20 January 2023
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European Medicines Agency

CTIS newsflash – 20 January 2023

Introduction

With the aim to enhance communication with the CTIS user community, this regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

A status update on the implementation of the Clinical Trials Regulation is also available on the CTIS public portal.

Spotlight: Start date of mandatory CTIS use

CTIS was launched on 31 January 2022, starting the clock for the one-year transition time for sponsors of clinical trials. During the first year of the transition period, clinical trial sponsors can choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive or under the Clinical Trials Regulation, via CTIS.

The last date for sponsors to submit initial Clinical Trial Applications under the Clinical Trials Directive is 30 January 2023.

Starting from 31 January 2023, the use of CTIS will be mandatory for all initial clinical trial applications in the EU. For trials authorised under the Clinical Trial Directive, sponsors can continue to submit amendments under the regime of the Clinical Trial Directive until the end of the transition period on 30 January 2025.

Upcoming Improvements

The next CTIS release will deliver further system improvements and enhance the user experience. The improvements are foreseen to be implemented in the week of 23 January 2023 and include:

- Member States Concerned will be able to submit Part I Disagreement for Substantial Modification (SM) part I only or SM part I and II in cases where part II was submitted only to the Reporting Member State (RMS), even if the RMS already issued a decision on the application.
- The authorise task will not include the list of conditions from Part II Conclusion of another Member State Concerned.
- Member States will be able to retrieve via Member State API the complete list of notifications present in a clinical trial application.

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- Improved display of page entries in Member State API.
- The title of a clinical trial updated in the context of a Non Substantial Modification or a Substantial Modification that has been authorised will be correctly displayed in all areas of the system.
- The decision date of a tacit decision will be correctly displayed with the due date of the Authorise task.
- The updated information in "number of subjects" created as a response to a Request for Information (RFI) by clicking on the "Change application" will be displayed in the authority workspace and Member State API only after submission.
- The decision section of an Additional Member State application will only include the Part I disagreement related to that application.
- The substance(s) information missing in some products will be correctly retrieved.
- The due date of the Consolidate Considerations and Submit RFI tasks will be calculated using Central European Time (CET) instead of Universal Time Coordinated (UTC).
- Behaviour of the Pop-up Cancel Button in the tasks section will be improved to ensure that the user action performed is indeed cancelled.
- The sponsor and Member State users will be able to download documents with special characters.

More information on the latest system improvements are available in the published release notes as well as in the Lists of known issues and proposed workarounds.

EMA continues to work closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience. By the time the use of the system becomes mandatory for all initial applications on 31 January 2023, the aim is to have no blocking issues in the core CTIS processes. The Agency has invested additional resources to achieve this goal.

CTIS Business Intelligence system for Member State Users

An initial release of a CTIS Business Intelligence (BI) system is foreseen to take place in February 2023. The CTIS BI system will provide a user-friendly dashboard and enable users to run faster and better queries, also allowing them to customise and save queries for future use. The BI system aims to reduce query load in CTIS, therefore improving overall performance of CTIS.

In the next few weeks, we will reach out to provide the opportunity for Member State experts to register and receive training and support in the use of the new CTIS BI system. Further information and details will follow in upcoming issues of the CTIS Newsflash.

CTIS Sponsor end user training course 7-10 February 2023

EMA offers a virtual training course, organised by DIA, to support sponsor user preparedness for CTIS and the new way of submitting a clinical trial application and managing the lifecycle of a clinical trial. A hands-on approach is taken to explaining and demonstrating the functionalities of the system, such as user management, how to submit an initial application as well as modifications, both substantial and non-substantial. Also, how to manage the lifecycle of a Clinical Trial, how to apply Deferral rules and respond to an RFI will be addressed. Further information is available on the event page.

Reminder: Access to CTIS Training Environment

Sponsor users who want to be trained on CTIS have the opportunity to express their interest in gaining access to the CTIS Training Environment, by filling in the ongoing survey. The Training environment is a simulation of CTIS used in production and allows users to get familiar with system functionalities in a safe environment.

More information

Are you a sponsor user starting out with CTIS? Please consult the 'Sponsor quick guide: Getting started with CTIS' or refer to the CTIS training material, including the new version of the 'CTIS Handbook for clinical trial sponsors'. The handbook provides useful information on how sponsors can navigate CTIS to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation (EU) No 536/2014.

