementation of ISO IDMP standards

If you are an SME stakeholder

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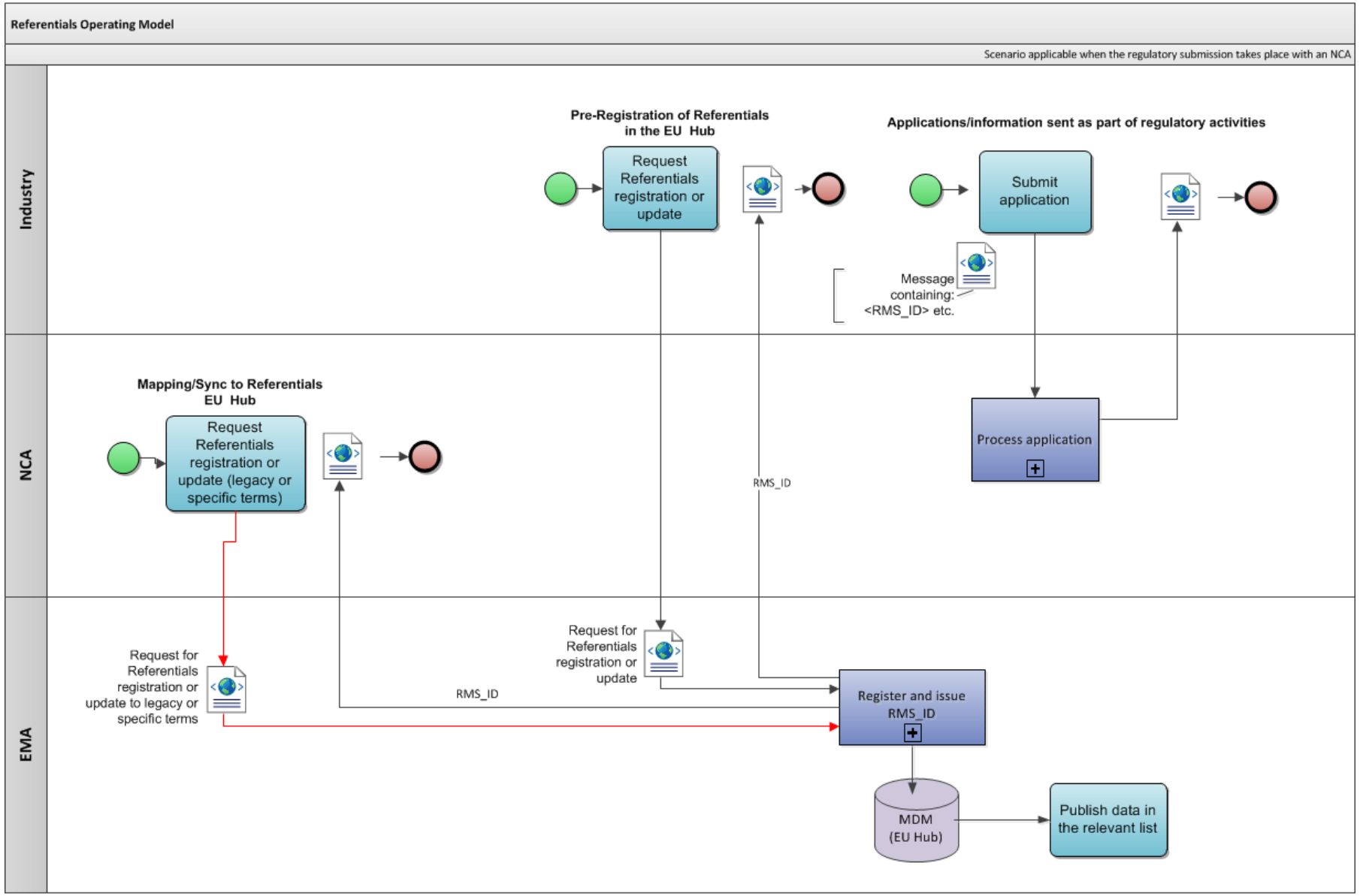
- If you are an SME and are not yet registered with the SME stakeholder office at EMA, we strongly recommend you to consider registering
- The SPOR change team will work with the SME stakeholder office and will use their established communications channels to disseminate information about SPOR
- As a registered SME, you will be able to keep up to date with SPOR data services via the SME office
- For more information on SMEs and what administrative, regulatory and financial support is available to companies assigned SME status by EMA, navigate the EMA website:
    - EMA home>Human regulatory>Supporting SMEs
    - EMA home>Veterinary regulatory>Supporting SMEs

