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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

User Access Management

How to search and create organisations in CTIS

CTIS Training Programme – Module 03
Version 1 – January 2023

Learning Objectives

- Understand how to search and create organisations locally in CTIS.

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Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1	Training material version published at CTIS go-live.	January 2023

Introduction

CTIS users need to populate organisation details in their trials. The main source for that data is Organisation Management Service (OMS). CTIS users can retrieve that information from OMS and use it in CTIS, using dedicated search functionalities. If users perform their search and cannot retrieve the organisation they are looking for, they can submit a change request to create a new organisation in OMS. More information can be found on the Quick Guides of Module 03 for OMS and CTIS.

But in the following five areas (four in Sponsor workspace and one in Authority workspace), CTIS allows users to create organisations locally in CTIS, without the need to register them in OMS.

- Part I Sponsor section – Third party organisations
- Part II – Trial sites
- Serious Breach notifications – Details of the site where the serious breach occurred
- Third Country Inspectorate Inspection – Third country inspection site
- MS Inspections – Inspected site

In the five areas above, the search functionality, in addition to the default search fields and buttons, has a set of radio buttons that allows users to perform a search for organisations; first in OMS and then in CTIS. After users perform searches for both OMS and CTIS without finding their organisations, listed in the results, they will be able to create them locally in CTIS.

This step-by-step guide explains the steps to search and create organisations locally in CTIS. The creation of a clinical trial site in Part II of an application is used as example to describe the process.

Search and create an organisation in CTIS

This section outlines the steps that users need to follow to create organisations locally in CTIS

Points to consider

This section outlines points that users need to consider when using organisations that have been created locally in CTIS

Searching organisations in OMS and CTIS

1. After clicking on the on the '+ New trial' or Add site' button, users must **search for** their organisations first.

Note. To **activate the 'Search organisation' button** and be able to perform their searches, users **need to populate** either the **'Name' field with at least three characters**, or the **'ID' field with at least one character**.

Note A. When **sponsor users create a new trial**, they need to search for **sponsor** organisations. They can search in, and retrieve data only **from OMS**.

Note B. In five other working areas, CTIS users are allowed to search for organisations not only in OMS, **but also in CTIS**. Besides the common search fields, the search functionalities in the below 5 working areas have a set of **radio buttons; 'Search in OMS' and 'Search in CTIS'.** Users can perform a search in CTIS, **after they do their search in OMS**.
- Part I Sponsor section – Third part organisations
- Part II – Trial sites
- Serious Breach Notifications – Details of the site where the serious breach occurred
- Third Country Inspectorate Inspection – Third country inspection site
- MS Inspections – Inspected site

To avoid creating **unneeded organisations** in CTIS, users are **encouraged** to carefully search for them first in OMS, and then in CTIS, using the respective buttons every time, as described in steps 2-3. To increase the scope of their search, users could use the **'contain' filter** and not the default 'starts with' filter. The filter can be found **above** the first three search criteria; 'Name organisation', 'ID' and 'City'.

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Searching organisations in OMS and CTIS

2a. If **sponsor users** do not find their **sponsor organisation** in OMS (red message displayed on the upper right corner), or is not listed in the search results, they need to submit a **change request** to register a sponsor organisation **in OMS**, following the instructions in the document "E - OMS Change Requests", found in the OMS document depository.

In cases that sponsor organisations are not registered in national business registries (part of the **required documentation** for the change requests in OMS), a different registration process can be applied, according to which users can attach to their OMS requests a filled headed registration letter. A template, "J - CT registration Headed letter template", is available in the OMS document depository. Completion of change requests to create new organisations in OMS might take up to ten days. Once sponsor users' requests are validated and processed by OMS team, they will be able to search for their organisations, retrieve them and use them in the respective CTIS fields.

2b. In the previously mentioned five working areas, if users do not find the organisation in OMS (red message displayed on the upper right corner), or is not listed in the search results, they **should perform a second search**, after selecting the **'Search in CTIS'** radio button.

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OMS document repository contains a lot of training materials to help users maintain their organisation data in OMS. To name few: E - OMS Change Requests, A3 - OMS FAQs, C - OMS Data Quality standards, V - SPOR Questions & Answers, Z - SPOR User Registration Manual.

Create new organisations locally in CTIS

3. If users do not find the site in CTIS (red message will be displayed on the upper right corner), or is not listed in the search results, they can opt **to create the site in CTIS** by clicking the button **'New Organisation'**, which will now appear enabled.

