EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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SPOR data management services - high level changes

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1. Introduction

RMS (Referentials Management Services) and OMS (Organisations Management Services) are the first two projects to be delivered as part of the phased implementation of SPOR and are key enablers of the implementation of ISO IDMP in the EU. The introduction of RMS and OMS will bring a number of key changes that can be classified as follows:

- New solutions providing access to SPOR data;
- Data stewards managing SPOR data;
- Data content to support ISO IDMP implementation;
- New RMS and OMS operating models;
- Ongoing data management activities;
- IT Service desk to support stakeholders.

The impact of these changes will be experienced in different ways by Human and by Veterinary National Competent Authorities (NCAs) and by industry due to the variety in size, infrastructure and complexity of systems and processes within these organisations. NCAs and industry therefore need to understand what is changing centrally and then draw up implementation plans based on how they determine the changes will specifically impact their own organisation.

At RMS and OMS go-live, submission processes will continue as before and there will be no immediate process changes for stakeholders. Some changes in the current submission processes are being explored and consultation is taking place with stakeholders on these.

More information will be provided in due course to explain any applicable process changes and timings.

2. New solutions for access and use of SPOR data

Stakeholders will be able to access and use the data within RMS and OMS via two methods:

- SPOR web interfaces – reached via a portal. The SPOR web interfaces will provide a user-friendly (human to system) means of exploiting the business services of the web-based RMS and OMS applications;
- SPOR APIs (Application Programming Interface) – a set of programming instructions and standards that organisations may choose to use to integrate with their local systems (system to system) in order to exploit the business services of the web-based RMS and OMS applications. The APIs can also be configured to manage automated data synchronisation.

2.1. RMS backward compatibility

At RMS go-live, NCAs that currently use EUTCT (EU Telematics Controlled Terms) via the web user interface will find that they can still view Substances Lists but no longer view the Referentials Lists that were housed in EUTCT. However, those NCAs that currently use the EUTCT API will still be able to access the Referentials Lists that were in EUTCT due to the built-in backward compatibility.

If users want to be able to view a complete set of Referentials Lists, i.e. those that include both Lists that were housed in EUTCT in addition to any new Lists, they will need to adopt the RMS API or RMS web user interface.

Table 1. RMS backward compatibility

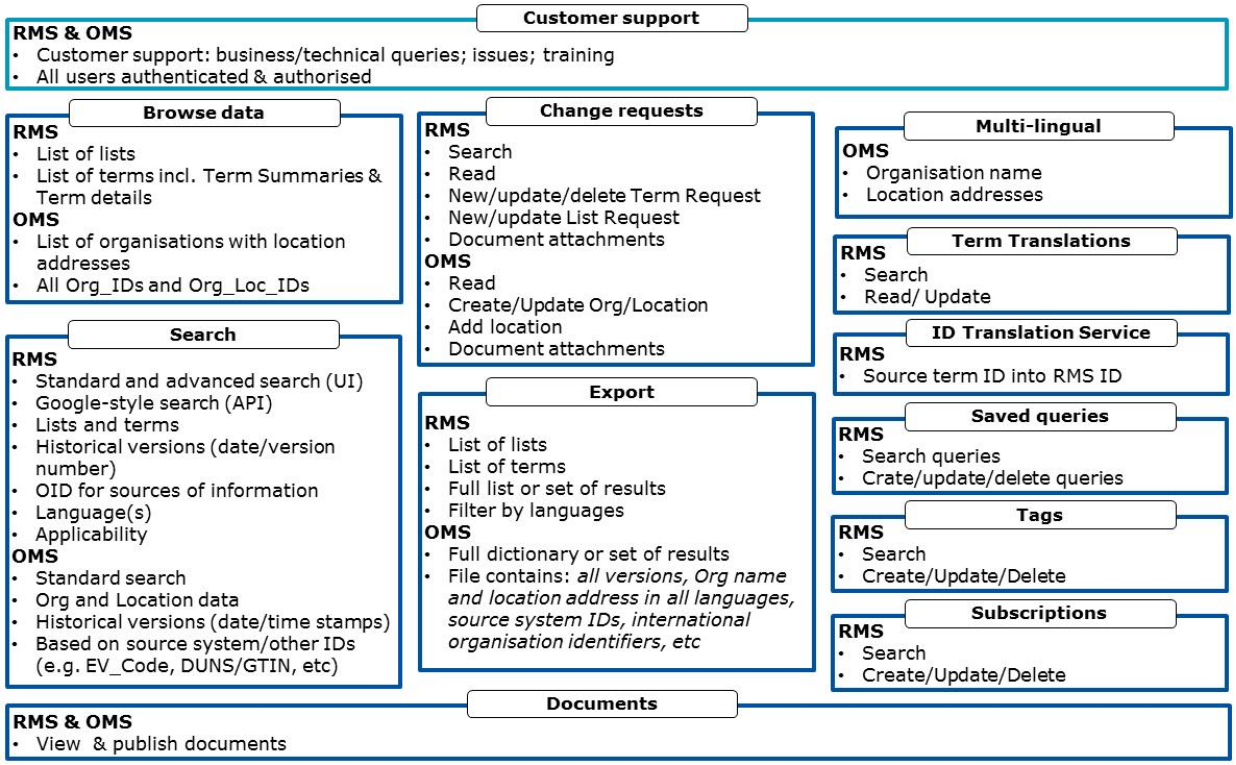
EUTCT web user interface	Backwards compatible EUTCT API	RMS web user interface	RMS API
Can only access Substances Lists	Can access Substances Lists	Cannot access Substances Lists	Cannot access Substances Lists
Unable to see Referentials Lists, which will have been migrated to RMS	Can access Referentials Lists, which will have been migrated to RMS	Can access **all** Referentials Lists in RMS (former EUTCT Lists plus new Lists)	Can access **all** Referentials Lists in RMS (former EUTCT Lists plus new Lists)

EUTCT is publicly available to NCAs, industry and any user for browsing but only NCAs can download the data and request changes to the data.

