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RMS web user manual

1.0

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1. Introduction

Factors such as the need to improve the current referential management tool –the European Union Telematics Controlled Terms (EUTCT)– as well as the external regulatory requirements with regards to ISO IDMP led to the implementation of a Master Data Management (MDM) tool covering four domains: Substances, Products, Organisations and Referentials (commonly abbreviated as "SPOR"). This tool consists of a common SPOR web portal containing the 4 above-mentioned domains.

The Referentials Management Services (RMS) is a tool that facilitates the registration and maintenance of controlled vocabularies (also known as referentials) and the provision of these controlled vocabularies through a web user interface (UI) and an Application Programming Interface (API). The number of controlled vocabularies contained in RMS can be expanded as required by business.

Of note, RMS is a centralised service where all requests for the creation/update of referential data should be sent to regardless of the person/entity triggering the request. The implementation of structured referentials data with unique IDs will also support the implementation of ISO IDMP standards such as the ISO 11615 for medicinal product identification and ISO 11238 for substance identification. Although these standards apply to human medicinal product only the SPOR services will also support veterinary regulatory activities.

This user manual provides users with step-by-step instructions on how to use the RMS web interface, including activities such as the creation or the update of a new term or a new list.

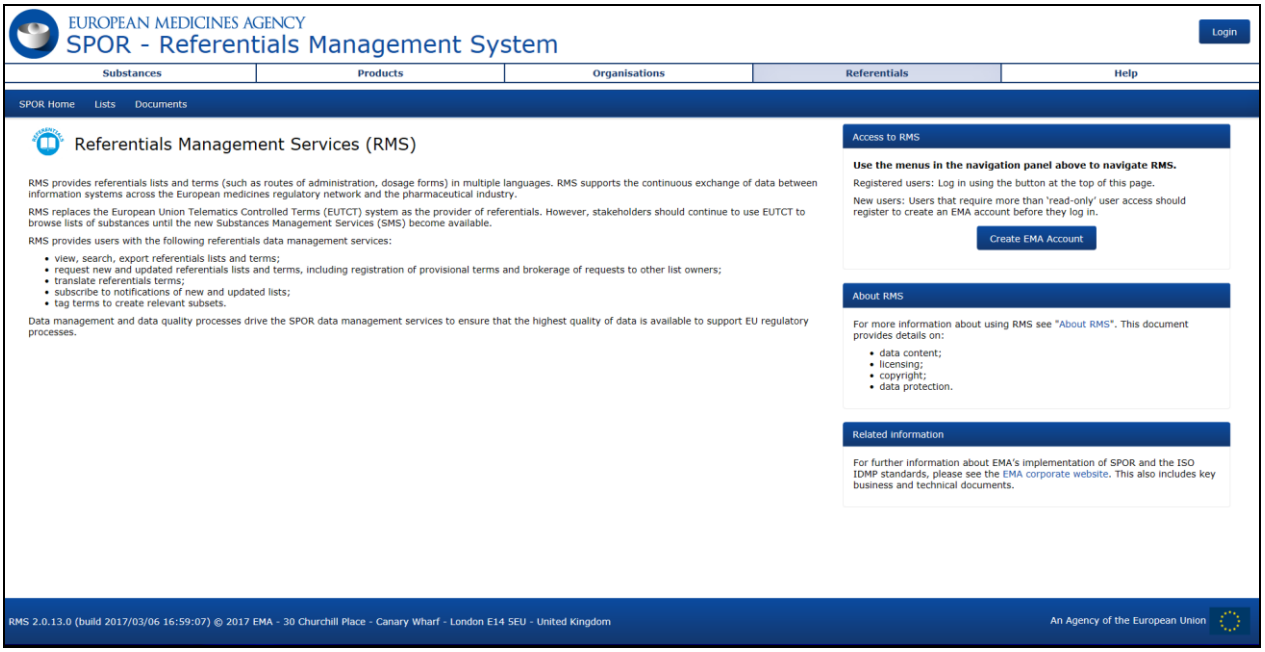
This manual does not describe the EMA internal data and process flows. Instead a separate manual ("RMS IDD&IDQ Manual") focusing on these aspects has been compiled for EMA data stewards. This manual is only for internal EMA use and therefore it is not published on the SPOR Help section.

All aspects regarding user registration, logging in SPORT, etc. are covered in another manual called "SPOR User Registration Manual", which can be found in the SPOR Help section.

2. Accessing RMS

2.1. Web landing

To access RMS, go to http://spor.ema.europa.eu/rmswi/#/. The landing page below will appear.



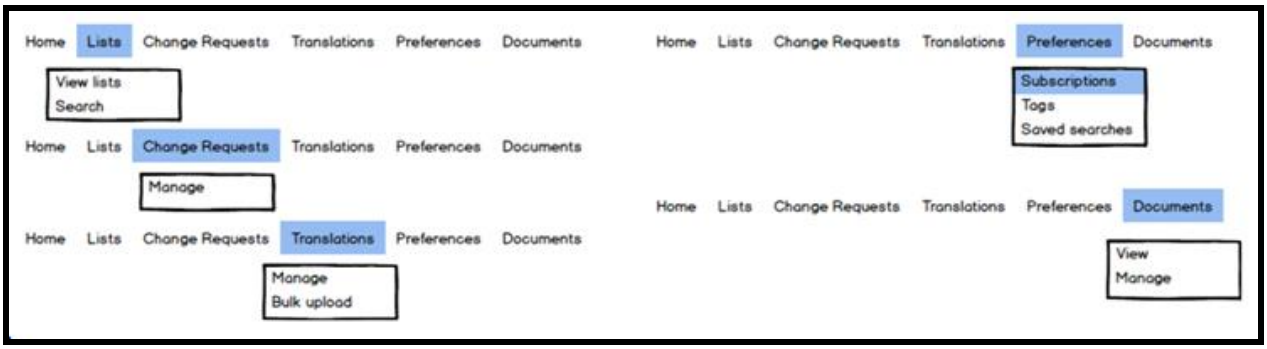
The landing page contains a description of RMS, as well as a link to an "About RMS" document which has information on licensing and copyright aspects, amongst others.

At the time of drafting this user manual, although the 4 domains of SPOR are shown in the landing page, only the Organisations and the Referentials areas are active. When the PMS and SMS projects are delivered in the future, this same landing page will allow for a seamless navigation between the four domains.

Once in the landing page, anybody can navigate within the Referentials area as a Guest user without the need to log in. However, in this case only public information (Lists and Documents) will be available for browsing only and no user preferences will be available.

All users (including guest users) can also access the Help documents by clicking on the "Help" tab, at the top right corner of the screen, which includes the web user manuals for RMS and OMS and other supporting documents. Documents such as the API specifications will be under the "Documents" tab in the menu bar, not under the "Help" button.

The screen below shows the functionalities available for registered users in RMS under each one of the tabs of the menu bar. The functionalities available to each user will depend on the user's role and the permissions linked to it (see more details in section *2.2. Stakeholder roles & permissions*). All of these functionalities will be explained in this user manual.


Home Lists Change Requests Translations Preferences Documents
View lists
Search
Home Lists Change Requests Translations Preferences Documents
Manage
Home Lists Change Requests Translations Preferences Documents
Manage
Bulk upload
Home Lists Change Requests Translations Preferences Documents
Subscriptions
Tags
Saved searches
Home Lists Change Requests Translations Preferences Documents
View
Manage

2.2. Stakeholder roles & permissions

The table below lists all the roles in the SPOR Services and provides a description of each one of them, including details on the permissions assigned to each role with regards to the MDM applications, the Web User Interface (UI) and Identity and Access Management (IAM). As mentioned in the introduction, this manual won't cover any aspects related to registration and logging in to SPOR. If required, please refer to the "SPOR User Registration Manual" located under the Help section of the SPOR landing page.

SPOR Role	**Description**	**MDM applications Permission Overview**				**Web Permission Overview**								**IAM**	
		IDD	IDQ	Active VOS	MDM Hub	OMS Web	RMS Web	View*	Export	Request	Translate	Preferences	Manage Docs	Approve access	Additional Attributes
EMA Admin	A logged in EMA user with permissions to the administrative and configuration functions within MDM, in addition to all data steward functionality. Typically an IT person.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y (EMA Data Steward)	None
Data Steward	A logged in EMA user with permissions to Informatica Data Director (IDD) and Informatica Data Quality (IDQ) Analyst. Responsible for managing the cleanse rules and profiling list data within IDQ. responsible for actioning change requests for new/amended SPOR data and for resolving potential merges raised by the match process within IDD	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y (Any Super user)	None
EMA Super User	A logged-in user employed by EMA who has been authorised as the super-user for EMA. They will be able to view and download data and to submit change requests. (They will also be able to authorise 'Unaffiliated Users' to become 'EMA Users', although the processing of that will be outside of the scope of SPOR).	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	Y (Any user within its organisation)	Organisation
EMA User	A logged in user employed by EMA and authorised by the super user for EMA. They will be able to view and download data and to submit change requests.	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	N	Organisation
Guest User**	Any user (registered or not) who accesses/views the publicly available information web portal without logging in.	N	N	N	N	Y	Y	Y	N	N	N	N	N	N	None
Unaffiliated User	A logged in user who has self-registered via the IAM platform but is not yet linked to any organisation. They will be able to view the same information as a Guest User, but will also be able to export that information. For OMS only, they will be able to submit change requests for a new organisation, limited to one pending request at a time.	N	N	N	N	Y	Y	Y	Y	Y***	N	Y	N	N	None
NCA Super User	A logged-in user who has been linked to a National Competent Authority and has been authorised, by EMA, as the super-user for that organisation. They will be able to view and download data and to submit change requests. (They will also be able to authorise 'Unaffiliated Users' to become 'NCA Users' although the processing of that will be outside of the scope of SPOR).	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	Y (Any user within its organisation)	Organisation
NCA User	A logged in user employed by a National Competent Authority and authorised by the super user of that NCA. They will be able to view and download data and to submit change requests.	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	N	Organisation
NCA Translator	A logged in NCA user with additional permissions allowing them to create and amend translations for one or more specified languages.	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N	N	Organisation Country Language(s)
Industry Super User	A logged-in user who has been linked to an organisation within the pharmaceutical industry that is not a National Competent Authority and has been authorised, by EMA, as the super-user for that organisation. They will be able to view and download data and to submit change requests. (They will also be able to authorise 'Unaffiliated Users' to become 'Industry Users' although the processing of that will be outside of the scope of SPOR).	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	Y (Any user within its organisation)	Organisation
Industry User	A logged in user, employed by an organisation within the pharmaceutical industry that is not a National Competent Authority and authorised by the super-user of that organisation. They will be able to view and download data and to submit change requests.	N	N	N	N	Y	Y	Y	Y	Y	N	Y	N	N	Organisation

2.3. RMS data classification

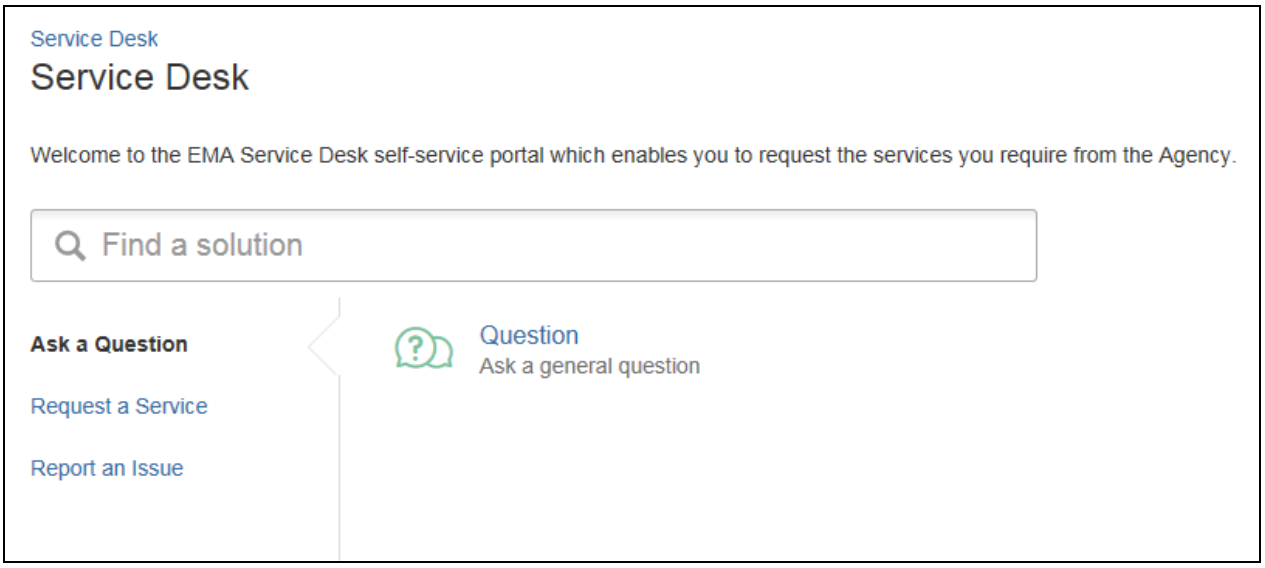
There are three levels of data classification in RMS which will determine what lists and terms a user will be able to view:

1. Public: available to all users (guest, unaffiliated, Industry, NCA and EMA groups);
2. Restricted: available to EMA and NCA users but not for Industry users;
3. Confidential: available to EMA users only.

2.4. EMA Service Desk ("JIRA")

The EMA Service Desk ("JIRA") is a customer support service that should be used to send any general or technical queries related to SPOR. To do so, log in EMA Service Desk (https://servicedesk.ema.europa.eu) and select the relevant category:

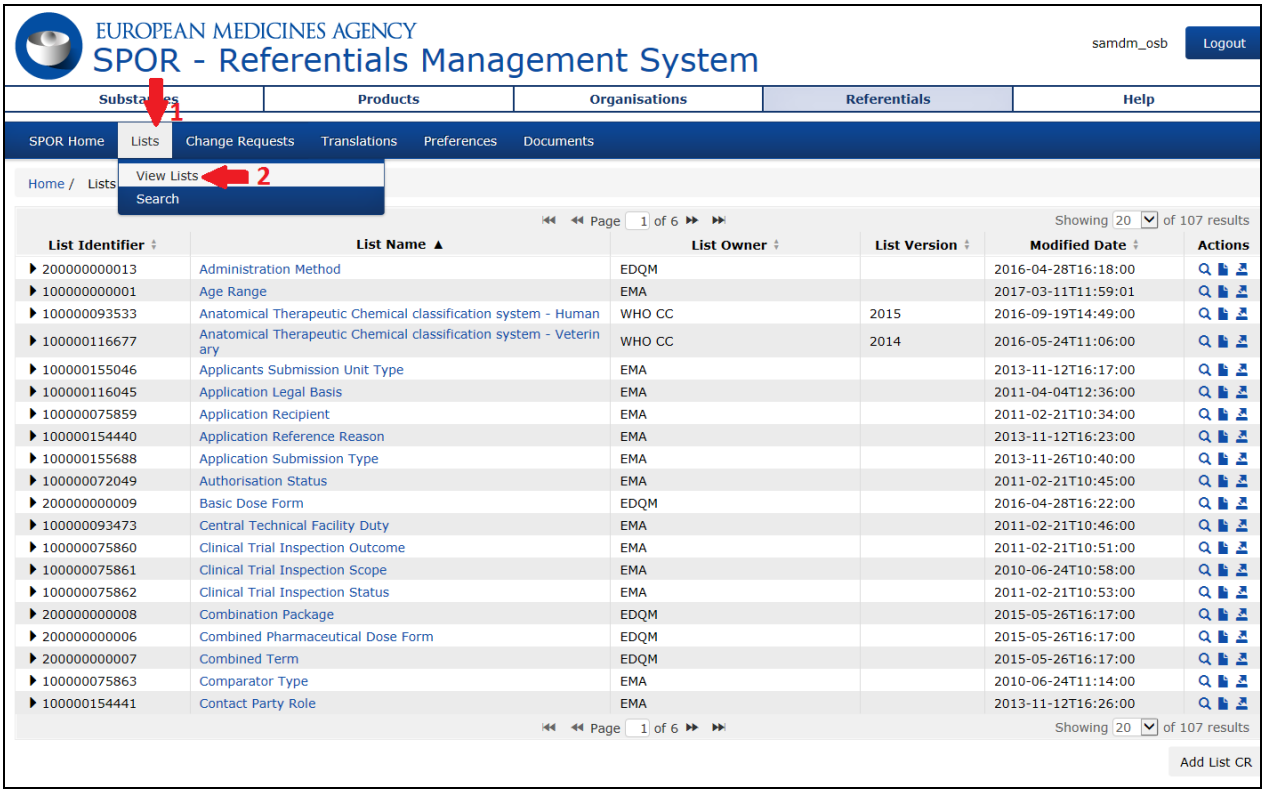
- For general or business-related questions on SPOR, click on "Ask a Question" link in the screen below.
- For any technical/software-related issues, click on "Request a Service" (as shown in the screen below) and on "Report an issue with business applications/software" in the next screen.
- To request SPOR Super User access, click on "Request a Service" and follow the instructions provided in "SPOR User Registration Manual".



3. RMS functionalities

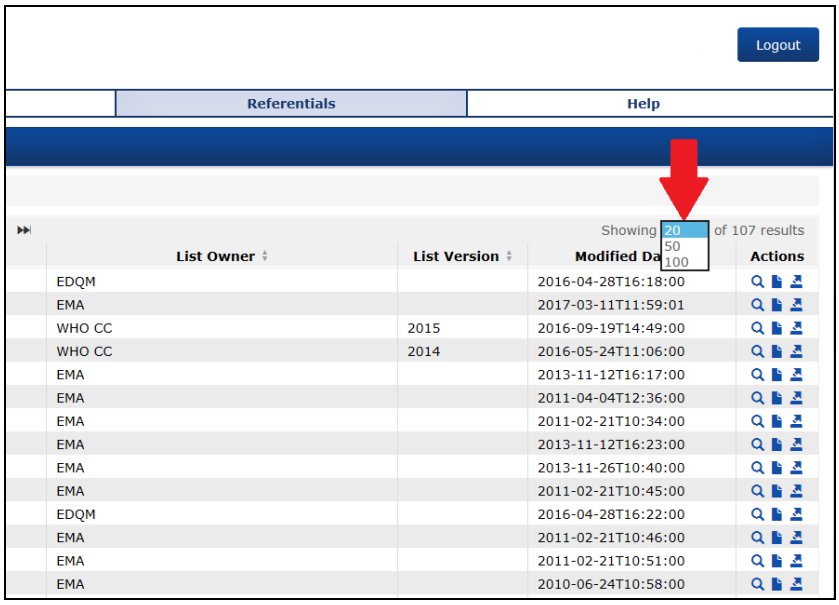
3.1. View Lists

In order to browse through the list of all the referentials lists that a user is authorised to view (based on his/her role and the RMS visibility values), the registered user should click on "Lists" on the menu bar and then on "View Lists", as shown on the screen below:

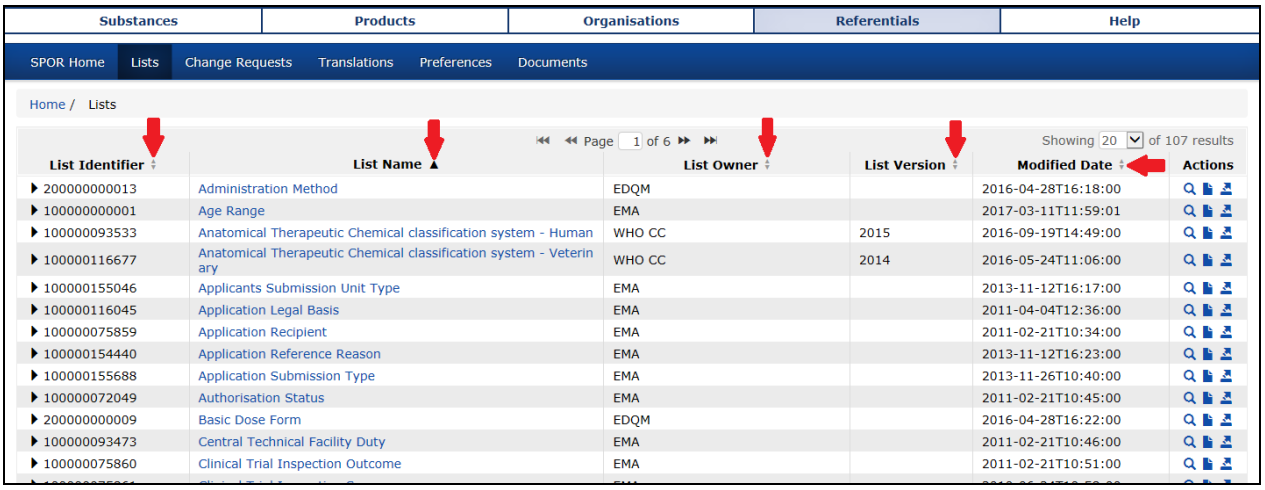


The lists appearing in this screen will always refer to the most up to date version. The high-level list attributes such as "List name", "List owner", etc. will also be visible in this view.

In addition, the number of lists to be displayed per page can be selected through the drop-down list on the top right corner of the screen as indicated by the red arrow below.

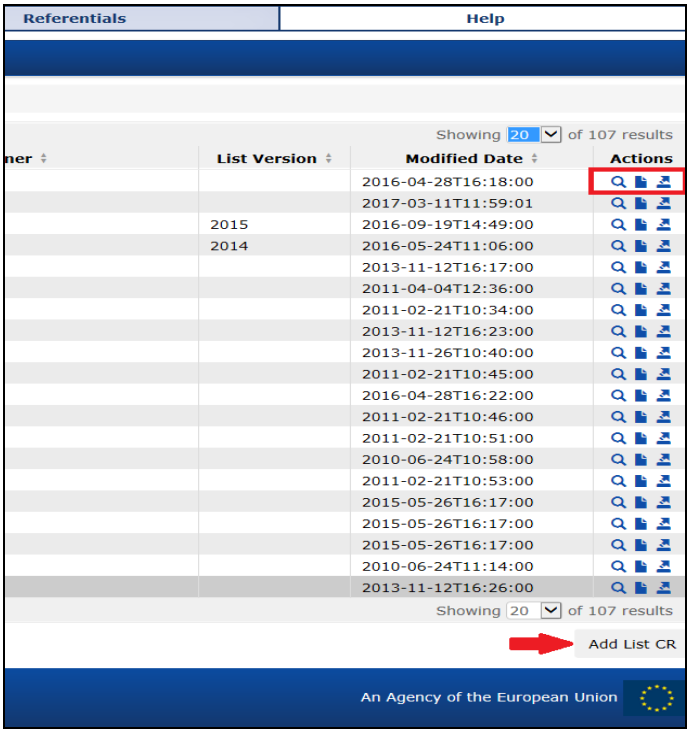


Lists are sorted by default in ascending alphabetical order (A to Z) by list name. However this can be altered by clicking on the arrows next to the column headings (marked below with a red arrow) do that the date is displayed in ascending or descending order.



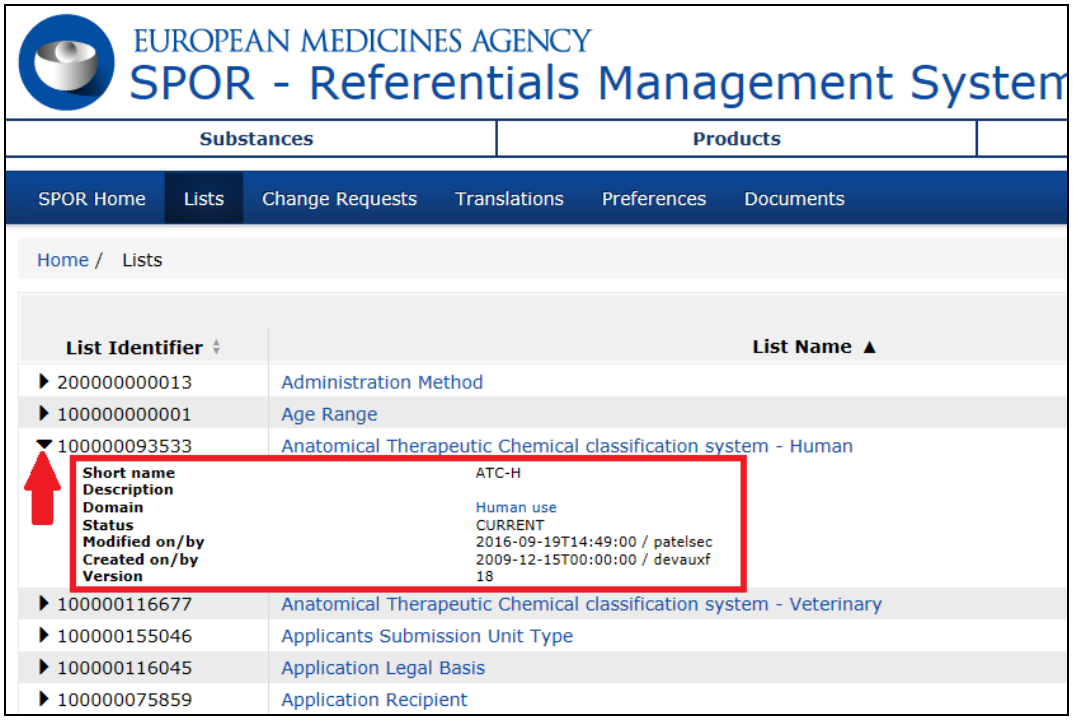
This view level also allows users to do the following (all of the functionalities below will be explained in detail further down in this document):

- View the contents of a list (by clicking on the magnifier icon in red below)
- View the "List Information" document (document icon in red below)
- Export a list (by clicking on the "Export" icon –diagonal arrow- in red below). Only export of individual lists one by one is available on this screen; Export of the list of lists is not allowed here but this can be achieved using the "Search" functionality (explained further down).
- Submit a change request to add a list (by clicking on the "Add List CR" button next to the red arrow at the bottom of the screen below).



3.1.1. View List attributes

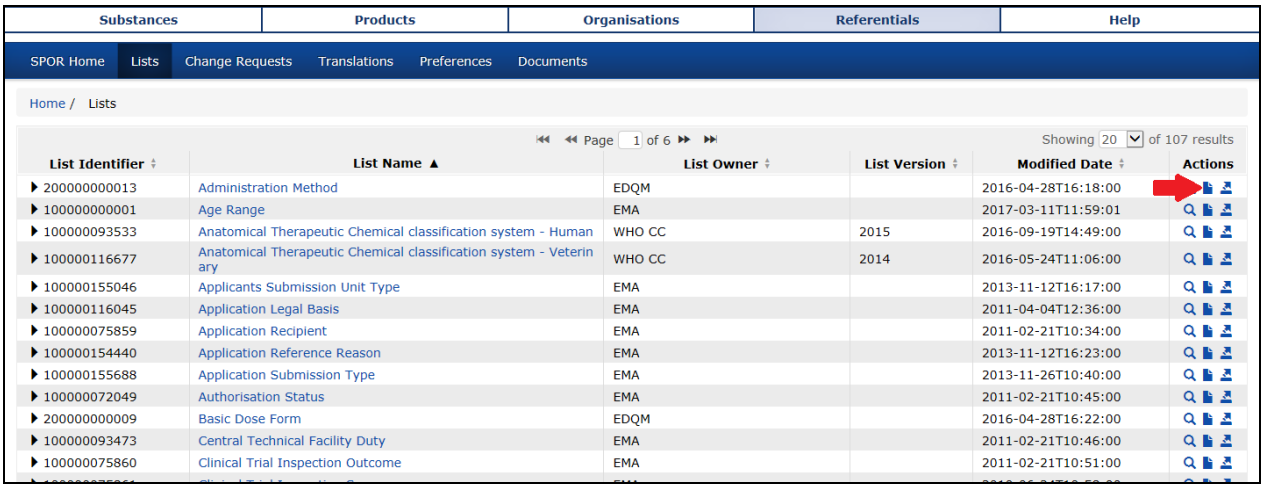
List attributes such as short name, description, domain, status, etc. can be seen by clicking on the black triangle to the left of the list identifier (list ID) as marked in the screen below with a red arrow:



This view shows lower-level list attributes that are not available in the "View Lists" view.

3.1.2. View List Information document

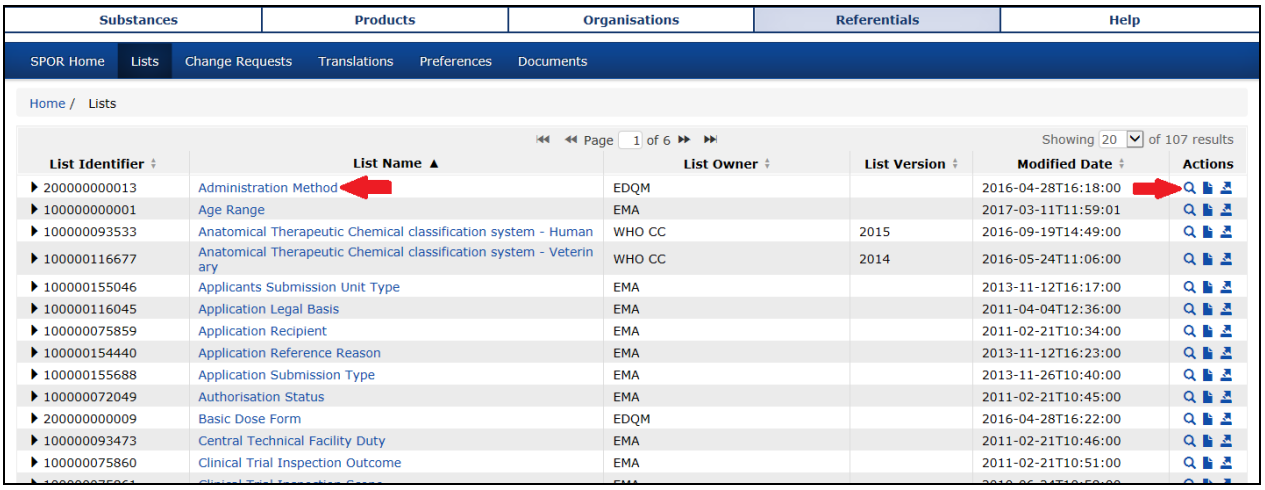
Each RMS list has a supporting document called the "*List information*" document. This is a word document that contains a business description of the list as well as information about the list owner, particularities of the list data structure –such as extended attributes–, an indication on whether users can request changes or not, details on the type of justification and supporting documentation required to submit a change request, etc. This document can be accessed by clicking on the document icon (under the "*Actions*" column) in the row of the relevant list as shown in red below.