Deep dive: Operating models

RMS Operating Model



Referentials data release plan

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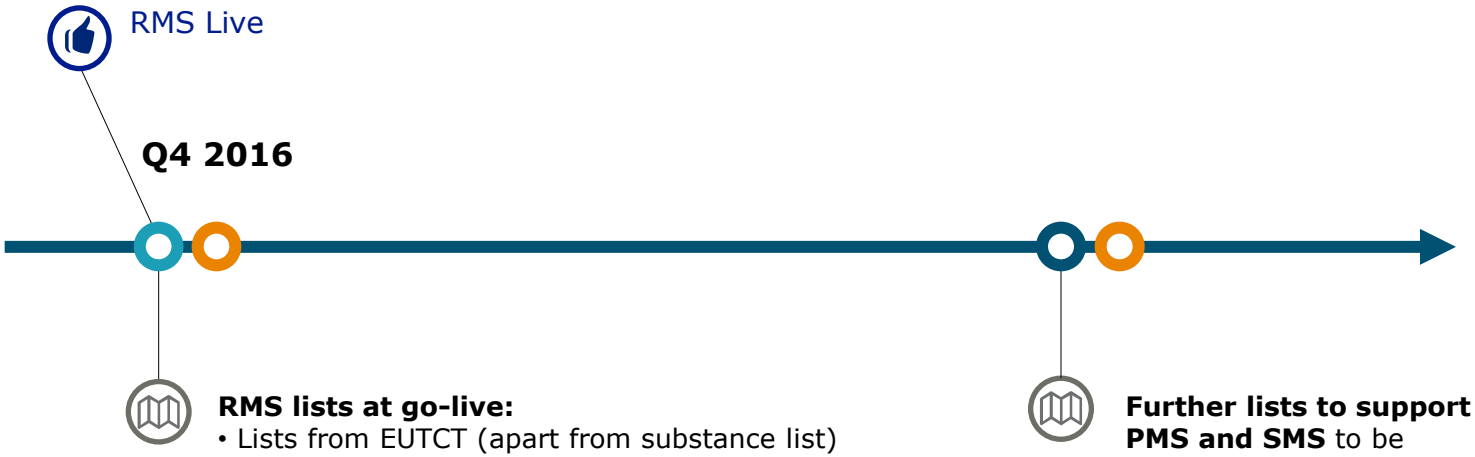
Post go-live users should access RMS and subscribe to be notified whenever a new list has been published

Key

- Points at which new Referentials list will be added
- Stakeholders should only start submitting Change Requests for Referentials once the data is published in RMS – not before.
- RMS go live

