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Information Management Division

Referentials Management Services (RMS) operating model

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1. Purpose of the document

This document is intended to provide both guidance and information for stakeholders who are supporting the implementation of the SPOR programme and for all stakeholders who will be using RMS data management services. The information applies to both human and veterinary stakeholders; however there may be different impacts experienced by NCAs and industry stakeholders.

2. Executive summary

Referentials data is the data used to categorise other data within applications and databases. It is usually referred to as controlled vocabularies, dictionaries, (drop-down) lists or domain values. Typical examples of referential data are pharmaceutical forms, units of measurement, routes of administration, countries, etc. Regulators and industry stakeholders require referentials lists and terms for regulatory procedures and submissions (e.g. pharmacovigilance, marketing authorisation applications or clinical trials) across the product lifecycle, and for products that are regulated in the EU.

Referentials Management Services (RMS) is part of the phased implementation of the **SPOR programme**. The goal of SPOR is to deliver services that will centralise the management of pharmaceutical and regulatory data for **Substances, Products, Organisations, and Referentials** (SPOR master data) and **enable** a consistent basis for **reuse** by EMA, NCAs and industry. Benefits of SPOR data are expected to be realised incrementally as all phases of SPOR are delivered and data is used by different business processes.

The key to achieving the goal of SPOR is the **RMS operating model**. It provides a common understanding of the RMS services by allowing visualising the services from a variety of stakeholder perspectives as each significant element of the RMS is represented. **People, process and functional capabilities** are key underlining components to ensure successful delivery of the service.

The **scope of RMS services** includes data content, new process, functional capabilities and a team of data stewards:

- **the central repository and provider of referentials master data;**
- [SPOR web portal](#)¹ and an application programming interface (**API**) via which data can be accessed;
- **a new process** to register and update referential data;
- **EMA Data Stewards** to manage data, applying consistent data quality rules and providing support to stakeholders.

The use of RMS will become mandatory, although staggered when a given regulatory business process begins to use RMS data. More detailed information will be provided (by the relevant business owner) of any process changes, the transition process and timelines. The mandating may vary between human and veterinary stakeholders depending on the implementation timescales and business processes using RMS data.

RMS is already integrated with Electronic Application Forms ([eAF](#)) and supplying referential master data to MAA-Human, Variation, Renewal, and MAA-Vet application forms. In 2018 a new tool to support orphan designation procedures (Scientific and Regulatory Evaluation Procedure Support [S-REPS](#) project) is expected to make use of a group of controlled terms lists.

¹ SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above).

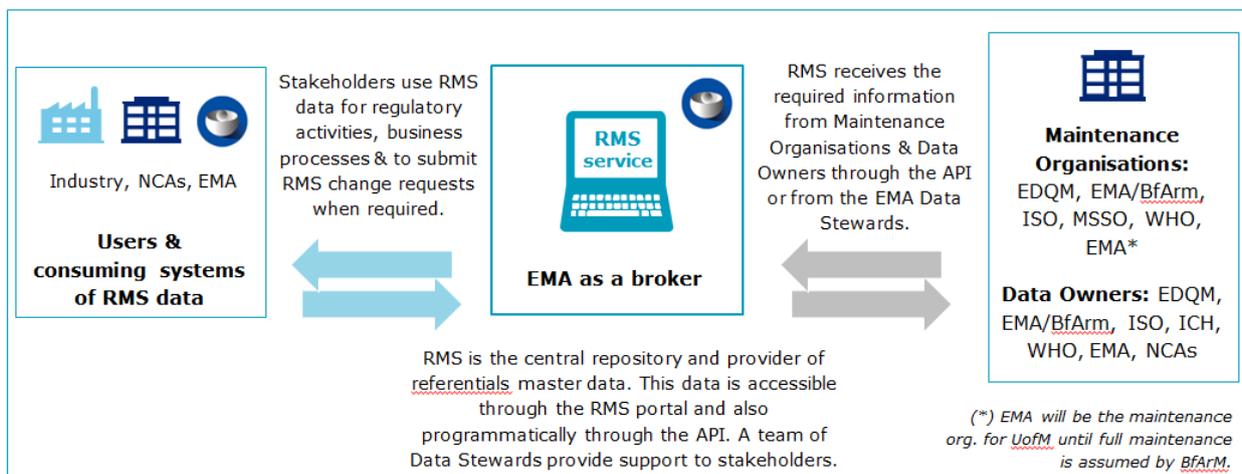
In future RMS data is expected to support regulatory submissions in Telematics systems such as the Common European Submission Portal (CESP), the Clinical Trials (CT) portal, and Art.57/xEVMPD.