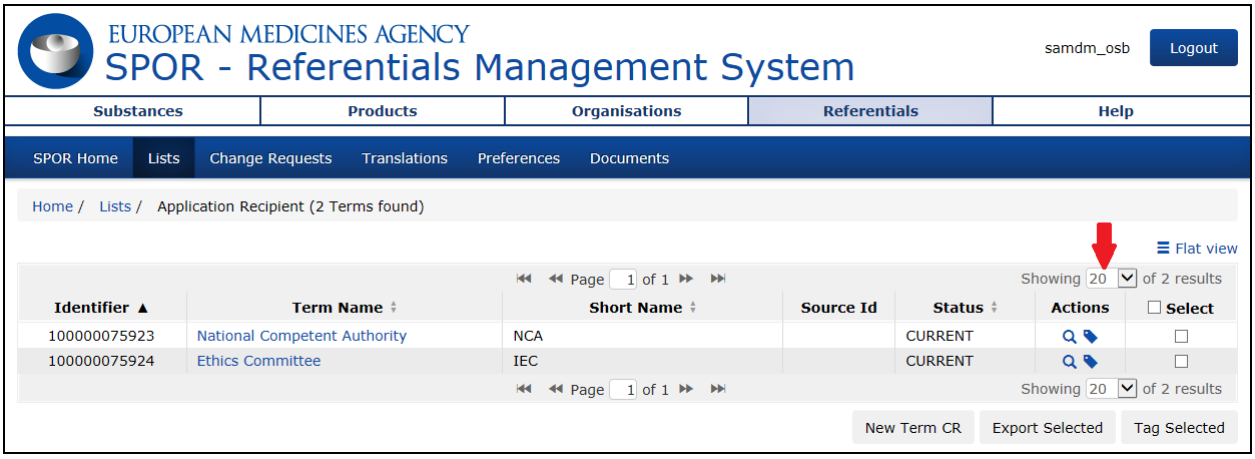
3.2. View List of Terms

3.2.1. Flat lists

To view the list of terms within a list, either click on the list's name or click on the magnifying glass symbol of the list under the "*Actions*" column as shown in red below.



A screen similar to the one below will appear:



Of note, only the terms that the user is authorised to see will be displayed.

Similarly to the "View Lists" screens, the "Identifier", "Term Name", "Short name" and "Status" columns can be sorted in ascending or descending order by clicking on the arrows next to the column headings.

In addition, the number of terms within a given list to be displayed per page can be selected through the drop-down list functionality marked with a red arrow on the top right corner of the screen above.

Also, this screen has a column named "Source Id" which provides the ID of the source where a particular term can be found. E.g. "EDQM" will appear as Source ID next to standard terms (routes of administration, pharmaceutical dose forms, etc.).

Other actions that can be performed in this screen are viewing term details (by clicking on the magnifying glass icon of a term), tagging single or multiple terms (button "Tag Selected"), selecting all/some terms, submitting a change request for a new/updated term (button "New Term CR"), and

exporting the selected terms (button "Export Selected"). All of these actions are described in further detail in section *3 RMS functionalities* of this user manual.

Terms have an equal or higher classification than its list. Therefore:

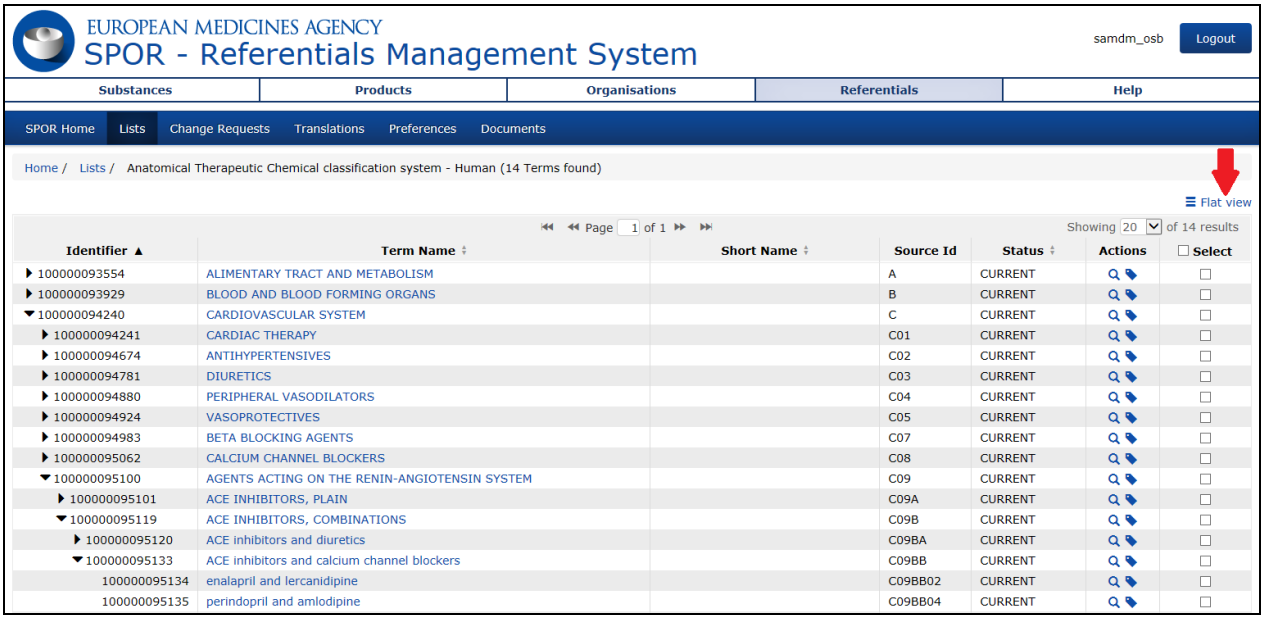
- If the list is confidential, all terms are confidential (available to EMA users only).

- If the list is restricted, terms can be restricted (available to EMA and NCA users but not for Industry users) or confidential.

- If the list is public, terms can be confidential, restricted or public (available to all users).

3.2.2. Hierarchical lists

The process for viewing hierarchical lists is exactly the same as for flat lists, i.e. the user should either click on the list's name or click on the magnifying glass symbol of the list under the "*Actions*" column. However, the view will be different as it will show the list of terms in a hierarchical way as follows:



The user can switch between hierarchical and flat view by clicking on the "Hierarchy View" or the "Flat View" button indicated with a red arrow on the top right corner of the screen above. Of note, this option will only be enabled for hierarchical lists.

Similarly to flat lists, the columns "Identifier", "Term Name", "Short name" and "Status" of hierarchical lists can be sorted by clicking on the arrows next to the column headings. However, by doing so all expanded children will collapse and by default hierarchical lists will be sorted by top level parent, not by the children previously expanded.

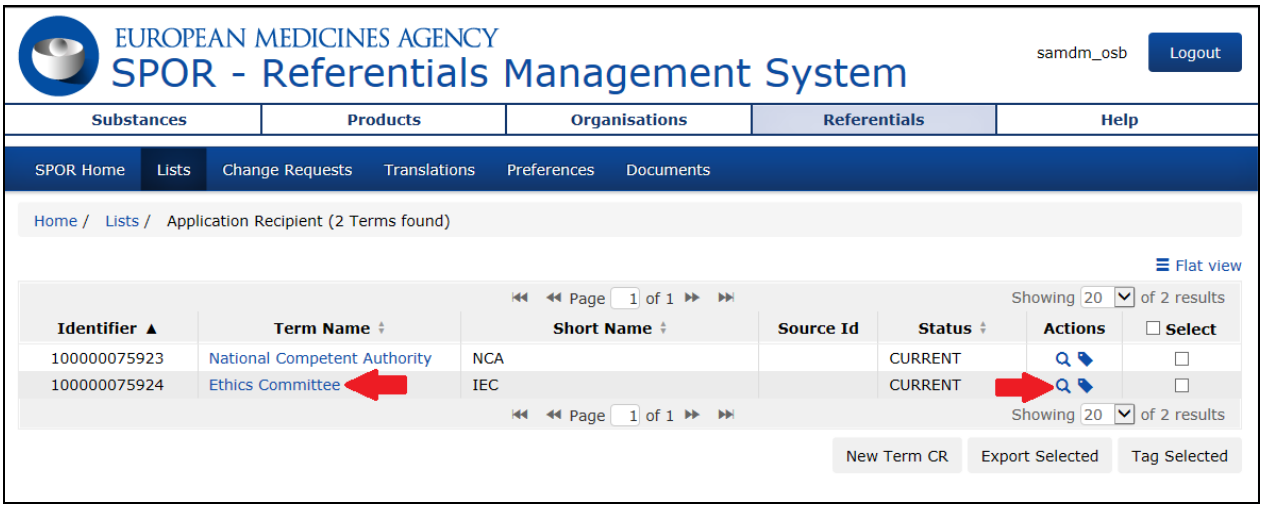
Because some of the lists in RMS are subject to copyright requirements and the full display of these lists is not allowed by the list owners, multiple nodes are expandable but there will only be one active path at a time. Therefore, by opening a new node the system will automatically close any other nodes that may be open and all expanded children of those nodes will collapse.

Other actions that can be performed in this screen are the same as in flat lists, i.e. view term details (by clicking on the magnifying glass icon), tagging single or multiple terms (button "Tag Selected"),

selecting all/some terms, submitting a change request for a new/updated term (button "New Term CR"), and exporting the selected terms (button "Export Selected").

3.3. View Term

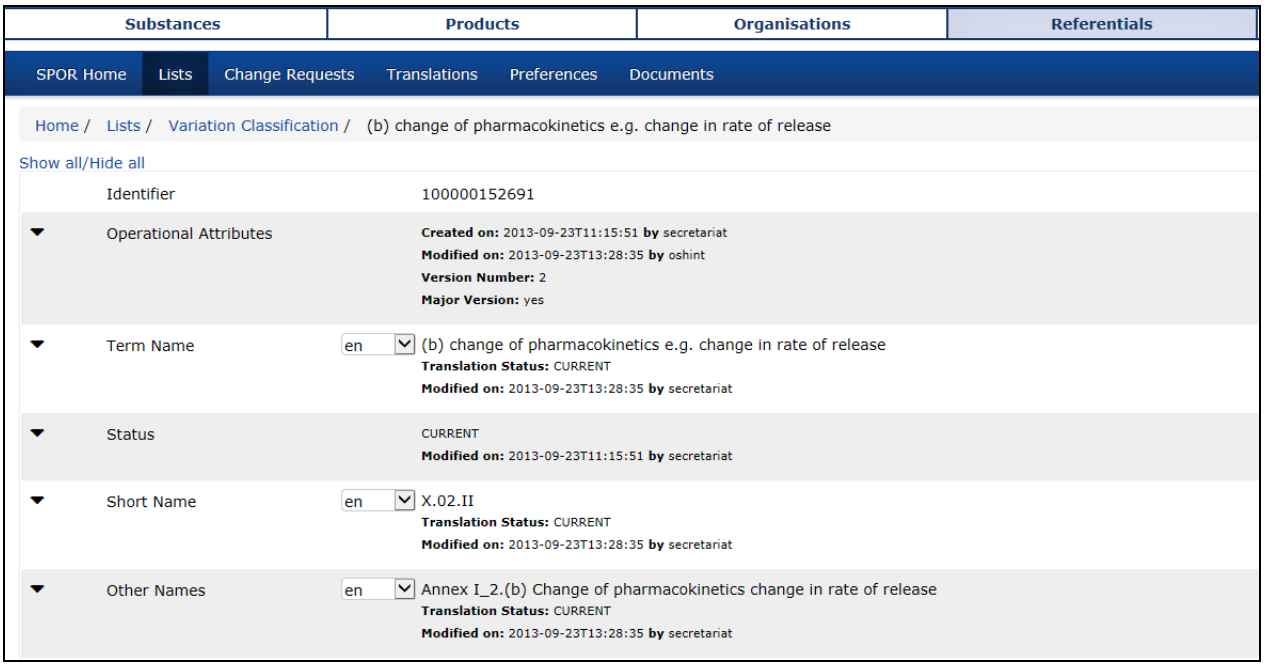
Once within the "View List of Terms" view, the details of a particular term can be seen either by clicking on the term name or on the magnifying glass symbol of the term under the "*Actions*" column as shown in red below:

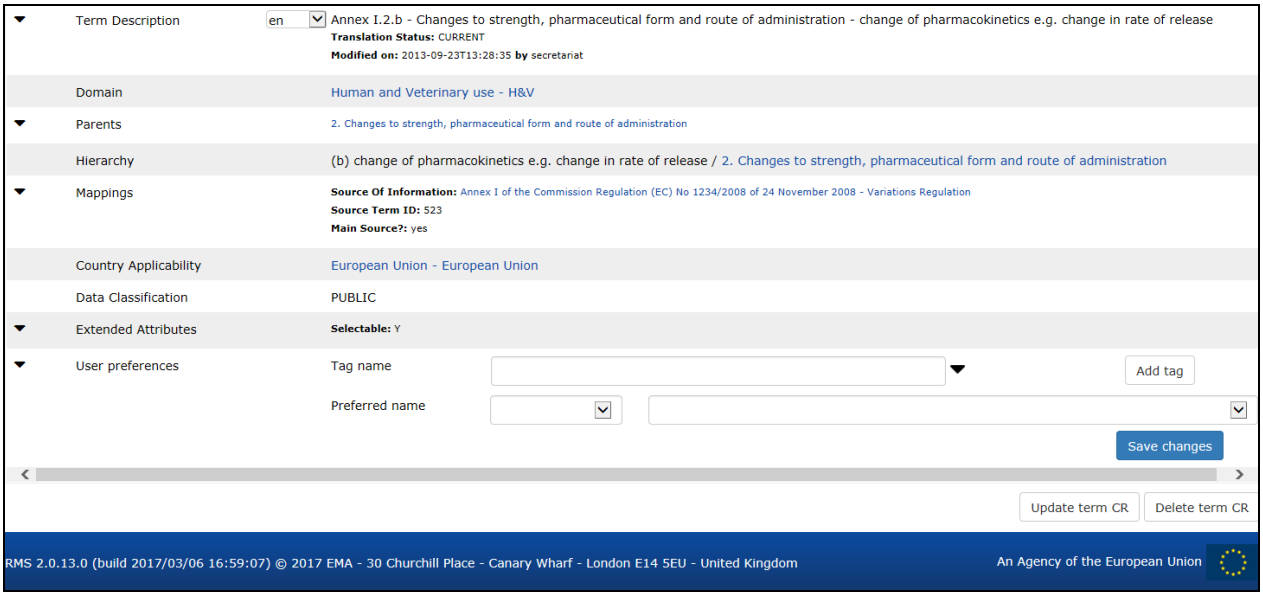


3.3.1. View Term: Common fields

Each particular term is not just composed by the main name and the identifier. RMS stores a big amount of additional information for a given term within a list, including the operational attributes, status, short name, other names, translations, descriptions, hierarchy, mappings, extended attributes (list-specific) and .

The screen below is a generic screen showing all the term details that can be associated to a term in RMS:





The comments in blue in the screen above are business rules which will not appear on the screen but are shown here for your information:

Identifier - This field contains the identifier of the Term. This is a unique sequential 12 digit number across all Lists within the system.

Operational attributes – This field contains the operational details of the term:

- Created on – date the Term was created
- Modified on – date the terms was last modified
- Version number –current version of the term (any change to a term, whether a minor typo correction, translation or any attribute generates a new version of the Term. In addition each version will also have an indicator of whether it is a major or minor change, see below).
- Major version - Flag to indicate if this version is a major one:

- Y= Major: New terms, Updates to term statuses, Updates to EN Term name/description (unless typo)
- N= Minor: updates to other term attributes including translations

Term name - This field contains Preferred name for the Term

Short name - If completed, this field contains any shortened name the Term might have, for example an acronym or other forms of abbreviation. This is usually created to facilitate display on screens where a shorter version might be friendlier and will be considered depending on the request for the list as well as its nature. We allow only one short name/language as it its meant to be the abbreviation of the preferred name which is also 1/language. If there is the need for more than one abbreviation they can be considered under other names (many/language) this way giving a preference to the abbreviation under short name. The association of a term name with the short name is implicit only as there is only one preferred name and one short name per term).

Other names – If completed, this field contains aliases (any other names other than preferred name and short name) in any language (and as many aliases/language as needed). There is no order of importance amongst them. The aliases in English are not specifically/explicitly synonyms of the preferred name or short name. The aliases in different languages are not translations of each other.

Term description – If completed, this field contains a detailed, concise and accurate description of the Term.

Status - This field contains the Term's status and contains one of the following values (status):

- Draft - When a Term is created by the requestor prior to submission to the RMS solution. This Draft Term is only visible to the requestor.
- Provisional - When a Term is created after validation by the EMA Data Steward but prior to approval by the List Owner. The full detail of this Term is visible to all users.
- Current – When a Term is approved by the List Owner for use in new applications/records.
- Nullified – When a Term has been published in error and needs to be removed.
- Non-current – When a Term is not approved by the List Owner for use in new applications/records and/or refers to legacy data.
- Under consultation – This will apply to Lists/Term which are being made available for consultation and indicates that the content of the List has not been sign-off by the List owner. This will only be used in exceptional circumstances.
- Modified on

Current Term – This field will only be completed if the status is either non-current or nullified. If completed, this field contains the indication of the current term(s) that should be used instead.

Domain - This field contains a link to a Term from the Domain List. This field describes which Domain the Term is from (Human only, Vet only, Human and Veterinary).

Parent - This field contains details of the Parent Term and the Parent Source Term ID. It is only visible for Terms within hierarchical Lists.

Hierarchy - This field describes the Term location in the hierarchical structure of its List. The Hierarchical Path is ascending. This is to say the system shows the child Term and then each

subsequent parent, up the hierarchy to the highest level. It is only visible for Terms within hierarchical Lists.

Mappings - A Term can be provided by one or more sources and, in such cases, this section contains that source information. The mapped term in other lists/vocabularies will be semantically equivalent to the RMS term, but its name in the external list/vocabulary might be slightly different to RMS.

- Source of information - External source of information the RMS Term is being mapped to
- Source Term id - Term identifier/code as provided by the source
- Source Term name - Term name as provided by the source
- Source version - Term version as provided by the source
- Main source - Flag to indicate that the mapped term is the main source for a given term

Applicability - Indicator of where the term is applicable therefore restricting the context of where the term is recommended for use

Comments

Data classification - Visibility of the term. The possible values are:

- Public - Available to all users (guest, unaffiliated, Industry, NCA and EMA groups);
- Restricted – Available to NCA and EMA users;
- Confidential – Available to EMA users only;

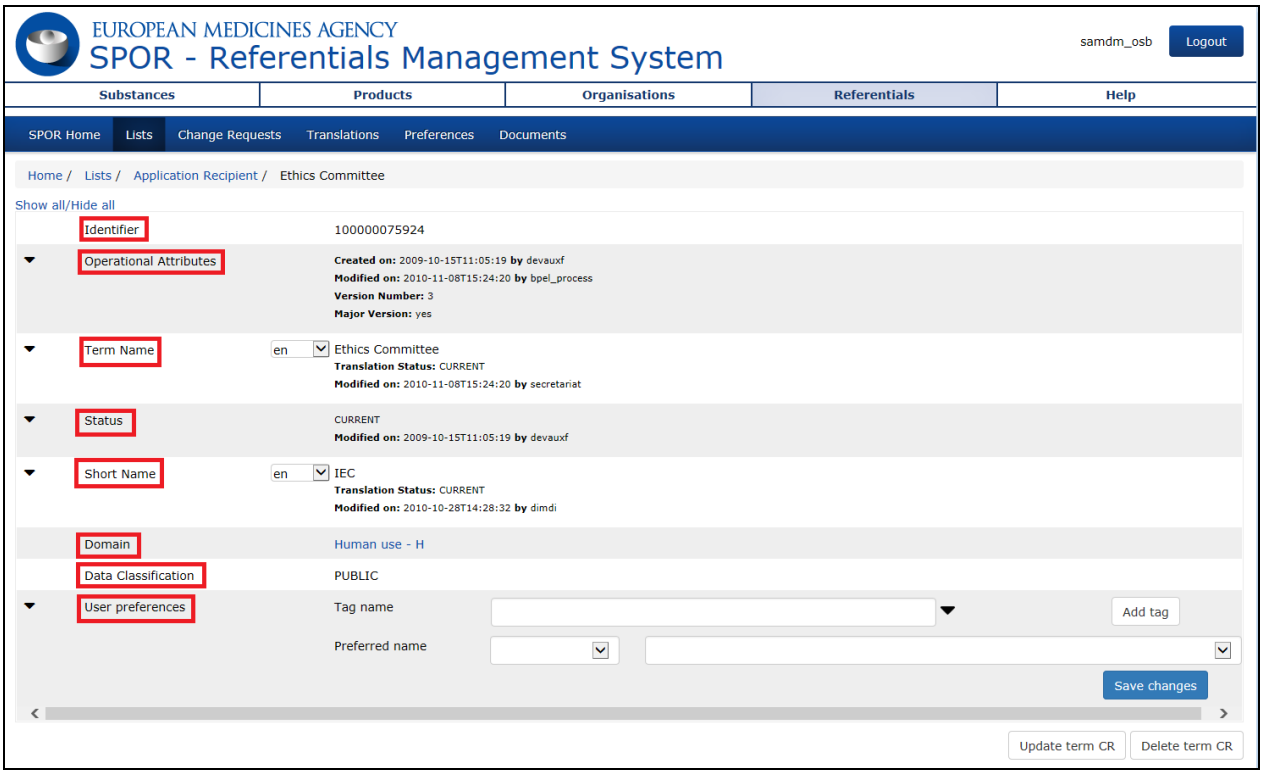
Extended attributes – list-specific attributes (e.g. "state of matter", "transformation", "intended site", in the "Dosage form" EDQM list; "dimension", "conversions" in the "Units of measurement" list). These can contain one or more elements of free text, numbers, dates, Booleans, or can even be used to relate terms across lists (e.g. to relate a country with a country grouping list, or to relate a target species with age, physiological status, or any other lists held in the system.). If a list contains any extended attributes, this information will be explained in the "List Information" document of that particular list.

User preferences

- Add tag
- Tags
- Preferred name

All expandable attributes (including translations, hierarchy, mappings, and extended attributes) would be collapsed on entry by default but are shown expanded here for completeness. In addition, any fields that are not populated for the term being displayed will not appear on the screen.

A more realistic example of a "View term details" screen is as follows:

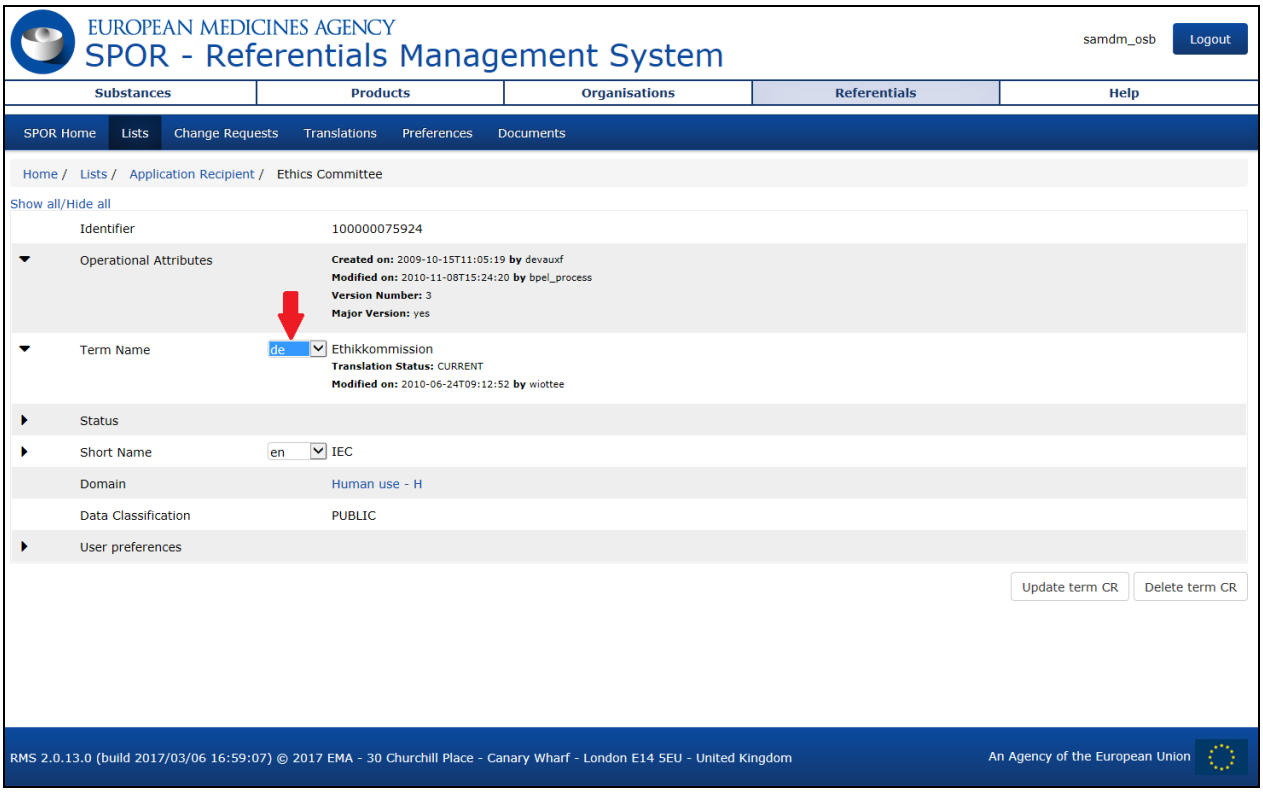


Term details particular for the term selected (in this case *"Ethics Committee"*) are marked in red.

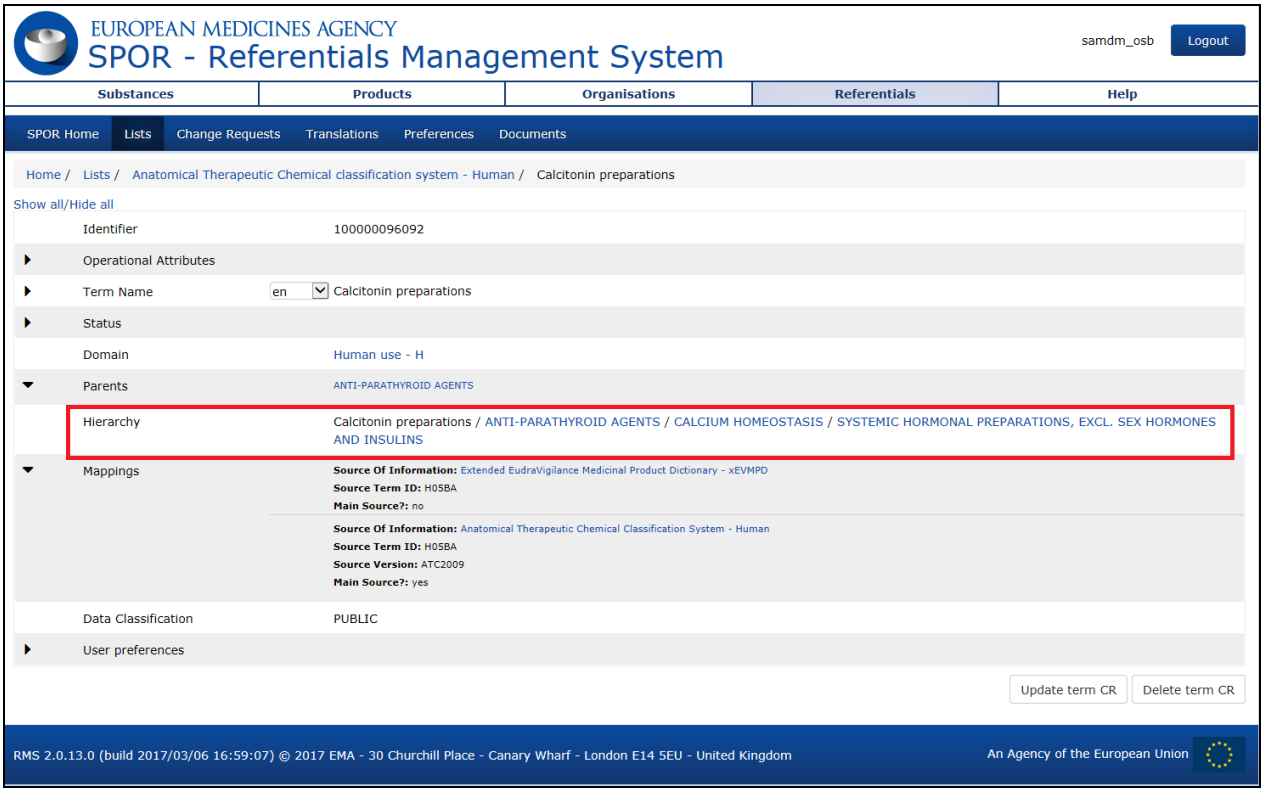
Users can submit a change request for the update or the deletion of any term from this screen by clicking on the "Update term CR" or "Delete term CR" buttons at the bottom of the screen above.