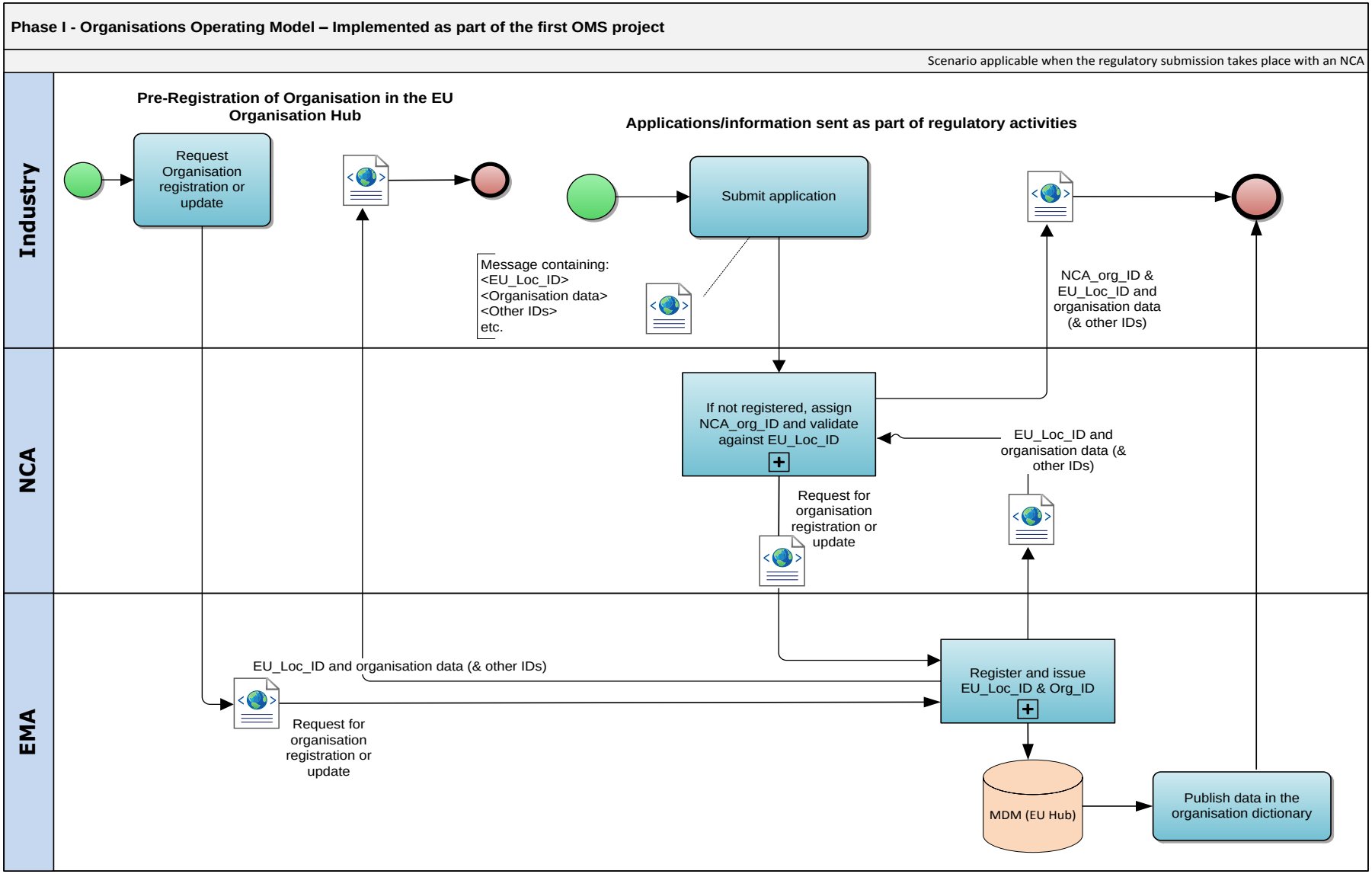


RMS lists at go-live:

- Lists from EUTCT (apart from substance list)
- Lists to support OMS project
- Lists for ISO 11239 (Pharmaceutical dose forms, units of presentation, routes of administration and packaging) and ISO 11240 (Units of measurement)
- Some lists to support PMS project (e.g. Material)