Annex: Step-by-step instructions to register sites in CTIS

The CTIS release on 12 December 2022 enabled the creation of organisations locally in CTIS, without the need to register them in OMS, in the following five areas of the system:

- Part I: Sponsor section- "Third-party organisations"
- Part II: "Trial sites"
- Serious Breach Notification: "Details of the site where the serious breach occurred"
- Third Country inspectorate Notification: "Third country inspection site"
- MS Inspections: "Inspected site"

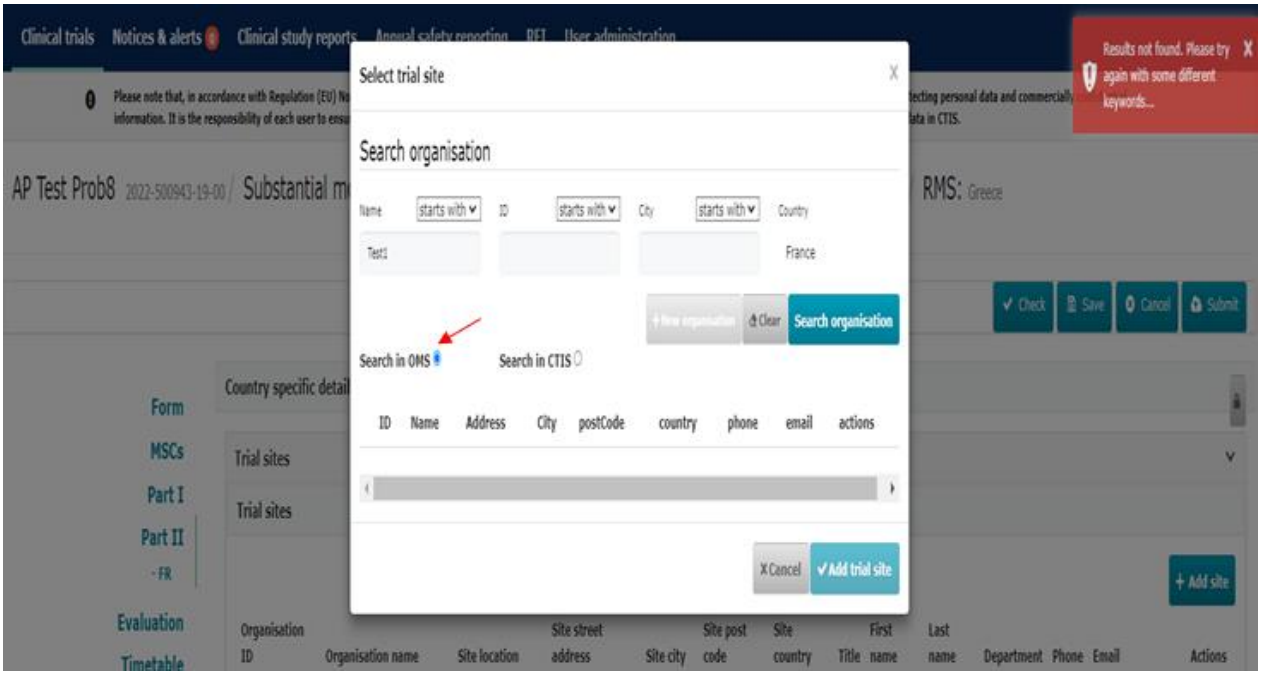
Organisations created locally in CTIS behave and function in the same way as the ones sourced from OMS and can be searched and selected once they have been registered in CTIS.

This new feature replaces the temporary process which was in place since 3 November 2022, enabling users to record organisations in OMS which were not registered in any public national business registry by attaching a CT registration headed letter to their OMS request. **Now that the new functionality is in place to allow direct recording of organisations in CTIS, the temporary process with the CT headed letter is discontinued.** Trial sites created in OMS under the temporary process will be removed from OMS. Sponsor users have to create these trial sites in CTIS under the new process. Importantly, draft Clinical trial applications created with the OMS trial sites (those created with the headed letter) can be submitted: The removal from OMS of the trial sites temporarily created with the procedure of the headed letter, does not change the draft applications created.