3.3.2. View Term: Translations & Mappings

If the term selected contains any translations, these can be seen by selecting the language required in the drop-down list next to the "Term Name" attribute marked with a red vertical arrow in the screen above:



Terms within hierarchical lists will show their corresponding hierarchical information within the "View Term" view as shown in red below:

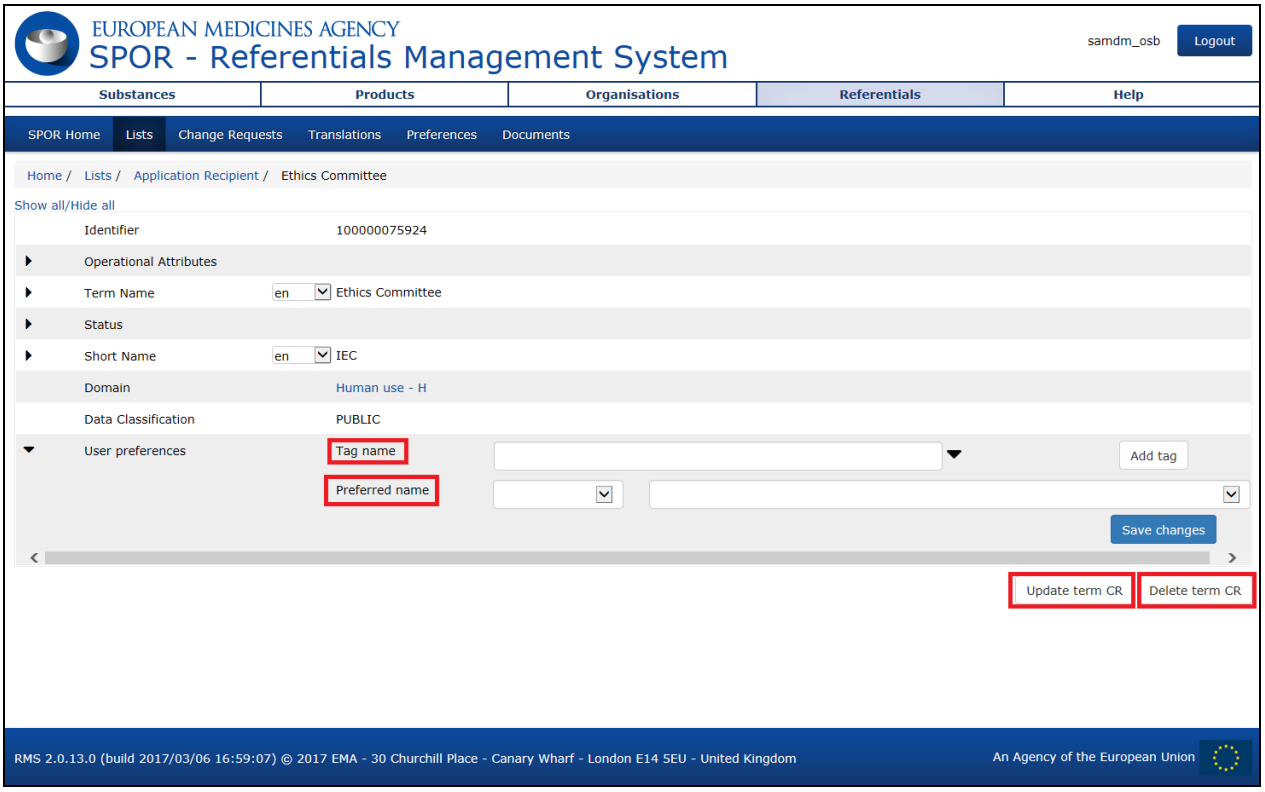


The hierarchy information in red above allows for navigation to any of the sections in blue as these are all hyperlinks.

Users can submit a change request for the update or the deletion of any term from this screen by clicking on the "Update term CR" or "Delete term CR" buttons at the bottom of the screen above.

3.3.3. View Term: User fields

Other self-service capabilities (located in the "User preferences" section of the "View Term" view), which include the possibility to add a term to an existing or to a subset of terms ("tagging"), to remove a term from a subset of terms ("untagging") or to choose the user's preferred name (by default this is the English term name) from either the term name, the short name or any other name in any language, will also be available in this view as shown in red below:



The responsibility for maintaining preferred names lies with the user and therefore it is advised that users adhere to the preferred names as shown in RMS. However, communication regarding a particular term is expected to happen seamlessly regardless of what the preferred term is since all names (term name, short name, synonyms, translations) use the same term ID.

These functionalities are explained in detail in section *3.10 Tags*.

From this view the user will also be able to submit a change request to either update or delete a term ("Update term CR" and "Delete term R" buttons respectively, as shown in red above).

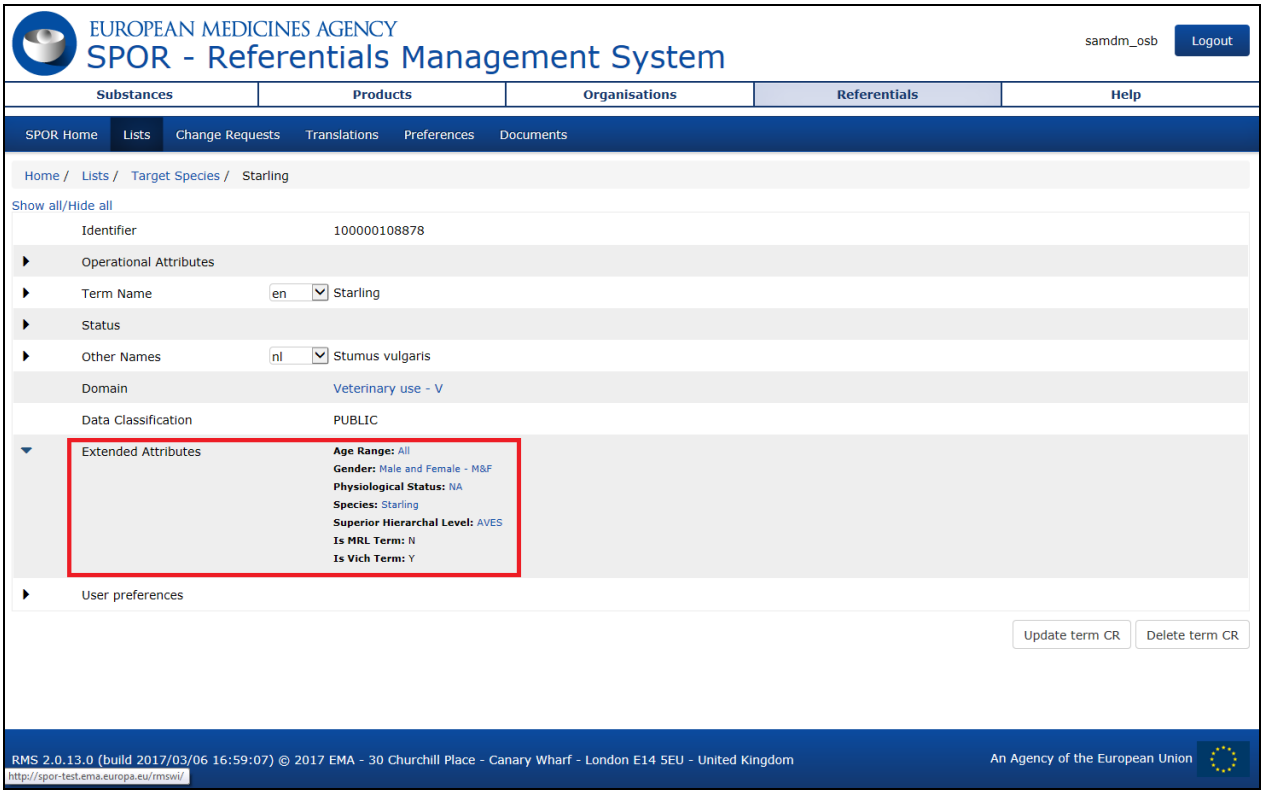
3.3.4. View Term: Extended Attributes

All terms across all lists share a common set of attributes. In addition, terms in specific Lists may have "Extended attributes".

Extended attributes can hold one or many free text fields, numbers, dates, booleans or can be used to relate terms across different lists.

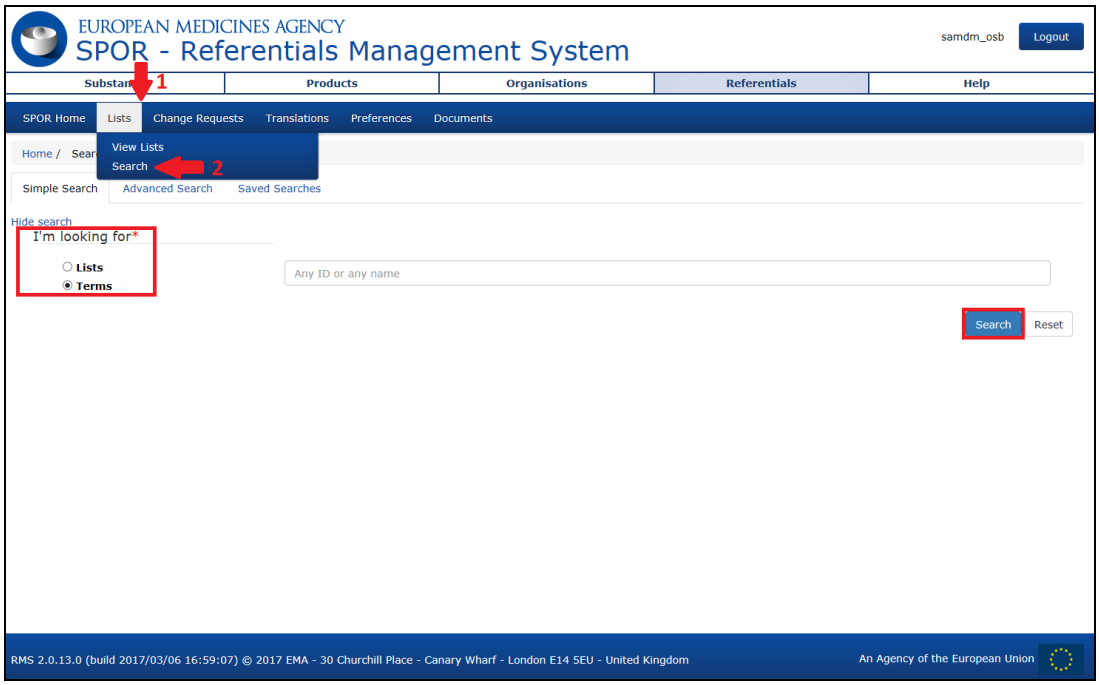
The List Information document contains information on whether the list has "Extended attributes" and what those are.

The screen below shows in red an example of extended attributes for a specific term within a specific list.



3.4. Simple Search

The "Simple Search" functionality allows users to search for lists or terms. Search can be done by any name in any language as well as by any IDs. To do so, users should click on "Lists" in the menu bar under RMS (next to the red arrow in the screen below) and then click "Search".



Under the "Simple search" tab, the user should specify if the RMS system should search for a list or a term in the box shown in red above.

Both lists and terms can be searched by typing either of the following information in the search bar:

1. Identifiers (ID): list IDs, term IDs or source term IDs (only exact matches are shown) –if search by OID is required then the "Advanced Search" should be used (see section *3.5 Advanced Search*).
2. Any names: list names, term names, term short names, term other names, source term names. When searching by name the following needs to be taken into account:
    - Search can be done in any language.
    - There is no predictive typing functionality available.
    - The system provides fuzzy matching (ignores accented characters, caps, common words and some typos), therefore there is no need for wildcards

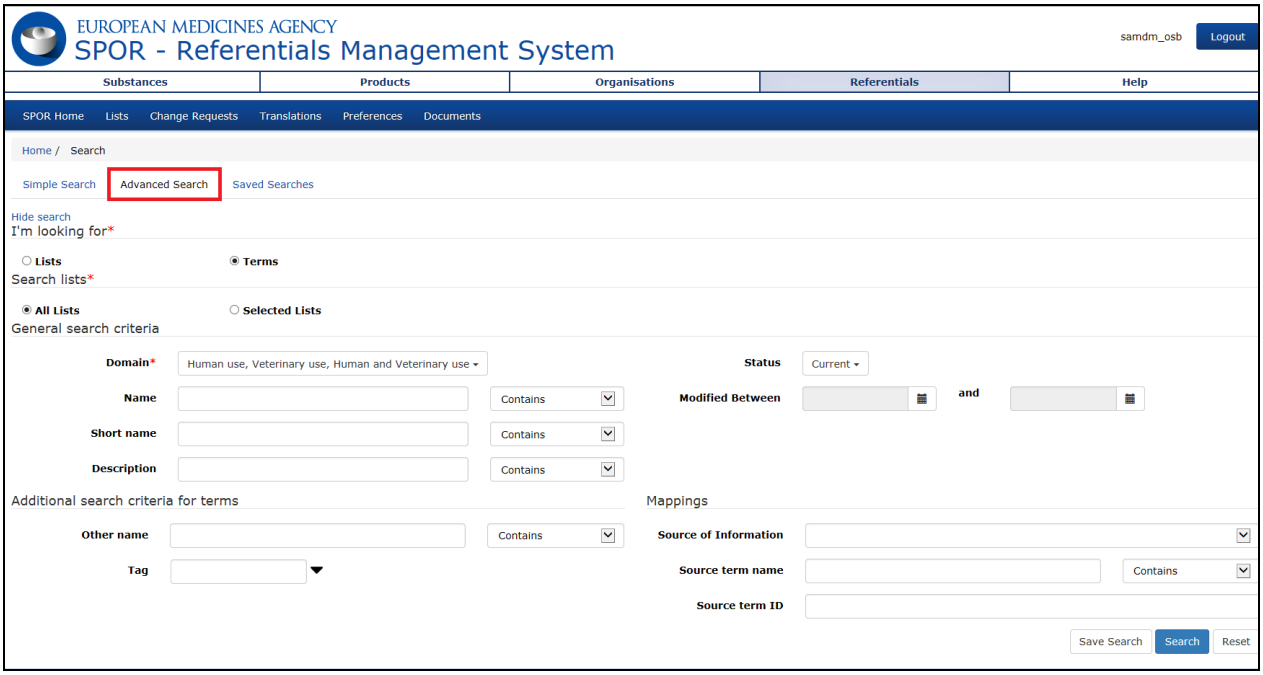
Once the search information has been typed in, the user should click on the "Search" button (in red above).

3.5. Advanced Search

Similarly to the "Simple Search" functionality, the "Advanced Search" functionality also allows users to search for lists or terms.

The "Advanced Search" can be used as a starting point for a particular search or alternatively to refine the search criteria once the user gets the search results from the "Simple Search".

To access the "Advanced Search", click on "Lists" in the menu bar under RMS, select "Search" (same as for "Simple Search") and then select the "Advanced Search" tab marked in red in the screen below. The following screen will appear:



At this point, the user should specify if the RMS system should search for a list or a term as explained in section *3.4 Simple Search*.

Of note, "Advanced Search" doesn't have the fuzzy matching functionality and therefore the system will only give exact matches as results.

3.5.1. Advanced Search (Lists)

When using the Advanced Search functionality to search for a list, the minimum search criteria that the user should enter is the "Domain" (Human/Veterinary/Human & Veterinary). In addition, the user may wish to type in other search criteria such as "Name", "Short name" or "Description" of the list, as well as "Status" of the list or a date range ("Modified between" attribute) where the list may have been modified, for a more accurate search, although filling in these attributes is not compulsory.

As a business rule, the maximum date range that the system allows for searching is one year as it's considered unlikely that users would need to search changes older than that. However, if this is required, users will have to consume the entire database.

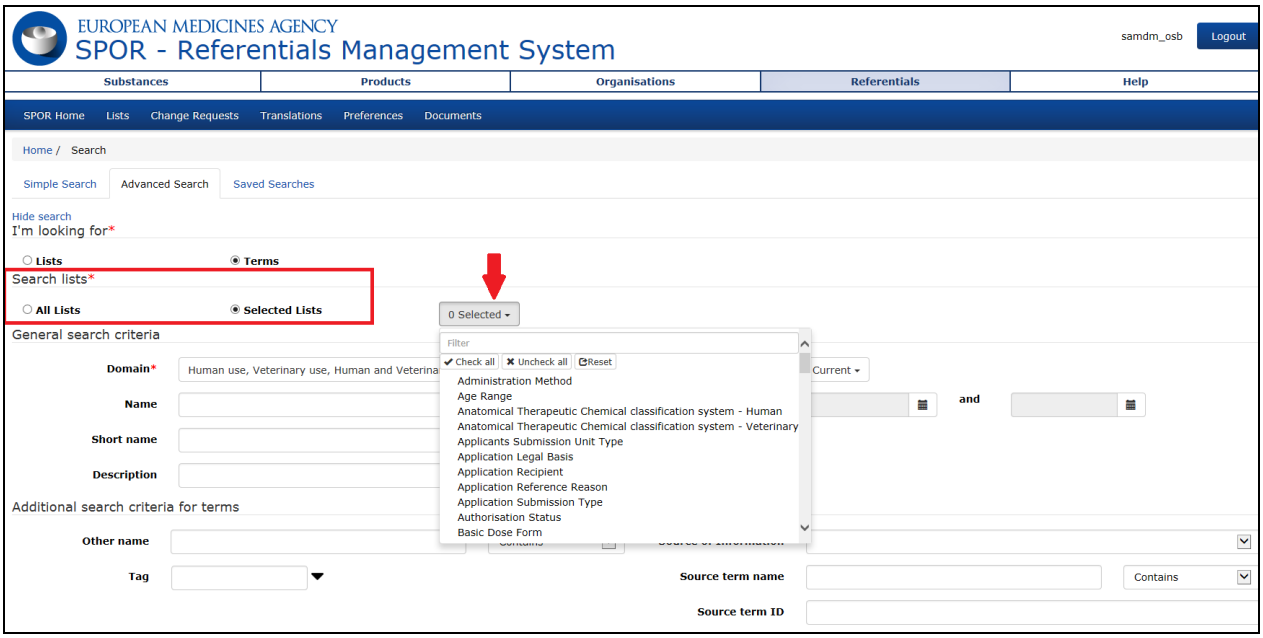
Partial searches can be done either using asterisks (*) as wildcards or selecting the options "Contains" or "Begins with" available next to the "Name", "Short Name", "Description" and "Owner" attributes in the screen above. However, as explained in the previous section, fuzzy matching functionality is not available in the Advanced Search.

Results can also be narrowed down by "Owner" or "OID" of the list, in case the user wants to search for an external OID.

At this stage, searches can be reset in case a new search is required or saved for future usage in case the user would like to reuse a specific set of search criteria.

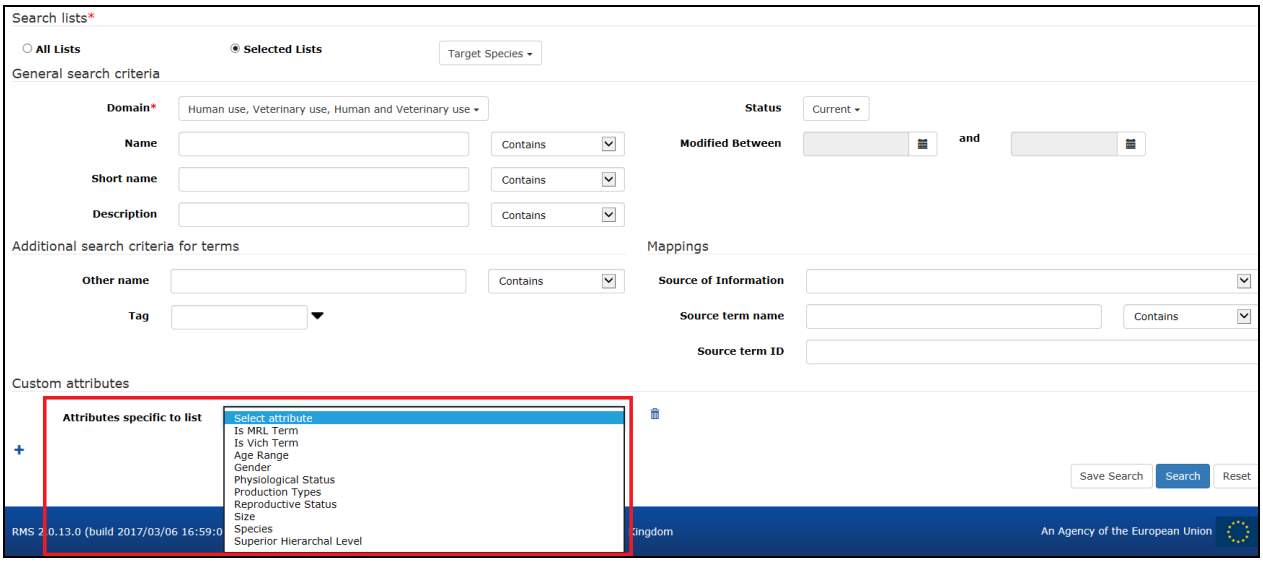
3.5.2. Advanced Search (Terms)

In order to use the Advanced Search functionality to search for terms, the user should select if the search is to be performed across all RMS lists, some of the lists or within one list only, as shown in red in the screen below. If the search should be only in one particular list or across a number of them, then those lists should be selected from the drop-down marked with a red arrow in the screen below.



Similarly to the "Simple Search", the minimum search criterion for "Advanced Search" of Terms is the "Domain" (Human/Veterinary/Human & Veterinary). In addition, other "General search criteria" can be specified to narrow down the search.

Some RMS lists contain extended attributes that can also be used as search criteria for narrowing down results. For instance, EDQM lists contain extended attributes such as "intended site" or "state of matter". If a user wants to type in any extended attributes as additional search criteria, the user should select the relevant list first and then the extended attributes of the list will appear on the screen. By doing this, the "Custom attributes" marked in red at the bottom of the screen below will change depending on the nature and the schemas of the list selected.

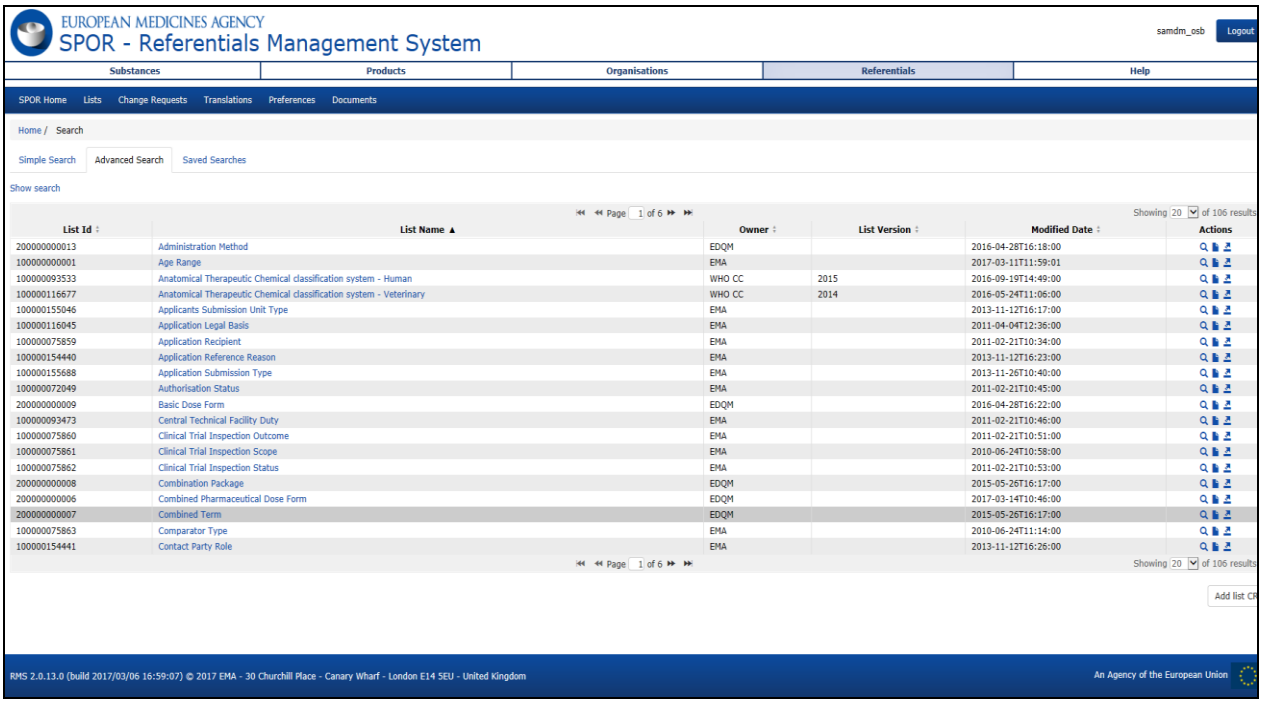


Similarly to the "Advanced Search" for lists, wildcards (*) can be used and partial searches can be performed by using the "Contains" and the "Begins with" options next to some of the attributes, and fuzzy matching is not available. In addition, the maximum date range for searching is one year and searches can be reset or saved for future usage.

3.6. Search Results

3.6.1. Search Results (Lists)

Once all the required search criteria for terms have been filled in and the "Search" button at the bottom of the "Search" screen has been clicked, a screen with list names and collapsed search criteria similar to the below will appear:



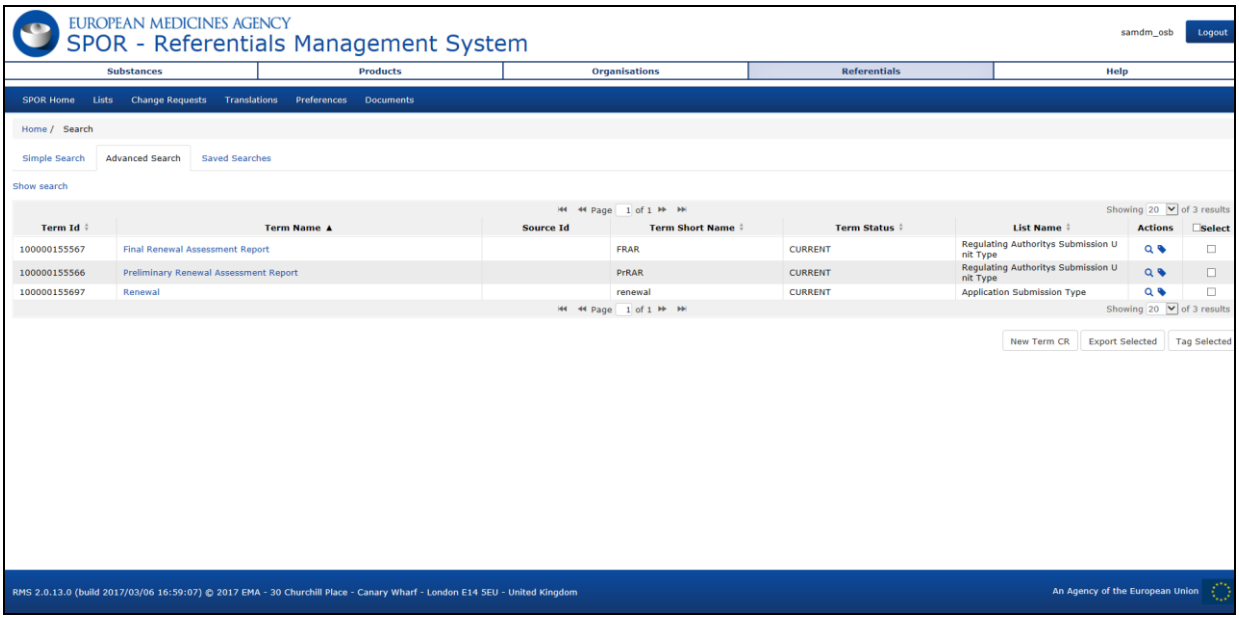
If the results come from a "Simple Search", then fuzzy matching will have been applied and therefore accented characters, caps, common words and some typos will be ignored. A maximum of 1,000 results will appear on the screen, sorted by relevance, and no user-driven sorting will be possible.

Taking this into account, if there are more than 1,000 search results and the user wants to see all of them, the user should go to the "View Lists" screen. If the user wants to narrow down the lists, then the user should go to the "Search" screen.

If the results come from an "Advanced Search", fuzzy matching will have not been applied and therefore the system will only provide exact matches as results. The maximum number of results to appear on the screen will also be 1,000. These will be ordered by List/Term name but user-driven sorting is also allowed.

3.6.2. Search Results (Terms)

The screen showing the results of a search for terms will be very similar to the one for list search and an example is shown below:



In addition, the same parameters regarding fuzzy matching vs. exact matches, maximum number of results and sorting of results for list search also apply for term search.

3.7. Change Requests

If the user has viewed or searched lists and/or terms and he/she hasn't found what was expected, a change request can be submitted for the creation of a new list/term or the update of an already existing list/term. In addition, change requests to delete a term can be submitted if it is considered that a term should be removed from a list.

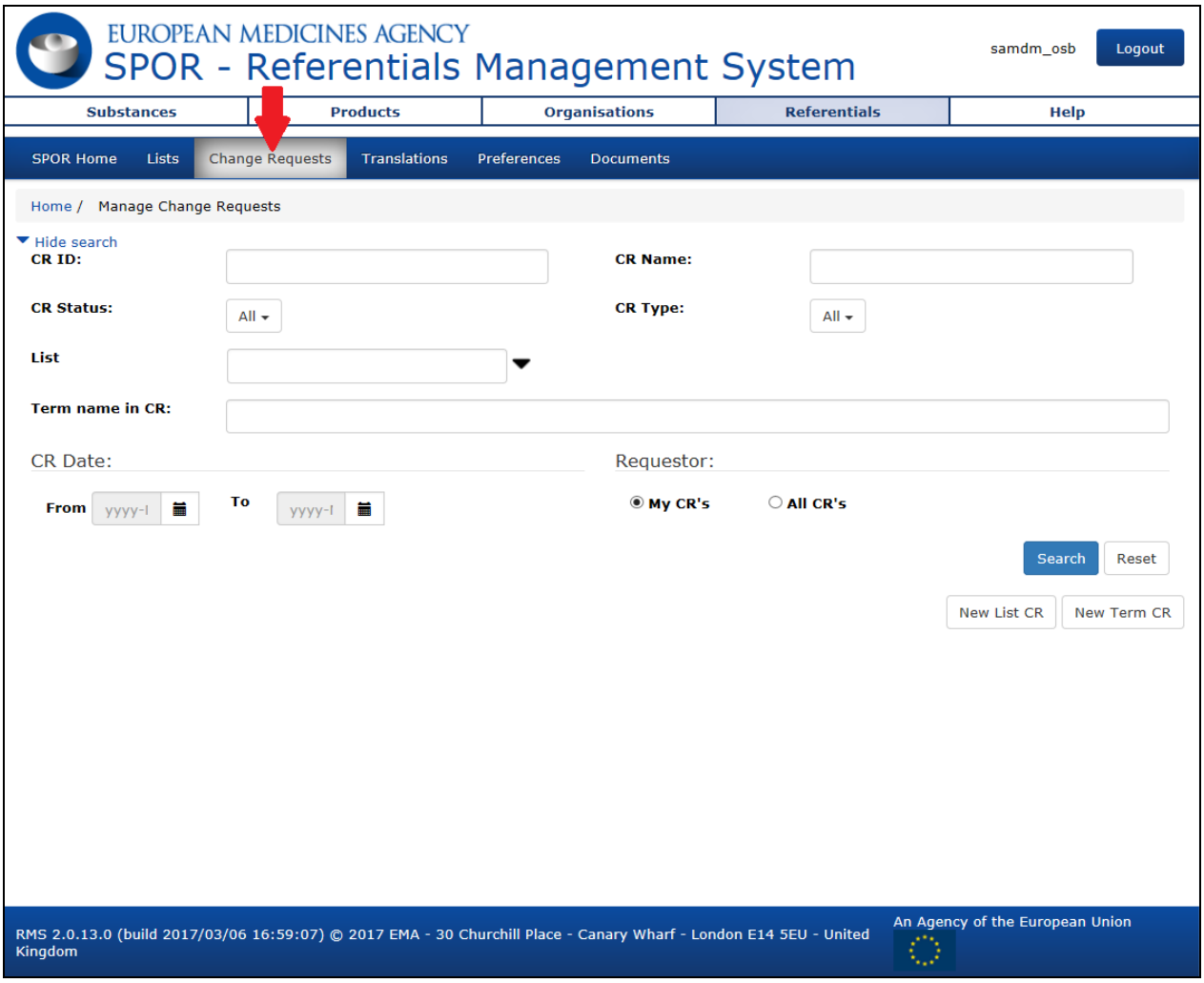
Once a change request is submitted, there will be an automatic duplicate check as well as an automatic data validation check and data quality check. In addition, the user will receive a notification confirming that the change request has been received in RMS.