2.2. RMS and OMS business services

RMS and OMS will offer a number of services and functionality, shown in the diagram below. All services will be available to all users with the exception of publishing documents which is only available to EMA and Term translations which are only available to NCAs.

Figure 1. RMS and OMS business services



3. Data stewards

Data stewards will be a specialised team of EMA staff that will manage the data (Referentials and Organisations initially). The overall objective of data stewards will be to apply consistent data quality

rules and standards. They will be responsible for validating access requests to SPOR data management services and for taking action on change requests for new/updated Referentials Lists/Terms and Organisations data. Data stewards will also be responsible to provide user support.

4. Data content

The introduction of structured RMS and OMS data accompanied by unique IDs will support the implementation of ISO IDMP standards.

4.1. Referentials List release plan

Referentials data will become available in RMS in phases over time. At go-live, the following Lists will be published:

- Lists from EUTCT (e.g. shelf life type, target species);
- New Lists to support OMS (e.g. party classification);
- New Lists to support PMS (e.g. material);
- Updated Lists for ISO 11239 (pharmaceutical dose form, routes of administration and packaging) and ISO 11240 (units of measurement).These Lists exist in EUTCT in a very flat structure and at go-live they will be structured with full ISO data elements.

Referentials data will subsequently be expanded with Lists to support ISO standards for products and substances: ISO 11238 – Referential data to support substance registration and ISO 11615 – Referential data to support products. Further Lists can also be added in the future upon request.

4.2. Content of the OMS dictionary[1]

The initial content of the dictionary at go-live included Regulatory Authorities/National Competent Authorities (NCAs). Data content will be incrementally expanded as part of maintenance work and the following data sets will be included:

Data set 1:

Marketing Authorisation Holders (MAHs): Human (H) + Veterinary (V) Centrally Authorised Products (CAPs) and Human (H) Nationally Authorised Products (NAPs);

- Marketing Authorisation Applicants (MAAs): (H+V) CAPs;
- Maximum Residue Limit (MRL) applicants (Veterinary).

Data set 2:

- Sponsors (H) CAPs and NAPs.

Data set 3:

- Manufacturers (H+V) CAPs.

Data set 4:

- Manufacturers (H+V) NAPs.

EMA will communicate in advance to stakeholders about the timing of the release of new Organisation data in the dictionary and specify when industry can start submitting change requests for the Organisation data that has been added.

[1] Section 4.2 was updated to reflected current OMS data release plan

Additional Organisation data will be published in the future and the prioritisation of its inclusion in the dictionary will be defined at a later stage:

- Veterinary MAHs for NAPs;
- Contract Research Organisations (CROs);
- Clinical trials sites;
- Academia;
- Hospitals;
- Wholesale distributers;
- MAA/MAH and manufacturers in the context of herbal and homeopathic medicinal products or compassionate use medicinal products;
- QPPV (Qualified Person for Pharmacovigilance).

5. RMS and OMS operating models

EMA will act as a broker by making available a single source of centrally-provided master data and accompanying data management services to NCAs, EMA itself, industry and other external stakeholders. These data management services will be supported by standard processes, also referred to as operating models, which will enable a more efficient and consistent way of managing data.

5.1. Key features of the OMS and RMS operating models

- Common process for industry to pre-register/update Organisations and Referentials data before submitting regulatory applications;
- Establishment of a centralised dictionary of Organisations and Lists of Referentials to be used as a reference for, and in support of, EU regulatory activities;
- Data validated by EMA data stewards and made available in a structured format in line with ISO/EU standards;
- Validated, re-usable, quality data;
- A system to generate and maintain Organisation IDs and Referential IDs for use in regulatory submissions from across EMA, industry and NCAs;
- Common API interface for exchange of Referentials and Organisations data.

6. Data management

In order to reflect changes/updates in SPOR data in their local systems, NCAs and industry may need to enhance their local data to align with ISO/EU data formats within RMS and OMS in the following ways:

- 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;
- Data mapping – where there is a need to maintain local data, e.g. local controlled vocabularies, mapping may be required between local data and central SPOR data to produce outputs in line with ISO/EU terminology and formats.

NCAs and industry will also need to synchronise or maintain mappings in their local systems with RMS and OMS on an ongoing basis in order to ensure they are using the correct data in regulatory submissions. They may choose to make use of the RMS and OMS web APIs to support them in automating the synchronisation of data or in the maintenance of the mapping of the data.

7. EMA IT Service Desk

The EMA IT Service Desk will provide technical support for SPOR data management services for all stakeholders. More information will be provided nearer to RMS and OMS go-live, such as contact details and the specific help that will be on offer.