Select trial site   ×

Search organisation

Name	contains ✔	ID	starts with ✔	City	starts with ✔	Country
Agrinio						Greece

[+ New organisation] [⬆ Clear] [**Search organisation**]

Search in OMS ○   Search in CTIS ◉

ID	Name	Address	City	postCode	country	phone	email	actions

4. Users need to complete the registration form. **Mandatory** fields are indicated with an **asterisk**.

Registration Request   ×

Requestor details

Contact email *	ct-site@email.com	Contact phone *	111111111111
Comment			

Organisation details

Organisation name*	Test Organisation Gotham		
Acronym		Organisation type *	Health care ✔

Organisation address

Address line 1 *	Robin Street 20	Address line 2	
Address line 3		Address line 4	
City		Post code	
Country *	Greece ✔	Email*	ct-site@email.com
Location phone	Intl.	Phone number *	111111111111	Ext.
DUNS ID		GS1 ID	

Attachments

[⬆ Add document]

[Cancel] [**Submit**]

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Organisations that are created locally in CTIS are **not validated** by EMA. But users are **encouraged** to keep in mind the OMS data quality standard set when they create their organisations in CTIS, reducing then the possibility to receive RFIs from assessing authorities regarding inaccurate data.

Submit the Registration Request form

Note. Users are advised to enter the **city and post-code**, although these fields are not highlighted as mandatory, to ensure notifications that include sites registered in CTIS **pass the technical validation**. Moreover, in the case of investigational sites/third party vendors, this is **relevant information for inspections**.

5. After filling in the form, users click on **'Submit'** button in the end of the form and a pop-up confirmation window appears.
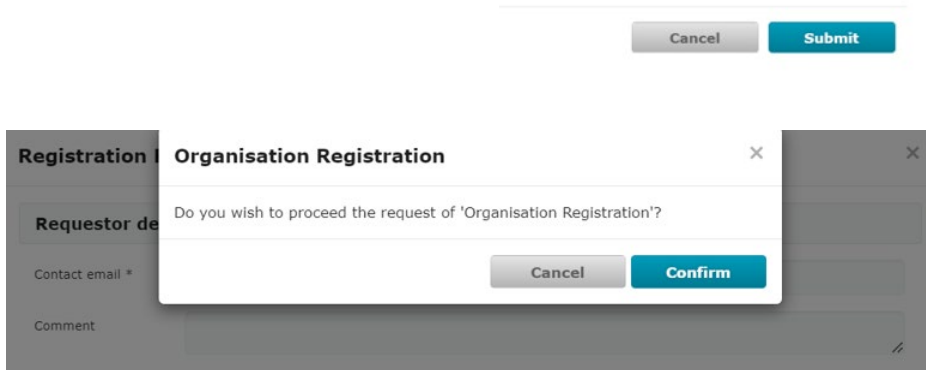
Note. **Organisation IDs** for organisations registered in CTIS **start with 'ORL-'** (while OMS-originated organisations' IDs start with **'ORG-'**). Users may wish to take note of this 'Organisation ID' for future reference, although they are always able to search for it, using the Organisation name or other organisation details in the search fields.

6. The organisation and its details appear in the overview. Users can click on the **'Add trial site'** button (the button might be labelled differently in the other working areas that creation of organisation in CTIS is allowed, i.e. 'Add third party').

7. The trial site is displayed. Users can remove it by using the **bin icon**, placed on the right side (in case details are mistyped) or use the **pencil icon** to fill in other information related to the organisation. In this case, users can use the pencil icon, to populate the **Investigator's information**. The pencil icon does not allow users to edit he details of the organisations they just created (i.e. to edit he name or the address).

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If users create a third party organisation, they could populate the activities assigned to the third party. In some other cases (i.e. Serious Breach notification), the pencil icon might not appear.

Points to consider

1. The user is given ample options to search for organisations (first in OMS, then in CTIS), with a view to **prevent duplication** and ensure **better quality of data**.

2. Once users register an organisation in CTIS, it will remain in **DRAFT status**. The draft organisation will be visible only **within the scope of the draft CTA or draft notification**, i.e. it will not appear when other sponsors (or even the same sponsors who created the organisation) search in CTIS.

3. Once the CTA or notification, which contains this organisation registered in CTIS (still in DRAFT status) is **submitted**, the locally registered organisation in CTIS **changes from DRAFT status to ACTIVE status**. This implies that the organisation is now **searchable by other users**, including users from different organisations such as other sponsors.

4. Organisations registered locally in CTIS with **ACTIVE** status are **no longer editable** (to edit details of the organisation such as address or name or country etc). If users need to update the organisation details, they will need to **remove** the initially created organisation from their application/notification and **add a new one** by following the process that is described in the previous pages. Users will have the chance to change the organisation by responding to assessment RFIs, or by submitting substantial modifications.