After these validations and checks, there will be the approval process (explained further down). The system will automatically submit notifications at each of step of the approval process.

It is highly recommended that users read the "List Information" document which provides details on whether a user can apply for a change request for a particular list/term, how to do that and what needs to be provided as supporting documentation.

3.7.1. Access to Change Requests

To access the Change Requests (CRs) functionality users should click on "Change Requests" in the menu bar under RMS (in red in the screen below).



The table above contains a list of the change requests, including the CR ID, CR name, CR Type (e.g. add term, update term, update list, etc.), name of the requestor, date of the CR as well as status of the request and status date.

Organisation Super users will not be able to see all change requests (CRs) raised by other users of the same organisation.

NCA users can see all CRs (their own CRs as well as any CRs submitted by anyone).

Other users can only see their own CRs which are account-specific (they won't be able to see CRs raised by other users within the same organisation).

- Users have one account/set of credentials per Organisation and as many accounts as needed (e.g. John Smith working for company X would have one account –John Smith/X–; if he then moves to company Y, a new account –John Smith/Y – would be created;
- Users need to login with different credentials to see CRs created on behalf of different organisations
- If a user moves Organisation their account should be inactivated by the Organisation Super user. E.g. in the example above, the Superuser of Organisation X should inactivate the account for John Smith/X.
- If a user moves Organisation but the account is active, the user will still have access to the CRs raised by him/her (including CRs raised by that user on behalf of organisations for which the

user worked in the past). The responsibility for ensuring that the list of RMS users of a given organisation lies with the Superuser of that organisation.

Useful Tips:

- Users should periodically export their CRs and share with colleagues, particularly before leaving an organisation (the RMS tool allows exporting a summary of CRs raised and the data within them by clicking on the "Export" button at the bottom of the "Manage Change Requests" screen –see screenshot above-).
- Users should ensure RMS notifications are shared with other colleagues. This can be done by:
    - Using a group work e-mail as contact point for the CRs (Organisation policy permitting) to avoid notifications being sent to users that have left the organisation from where the CR was raised.
    - Creating a forwarding rule

3.7.2. Manage Change Requests

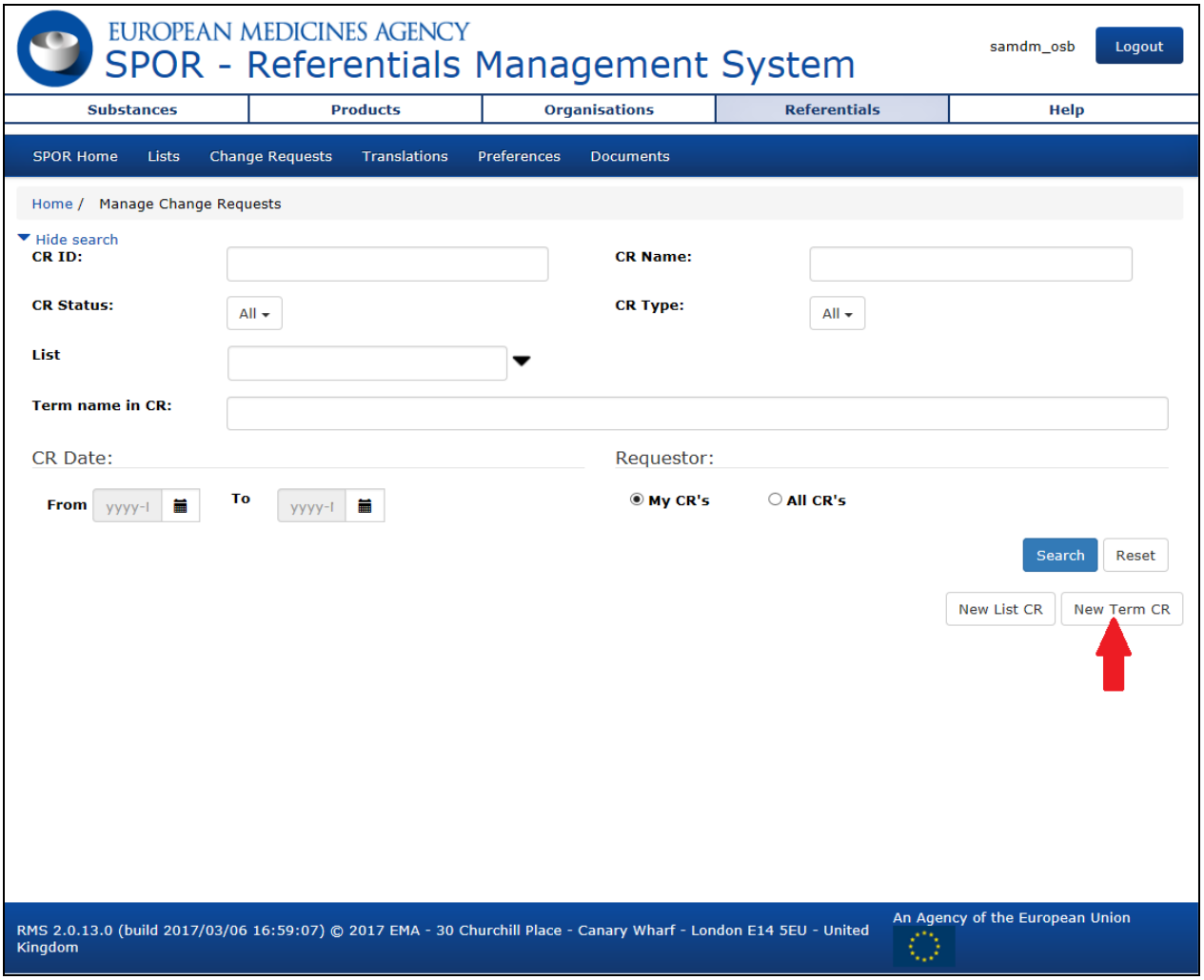
The actions that can be performed with CRs in RMS are as follows:

- Search CRs
    - *View your own list of CRs – account-specific due to confidentiality aspects*
    - *All CRs only available to NCAs*
- View CRs & progress
- Edit (square icon with a pencil)/Save/Delete (bin box icon) CRs
    - *Only own CRs*
    - *CRs can be edited, saved and deleted only if not yet submitted (not possible anymore after submitting the CR)*
    - *CR Type, List and Term can't be edited*
    - *CRs that are being drafted/edited/saved in RMS will only be visible to the user. Data stewards dealing with RMS will only see the details of the CR once they are submitted by the user.*
- *Specify a date range for CR (there is no maximum)*
- Submit a CR to add a List or update a List (New List CR) – the system doesn't cater for deleting a list as this is considered as a very exceptional process.
- Submit a CR to Add, Update or Delete a Term (New Term CR) – further details on the Change request process can be found in the List Info document
- Export your own list of CRs (to share it with colleagues, for instance)

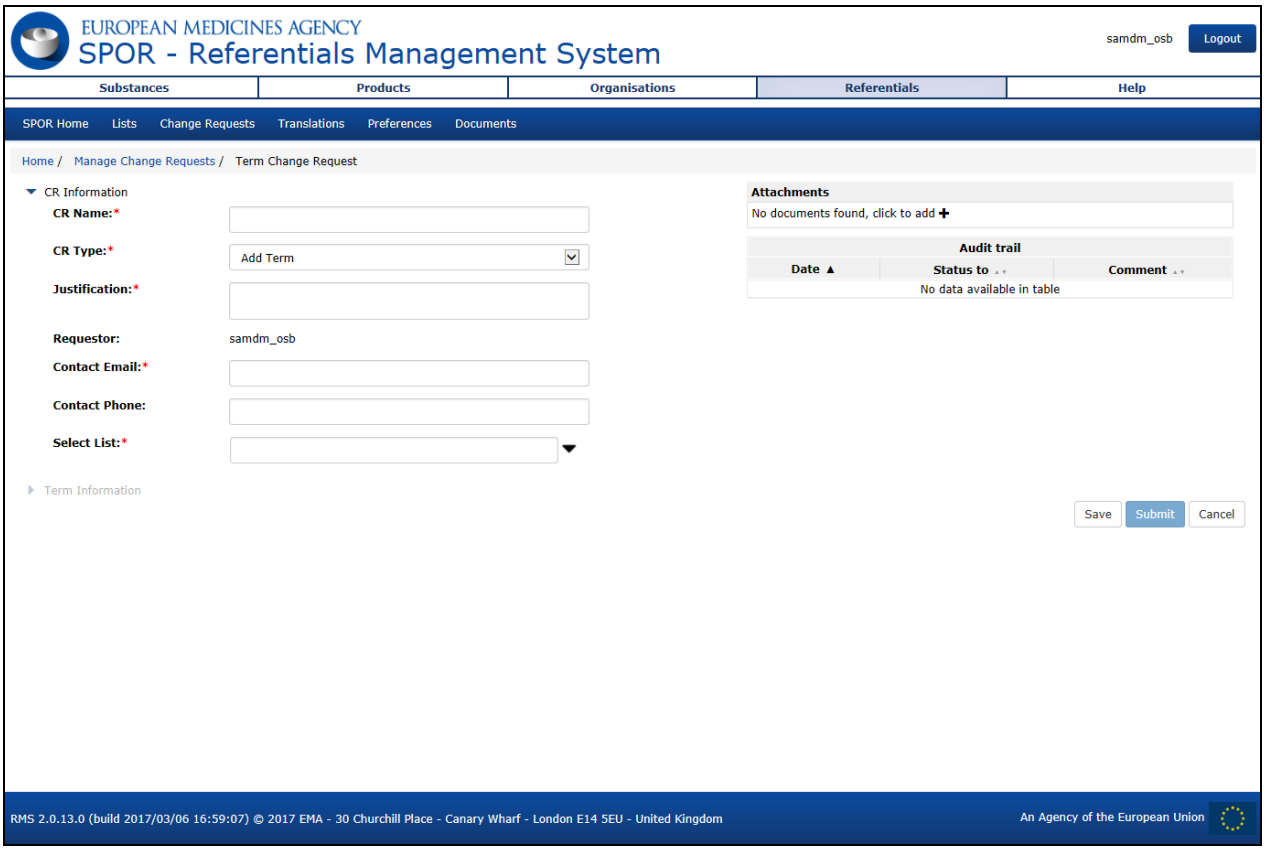
As a reminder, CRs can also be submitted from the "View Lists", "View List of Terms" or "View Term" screens, as explained earlier.

3.7.3. Add Term

To add a new term to a particular list, the user should click on the "New Term CR" button in red at the bottom of the "Change Request" view screen below:



A screen similar to the following will appear:



3.7.3.1. Add Term - Change Request Information

In order to add a term, the details of the change request should be filled in. This is the general information of the CR which sits at the top part of the screen.

The following fields are mandatory in order to submit a CR for a new term:

- CR name (manually assigned by the user)
- CR type (Add term should be selected)
- Justification
- Requestor details (e-mail and contact phone, both will appear automatically as this will be filled in with the log in details –this can be overwritten if required-)
- List (where the term should be added)

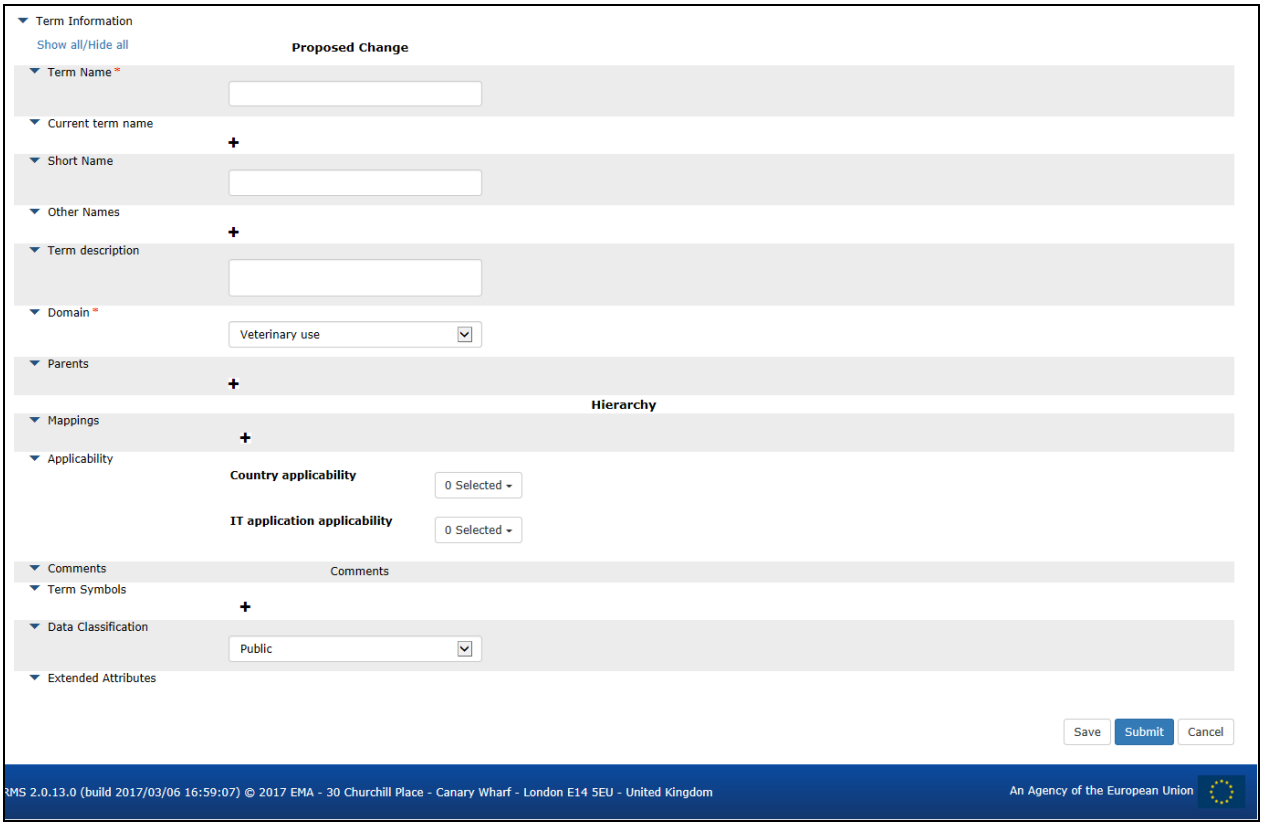
In addition, a maximum of 5 documents (PDF/Word/Excel) can be attached to the request as supporting documentation.

The "Audit trail" box in the Change request screen shows the request history including the dates where the request was saved/submitted/returned and any additional comments (if relevant).

At this point the user can "Save", "Submit" or "Cancel" the CR.

3.7.3.2. Add Term - Term Information

Below the "CR Information" section of the Term Change Request screen, there is the "Term Information" section where the user should enter all the mandatory information regarding the term and any other relevant term attributes -in English only- (see below):



These mandatory attributes (all in English only) are:

- Term Name
- Current term name (only to be completed when adding a legacy term –a term that is not current but still used in an approved product– if the status of the term is either non-current or nullified; if required, this field should contain the current term(s) that should be used instead of the legacy term).
- Short Name
- Other Names
- Term description

The Term Change Request screen allows the user to perform the following 3 actions:

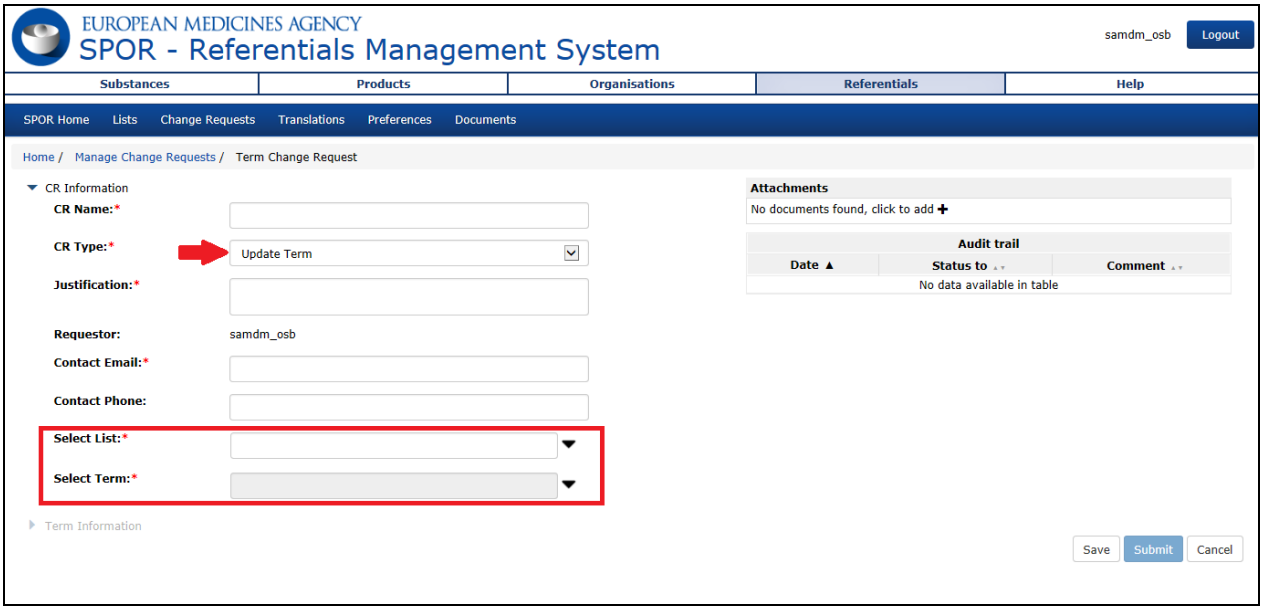
- Save: saves the information completed in the CR up to that point to continue working on the CR at a later stage.
- Submit: sends the CR assuming that all of the required information has been completed.
- Cancel: deletes all of the information completed up to that point, in case the user considers the CR is not correct or needed any more.

3.7.4. Update term

To update a term from a particular list, the user should click on the "New Term CR" button as shown in section *3.7.3. Add Term* and follow the steps below.

3.7.4.1. Update term - Change Request Information

In the "Term Change Request" view, select "Update Term" in the drop-down list next to "CR Type" (see red arrow below) and select the list and the term to be updated (see in red below).



Then proceed to fill in the "CR Information". In particular, the following fields are mandatory in order to submit a CR for a new term:

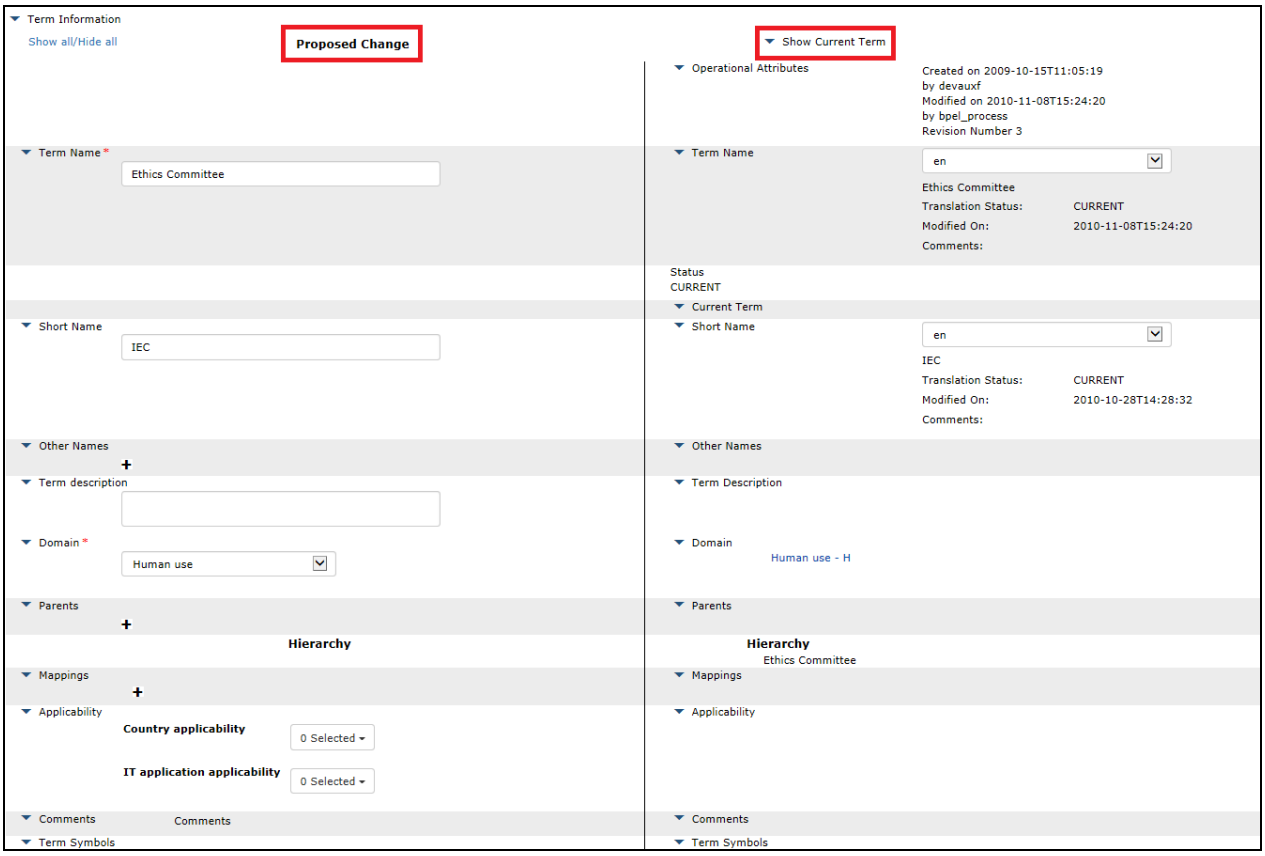
- CR name
- CR type (Add term, Update term, Delete term)
- Justification
- Requestor details (e-mail and contact phone, both will appear automatically as this will be filled in with the log in details)
- List (where the term should be added)
- Term (the term that should be updated –this is the main difference between adding and updating a new term–).

In addition, a maximum of 5 documents (PDF/Word/Excel) can be attached to the request.

The "Audit trail" box in the Change request screen shows the history of requests including the date, status and comments (if relevant).

3.7.4.2. Update term - Term Information

Below the "CR Information" section of the Term Change Request screen, there is the "Term Information" section which contains information about both the current and the proposed change(s) (see in red below):



As shown in the screen above, the proposed term attributes (editable) will appear on the left hand side of the screen and the current term attributes on the right hand side to facilitate comparison.

In order to update a term, the relevant term attributes should be edited and this should be in English only.

At least one change is needed to update a term and current terms can be entered for legacy terms.

The Term Change Request screen allows the user to perform the following 3 actions (buttons at the bottom right corner of the screen):

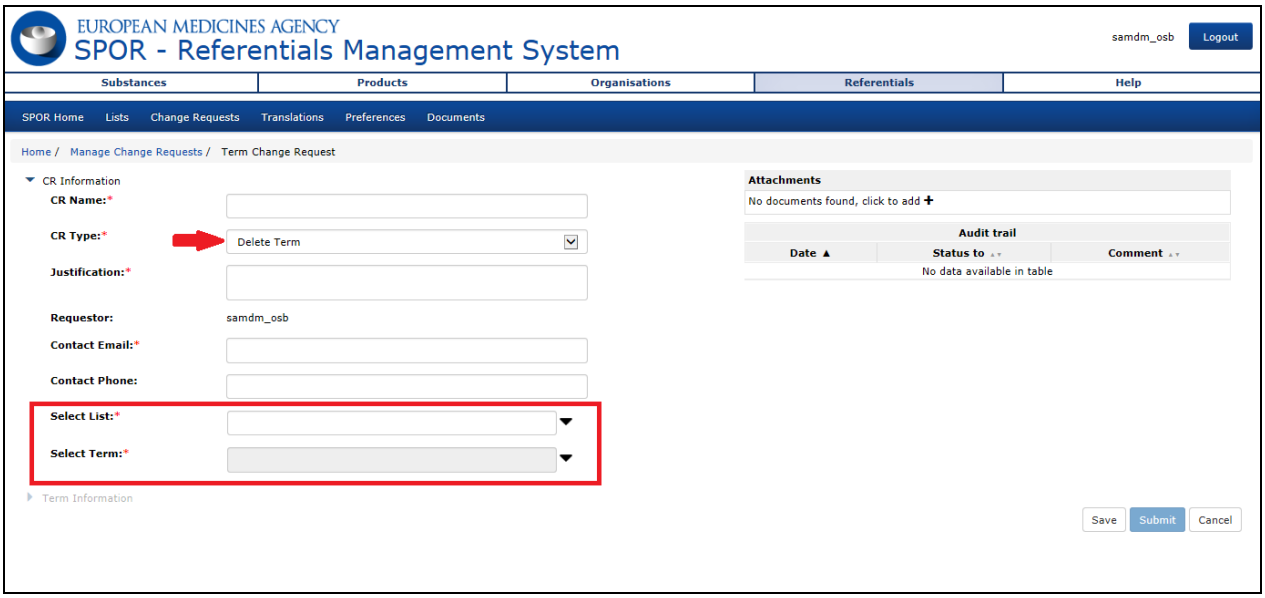
- Save: saves the information completed in the CR up to that point to continue working on the CR later
- Submit: sends the CR and all of the required information has been completed.
- Cancel: deletes all of the information completed at that point, in case the user considers the CR is not correct or needed any more.

3.7.5. Delete Term

To delete a term from a particular list, the user should click on the "New Term CR" button as shown in section *3.7.3. Add Term* and follow the steps below.

3.7.5.1. Delete Term - Change Request Information

In the "Term Change Request" view, select "Delete Term" in the drop-down list next to "CR Type" (see red arrow below) and select the list and the term to be updated (see in red below).



Then proceed to fill in the "CR Information". In particular, the following fields are mandatory in order to submit a CR for a new term:

The following fields are mandatory in order to submit a CR for a new term:

- CR name
- CR type (Add term, Update term, Delete term, Add List, Delete List)
- Justification
- Requestor details (e-mail and contact phone, both will appear automatically as this will be filled in with the log in details)
- List (containing the term to be deleted)
- Term (the term that should be deleted)

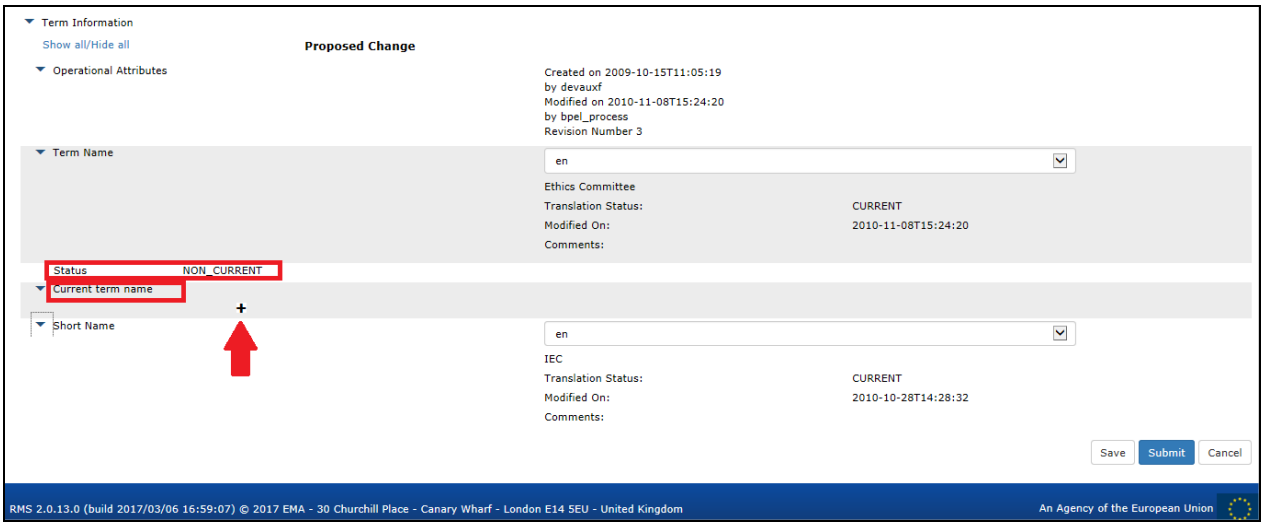
The requestor information will appear automatically as this will be filled in with the user's details.

In addition, a maximum of 5 documents (PDF/Word/Excel) can be attached to the request.

The "Audit trail" box in the Change request screen shows the request history including the dates where the request was saved/submitted/returned and any additional comments (if relevant).

3.7.5.2. Delete Term - Term Information

Below the "CR Information" section of the Term Change Request screen, there is the "Term Information" section which should be completed by the user (see below):



If the user selects the "Delete term" type of CR in the "Term Change Request" screen, then the "Status" field (see in red in the screen above) will be automatically changed to non-current (the term will not be physically removed from the system).