Further lists to support PMS and SMS to be included as and when available

OMS Operating Model – Phase I

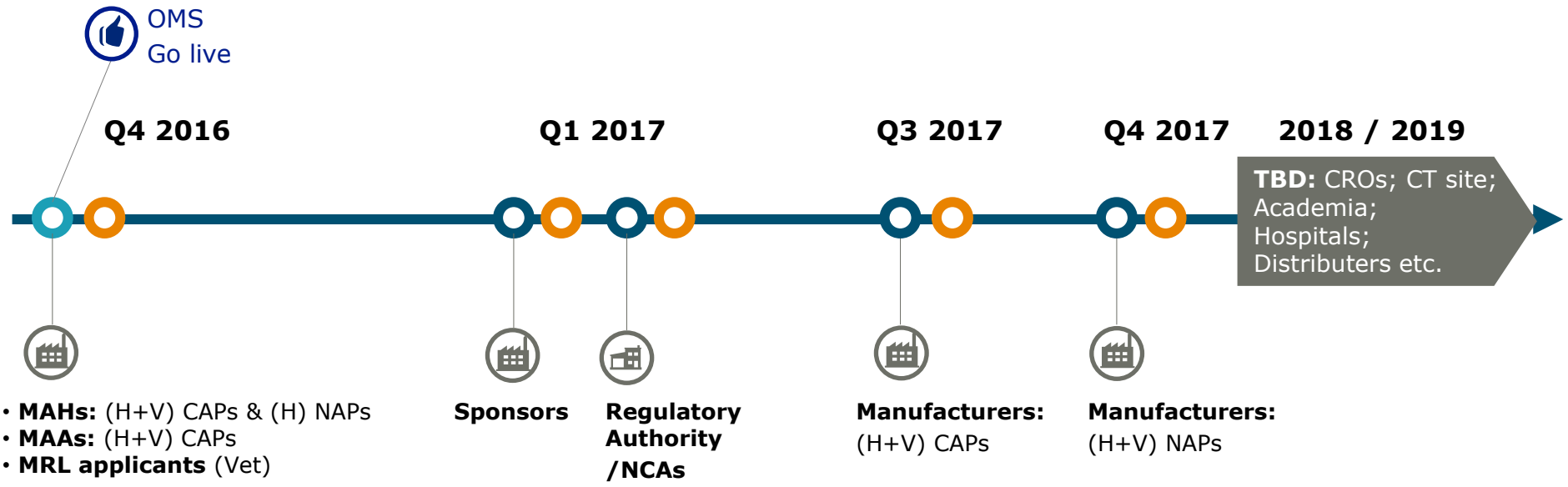


Organisations data release plan

EMA will issue advance communications to notify all stakeholders that new data is being published on OMS and that Change Requests for that data can be submitted now that it has been published on OMS (not before).

Key

- Points at which new organisation data is published in OMS
- Industry should only start submitting Change Requests for Organisations once the data is published in OMS – not before.
- OMS go live



Operating Model advantages

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- SPOR data is hosted by EMA, accessible to and used throughout EMA and by external stakeholders
- SPOR data is a **single and trusted source** of data
- **Common process** which requires industry and other parties alike **to request registration** of Referentials and Organisations data before regulatory submission
- **Common process to request changes** to the OMS dictionary and to Referentials lists/terms
- Referentials and Organisation **data validated by the EMA Data Stewards** and available in a **structured format**
- Establishes a complete and high quality **dictionary of Organisations and lists of Referentials terms** to be used as a reference and in support of EU regulatory activities
- **Single format and simplified process** to consume Referentials lists and keep them updated

RMS and OMS Services

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The use cases and operating models for SPOR require stakeholders to interact with SPOR data. To support these interactions, stakeholders will be able to make use of SPOR data services:

Customer support

RMS & OMS
- Customer support: business/technical queries; issues; training
- All users authenticated & authorised

Browse data

RMS
- List of lists
- List of terms incl. Term Summaries & Term details

OMS
- List of organisations with location addresses
- All Org_IDs and Org_Loc_IDs

Search

RMS
- Standard and advanced search (UI)
- Google-style search (API)
- Lists and terms
- Historical versions (date/version number)
- OID for sources of information
- Language(s)
- Applicability