The use of RMS data is also envisaged by the CTS system (Communication and Tracking System) which is used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures.

3. RMS operating model in summary

In the RMS operating model, the stakeholders, new process and functional capabilities are the key components to ensure delivery of the service. This document describes the range of services available for stakeholders to use, the process to register referential terms or request data updates. It also outlines stakeholder interactions and identifies roles. The high-level concept of the RMS Operating Model is shown in Figure 1 below.

Figure 1. RMS operating model.



RMS replaces [EUTCT](#) (EU Telematics Controlled Terms) as the central repository and provider of referentials data for the EU medicines regulatory network (EMRN). All lists previously published in EUTCT were migrated from EUTCT into RMS, with the exception of all substance-related lists which will remain in EUTCT until the Substances Management Services (SMS) is delivered (*EUTCT should be used only for browsing and downloading the Substances-related lists*). Therefore, RMS contains over 100 lists of controlled terms including, amongst others:

- EDQM lists of standard terms and Units of Measurement (UoM) lists: these are ISO IDMP standard lists ISO 11239 (pharmaceutical dose form, routes of administration and packaging) and ISO 11240 (units of measurement);
- EudraVigilance lists;
- new lists required for Organisations Management Service ([OMS](#)).

Referentials data will in future be expanded with lists to support ISO standards for Products² and Substances³ (ISO 11238 – referential data to support substance registration, and ISO 11615 – referential data to support products). Further lists can also be added upon request.

² Product Management Service (PMS)

³ Substance Management Service (SMS)

Users (industry stakeholders, NCAs, EMA and other parties) can access the referentials data through the [RMS web portal](#), or programmatically through the application programming interface (API). These users can also request changes/additions to referential data using the RMS portal. The following requests can be submitted:

- creation of new lists and/or terms, or
- request update of existing lists and/or terms, or
- request deletion of terms.

EMA acts as **data broker** (the one-stop shop) and liaises with **Maintenance Organisations** and **Data Owners** to consolidate referentials lists into a single place and structured format and, where relevant, in line with ISO IDMP standards. There are some exceptions when submitting change requests for referentials should not be done via the RMS portal but via the website of the Maintenance Organisation, and these are explained in section 4.1.

In most cases the Maintenance Organisation and Data Owner are the same. The two roles exist for the cases where the Ownership/Accountability lies with one organisation, e.g. ICH, whereas the day to day data management has been delegated to another organisation, e.g. MSSO. Their role, in the context of RMS, is outlined below:

Maintenance Organisations (EDQM, EMA/BfArm, ISO, MSSO, WHO, EMA):

- undertake data management activities for referential terms/lists that they maintain e.g. regular lists updates, improvements of publication formats;
- register legacy terms in RMS.

Note: EMA will assume the role of a Maintenance Organisation for new lists where no maintenance organisation currently exists.

Data Owners (EDQM, EMA/BfArm, ISO, ICH, WHO, EMA, NCAs):

- decide how each term within the list should look and how it will be approved/published;
- map and register legacy terms specific extensions in RMS;
- undertake translations of referential terms/lists (only NCAs).

4. RMS process in the regulatory context

EMA manages the process for industry stakeholders and other parties to **register** new terms or to request **updates** of existing **terms** via the **RMS** portal (“submitting a Change Request”). In the context of regulatory procedures, this step is required **before** submitting a regulatory application to the relevant NCA or EMA and is hereafter referred to as “**pre-registration**” of a **new term/term update**.

Pre-registration is already mandated in some regulatory business processes, i.e. in the eAF submissions. If the term is not in the eAF drop-down list, it should be requested through the RMS portal before the application is submitted to the relevant regulatory authority. EMA Data Stewards will undertake a data quality check upon pre-registration of new or updated terms, independently of whether the lists are owned by EMA (e.g. target species) or not (e.g. standard terms). For terms owned by external organisations, EMA will check with that organisation to validate any requested changes.