The only field that can be edited in this screen is the "Current term", assuming that the status of the term is non-current or nullified and that there is a current term that is a better option which should be used instead. To do this, click on the "+" button next to the red arrow above to add the current term.

The Term Change Request screen allows the user to perform the following 3 actions (buttons at the bottom right corner of the screen):

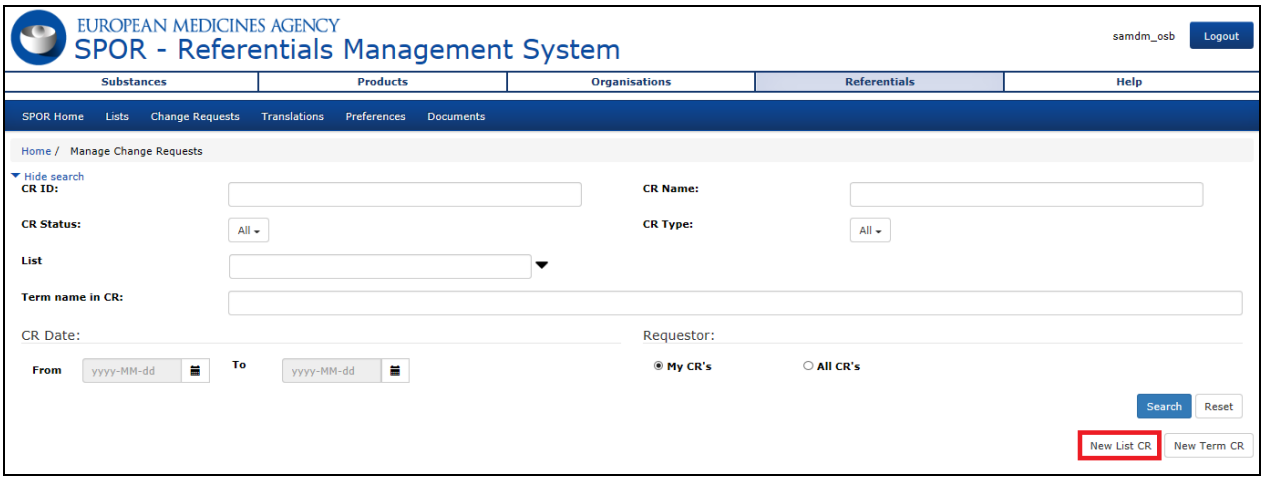
- Save: saves the information completed in the CR up to that point to continue working on the CR later
- Submit: sends the CR and all of the required information has been completed.
- Cancel: deletes all of the information completed at that point, in case the user considers the CR is not correct or needed any more.

3.7.6. Add List

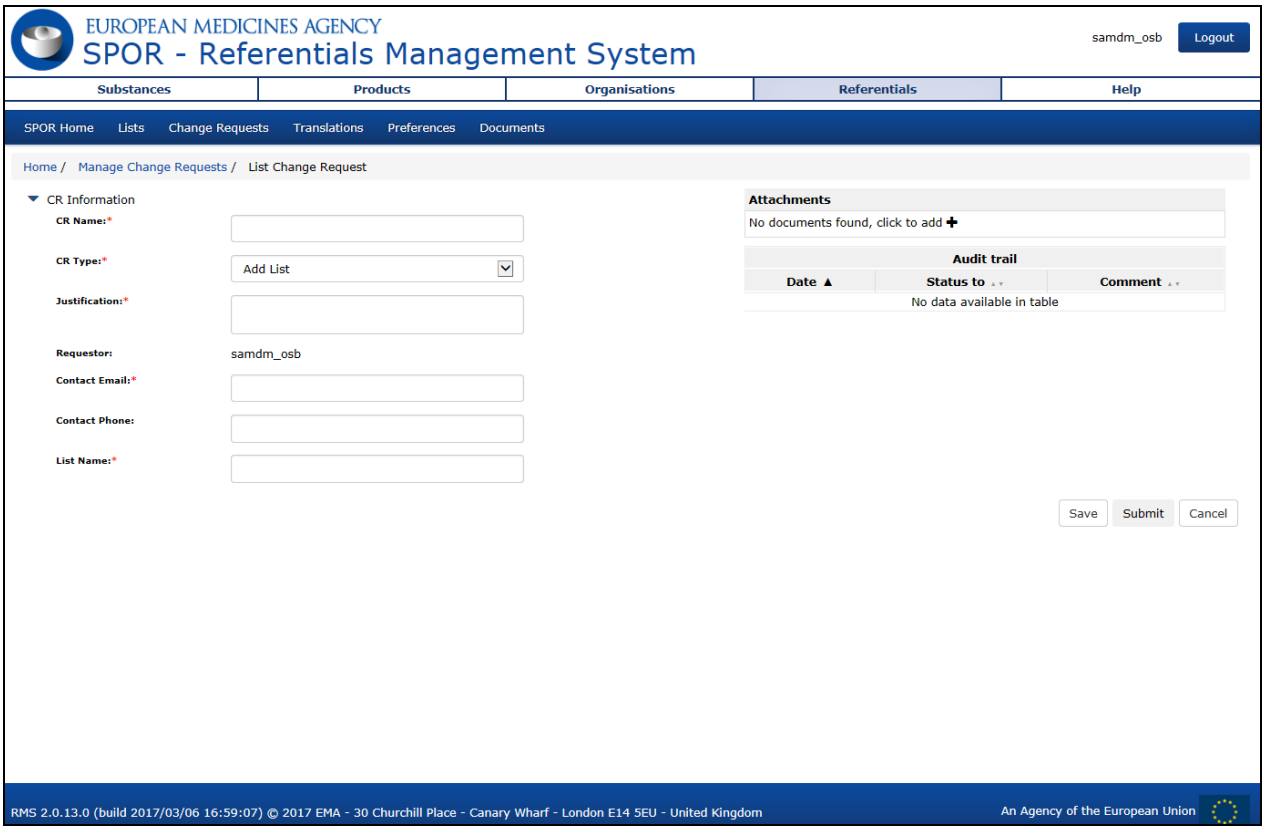
Requests for new lists will typically come from National Competent Authorities (NCAs). RMS has a service to add and publish lists required for Telematics systems. For example, if the new Clinical Trial portal needs a new list, RMS is where the list should be requested to be created and published.

The creation of lists required by systems other than Telematics are outside the scope of RMS.

To add a new list in RMS, the user should click on the "New List CR" button at the bottom of the "Change Requests" screen (in red below):



The following screen will appear:



The user should enter the change request (CR) details in this screen. The mandatory fields for a CR to add a list are as follows:

- CR name
- CR type ("Add List" should be selected here)
- Justification
- Contact e-mail (where RMS notifications should be sent – *see section 4.7.1. Access to Change Requests*)
- List name

- 1 attachment as a minimum (i.e. the "List template" document, which has the draft content of the list or at least a few examples to understand what the list is about, how it's going to be used, etc.); a maximum of 5 documents (PDF/Word/Excel) can be attached to the request.

The "List Template" document (located under the "Documents" tab in RMS) should be used by anyone needing a new list for a Telematics application.

The requestor information will appear automatically as this will be filled in with the user's details.

The "Audit trail" box in the Change request screen shows the history of requests including the date, status and comments (if relevant).

The Term Change Request screen allows the user to perform the following 3 actions (buttons at the bottom right corner of the screen):

- Save: saves the information completed in the CR up to that point to continue working on the CR later.
- Submit: sends the CR and all of the required information that has been completed.
- Cancel: deletes all of the information completed at that point, in case the user considers the CR is not correct or not needed any more.

3.7.7. Update List

"Update list" should be used mostly by EMA data stewards as a placeholder to register that there is a list that needs to be updated. Example: if we have a file with the latest version of ATC codes which requires a big number of changes to the ATC list, we will use this functionality to load the file, log a task to update the ATC list and do the actual update.

To update the List attributes/List info please log a call in JIRA (see section *2.4. EMA Service Desk ("JIRA")*).

If a user wants to update a list with one or several terms (i.e. to ask for changes to one or several terms in a list), this should be done through the "Term Change Request" functionality. Each term change request can only contain one term. For instance, if a user wants to add 10 terms to a particular list, 10 individual term change requests will be required.

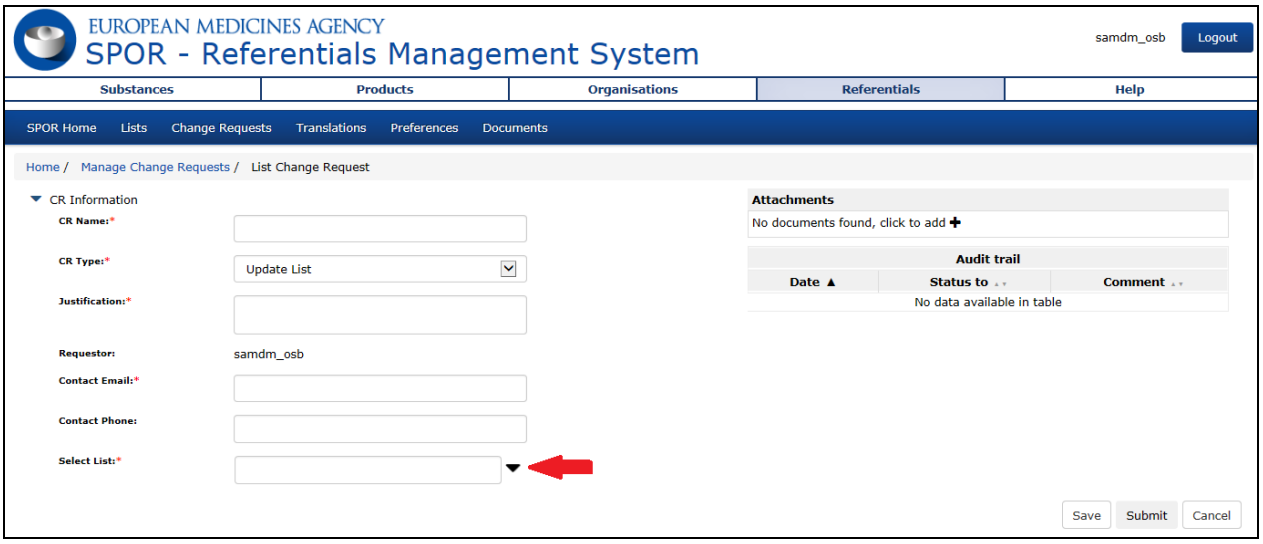
If a user sends a single update list request with changes to several terms, the request will be invalidated unless there is a very good reason for this and the user will be asked to send individual term change requests for each term.

Exceptionally, "Update list" could be accepted to perform bulk uploads if the change is the same across multiple terms and assuming a high-volume.

However, "Update list" should not be used to bulk load translations as there is a specific functionality for this – see section *3.8.2. Offline Bulk Upload of Translations*.

To update an existing list in RMS, the user should click on the "New List CR" button as shown in section *3.7.6. Add List*.

In the next screen, the user should select "Update list" in the "CR type" field and select the list to be updated next to the red arrow below:



The mandatory fields for a CR to update a list are as follows:

- CR name
- CR type ("Update list")
- Justification
- Contact e-mail (where RMS notifications should be sent – *see section 3.7.1. Access to Change Requests*)
- List (select the one to be updated)
- 1 attachment as a minimum (either the "List template" under the "Documents" section of RMS or an updated export of the list); a maximum of 5 documents (PDF/Word/Excel) can be attached to the request.

The requestor information will appear automatically as this will be filled in with the user's details.

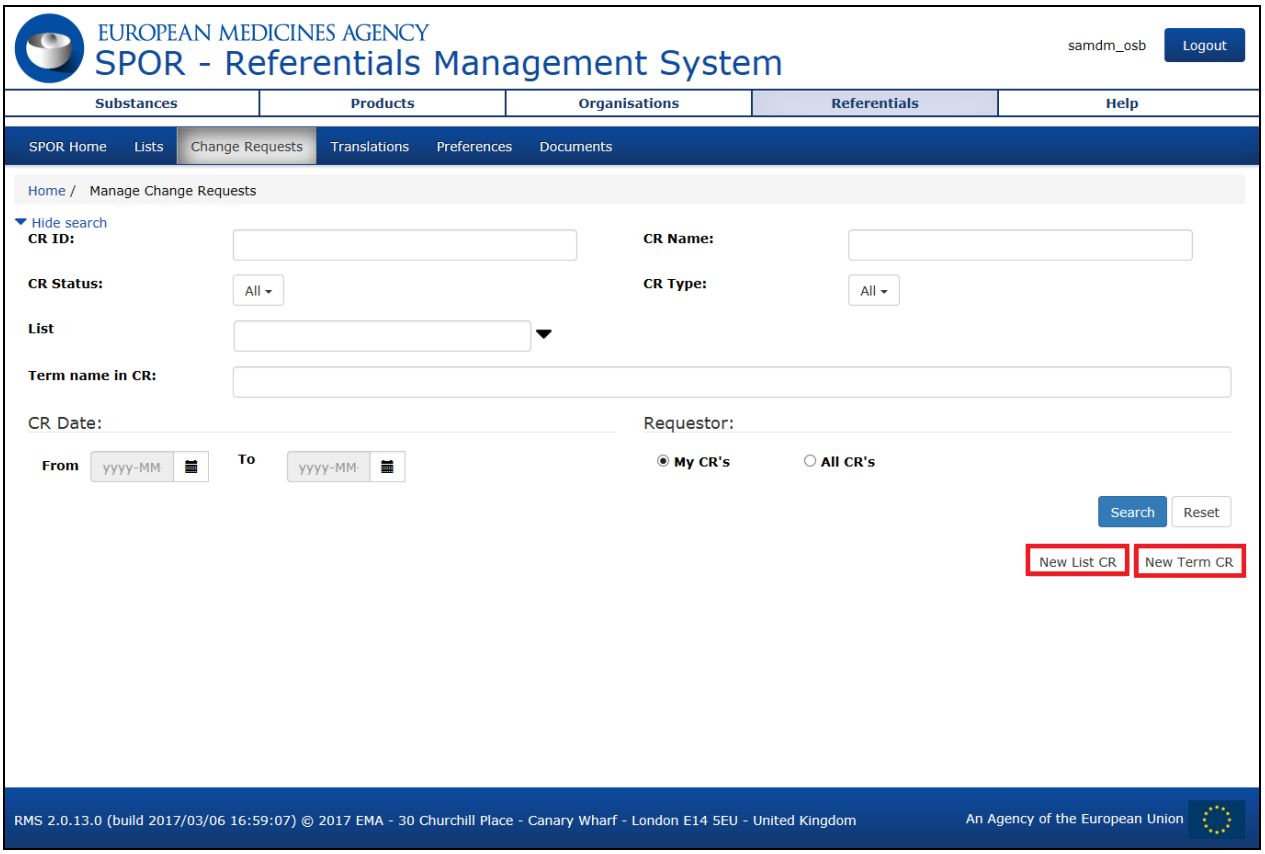
The "Audit trail" box in the Change request screen shows the request history including the dates where the request was saved/submitted/returned and any additional comments (if relevant).

Similarly to the "Add List" Change request, the "Update List" Change request screen allows the user to perform the following 3 actions (buttons at the bottom right corner of the screen):

- Save: saves the information completed in the CR up to that point to continue working on the CR later
- Submit: sends the CR and all of the required information that has been completed.
- Cancel: deletes all of the information completed at that point, in case the user considers the CR is not correct or needed any more.

3.7.8. Change requests from "View" screens

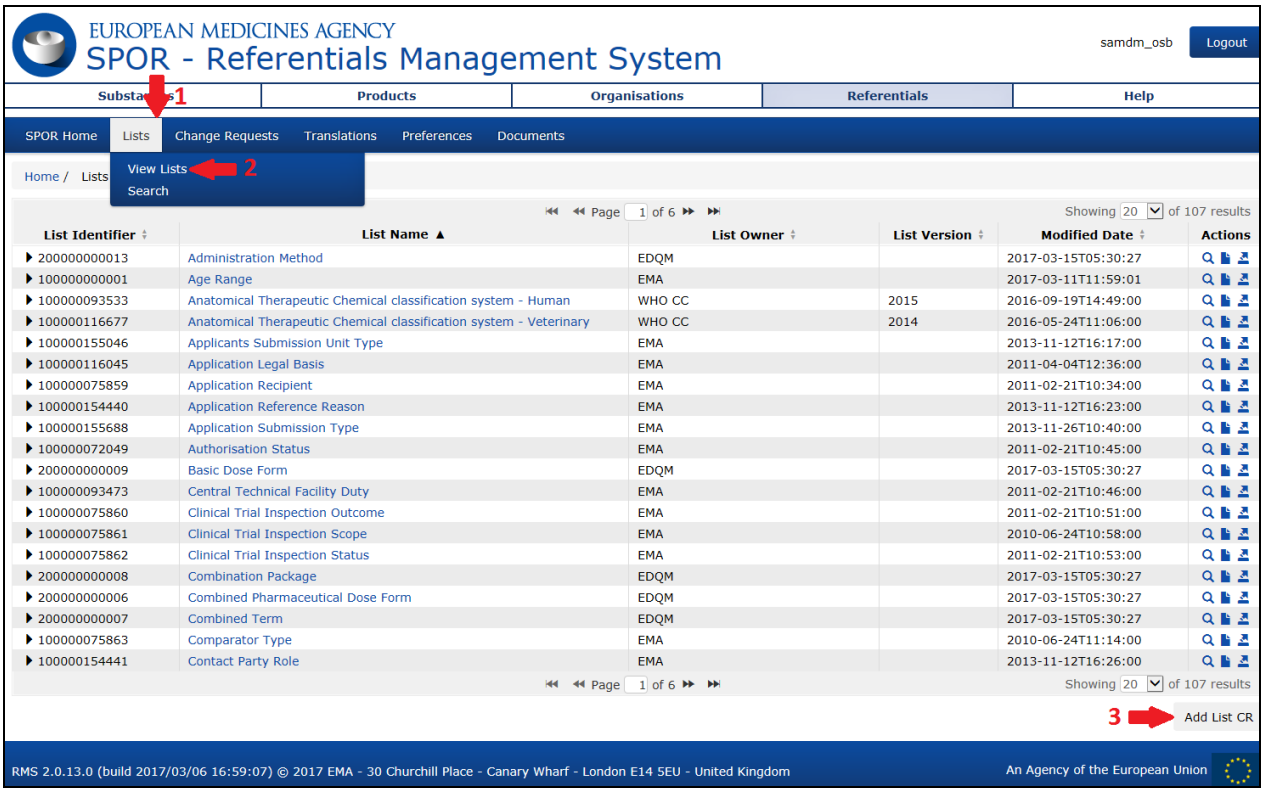
Sections 3.7.3. to 3.7.7. of this user manual explain how users can submit change requests by clicking on the "Change Requests" option in the RMS menu bar and then by clicking either on the "New List CR" or the "New Term CR" buttons (in red in the screen below).



However, the RMS tool also allows for the submission of change requests from several "View" screens, as explained in sections 3.7.8.1 to 3.7.8.3 below.

3.7.8.1. Change Request from "View Lists"

Change requests to add a new list (not to update a list) can be submitted from the "View Lists" screen by clicking on the "Lists" option (1) on the RMS menu bar, then on "View Lists" (2) and subsequently on the "Add List CR" button (3) at the bottom of the screen (in red below):

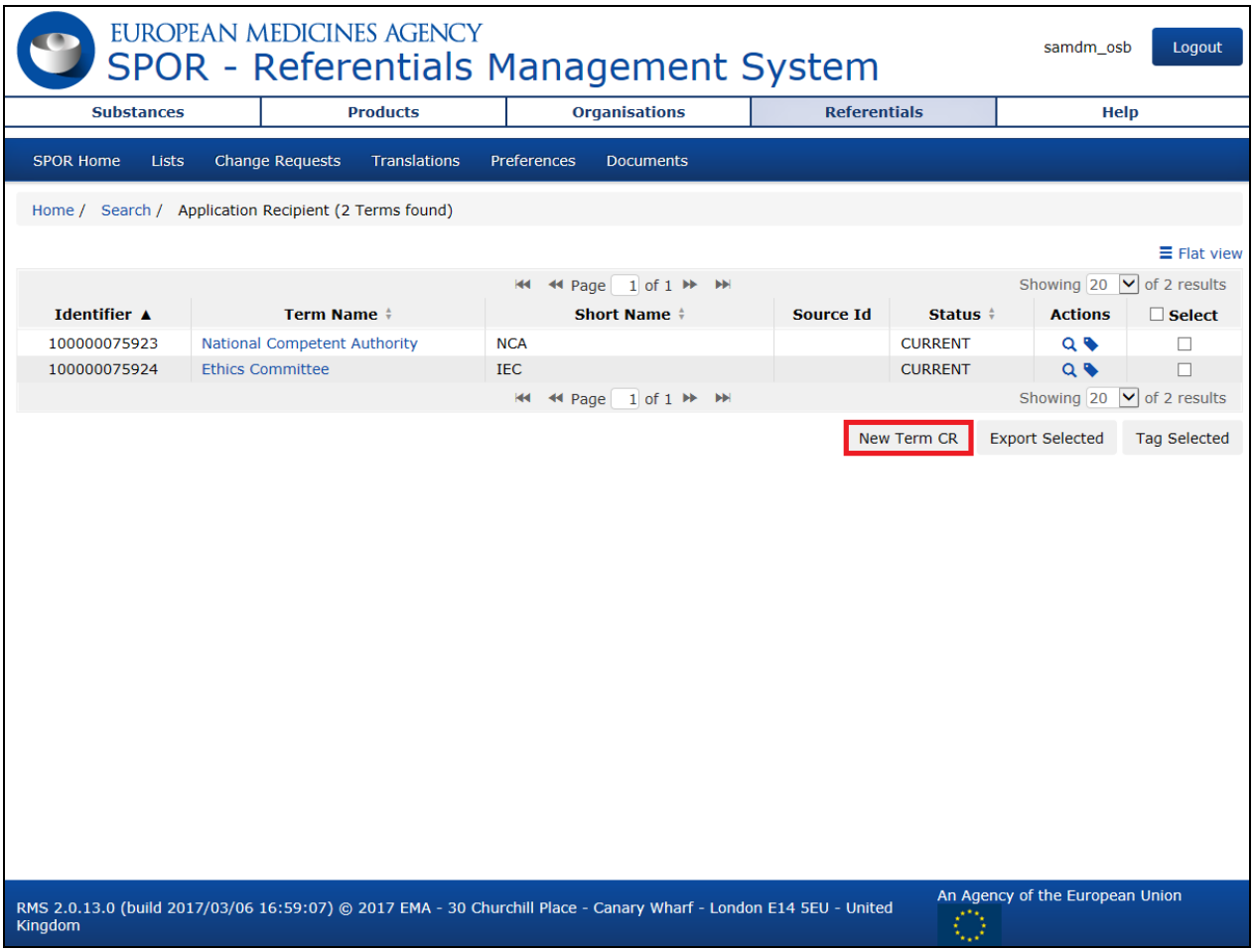


Other actions that can be performed from this screen are as follows:

- View available Lists
- View List attributes
- View List of Terms
- View List information
- Export List (1 at time)
- Export List of Lists via Search

3.7.8.2. Change Request from "View List of Terms"

Change requests regarding terms (generally "Add Term CR" but also sometimes "Update Term CR" or "Delete Term CR") can be submitted from the "View List of Terms" screen by clicking first on the "Lists" option on the RMS menu bar, then on "View Lists" and then selecting a particular list. By doing this, the user will reach a screen showing the terms within the list selected and the button "New Term CR" (in red in the screen below) should be clicked.



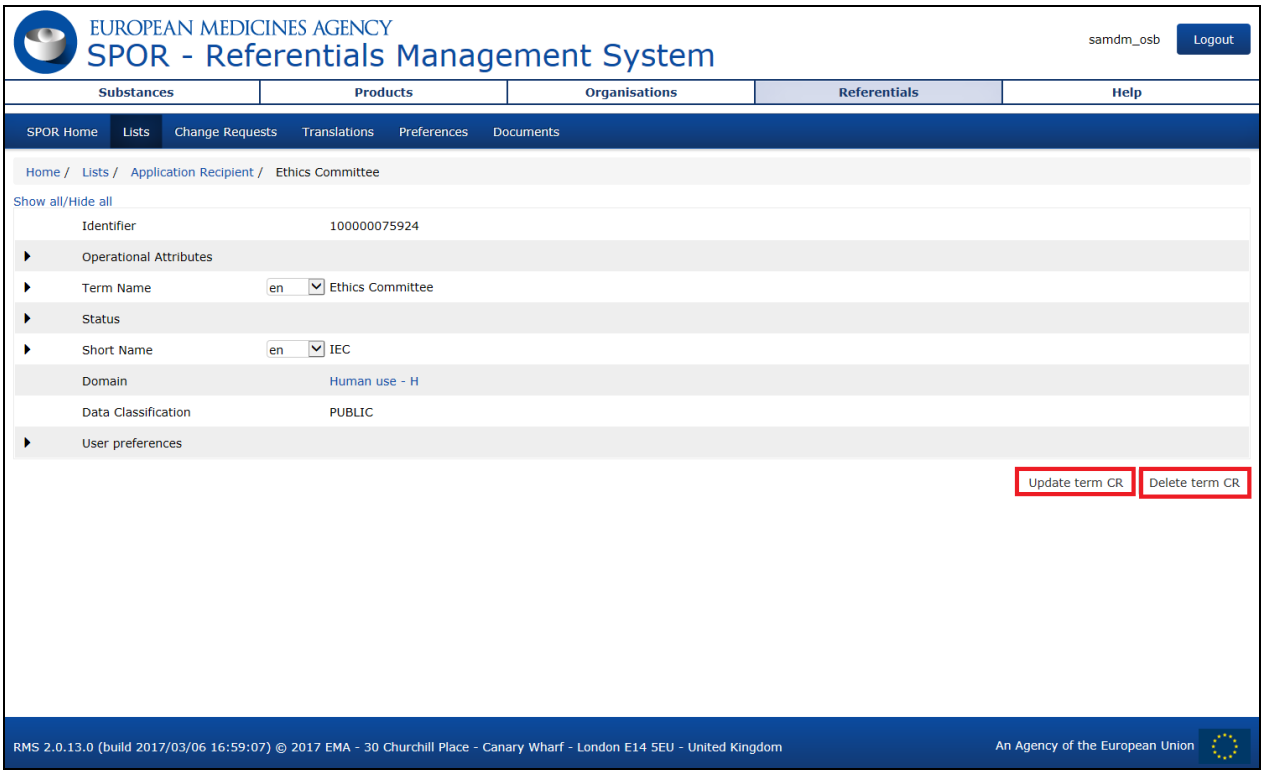
From this point, the user should follow the instructions provided further up to add a term (section *3.7.3.*), update a term (section *3.7.4.*) or delete a term (section *3.7.5.*).

Other actions that can be performed from this screen are as follows:

- View List of Terms, flat *(latest version)*
- Sort by key columns e.g. Source Term ID
- View Term details *(latest version)*
- Tag Single Term
- Select all/some terms
- Export Selected
- Tag Selected

3.7.8.3. Change Request from "View Term"

"Update Term CR" and "Delete Term CR" can be accessed bypassing the "Change Requests" option on the RMS menu bar. To do so, click first on the "Lists" option on the RMS menu bar, then on "View Lists", then select a list in particular and afterwards select a specific term. By doing this, the user will reach a screen showing the details of the term selected. The buttons "Update Term CR" and "Delete Term CR" (in red in the screen below), located at the bottom of the screen, can be clicked to perform those actions.



Of note, the "Add Term CR" functionality is not available from this screen. To do so, the user should click on the "New Term CR" button in red at the bottom of the "Change Request" view screen as explained in section *3.7.3. 3.7.3.* .

3.7.9. Back end process after submission of Term CR

Upon submission of a CR the RMS system automatically:

- Performs duplicate term check (Add Term CR only)
  - ✓ Checks if term with the same or similar name already exists
  - ✓ Checks draft terms
  - ✓ Checks name, other name and short name only
  - ✓ If the system finds anything that could be a duplicate, the system will show a warning to seek confirmation to submit CR – the CR can still be submitted and this would still be validated by data stewards
- Performs input data validation (All CR Types – same as MDM)
  - ✓ Ensures that data of the correct type is supplied (e.g. free text, number, dates, etc.)
  - ✓ Ensures that selections are valid
  - ✓ Ensures that mandatory data is supplied
  - ✓ Ensures the right amount of data is supplied
  - ✓ Error messages shown against fields with issues – CR cannot be submitted until resolved

- Applies data quality rules to free text fields (All CR types - same as MDM)
    - ✓ Remove double spaces
    - ✓ Capitalisation
    - ✓ Remove leading and trailing spaces
    - ✓ Other list specific rules
    - ✓ Issues automatically corrected

Additional considerations

- Duplicate Term check is not performed on submitting a change request to update or delete a term.
- Other updates to the term might still be valid even if the change to the name was not, and investigation into whether or not the update would create a duplicate is something that should be done by a data steward, rather than discouraging the submission of a change request.

3.7.10. Change Request statuses

The lifecycle of a change request is as follows:

Saved – When the CR has been created and saved before it has been submitted. This enables users to edit the CR as many times as required or to delete it before submitting it. As long as the user makes changes to the CR without submitting them, those changes will only be visible to the user. A CR can be kept saved for as long as required. Data stewards will only see the details of the request once the CR is submitted.

Submitted – Once the CR has been submitted (at this point the user receives a notification) and before the EMA Data Steward acts on the CR. At this stage the data steward will perform the validation of the CR (this only applies for RMS –not for RMS- and its main objective is to check if the request makes sense and if there is enough information for the CR to be assessed).

Returned – When the CR could meet the process requirements but requires further input from the requestor. This enables the requestor to edit/delete the CR and submit it again if relevant. This only applies for RMS requests, not for OMS, as some of the RMS requests may be more abstract and more information may be needed for the assessment.

Valid – When the CR meets the process's requirements. At this stage the CR is sent to whoever is the approver (EMA for internally managed lists or other maintenance organisations -e.g. WHO, EDQM, etc.- for externally managed lists).

Invalid – When the CR does not meet the process's requirements.