OMS
- Standard search
- Org and Location data
- Historical versions (date/time stamps)
- Based on source system/other IDs (e.g. EV_Code, DUNS/GTIN, etc)

Change requests

RMS
- Search
- Read
- New/update/delete Term Request
- New/update List Request
- Document attachments

OMS
- Read
- Create/Update Org/Location
- Add location
- Document attachments

Export

RMS
- List of lists
- List of terms
- Full list or set of results
- Filter By Languages

OMS
- Full dictionary or set of results
- File contains: *all versions, Org name and location address in all languages, source system IDs, international organisation identifiers, etc*

Multi-lingual

OMS
- Organisation name
- Location addresses

Term Translations

RMS
- Search
- Read/ Update

ID Translation Service

RMS
- Source term ID into RMS ID

Saved queries

RMS
- Search queries
- Crate/update/delete queries

Tags

RMS
- Search
- Create/Update/Delete

Subscriptions

RMS
- Search
- Create/Update/Delete

Documents

RMS & OMS
- View & Publish documents

Key contacts

Industry Change Liaisons

EUROPEAN MEDICINES AGENCY

- These are the Industry Associations represented by Industry Change Liaisons.
- A contact email address for each Industry Association will be published on the SPOR public website, which will be monitored by Industry Change Liaisons in order to provide you with a dedicated channel for queries relating to SPOR.

Association of the European Self-Medication Industry

AESGP

European Group for Generic Veterinary Products

EGGVP

EuropaBio

EuroPharm SMC

European Biopharmaceutical Enterprises

ebe european biopharmaceutical enterprises

Eye-Care Industries – European Economic Interest Grouping

European Confederation of Pharmaceutical Entrepreneurs

EUCOPE European Confederation of Pharmaceutical Entrepreneurs AISBL

International Federation for Animal Health Europe

Europe IFAH Representing the European Animal Health Industry

European Federation of Pharmaceutical Industries and Associations

efpia European Federation of Pharmaceutical Industries and Associations

Medicines for Europe

medicines for europe better access. better health.

European Federation of Statisticians in the Pharmaceutical Industry

EFSPI

Vaccines Europe

Vaccines Europe An industry for healthy lives

NCA Change Liaisons

EUROPEAN MEDICINES AGENCY

These are the NCAs represented by NCA Change Liaisons. If you need to contact your NCA regarding SPOR, please use the general information contact address provided by that NCA.

Country	Organisation
Austria	Austrian Medicines and Medical Devices Agency (AGES-MEA)
Belgium	Federal Agency for Medicines and Health Products (FAMHP)
Bulgaria	Bulgarian Drug Agency (BDA)
Croatia	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
Cyprus	Department of Information Technology Services (DITS), Ministry of Health
	Veterinary Services - Ministry of Agriculture, Rural Development and Environment
Czech Republic	State Institute for Drug Control (SÚKL)
Denmark	Danish Medicines Agency (DKMA)
Estonia	Estonian State Agency of Medicines (SAM)
Finland	Finnish Medicines Agency (FIMEA)
France	National Drug and Health Products Safety Agency (ANSM)
	French Agency for Veterinary Medicinal Products (Anses-ANMV)
Germany	Paul-Ehrlich-Institut
	Federal Institute for Drugs and Medical Devices (BfArM)
Hungary	Directorate of Veterinary Medicinal Products, National Food Chain Safety Office (NFCSO - NEBIH)
	National Institute of Pharmacy and Nutrition (OGYEI)
Iceland	Icelandic Medicines Agency (IMA)
Ireland	Health Products Regulatory Authority (HPRA)
Italy	Italian Medicines Agency (AIFA)