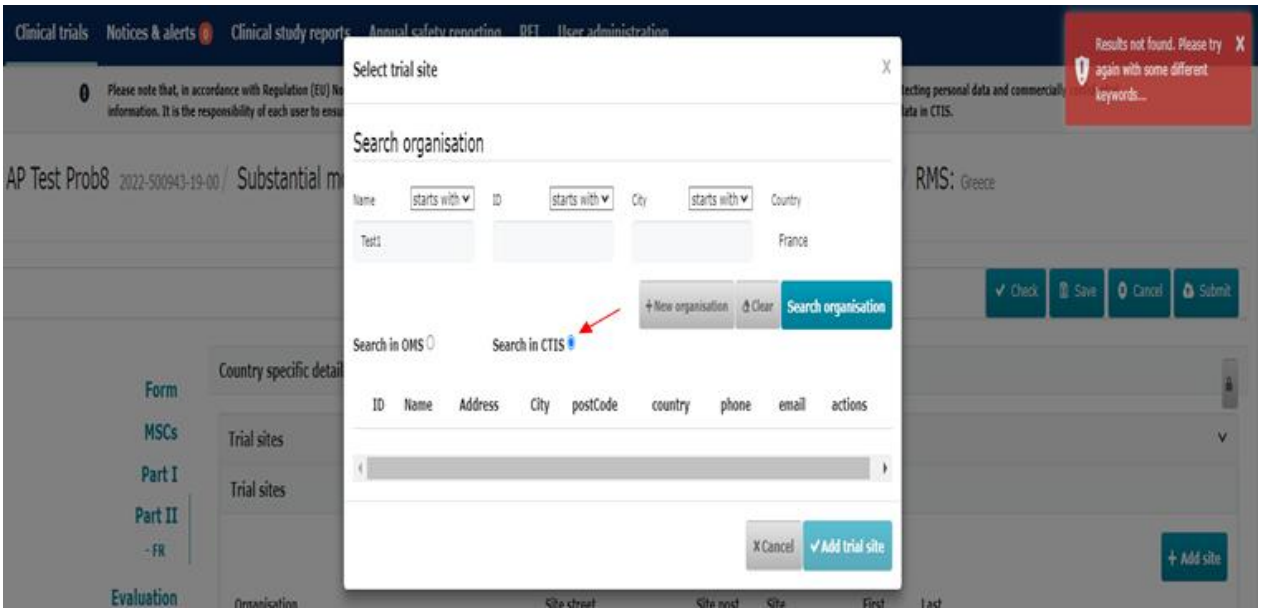
Step-by-step instructions on how to register sites in CTIS are included below. The CTIS training material will be revised accordingly and updates will be provided in future issues of the CTIS Newsflash.

The following example refers to the registration of an investigational site. Please note the process is also applicable to the other four CTIS areas where this functionality has been enabled (see above).

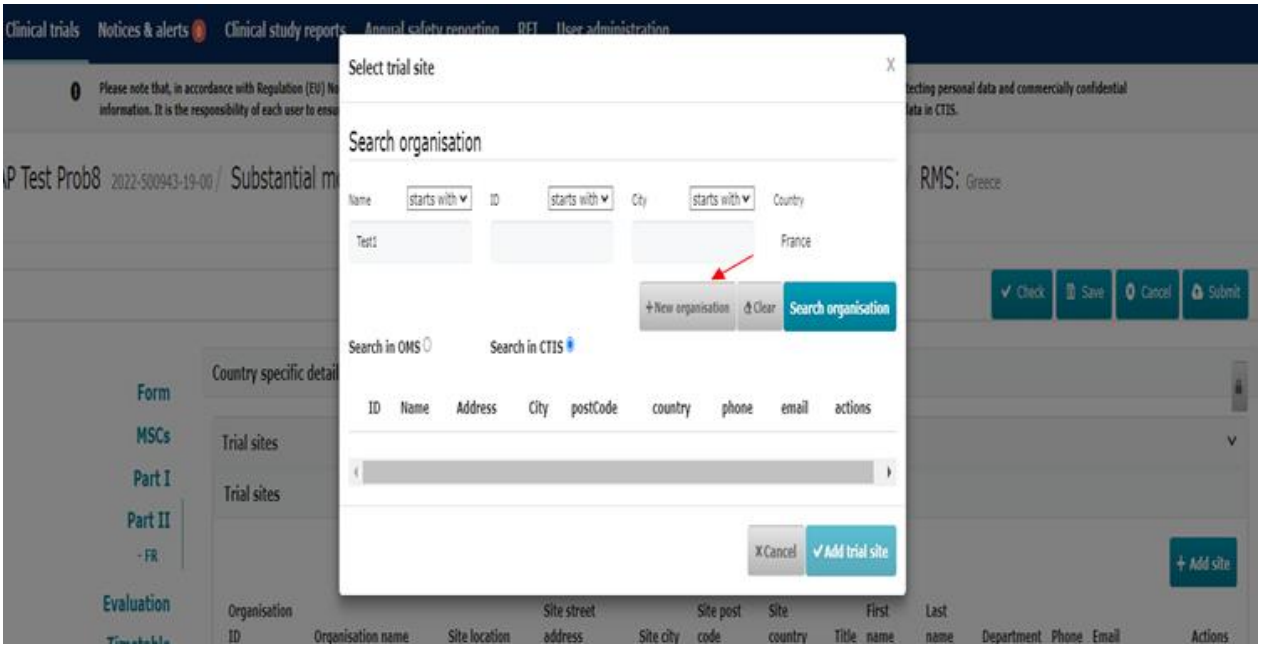
Step 1 – The user must first search OMS, as the "Search in OMS" radio button is ticked by default.