Approved – When a CR has been discussed and approved by the Data owner exactly as it was requested.

Approved with changes - When a CR has been discussed and approved by the Data owner with some minor changes.

Rejected - When a CR has been discussed and declined by the Data owner.

3.7.11. Term statuses

The lifecycle of a term can be described as follows:

Draft - When a term is created and saved by the requestor prior to submission to the RMS solution. This draft term is only visible to the requestor.

Provisional – As soon as the CR is validated by the data steward (once it's been confirmed that the request makes sense and is complete) the term is created as provisional and becomes visible to all users (at this point the term becomes public). This is prior to approval by the List Owner.

Current – When a term is approved or approved with changes by the List Owner for use in new applications/records (either EMA for internally-managed lists or another maintenance organisation –such as EDQM, WHO, etc. – for externally-managed lists).

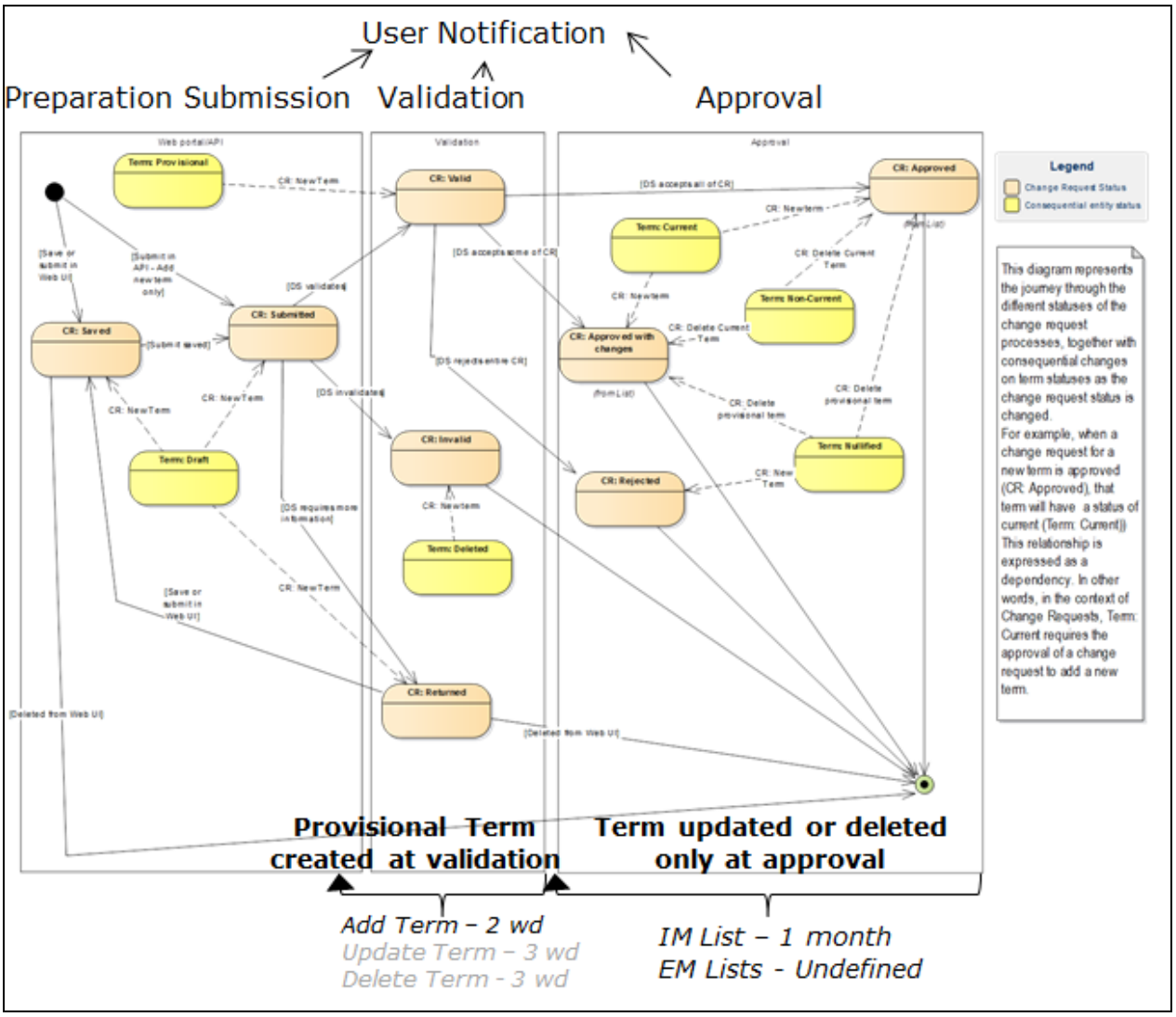
Nullified – When a provisional term is considered not to be acceptable and therefore is rejected.

Non-current – When a term is not approved by the List Owner for use in new applications/records and/or refers to legacy data.

Under consultation – This will apply to lists/ terms which are being made available for consultation and indicates that the content of the List has not been sign-off by the List owner. This will only be used in exceptional circumstances.

Terms get updated/deleted only when the CR is approved.

The diagram below shows the changes of status and transitions as one progresses through the CR process. The draft status of a term is unchanged if a CR is returned, which is why there is no connector between draft and returned. By only dealing with changes, the diagram is kept as uncluttered as possible. For example, a CR can be submitted against a current or provisional term, so each of these statuses would need to be associated with earlier steps in the process.



The user is notified when:

- The CR is submitted (the CR ID is provided with the notification)
- The CR is validated (the provisional term ID is provided with this notification)
- The CR is invalidated/rejected (this notification will include the reason(s) for the invalidation/rejection and, if possible, a recommendation as to the term -and term ID- that should be used instead)
- The CR is approved (the notification will contain the current term ID)

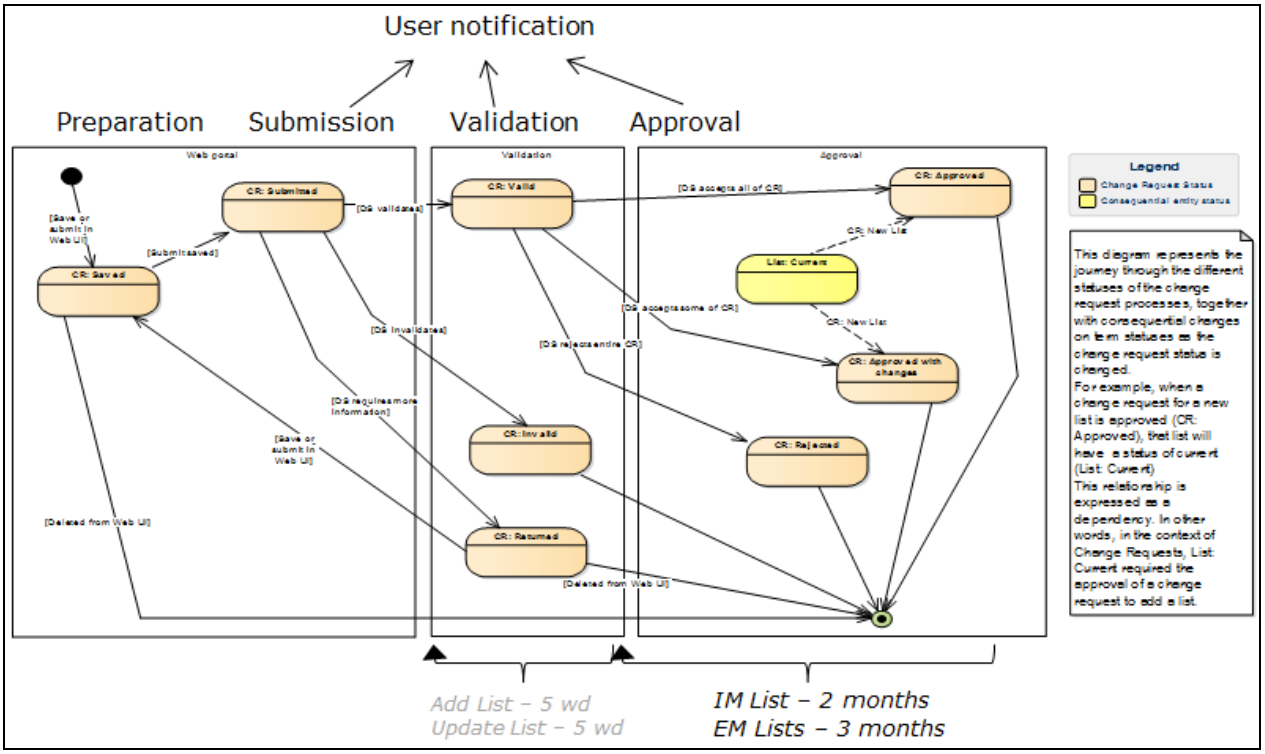
3.7.12. List statuses

RMS users can send CRs for the creation of new lists. The user can save a list CR and edit it as many times as needed before submitting it.

Similarly to CRs for new terms, there is also a validation process for CRs for new lists by which the data steward can either validate the CR, return it (in case the request is incomplete) or invalidate it.

The main difference between term CRs and list CRs is that whereas terms are created as provisional (with a provisional ID) once the CR has been validated, lists are not created as provisional following validation of the CR. Instead, a list will only be created after it has been approved, once all the information related to that list is considered acceptable. The list ID will only be provided once approved.

The diagram below shows the changes of status and transitions in the CR process.



The user is notified when:

- The CR is submitted
- The CR is validated (list details are not checked at this point and no provisional lists will be created –lists are only created once the CR is approved)
- The CR is invalidated/rejected (in which case the notification will contain the reasons for the invalidation/rejection)
- The CR is approved/approved with changes (the notification will contain the list ID)

3.7.13. User notifications

The templates below show the main information that will be included in the notifications that will be automatically sent by the RMS system to users in the context of change requests for terms and lists.

TO REQUESTOR ON SUBMISSION

Subject: RMS CRxxxx Step 1 Change Request - Submitted

Dear Sir/Madam,

RMS has received a new Change Request "CR name" with the identifier CRxxx.

Type of Change Request: [request type]

Reason for request: [Request justification]

You can click here to see this Change Request in RMS.

Regards,

SPOR Data Management

...

TO REQUESTOR ON VALIDATION

Subject: RMS CRxxxx Step 2 Change Request – Valid/Invalid

Dear Sir/Madam,

The Change Request "CR name" with the identifier CRxxx has been validated and found to be **Valid/Invalid.**

Type of Change Request: [request type]

Reason for request: [Request justification]

(If Valid CR type = Add Term) The Controlled Term that was the subject of this Change Request is now available in

RMS with the status of "Provisional" and an identifier of 100000xxxxxx.

The following comments apply: "comments text"

You can click here to see this Change Request in RMS.

You will receive a further notification when this Change Request has been reviewed.

Regards,

SPOR Data Management

...

TO REQUESTOR ON APPROVAL

Subject: RMS CRxxxx Step 3 Change Request – Approved/Rejected

Dear Sir/Madam,

The Change Request "CR name" with the identifier CRxxxx has been **Approved/Rejected.** *(If Approved)* These changes are now published on [list ID]

Type of Change Request: [request type]

Reason for request: [Request justification]

The following comments apply: "comments text"

You can click here to see this Change Request in RMS.

Regards,

SPOR Data Management

…

3.8. Translations

The translations functionality in the RMS tool involves National Competent Authorities (NCAs) only translating data. No translations are expected from industry users.

RMS allows for the insertion of translations in two different ways: online (strongly recommended) and offline bulk upload (strongly discouraged as it comes with a lot of risks). Sections *3.8.1.* and *3.8.2.* below will describe this process in more detail.

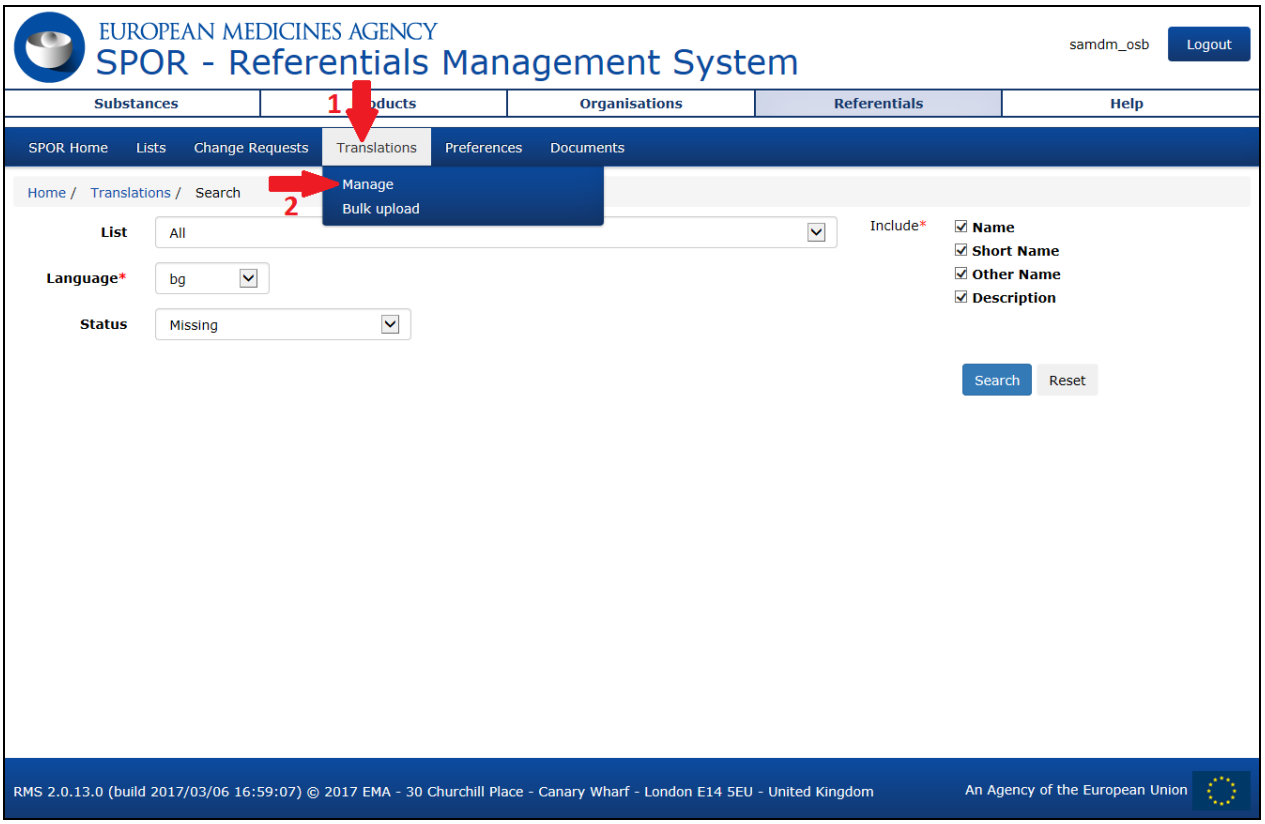
3.8.1. Adding translations online

This is the method recommended for adding translations since it has fewer risks than adding translations offline (see details in section *3.8.2. Offline Bulk Upload of Translations*).

In order to add translations online, the user should do a translation search first and then select the terms to be translated among the translation search results. From here, translations can be added. Detailed instructions on how to do this are described in sections 4.8.1.1. to 4.8.1.3. below.

3.8.1.1. Translation Search

The translation process starts with a search. In order to search for translations, click on "Translations" option in the RMS menu bar (1) and then on "Manage" (2). The following screen with search criteria will appear:



In the "List" field, the user can specify whether translations need to be searched just within one particular list (in which case the user needs to pick it from the drop-down list) or across all lists. The RMS system doesn't allow for the search of translations in several lists (it's either all lists or just one list).

The "Include" field can be completed by the user to specify one or many fields (e.g. name, short name, description, etc.) to be translated. For example, a user can search for terms across all RMS lists where the French translation of the description is missing or for terms in a particular list where the Portuguese translation of the main term name is missing.

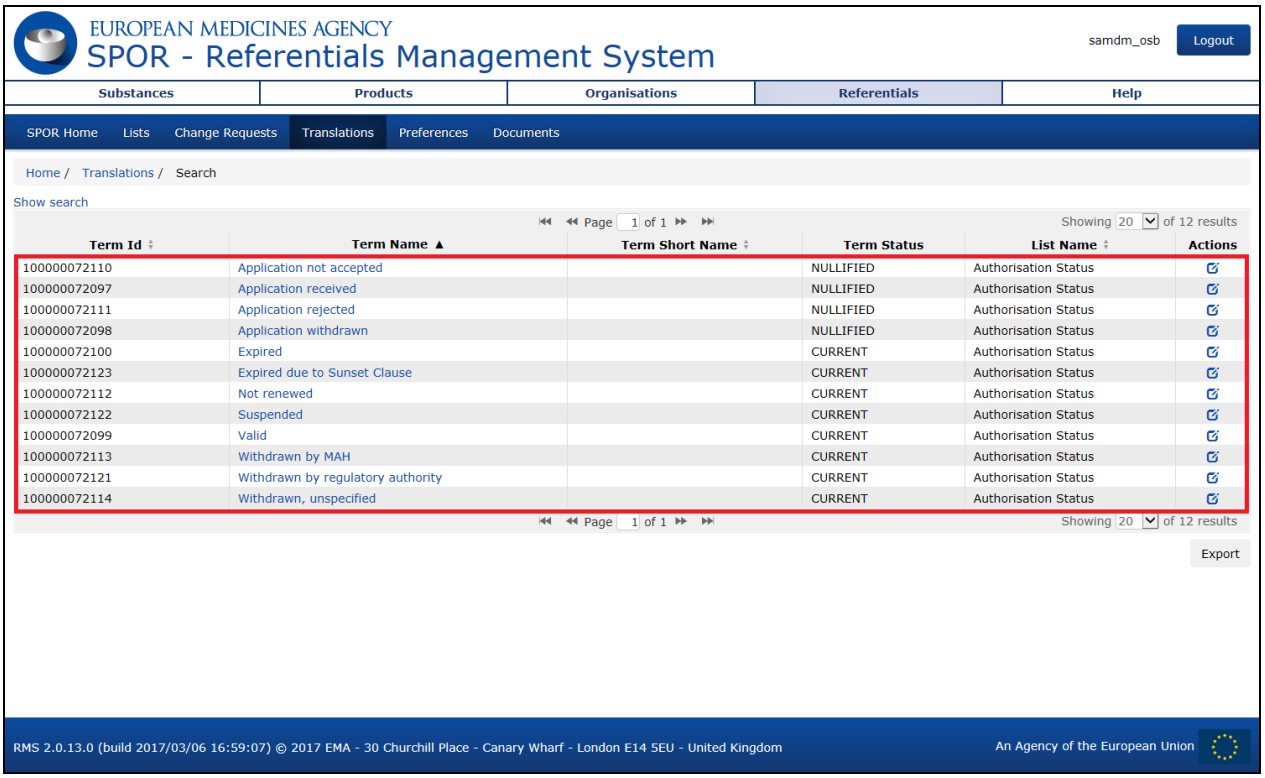
The language(s) and country for which the user is approved to enter translations (e.g. DE-DE) can be selected (one at a time) in the "Language/Country" field.

In the "Status" field the user can select the status of the translations required (i.e. "No translation", "Provisional, "Current", "Non-current", "Nullified").

To start the search, the user should click on the "Search" button at the bottom of the screen.

3.8.1.2. Translation Search Results

Once the search criteria have been completed and the "Search" button has been clicked, a screen similar to the following will appear with the search results at the bottom of the screen (in red):



Translation search results will appear as a "View List of Terms" view and the search criteria should appear collapsed so that there is more space in the screen for the search results.

These results will be matched by criteria, ordered by List/Term name (although user-driven sorting is possible) and there is no limit in the number of results shown in the screen (whereas in the normal search there is a limit of 1,000 results).

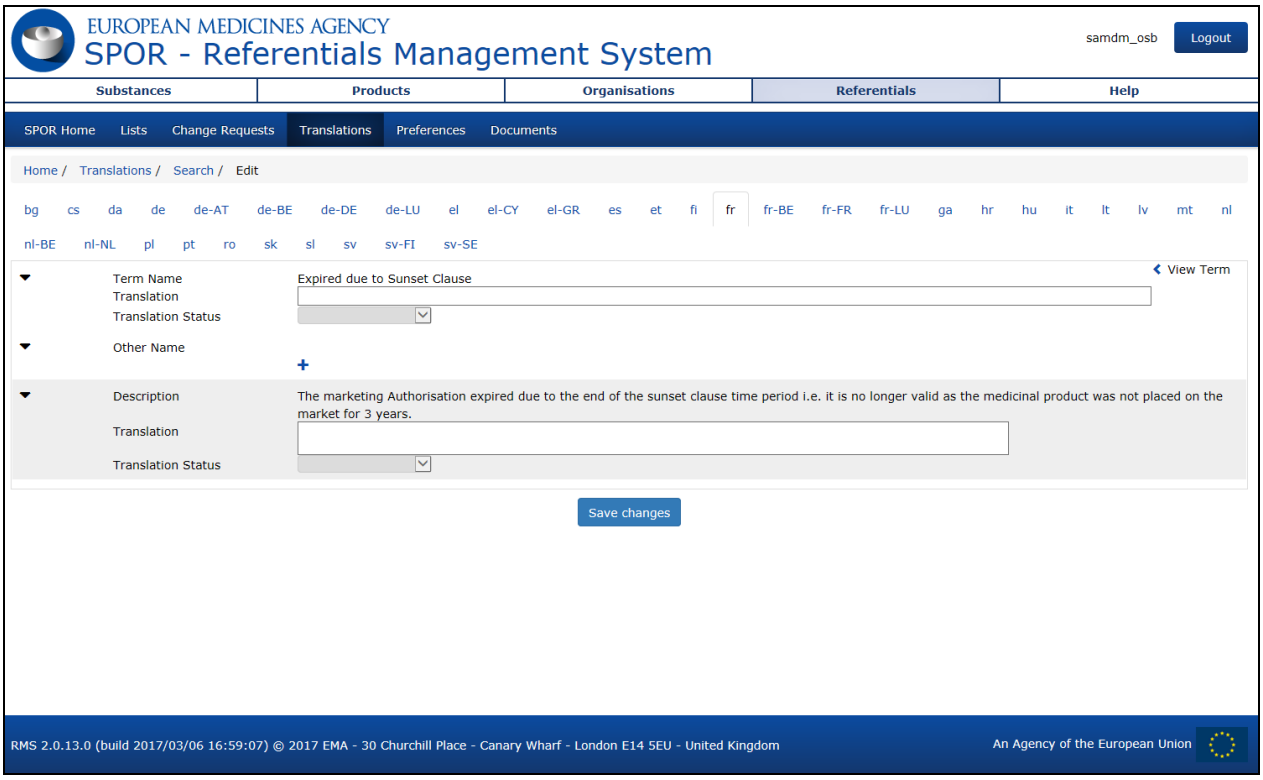
Exporting of results is possible at this stage by clicking on the "Export Results" button at the bottom of the screen above. The following needs to be taken into account when exporting translation results:

- The export of Translation Search Results can only be done in CSV format (for other types of export it can be either CSV or XML format)
- One file will be created per list exported (i.e. if the terms selected to be exported belong to 10 different lists, the system will create 10 files)
- All term attributes will be exported, including extensions
- The export will contain the term in English and in the language selected by the translator (or a blank row if the translation is missing)
- It's not possible to export only some languages as the report is user-profile driven (for instance, if the translator has been approved to provide translations only in Italian, the export will only contain terms in English and Italian).
- Exporting (or browsing) any or all languages can be done from the "View Lists".
- Exporting results across all lists is not possible.

3.8.1.3. View/Update Translation

In order to view or update a translation, the user should access the "Summary of Term details" screen which includes both translatable (and therefore editable) and non-translatable (view only) attributes.

To access this screen, the user should click on any of the translation search results as shown in the previous section (section *3.8.1.2.Translation Search Results*). A screen similar to the one below will appear:



Fields where a translation applies (term name, short name, other name and description) should be edited taking into account the following rules:

- The attribute "Term name" should always be translated (same text in another language)
- The attributes "Short name" and "Description" can only be translated if there is English text existing (same text in another language), although this is optional
- Users can optionally enter one or several "Other names" in other languages even if no "Other name" in English exists. However, users need to make sure that if there are any translations added to an "Other name" in English they should be an exact translation of that "Other name". If the translator believes that the term is not an exact translation, then this should be added as a different "Other name".

Fields that can't be translated will not appear in the screen.

In addition, the user should select the "Translation status" of each one of the attributes edited:

- Users can enter provisional/current translations
- Users can update a translation status to non-current or nullified
- Users can delete translations

Of note, if a term name in English is updated for which translations in several languages existed, the status of all those translations will be reset to provisional since changing the English name can have an impact on the accuracy of the translations. Therefore, translators will be expected to validate those translations, provide an alternative translation if the previous one is not adequate anymore and update the status to current if relevant. This means that even if a translator has already inserted a translation for a particular term, he/she may need to review the translation again in case the term name in English has been modified.

3.8.2. Offline Bulk Upload of Translations

This functionality is currently not available. It will be made available in a future RMS release.

Bulk upload is a translation process whereby translators from National Competent Authorities (NCAs) provide translations offline in a list of terms exported from RMS. This process is limited to NCAs only and it is not the recommended process for providing translations given the number of risks described further down in this section.

The first part of this process is similar to the process of adding translations online: the user needs to do a translation search (see section *3.8.1.1. Translation Search*), then select the terms to be translated and export them (see section 3.8.1.3. *View/Update Translation*).

At this stage the translator should open the exported .csv file and add the missing translations in the relevant cells following the rules described further down and ensuring that no information other than the required translations is amended.

The following advice should be followed when performing translations offline:

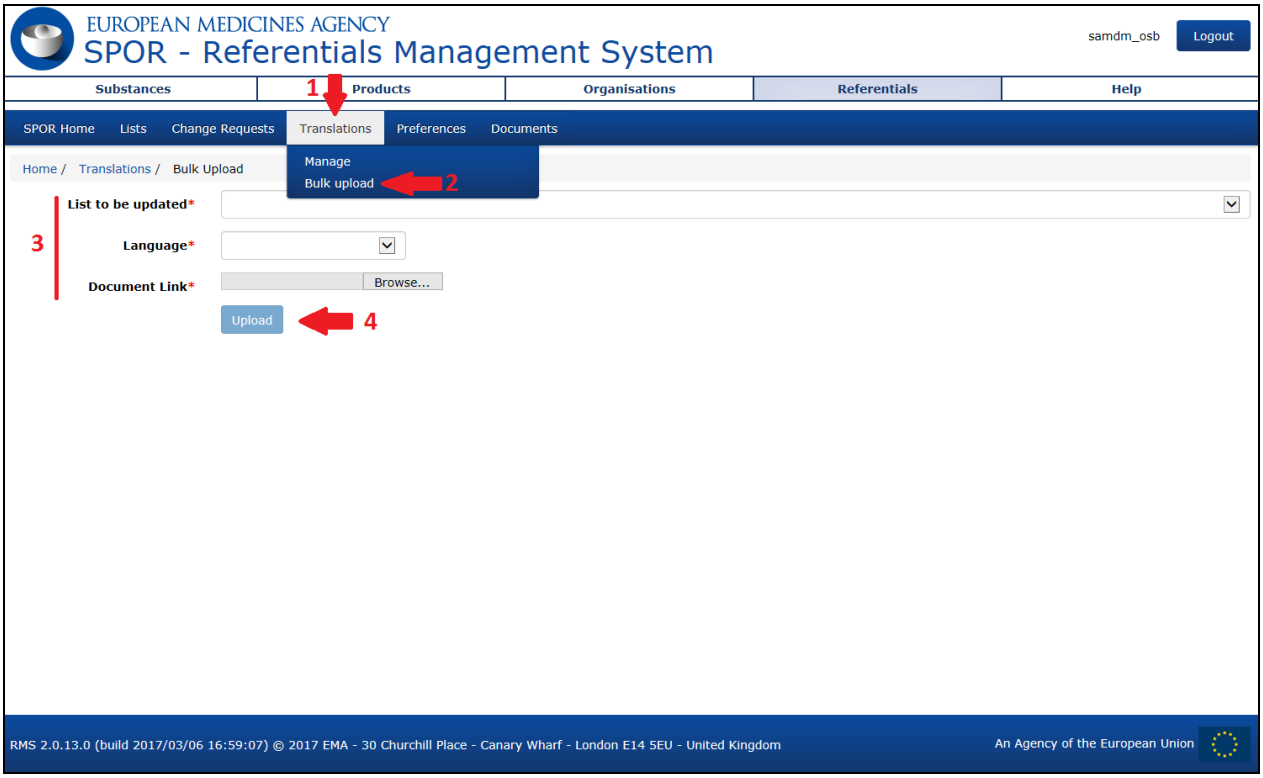
1. Only export search results you will work on.
    - If translating only a small number of terms, use the online functionality instead.
    - If translating a large number of terms offline beware that this may take a while and terms (in English) may be changed online in the meantime. Translations will only be uploaded if the English version matches (if the version of any of the terms translated doesn't match, the file will be rejected). In order to avoid this issue, the user should only export and translate smaller subsets at a time.
2. Edit fields where a translation would apply
    - Always translate the Term name (same text in another language)
    - Only translate Short name/description if there is English text (same text in another language)
    - Optionally enter Other names in other languages even if no English exists (other names in different languages do not relate to each other)
3. Select the translation status (if not, it will default to "provisional")
    - Enter provisional/current translations
    - Delete translations or change them to non-current/nullified
    - Users should only upload translations that they have worked on (i.e. translations that have been changed). E.g. if a user exported a list of 5000 records and only added translations

for 20 terms, the 5000 records will be overwritten –even if the translator didn't work on most of them. This is why the EMA strongly discourages the use of this process.

Similarly, the following rules should be adhered to:

1. Do not change the English version of the attributes.
2. Do not change the layout/format of the exported file
3. Do not upload unchanged records/translations
   - The Upload Translation process does not detect deltas!
   - The Upload Translation process overwrites any existing translation and generates new minor versions for every term loaded (even if there have been no changes to those records).

Once all translations have been inserted and the file is considered ready to be uploaded in RMS, save the updated .csv file. The next step is to upload the translations in the system. To do so, the user should click on the "Translations" option (1) in the RMS menu bar, then on "Bulk upload" (2). In the following screen (below), the user should select the list to be updated, the translation language that is being provided with the file and the location of the document as shown below. Once this is done the user should click on the "Upload" button as shown below.