Country	Organisation
Latvia	State Agency of Medicines (ZVA)
Liechtenstein	Office for Public Health
Lithuania	National Food and Veterinary Risk Assessment Institute (VET)
	State Medicines Control Agency (SMCA - VVKT)
Luxembourg	Ministry of Health Luxembourg
Malta	Medicines Authority Malta
Netherlands	Medicines Evaluation Board (CBG-MEB)
Norway	Norwegian Medicines Agency (NoMA)
Portugal	National Authority of Medicines and Health Products, IP (INFARMED)
	Portuguese National Authority for Animal Health, Directorate General of Food and Veterinary (DGAV (DGAMV))
Romania	National Agency of Medicines and Medical Devices (ANM)
Slovak Republic	Slovakian Medicines Agency - State Institute for Drug Control (SUKL)
	Institute for State Control of Veterinary Biologicals and Medicaments
Slovenia	Agency for Medicinal Products and Medical Devices (JAZMP)
Spain	Spanish Agency of Medicines and Medical Devices (AEMPS)
Sweden	Medical Products Agency (MPA)
UK	Medicines & Healthcare products Regulatory Agency (MHRA)
	Veterinary Medicines Directorate (VMD)

(as at 5 May 2016)

In summary

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SPOR data services: Delivering quality data services on Substances, Products, Organisations and Referentials to power EU regulatory activities

- SPOR data services will act as the vehicle for implementation of ISO IDMP standards
- SPOR data services will enable the realisation of benefits at all stages of the product lifecycle due to future integration of regulatory processes with SPOR's standardised data and central data management services
- Implementation of RMS and OMS is the first step in a phased approach to roll-out of SPOR and of other Programmes dependent on SPOR data
- In order to be ready for the future changes brought about by SPOR and by integration with other Programmes, Industry should prepare now to ensure they have the foundations in place through alignment with RMS and OMS

Glossary

Glossary

API	Application Programming Interface is a set of programming instructions and standards for accessing a Web-based software application or Web tool
Backward compatibility	Capability of a new solution to successfully interface/work with previous versions of software/hardware
CESSP	The Common European Single Submission Portal (CESSP) is an ongoing Telematics programme that aims to integrate the electronic Application Form (eAF) data sets in to CESP. CESP is the current submission channel for all procedures (not technically integrated with eAF)
Change Network	A collection of representatives from Industry and regulators with responsibility for acting as the central contact point for Industry stakeholders in relation to SPOR data services.
Controlled vocabularies	(aka Referentials) are lists of terms that refer to attributes of medicinal and pharmaceutical products e.g. dosage form, route of administration, unit of measurement
CT Portal	(aka EU Portal and Database) will be the upgraded version of Eudra CT enabling a single entry point for submission and assessment of clinical trial applications at an EU level
eAF	The eAF is a collection of Application Forms that facilitate electronic submission of data relating to Renewals, Variations, Marketing Authorisation Applications (Human & Vet)
Eudra CT	The existing platform for submitting and viewing information relating to regulatory activities relating to Clinical Trials

Glossary

Eudra GMDP	EMA database that includes information relating to Manufacturing and Distribution good practice supporting coordination and output from Inspections activities
EUTCT	A repository and provider of controlled terms (or controlled vocabularies) in multiple languages. It is the predecessor of RMS. RMS will replace EUTCT with regards to management of controlled vocabularies. EUTCT can only be fully replaced after SMS implementation as it also contains substances
HL7	Health Level Seven (HL7) is a set of messaging standards that defines the format for the electronic exchange of data that is compliant with ISO IDMP technical specifications
Master data	Any information that is considered to play a key role in the core operation of a business and is re-used for multiple purposes
Unique identifiers	The ISO IDMP standards outline a set of attributes/data elements that make up a **unique identifier** . This enables the creation of a unique record for each medicinal product, packaged product, pharmaceutical product, substance and referential

Thank you for your attention

Further information

Please send any queries for the change team to:
SPOR-Change-Liaisons@ema.europa.eu

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Contact

You can contact the EMA SPOR Change team at: SPOR-Change-Liaisons@ema.europa.eu