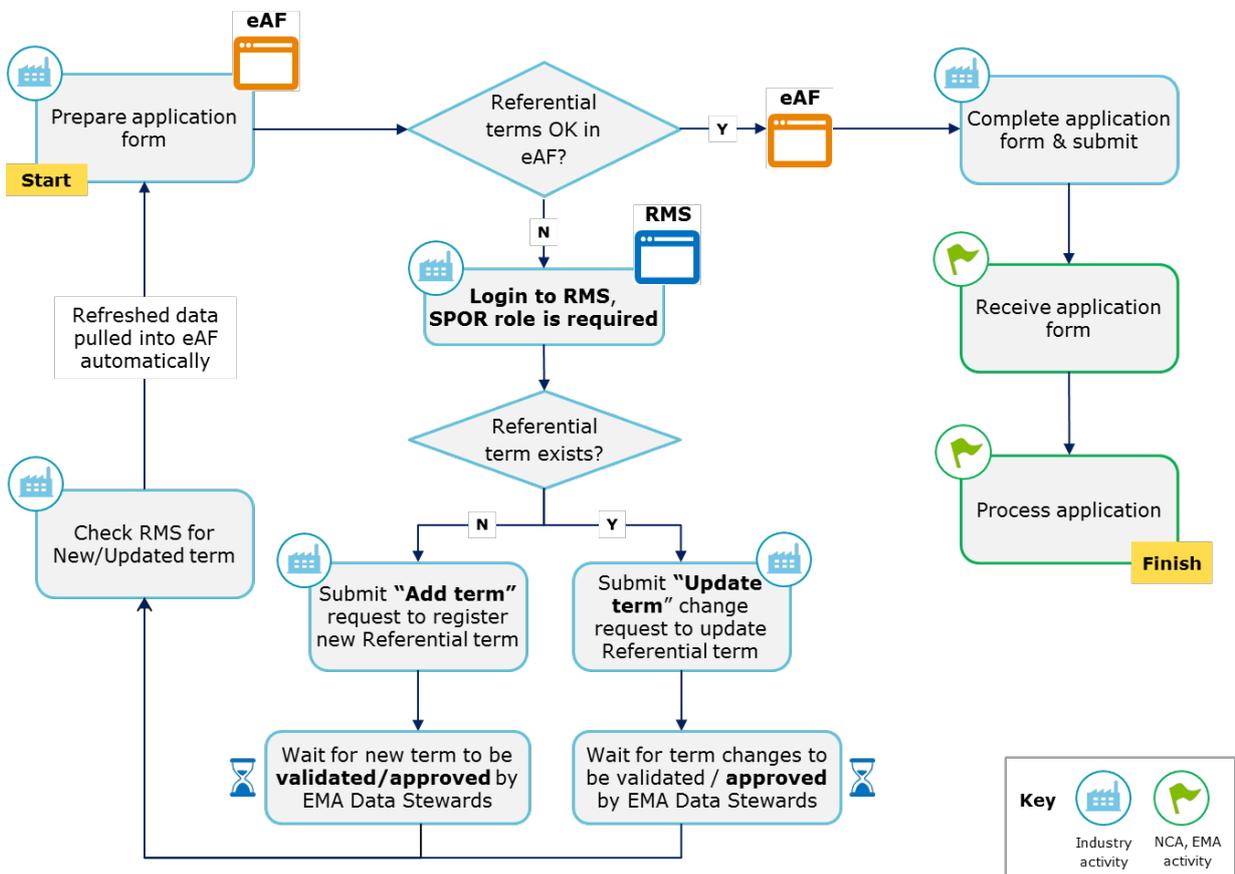
Once a term is registered, it will be made available in the RMS portal and supplied to the eAF. At that point, the applicant can continue with the completion and submission of the application form. The **relevant authority (NCA or EMA) will receive the application and can process it without the need to validate Referentials data against RMS** (as long as the Referentials data supplied to the application form is from a list that is available in RMS at that time).

- In case an NCA disagrees with a term as used by the applicant, they should ask the applicant to update the Referentials list before re-submitting the regulatory application with the correct term.
 - NCAs can request new terms and updates to terms on behalf of an applicant; however, they are encouraged to advise applicants to submit these requests themselves.

Figure 2 below summarises the high-level RMS process in the context of eAF submissions. It identifies activities undertaken by the applicant, EMA Data Stewards, and regulatory authority.