When uploading the file(s), there will be some validation checks done by the RMS system. If there are any issues encountered during validation an error message will pop up and the file will not be uploaded (i.e. even if the file contains only one minor error, the entire file will be rejected!). The system will not point exactly at the problematic record(s) but should give a hint of the issue. The user should then check the entire file and correct the file and try the upload again.

Of note, the RMS system doesn't detect deltas. Instead, it overwrites any existing translations and generates new minor versions for every term loaded (even if no changes have been made to some of the terms). Therefore, the user should ensure that only terms that have actually been edited are loaded through the bulk upload process.

3.8.3. Follow-up of Translations

Translators can be triggered to do their translation work and can find out what terms are pending to be translated through the follow-up of translations. This follow-up can be performed using either the "Subscriptions" or the "Saved Searches" functionalities (both explained in sections *3.9.Subscriptions* and *3.11.Saved Searches* below).

Subscriptions can be set up so that users get notifications informing about changes in a particular list. To do so, users should subscribe to the lists that are relevant to them (see details in the section below).

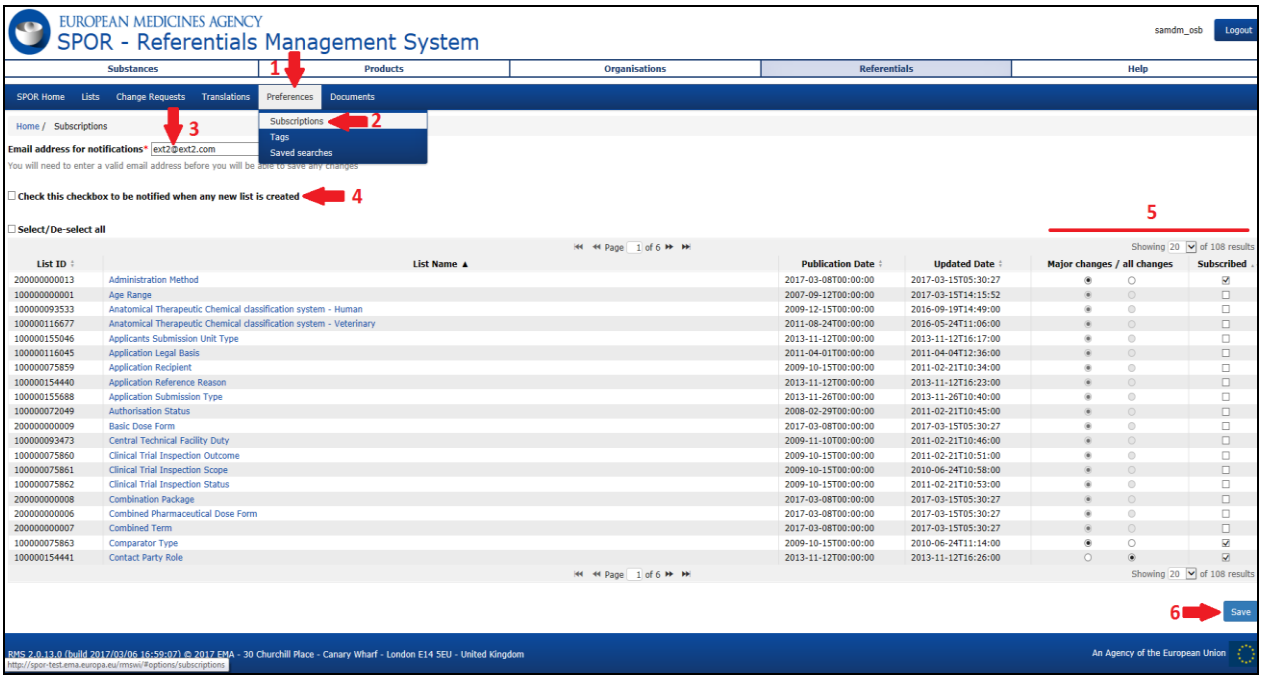
Once subscribed to a particular list, users will receive an automated notification every time that there is a change in that list. Through this process translators can be reminded and prompted to do translations as new terms get created.

Subscription notifications do not tell users whether the translation is missing or provisional, nor what has changed in the list. Therefore, the user should still run a Translation Search (see section *3.8.1.1. Translation Search*) to identify what exactly has changed.

The other mechanism to check on pending translations is through "Saved Searches" (see details in section *3.11. Saved Searches*). Users can save their frequent List searches (e.g. search terms in German (DE), search term names only, search missing translations only, etc.) By doing so, users can quickly run a search at any point in time and identify if there are any missing/pending translations. By specifying a range of "modification dates", users can easily identify what has changed in the list since the last time they checked.

3.9. Subscriptions

The purpose of the "Subscriptions" functionality is to keep users informed of changes in particular lists by means of an e-mail notification. It is located under the "Preferences" option (1) in the RMS menu bar. Once the "Subscriptions" option (2) is clicked the following screen will appear:



At this point, the e-mail address where notifications should be sent should be specified in the e-mail address box (3). This should be a company e-mail address (ideally a group e-mail address) to ensure notifications reach someone in case a user is on holiday or leaves a company. If this is not possible, then a forwarding rule is highly recommended to avoid the issue above.

In addition, the user can choose to be notified every time that a new list is created in RMS (option just below the e-mail address box -4-).

Next, the user should browse the list of lists appearing in the lower part of the screen above and tick/untick the "Subscribed" box (5) in the last column of the table, as required. The system also allows to select/deselect all lists by ticking the box just above the list of lists.

For each list to which the user is subscribed, the user should specify (5) whether they would like to subscribe to major changes (i.e. new terms, updates to term statuses or updates to EN Term name/description) or to all changes (this includes major changes as well as any other minor changes such as translations or updates to other term attributes). Of note, all major changes require translations to be checked.

Once all the relevant information has been completed, the "Save" button at the bottom of the screen above should be clicked.

Notifications will be sent to users as a monthly e-mail, and will include the list ID, the list name and a brief description of the type of changes (i.e. creation, deletion or update of a list). However, the notification will not have any more detailed data content. Therefore, users requiring more details will need to log on to the system and browse the list to identify what those changes are. Searching by modification dates (e.g. search for changes implemented after a specific day) is recommended in this case for a more efficient search. From here, the user can choose to export, tag, translate, etc.

An example of a notification follows below:

To: myemail@emailme.com
From: MDM-noreply@emea.europa.eu
Subject: RMS Subscriptions (mm/yy)

Dear Sir/Madam,

Please be informed that in Mmmm yyyy:

a) The following list(s) you have subscribed to have been updated:
(List Identifier -- List name --List shortname -- Type of change)
100000093533 -- Anatomical Therapeutic Chemical classification system -- Human -- ATC-H -- Major
100000000002 -- Country -- Country -- ATC-H -- Minor

b) The following list(s) you have subscribed to have been de-activated:

(List Identifier -- List name -- List shortname)
100000155046 -- Applicants Submission Unit Type -- applicantsumbunittype

c) The following new list(s) have been created:

(List Identifier -- List name -- List shortname)
100000075859 - -Application recipient

For more information on these changes please use the links above to visit individual lists or click here to sign in to the RMS system.

Regards,
SPOR Data Management

(This is an automated e-mail - please do not reply as e-mails to this address will not be monitored.)

This is also the type of notifications that translators will receive in case they subscribe to lists (i.e. there is not a specific subscription system for translators).

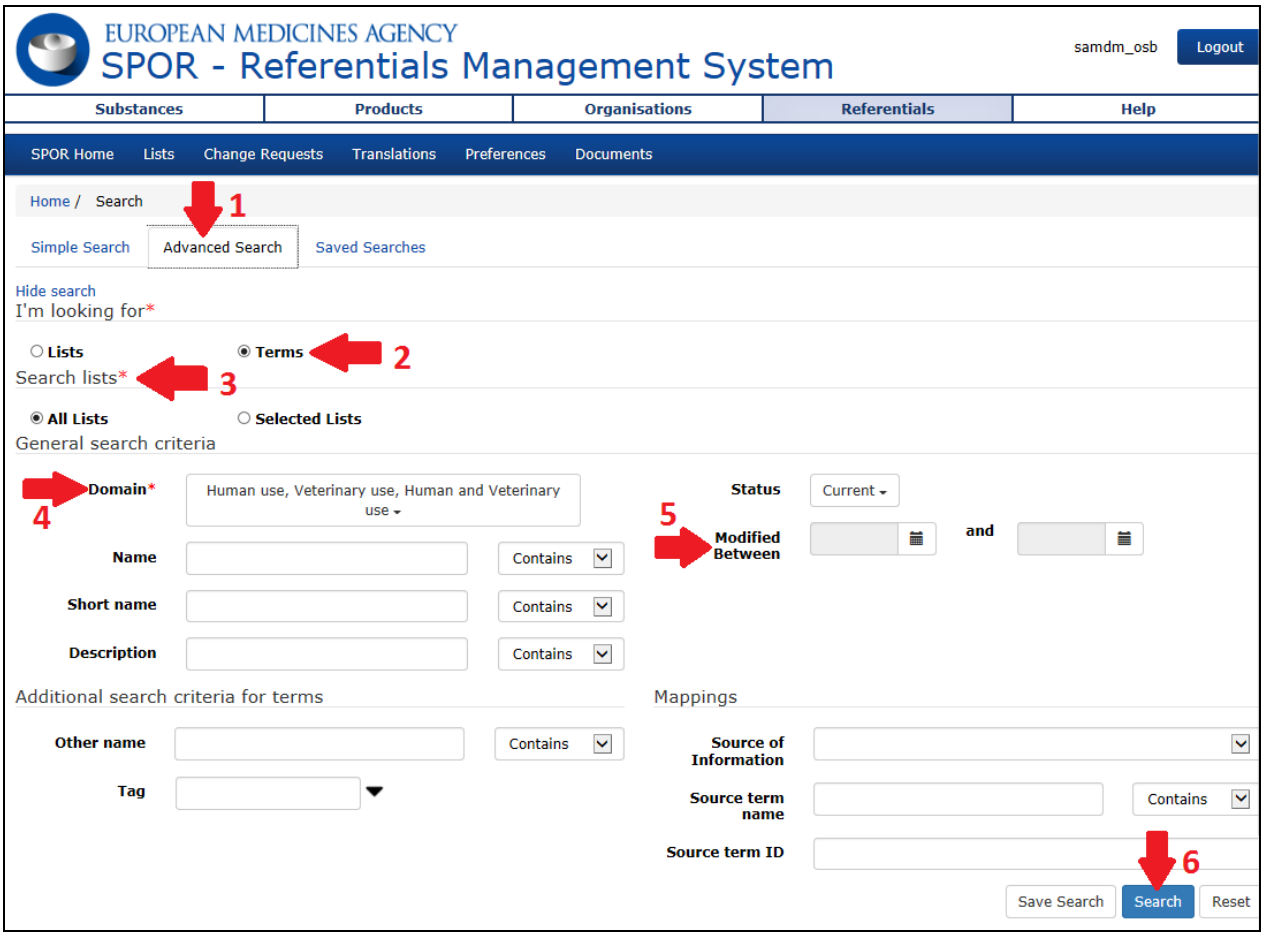
The reason behind the frequency of one e-mail notification per month is to minimise the number of e-mails to be received by users given that RMS lists may undergo a big number of changes per day.

Needless to say that this functionality is redundant for those stakeholders using an API to make more frequent and automated updates to their systems or manually checking for changes in RMS with a higher frequency. However, it's still a valid option for those stakeholders who are planning to manually check for changes in lists without the API as this notification system will provide a quick summary of what has changed in a given period of time. This functionality also has the advantage of notifying the users whenever a new list has been created or deleted.

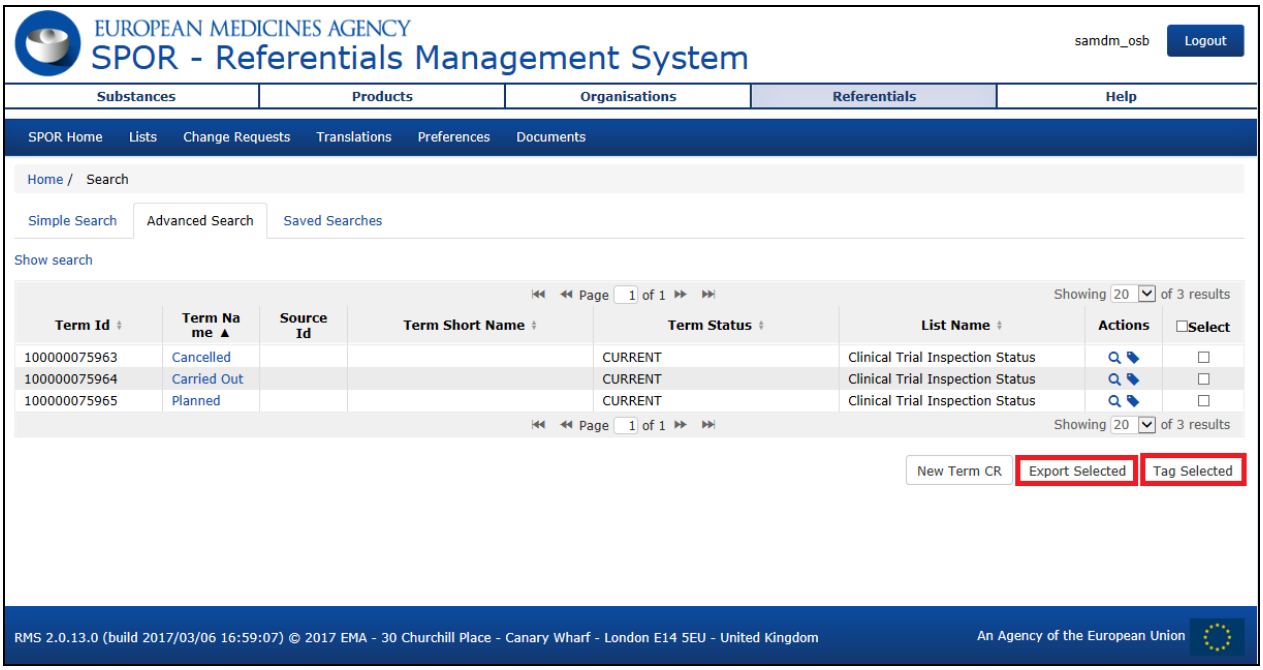
3.9.1. Follow-up of Subscriptions

Once a subscription notification has been automatically sent to a user about an update of a list, the follow up in RMS has been envisaged as follows:

The user should go to the "Advanced Search" functionality by clicking on "Lists" and then on "Search". The "Advanced Search" tab should be selected in the following screen (1).



The user should select the option to search for "Terms" (2) -as opposed to "Lists"-, as well as the list (3) that has been updated from the drop-down list, the domain (4) and the relevant date range (5) for searching purposes. After clicking on "Search" (6), a screen similar to the below should appear:



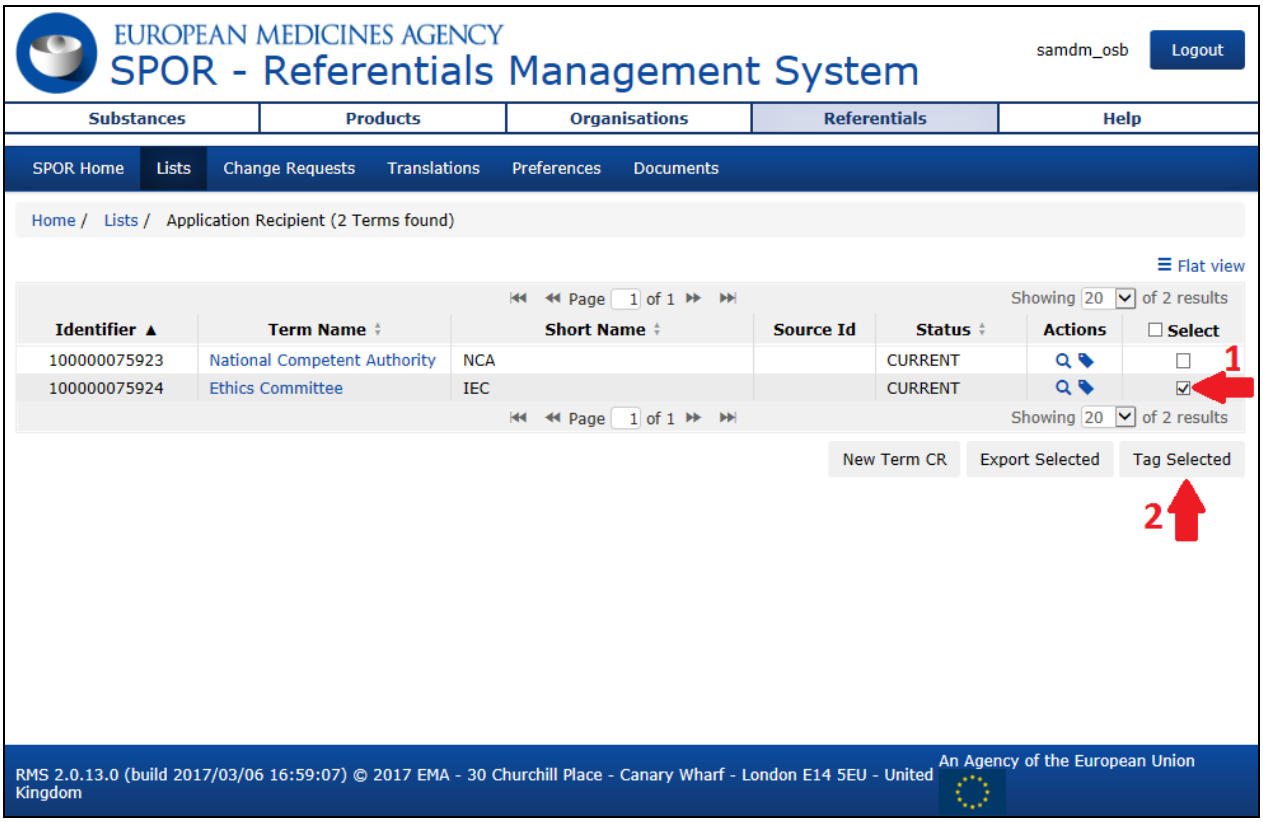
Two functionalities that the RMS offers to follow-up on subscriptions are exporting and tagging selected terms ("Export Selected" and "Tag Selected" buttons in red in the screen above).

3.10. Tags

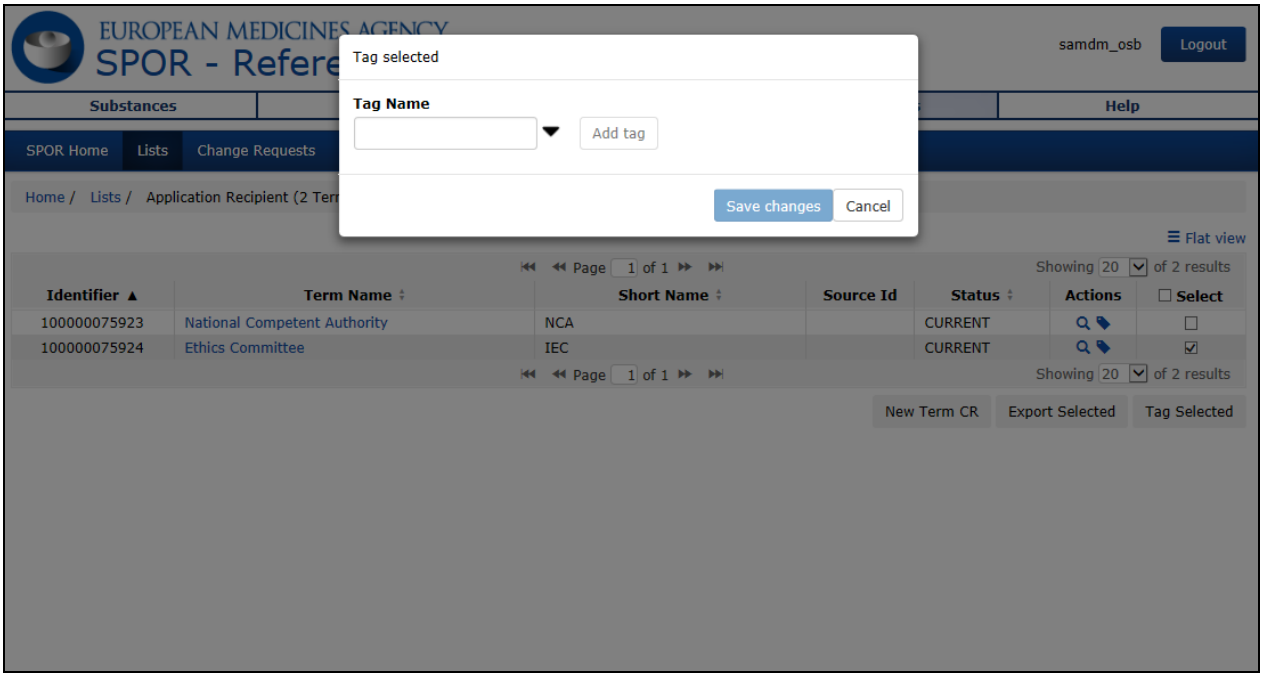
Tagging is a self-service functionality located under the "Preferences" option in the RMS menu bar and its purpose is to create subsets of terms within a list or even across lists so that users can access the terms that they require in a quicker way without the need to browse through hundreds or thousands of terms.

For instance, if the "Country" list contains 200 countries and a user only requires 20 out of those 200, the user can create his/her own subset by tagging those 20 countries hence saving some time.

To tag terms, the user should open a list to view the terms of that list (or search across lists), select the term(s) to be tagged by clicking the "Select" box (1) next to the relevant term and click on "Tag Selected" (2).



The following screen will appear:



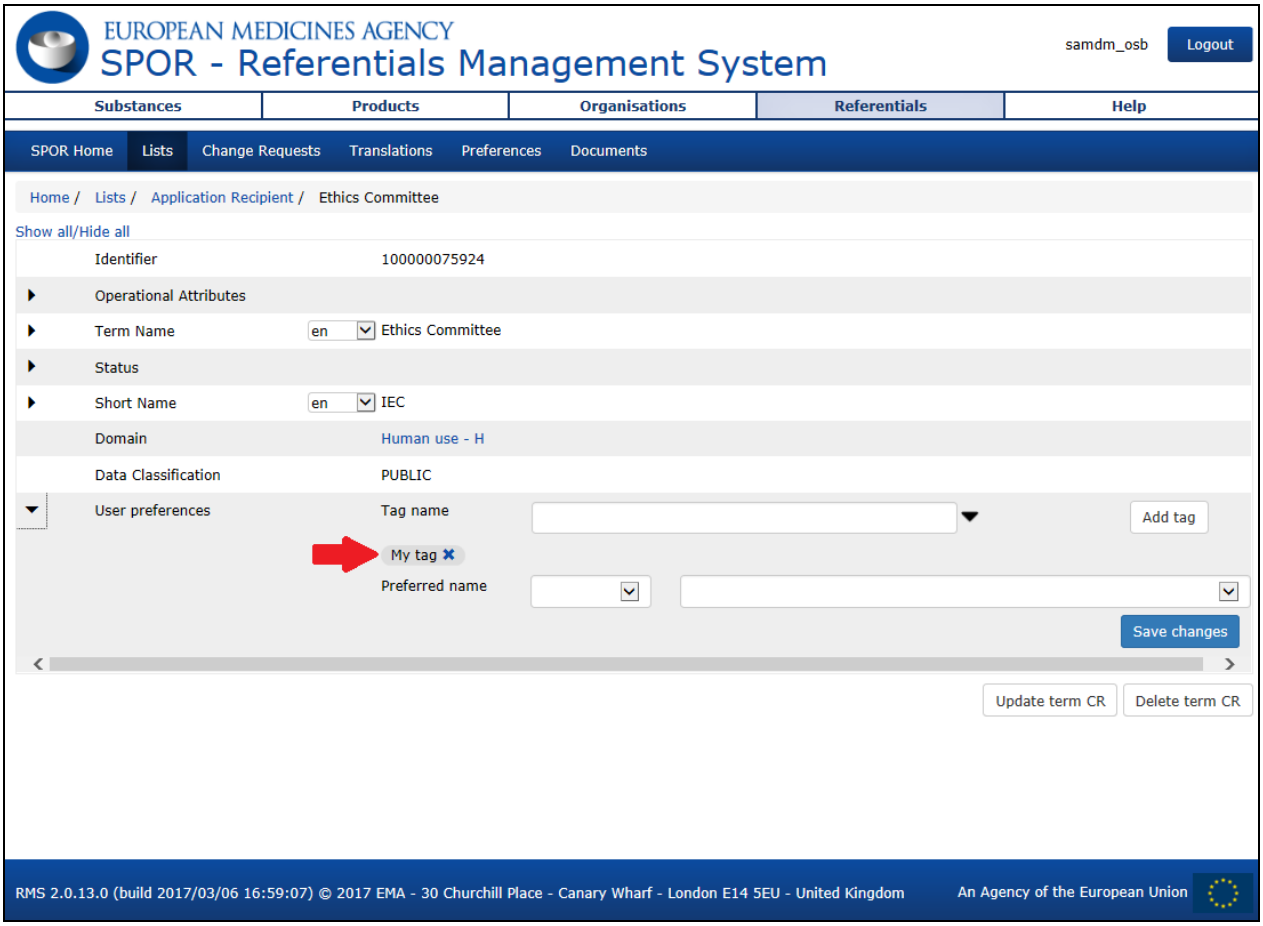
In this screen the user should either add the terms to an existing tag (by typing the first letters of the tag's name and selecting it from the drop-down list) or add them to a new tag (by typing the name of the new tag, then clicking on the "Add tag" button and on "Save changes"). The system doesn't allow for the creation of two tags with the same name so each tag should have a unique and meaningful name.

The user fields in the "View Term" screen allow the user to do the following actions (all marked in red in the screen below):

- add terms to tags (either new or existing tags)

- delete terms from tags

- select the preferred name of the user (amongst term name, short name or any other name in any language). In this case, that name will appear with a flag as the user's preferred name and will only be visible to that particular user (in red below). This can be particularly useful for stakeholders having particular naming requirements for certain lists.