Step 2 – If the user does not find the site in the OMS (red error message displayed) or the organisations displayed are not the ones the user is looking for, the user should then search for the site in CTIS by selecting the second radio button "Search in CTIS".

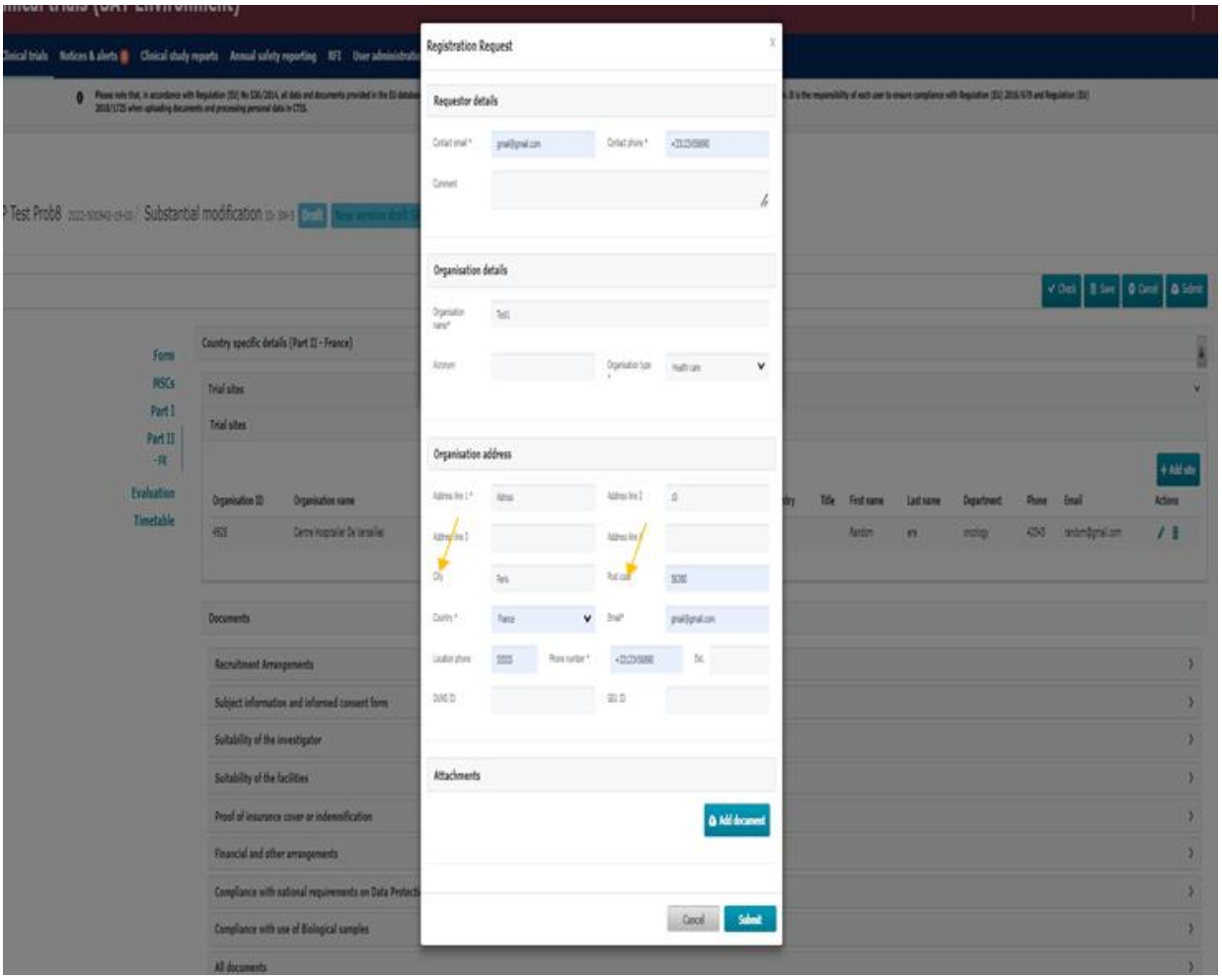


Step 3 – If the user does not find the site in CTIS (red error message displayed) or the organisations displayed are not the ones the user is looking for, the user can opt to create the site in CTIS by clicking the button "New Organisation", which will now appear enabled.