Note: this RMS process can be similarly applied to any other applications/business processes using RMS data.

Figure 2. RMS process in the regulatory context (example of eAF).



The process starts with the preparation of the eAF application by the applicant and allows for different scenarios:

1. Referential term exists and does not require changes

In this scenario, the electronic application form contains the referential term that you require for your application. Complete the application form by selecting the relevant term from the drop-down list

(which is populated with data from RMS), complete the rest of the form, and then submit it. The Regulatory Authority will receive and process the electronic application form.

Note: A SPOR user role is not required in this case.

2. Referential term exists and requires an update – “Update Term”

In this scenario, the referential **term** already **exists**, but a data change is needed. The user should login to the RMS web portal and submit a change request for a term update.

Note: A SPOR user role is required to submit an RMS change request.

After submitting an “**Update Term**” change request, EMA Data Stewards will **validate** the request. Validation usually takes 3-5 working days. Most of the RMS lists feeding into eAF synchronise overnight. However, ATC code and Routes of Administration, for instance, are live (they synchronise almost immediately after the update takes place in RMS). EMA Data Stewards can reject the request at the validation stage if the proposed changes are not acceptable. In other cases, the user should submit a revised “Update Term” request if further information or clarifications are required.

Following the validation stage there is a separate **approval process** that can take up to two months (when the list is owned by RMS):

- if the “Update Term” request is approved the requested changes become visible in RMS (and therefore in eAF) and the term version should be increased;
- if the “Update Term” request is rejected then there is no change in the term details presented by RMS (or eAF). Or
- current terms that are subsequently rejected their status will be updated to NON-CURRENT (no longer recommended for use). In this case the non-current term should be pointing to a CURRENT term that should be used instead.

3. Referential term does not exist – “Add Term”

In this scenario the application form does **not** contain the required referential term for your application. Login to the RMS portal and submit a change request to add a new term.

Note: SPOR user role is required in order to submit an RMS change request.

After submitting an “**Add Term**” change request, the EMA Data Stewards will **validate** the request. Validation usually takes 2-3 working days. Once validated, the new term will become **provisional** and will be available for selection in eAF.

EMA Data Stewards can reject the RMS change request at the validation stage if the request is clearly not valid – a new “Add Term” request would then have to be submitted.

EMA Data Stewards can also return the request at the validation stage in case it is not complete or if additional details are required – the requestor would need to re-submit it with additional information.

Following validation, there is a separate **approval process** that determines the final term naming conventions. Depending on individual List Owners, this can take anything from 1 to 2 months when owned by RMS (there are no approval SLAs for lists owned by external organisations).

- When terms are approved their status becomes CURRENT (approved);
- When provisional terms are rejected their status becomes NULLIFIED.

Requests for new lists and updated lists

Requests for new lists will typically come from National Competent Authorities (NCAs). RMS has a facility to add and publish lists required for Telematics systems. For example, if the new Clinical Trial

portal needs a new list, RMS is where the list should be requested to be created and published. The creation of lists required by systems other than Telematics is outside the scope of RMS. There is also a possibility to “update list”, and this should mostly be used by EMA data stewards.

4.1. RMS business process particulars

There are some exceptions how to register new or updated terms in cases where EMA is not the Maintenance Organisation. Users can see who the list owner is in the RMS portal by selecting the tab > Lists > View lists.

Translation of Terms is an activity undertaken by NCAs only. Technically RMS allows for all terms to be translated, but there are business constraints, as to which terms should not be translated through the RMS portal (i.e. EDQM, WHO, MSSO).

The core RMS functionality and business process exceptions are outlined below according to the stakeholder group.

NCAs:

- Can access and download **all** Lists available in RMS;
- Can request changes to all lists/terms through the RMS portal except for changes to MSSO terms, for which requests need to be sent directly to MSSO (changes will be available in RMS portal via updates from MSSO).
- Translations of terms are undertaken by NCAs only:
 - NCAs can add/amend translations through the RMS portal for Lists maintained by the EMA. To enter translations for the lists not maintained by EMA (i.e. EDQM, WHO, MSSO lists) NCAs will need to follow their usual external processes. For example, for EDQM Terms, NCAs will need to follow the EDQM Standard Terms Working Party process to enter translations to terms owned by EDQM.
 - EDQM has agreed that EMA can create provisional terms in the English language for Terms/Lists maintained by EDQM (to enable EMA to progress their work). However, EMA cannot accept requests for translations into other languages for EDQM Terms. Such translations will come centrally from EDQM as they wish to retain control for translations of Referentials Lists that they maintain.