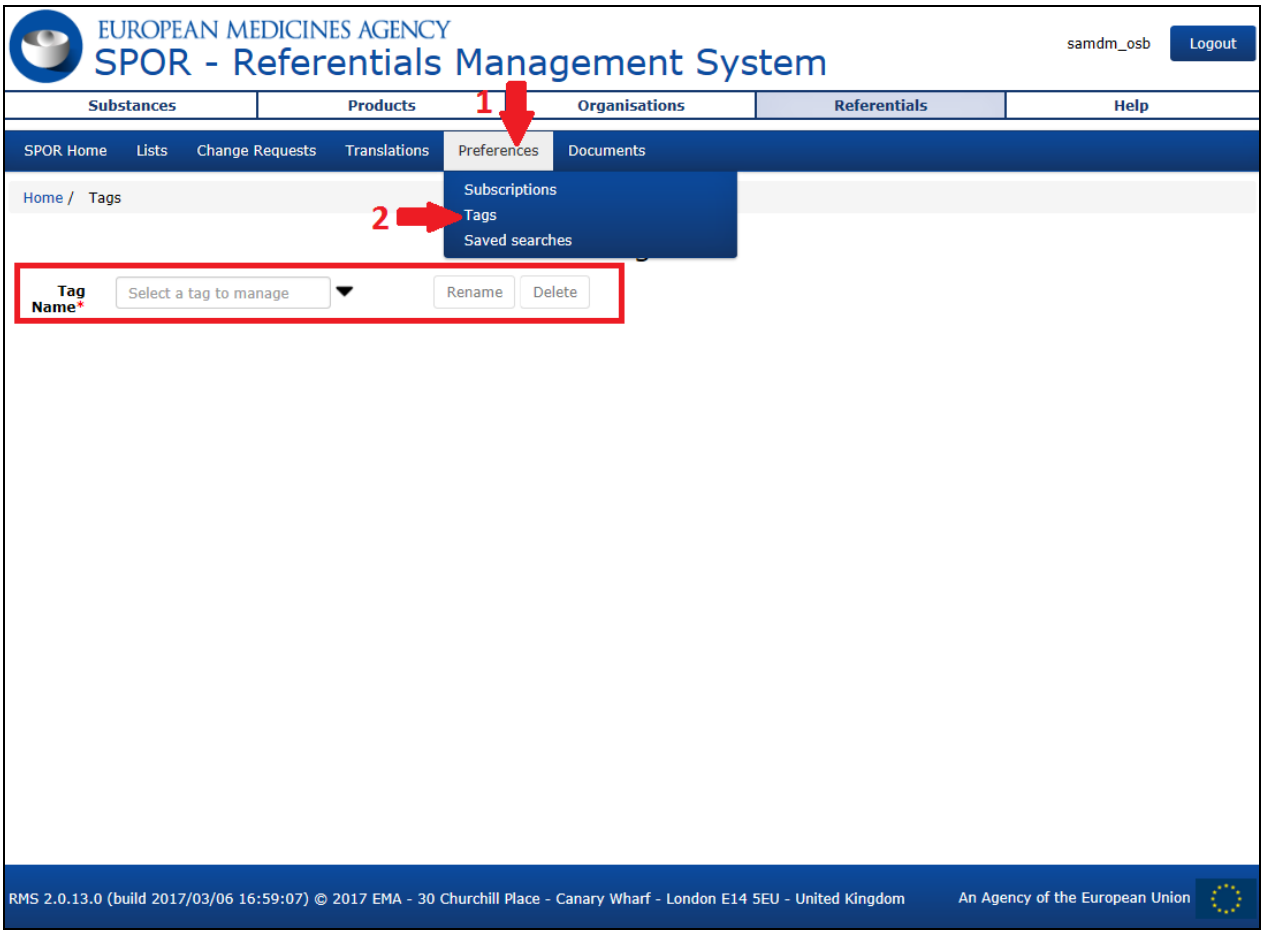


The following rules apply for tagging:

- By tagging the user can chose to add the selected terms to a new tag or to an already existing tag.
- Each user can create a maximum of 1,000 tags (1,000 subsets of terms).
- Each tag can contain a maximum of 1,000 terms (if more than 1,000 terms are required then the user should refer to the entire list)
- There is a maximum of 50 tags per term per user

3.10.1. Manage Tags

Tags can be managed by clicking on the "Preferences" option (1) of the RMS menu bar, then on "Tags" (2) and then selecting the tag to be managed in the "Tag Name" field, as shown below in red:



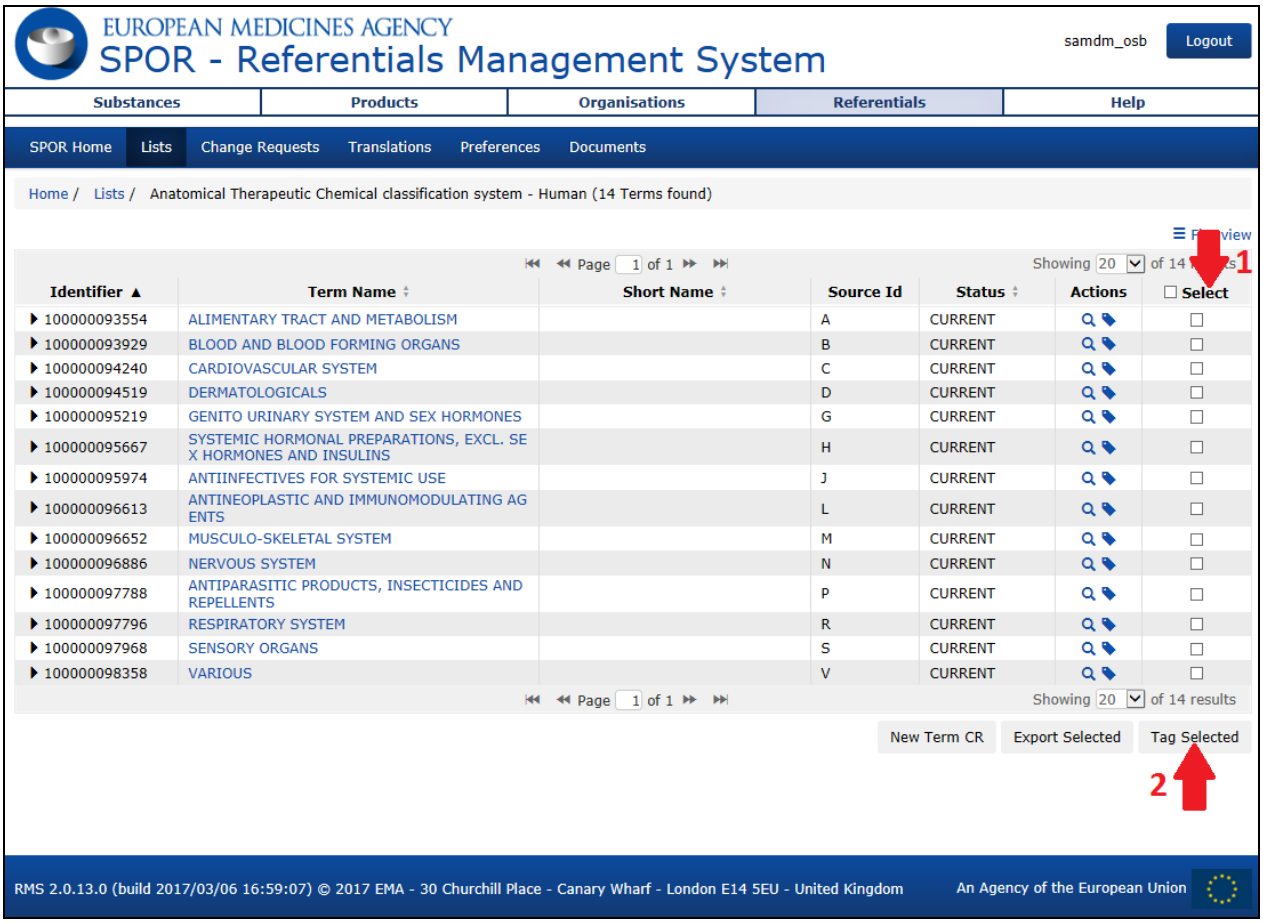
Once the tag to be managed has been selected, the following actions can be taken:

- Rename Tag
- Delete Tag (from all terms)
- Untag selected (remove certain terms from the tag)
- Export selected

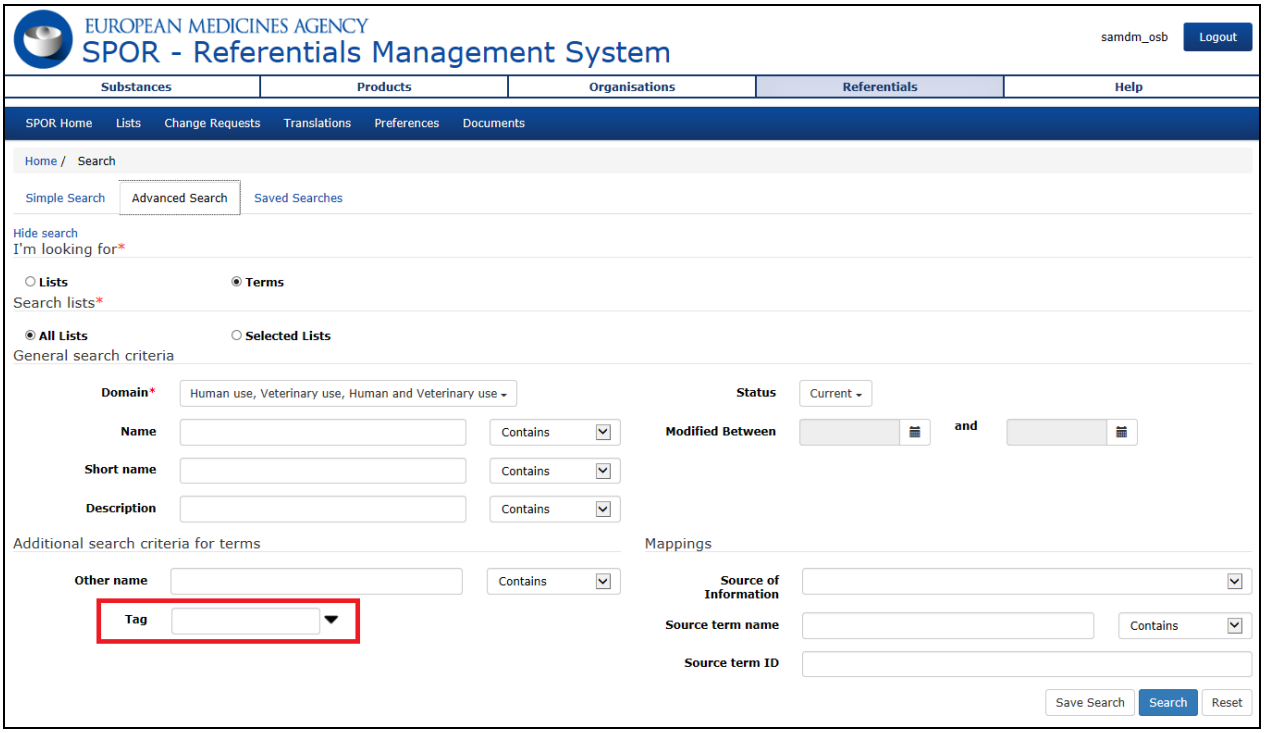
Similarly to subscriptions, the maintenance of tags will remain with each user since this is a self-service capability.

Tags can also be managed from other screens as follows:

- In the "View List of Terms" (both flat and hierarchical lists), the user can select a number of terms and click on "Tag Selected" (see below in red):



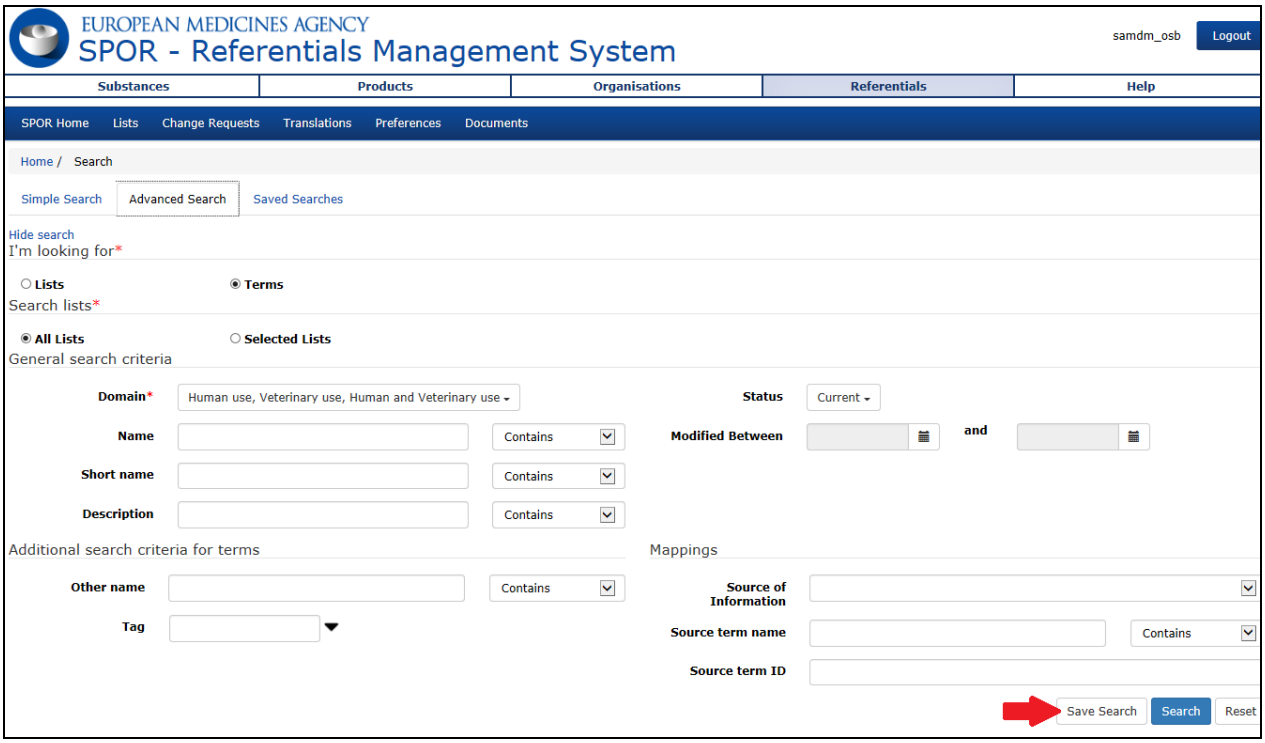
- In the Advanced Search, the user can search for terms in a specific tag -one at a time- (see below in red):



3.11. Saved Searches

Searching across several lists of different nature with lots of different data attributes can be time-consuming. The "Saved Searches" functionality was created so that complex search queries that are run frequently can be saved and reused in the future.

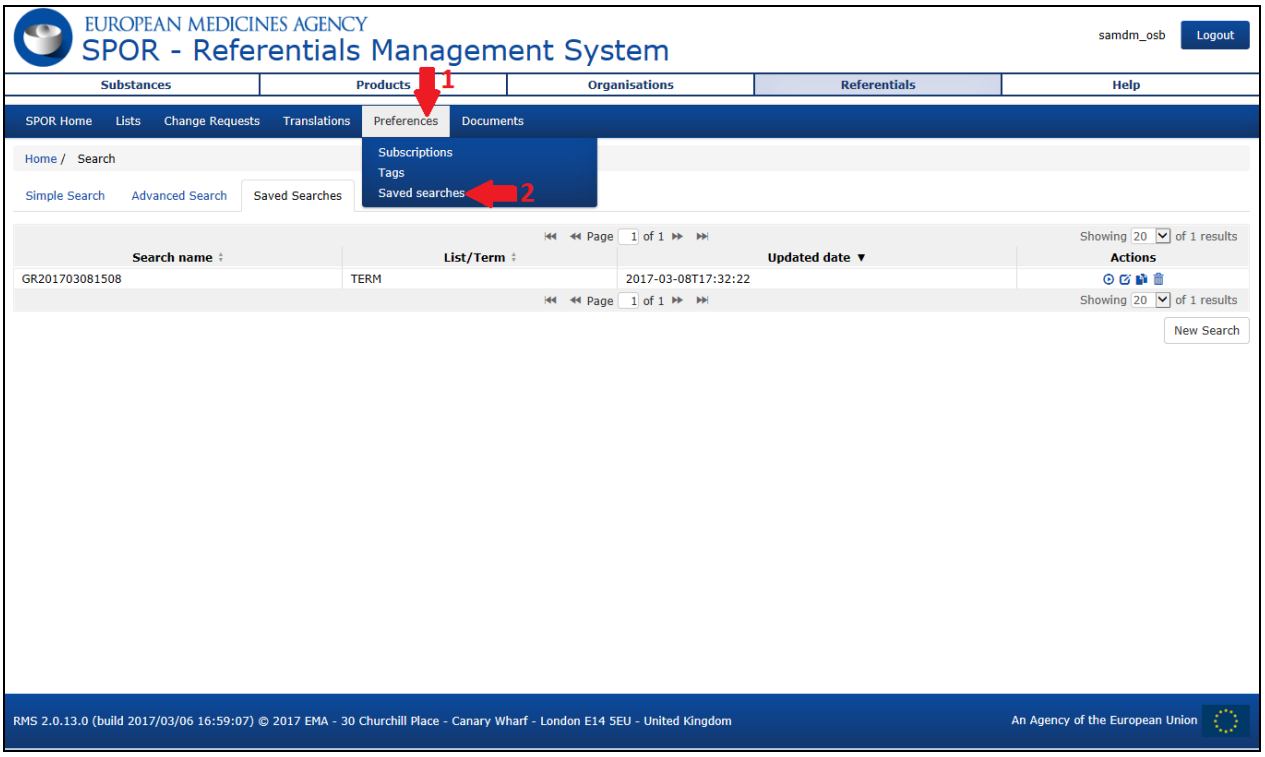
As explained under section *3.5.2 Advanced Search (Terms)*, a particular set of search criteria can be saved for future use if needed by entering all the required search criteria in the "Advance Search" tab, by clicking on the "Save Search" button at the bottom of the screen (in red below) and by giving it a name.



This functionality can be redundant for those using the API but remains a good alternative for those stakeholders not planning to use the API services.

3.11.1. Manage Saved Searches

Saved Searches can be managed by clicking on the "Preferences" option (1) on the RMS menu bar and then on "Saved Searches" (2). A screen similar to the below, with the search criteria collapsed, will appear:

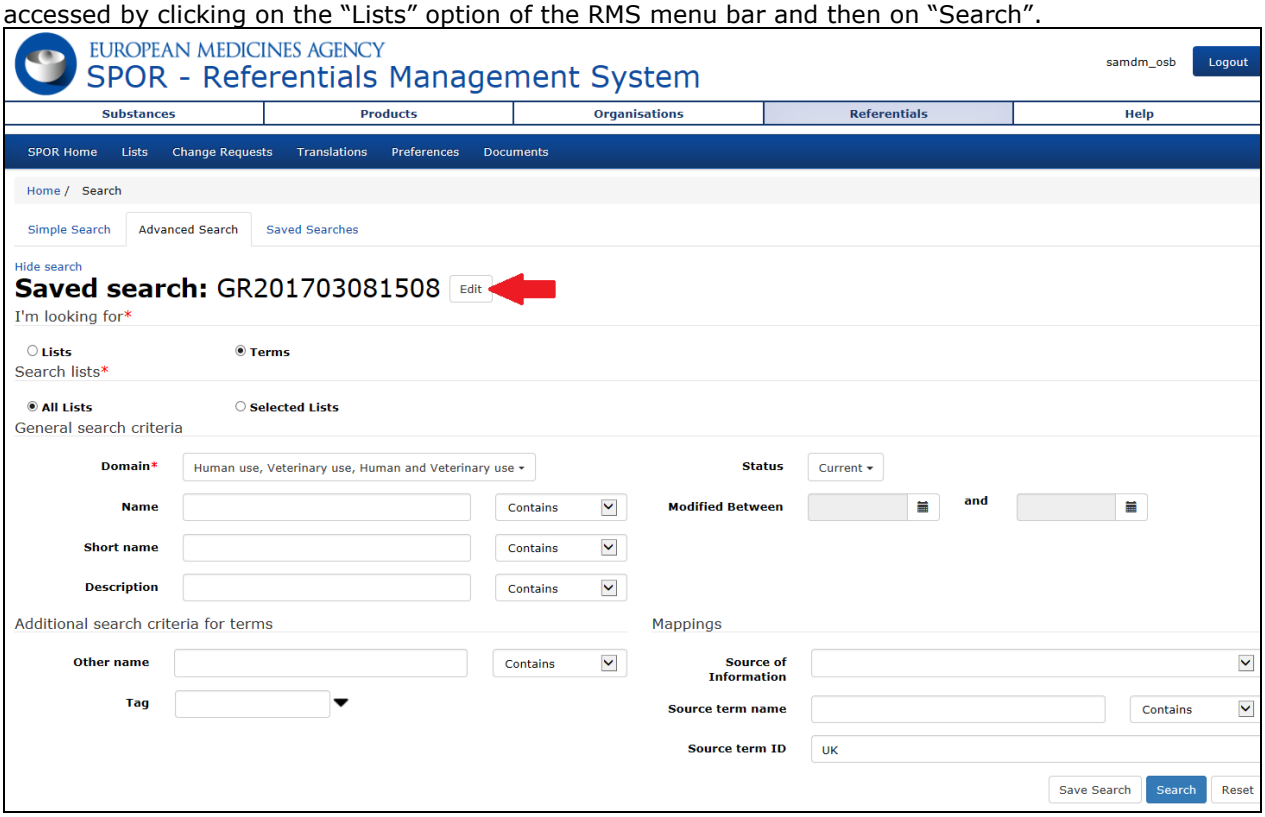


There are 4 different actions that can be taken, represented by the icons below:

- "Run" the Saved Search (arrow icon): allows the user to generate fresh results by running the saved search query criteria that were selected in the past.
- "Edit" Saved Search (pen and paper icon): allows editing the search criteria
- "Duplicate" Saved Search (double document icon): allows editing the search criteria of the duplicate Saved Search. In this case a pop-window "Saved Search" will appear (see below in red) prompting the user to name the duplicate Saved Search since each Saved Search should have a different name.
- "Delete" Saved Search (bin icon): deletes the Saved Search
- In addition, in the bottom of the screen there is a "New Search" button that allows creating a new Search with new criteria and a name and save it.

As an alternative to clicking on the "Edit" icon (pen and pencil icon) in the "Saved Searches" tab, the user can edit the name of a Saved Search by clicking on the "Edit" button next to the "Saved Search" field at the top of the "Advanced Search" tab (in red below). The "Advanced Search" tab can be

accessed by clicking on the “Lists” option of the RMS menu bar and then on “Search”.



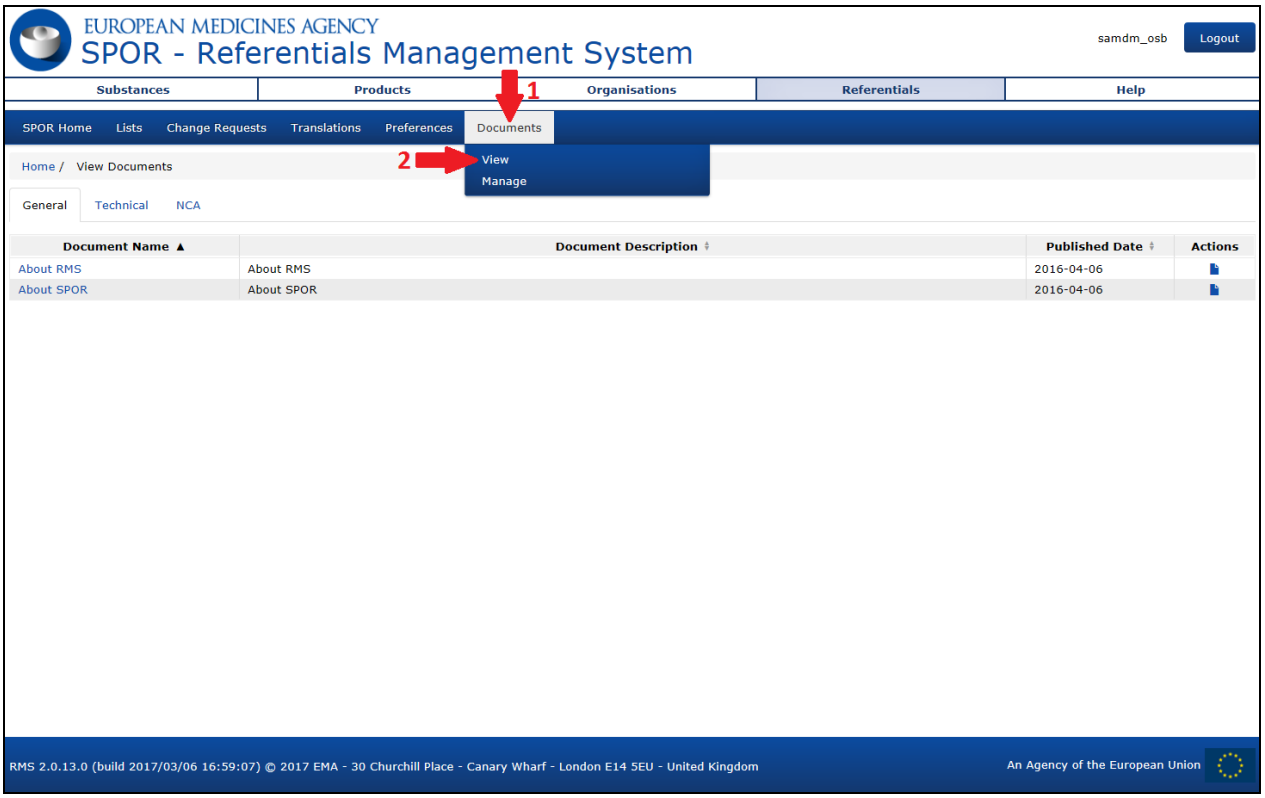
Additionally, the saved search criteria can also be edited by entering the amended information in the relevant field.

These additional capabilities allow the user to manage the search criteria only. Once done the user would still have to press the search button.

3.12. View Documents

A number of documents relevant to the four domains of the MDMS tool (Referentials, Organisations, Substances and Products) will be maintained in the SPOR Services.

The RMS tool contains a number of reference documents under the “Documents” in the menu bar. To access them, first click on “Documents” (1) and then on “View Documents” (2). A screen similar to the one below will appear.



Documents are divided into the following 3 tabs:

- General – Documentation for all users, usually of non-technical nature such as process instructions, templates, "About RMS", Access users and roles, etc.
- Technical – Documentation for technical users such as API specifications, schemas, and other technical guidance that we may issue in the future.
- NCAs - documentation that due to its confidential nature can only be shared with NCAs e.g. NCA super user contacts list.

All of the above documents can be viewed, downloaded and saved depending on the browser settings.

In addition, there are additional documents such as "About RMS" in the "Help" area in the top right corner. Of note, the Help button is domain sensitive, i.e. the content shown by clicking on this button will differ according to what domain is selected. Therefore, the user needs to ensure first that the correct domain (SMS, PMS, OMS or RMS) is selected and then click on the "Help".

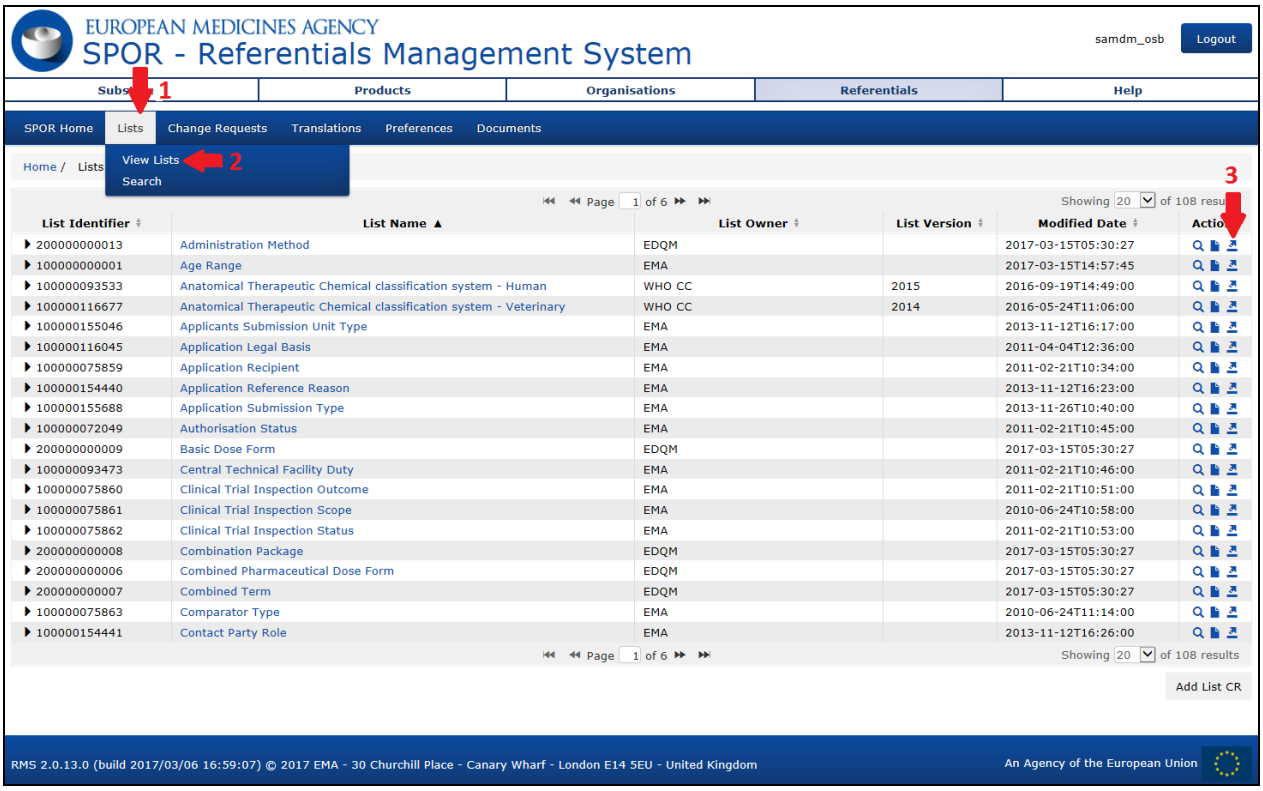
3.13. Export

The RMS system allows users to export entire lists, lists of results, translations and change requests. The table below explains what data can be exported and how:

From where	How	What
View Lists	Export 1 full list at a time	• CSV & **XML** • 1 file/list • All term attributes inc extensions • **All languages** • Tags • Preferred name
View List of Terms	Export all terms / selected terms (1 full list at a time)	
Search results	Lists: Export 1 full list at a time Terms: Export all terms / selected terms (across lists)	• CSV & **XML** • **1 file across all lists i.e. per search** • All term attributes inc. extensions • **All languages** • Tags • Preferred name
Translations	Export all terms (1 single list at a time)	• **CSV only** • 1 file/list • All term attributes inc. extensions • **EN + selected language** • Tags* • Preferred name* * for the largest lists, we will need to export static files which will not have tags and preferred names in.
Change requests	Export all /selected change requests	• **CSV only** • 1 file only • Key **CR attributes** + Term ID + proposed term name

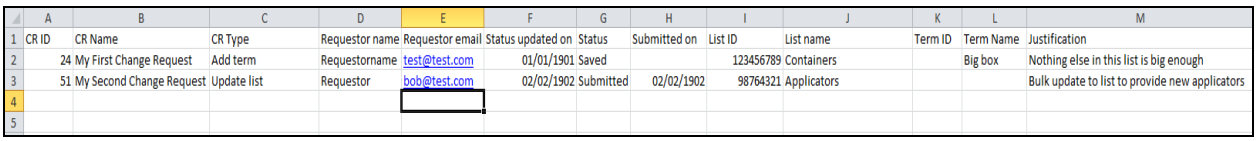
As explained in the table above, lists can be exported in either CSV or XML format.

This can be achieved by clicking on "Lists" (1), then on "View Lists" (2), and then on the "Export" icon (3) of the list to be exported.



This triggers the "Export format" pop-up window which prompts the user to choose the format in which the list should be exported.

The following screen is an example of an export of a list of change requests:



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	CR ID	CR Name	CR Type	Requestor name	Requestor email	Status updated on	Status	Submitted on	List ID	List name	Term ID	Term Name	Justification
2	24	My First Change Request	Add term	Requestorname	test@test.com	01/01/1901	Saved		123456789	Containers		Big box	Nothing else in this list is big enough
3	51	My Second Change Request	Update list	Requestor	bob@test.com	02/02/1902	Submitted	02/02/1902	98764321	Applicators			Bulk update to list to provide new applicators
4													
5													

4. Additional documentation

The following additional documentation can be found under the "Documents" tab in the RMS Web portal:

- About SPOR
- About RMS
- RMS List update template
- SPOR SLAs
- SPOR API specification
- SPOR API Schemas

5. RMS Operating Model particularities

		RMS All these lists will be held in RMS				
		RMS/EUTCT	**EDQM**	**Bfarm/ UCUM***	**WHO**	**MSSO**
		- Country/Language - Target species, Vet lists - EudraCT lists, TIGes lists, etc - VedDRA	- Dosage Forms - Routes of Administration - Containers/packaging - Units of Presentation	- Units of measurement * Done by EMA in the first phase	- ATC Human - ATC Vet - INN	- MedDRA
		Lists in RMS to which stakeholders have access				
NCAs	**Download/access lists via RMS**	Yes	Yes	Yes	**Yes**	Yes
	Requests changes to lists/terms via RMS	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	**Request to WHO first and then to EMA**	No, request to MSSO Only available in EMA via updates from MSO
	Add/amend translations via RMS	Yes	No, through EDQM only	Yes	**Yes**	No
INDUSTRY	**Download/access lists via RMS**	Yes	Yes	Yes	No Browse only Access through WHO	No Browse only Access through MSSO
	Requests changes to lists/terms via RMS	Yes	Yes	Yes	**Request to WHO first and then to EMA**	No, request to MSSO Only available in EMA via updates from MSO
	Add/amend translations via RMS	No	No	No	No	No