Step 4 - The user completes the displayed form.

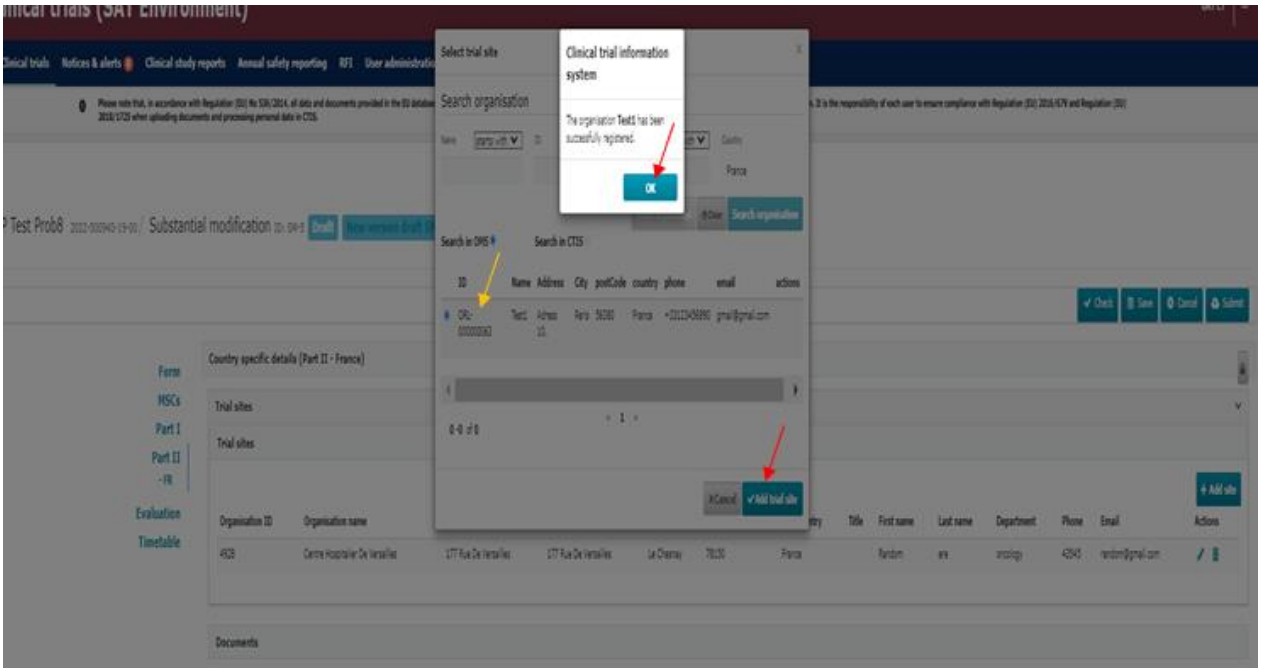
IMPORTANT: Users are advised to enter the city and post-code, although these fields are not highlighted as mandatory, to ensure notifications that include sites registered in CTIS pass the technical validation. Moreover, in the case of investigational sites/third party vendors, this is relevant information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



Step 5 - The user then clicks submit and a pop-up confirmation window appears.

Please note that organisation IDs for organisations registered in CTIS will start with ORL. Users may wish to take note of this "Organisation ID" for future reference, although they are always able to search using the Organisation name.

Step 6 - The user should confirm and click the "Add trial site" button.



Step 7 - The trial site is displayed. In this particular case, for trials sites, the user can edit the additional pending information by using the pencil.

IMPORTANT NOTES:

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

2. Once the user has registered 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 search in CTIS.

3. Once the CTA or notification, which contains this Organisation registered in CTIS in DRAFT status, is submitted, the locally registered site in CTIS is changed from DRAFT status to ACTIVE status. This implies that the site is now searchable by other users, including users from different organisations such as other sponsors. This also implies that the local site is no longer editable. If the user now wishes to change or remove the site from the Clinical Trial application or Notification, the user will have to raise a modification or update the notification, respectively.