Quick guide

How to use the Organisation Management Service (OMS)

CTIS Training Programme – Module 3
Version 1.0 – December 2021

Learning Objectives

• Understand how to search for an organisation in the Organisation Management Service (OMS).
• Understand the process of submitting a Change Request for a new organisation in OMS.
• Understand the process of submitting a Change Request to update the information of an existing organisation in OMS.
CTIS interacts with five main databases and systems. These allow to register users, search for information on organisations and medicinal products, and store data and documents provided to CTIS. All these databases and systems are managed by EMA.

One of these databases, the Organisation Management Service (OMS) provides a single source of validated organisation data for CTIS, such as organisation names and location addresses. Additionally, the OMS Portal includes a number of guidance documents, maintained by EMA, and accessible through Google Chrome or the Microsoft Edge browser.

In the OMS Portal, users can click on the ‘Documents’ sub-tab to access all the documentation on the use of OMS. To view the documents, users can select the ‘View document’ icon on the right side of each document.

On this page, important documents can be found, such as C (OMS standards used maintaining a record); C3 and C4 (guidance on how data is standardised); E (required documentation per type of change request); F (full manual); Z (SPOR user registration manual). It is not necessary to log into the OMS portal with an EMA account to access the guidance documents.

If users need to create a new organisation or to update the details of an existing one, they need to submit a Change Request. To be able to submit a Change Request to OMS, users will need to log in to the OMS portal with their EMA account. Every user with an EMA account is assigned automatically the substances, products, organisations, and referentials (SPOR) ‘Unaffiliated user’ role and therefore can request the creation of a new organisation (see section Change Request for a new organisation). By having that role, users are not affiliated/associated with any organisation that exists in OMS.

If users need to submit a Change Request to update the details of an existing organisation or to add a new location, users will need first to affiliate themselves with their the organisation—you don’t need to be affiliated with a certain organisation to update its details. Users need to obtain the role of SPOR National Competent Authority or Industry user (depends on whether they are authority users or sponsor users, including Pharmaceutical companies, CROs, Academia) for their organisation via the EMA Account Management. Only after the access is approved will users be considered affiliated with the organisation and be able to request changes to any of the records published.

For more information on the various SPOR roles, users may refer to document "Z - SPOR User Registration Manual", stored in the "Documents" section of the OMS portal.
Sections of this quick guide

This quick guide is structured in three sections:

**Search an organisation**

This section outlines the steps that users can follow to search for an organisation in OMS.

**Create a new organisation**

This section outlines the steps that users can follow to submit a Change Request to create a new organisation.

**Update an existing organisation**

This section outlines the steps that users can follow to submit a Change Request to update information of an existing organisation.
Search an organisation

If users need to create a new organisation or to update the details of an existing one, users must submit a Change Request. But first, users must search if their organisation exists in the OMS Portal. These steps are applicable for all types of organisations (sponsor, CRO, investigational site, authorities’ organisation, etc).

To do that, users must log in to the OMS portal with the user’s EMA account credentials. Once in the OMS Portal, the user can click on the ‘Organisations’ sub-tab, found on the ‘Organisations’ tab of the OMS home interface.

Users can submit Change Requests to request the creation of a new organisation in OMS, or to update the data of an existing organisation. Before submitting any request to the OMS, the user must search the organisation in the available records.

Users can then use the search fields to retrieve their organisation. Only the ‘location status’ field is mandatory, which by default is set in ‘ACTIVE, INACTIVE’. If multiple search fields are used, the system will narrow down the search.

Users can use the drop-down list on the right side of each field to indicate whether the details of the results begin with, or contain the keyword(s), used in the search fields.

Once the user has populated the search fields, the user can click on the ‘Search’ button.

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If users face any issues with accessing the OMS portal, it is suggested to clean the cache memory or history. If the issue persists, it is suggested to use the browser in Incognito/Private mode.
Create a new organisation

If no results are retrieved from the search, a relevant message appears on the top part of the search fields, indicating that no results matching the search criteria have been found.

At the same time, a new button appears at the bottom-right corner of the search fields. Users can click on the 'Request new organisation' button, which will redirect them to the registration form.

Users can then fill in the fields of the registration form accordingly. By default, the email is automatically populated coinciding with the email of the EMA user account of the creator of the organisation. The field can be edited, and the user may populate a different email for further communication during validation.

After populating all the information, users are expected to upload the appropriate documentation in the “Attachments” placeholders, next to the populated information, by selecting the ‘+’ button. If the documentation attached to the request is not compliant with OMS’s requirements, it may lead to the rejection of the request.
Use of Organisation Management Service (OMS)

Once users have populated all the information of the new organisation and attached the appropriate documentation, users select the checkbox under the information fields, acknowledging that they are aware that the information included in the request will be published by EMA on the OMS public website.

After clicking the checkbox, users can select the 'Submit' button in the bottom right corner. This will redirect the users back to the 'Search Organisations' page, in which a message above of the search fields will appear, informing the user that the request has been submitted successfully and displaying a Change Request ID.

Users can track the status of their requests by accessing the 'View Request' sub-tab which will be active once a request has been submitted. Users cannot retrieve a Change Request ID in the search functionality. Therefore, these can only be tracked through the 'View Request' sub-tab.

In the 'View Requests' sub-tab, users can view the information of the their submitted requests including: the Change Request ID, the Change Request type, the name of the requestor, the Change Request date, the organisation name, the address, the status, and the status date.

#CTIS insights

The ID provided after a request is submitted is not the final Organisation ID. Any ID starting with ORQ refers to the Change Request ID.
In case users need to update the details of an existing organisation, users will need to submit a Change Request. To do that, users can search their organisation, and click on the spyglass icon next to the organisation on the results page.

This will redirect users to the organisations’ page in which the information is displayed. Once on the organisation’s page, users can select the button ‘Request change’. For users to be able to request a change to an existing organisation or to add a new location, users need to be affiliated to an organisation available in OMS – not necessarily to this particular organisation for which they are updating the details. Anyone can submit a change regardless of the organisation they are affiliated; they need at least one affiliation to be able to submit modification requests of existing organisation details.

Nonetheless, the requirement remains that a valid supporting documentation should be provided to support the change request in OMS.

Users can obtain the role of SPOR NCA or Industry user for their organisation (depending on whether the user corresponds to an authority or a sponsor organisation, including Pharmaceutical companies, CROs, Academia), via the EMA Account Management portal.

Only after the access is approved the user will be considered affiliated with their organisation and will be able to request changes. Change requests for updating an organisation can entail: updating the organisation’s name, adding a new location, updating a location, deactivating an organisation, or deactivating a location. Users can select the scope of their update in the ‘Request reason’ field.

For more information on how SPOR roles are requested and managed in the EMA Account Management portal, users may refer to the ‘Request user access’ guide.
For more information on how affiliated users can submit a Change Request to update details of an existing organisation, users may refer to the document ‘E - OMS Change Request’ and ‘F - OMS Web User Manual’, stored in the ‘Documents’ section of OMS portal.
Clinical Trials Information System (CTIS).

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