Table: RMS business process particulars applicable to NCAs.

Lists held in RMS						
	RMS/EUTCT	EDQM	Bfarm/ UCUM*	WHO	MSSO	
	- Country/ Language - Target species, Vet lists - EudraCT lists, TIGes lists, etc	- Dosage Forms - Routes of Administration - Containers/ packaging - Units of Presentation	- Units of measurement * EMA is the maintenance org. for UoFM until BfArM fully maintains it.	- ATC Human - ATC Vet - INN	- MedDRA	
RMS business process particulars						
NCAs	Download/access lists through RMS	Yes	Yes	Yes	Yes	Yes
	Requests changes to lists/terms through RMS	Yes, however NCAs are expected to submit CRs mostly for legacy terms. Majority of CRs are expected to come from industry in the context of regulatory submissions.	Yes, however NCAs are expected to submit CRs mostly for legacy terms. Majority of CRs are expected to come from industry in the context of regulatory submissions.	Yes, however NCAs are expected to submit CRs mostly for legacy terms. Majority of CRs are expected to come from industry in the context of regulatory submissions.	Yes. However, this scenario is unlikely as industry would request term through WHO in the context of preparation of a regulatory submissions.	No, NCAs should submit requests to MSSO. Up-to-date list will be available in RMS through updates from MSSO.
	Add/amend translations through RMS	Yes	No	Yes	No	No

Industry stakeholders

- Can access and download, request changes / updates to EUTCT, EDQM and BfArM lists;
- In case of WHO and MSSO lists, industry stakeholders:
 - can browse these in the RMS portal but will need to go directly to the Maintenance Organisation website to download lists.
 - request changes to lists/terms to WHO first and then to EMA (providing the evidence).
 - RMS doesn't accept CRs for the MedDRA list. Requests should be sent directly to MSSO and the MedDRA list in RMS will be updated soon after every official MedDRA revision.
- Industry stakeholders do not have access to the translations functionality in RMS, as this functionality is only available to NCAs, although they can browse term translations when available.

Table: RMS business process particulars applicable to industry.

Lists held in RMS						
RMS/EUTCT	EDQM	Bfarm/ UCUM*	WHO	MSSO		
- Country/ Language - Target species, Vet lists - EudraCT lists, <u>TIGes</u> lists, etc.	- Dosage Forms - Routes of Administration - Containers/ packaging - Units of Presentation	- Units of measurement <i>* EMA is the maintenance org. for UofM until BfArM fully maintains it.</i>	- ATC Human - ATC Vet - INN	- MedDRA		
RMS business process particulars						
Industry stakeholders	Download/access lists through RMS	Yes	Yes	Yes	Browse only in RMS.	Browse only in RMS. Download through MSSO.
	Requests changes to lists/terms through RMS	Yes	Yes	Yes	Submit CRs to WHO, and additionally to EMA if ATC code required in RMS before next ATC release is published.	No, industry should submit requests to MSSO. Up-to-date list will be available in RMS through updates from MSSO.
	Add/amend translations through RMS	No	No	No	No	No

5. Access to the RMS portal

Any member of the public (as a guest user) can view and search all RMS lists and terms content, without having to log in.

Users must be registered with the [EMA Account Management portal](#) (this is a central point to manage access to EMA systems, including SPOR) and have a relevant SPOR user role to request changes and additions to existing referential data. They will need to be affiliated with a specific industry or NCA organisation.

From 1 July 2018 the use of the RMS web portal will be mandated for submitting RMS data change requests – at this point submission of change requests via mdms@ema.europa.eu will no longer be accepted.

6. Where to find related information and documents

A selection of documents produced as part of the SPOR programme development, as well as slide decks, form numbers of webinars SPOR team held in 2017-2018, are available on the EMA corporate web [site](#). These documents may be a useful starting point for those who are new to the SPOR programme or are part of the implementation teams. More comprehensive documents such as user guides or technical documents are published on the [SPOR portal](#) under the RMS>Documents section.

RMS training videos are published on the [@emainfo](#) YouTube channel. These cover the core functionality for users of RMS.