26 July 2024
EMA/334159/2024
European Medicines Agency

# CTIS newsflash – 26 July 2024

## Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 9 August 2024.

Previous issues of the CTIS Newsflash are available on the EMA website.

## Advice for CTIS users

- **Notices & Alerts**: For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" and/or "Requests for Information (RFI)" instead of relying solely on the notices and alerts.
- **Timetable**: During the assessment of a clinical trial application, the timetable may show different due dates/status/information than the actual due dates/status on the Tasks page and RFI page. This does not impact the workflow and the actual due date of the task and RFI: users are recommended to comply with the due dates recorded in the individual tasks and RFI.

## Reminder: Transition ongoing trials from CTD to the Clinical Trials Regulation

Sponsors are advised to transition any clinical trial expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR).

Sponsors should take into account the time necessary for completion of the Member State(s) evaluation procedure, which can take up to 3 months. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

Sponsors can consult CTCG's recently updated best practice guide on transition, Annex I: Cover letter template, and the newly published Annex II: Fees for transitional trials in EU/EEA Member States. Further resources to support sponsors transitioning trials are available on the CTIS website.

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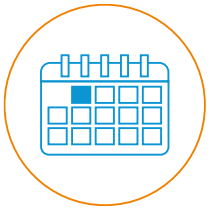
## Revised CTIS transparency rules: resources for sponsors

With the successful launch of a new version of the CTIS public portal on 18 June 2024, the revised CTIS transparency rules are now applicable.

For support in the implementation of the revised rules, sponsors can consult the updated quick guide for users, guidance, annex I and Q&A document on the protection of personal data and CCI in CTIS.

The latest quick guide for users and Q&A (question 1.9) include details on cases where only 'track-changes' versions of certain documents, which are no longer subject to publication, are present in the CTIS workspaces.

All documents are available under the "Transparency in CTIS" section of the ACT EU website.



## Save the date: events in September 2024

CTCG, with support from ACT EU, is hosting a stakeholder meeting of the CTR Collaborate initiative on 11 September 2024. The open session will be live-streamed, sharing insights from the work of CTR Collaborate. To participate in the closed breakout sessions, stakeholders can pre-register until 30 August 2024.

EMA is hosting a CTIS Walk-in Clinic on 18 September 2024 dedicated to answering users' questions on the transition of trials from the Clinical Trials Directive to the Clinical Trials Regulation. Participants will be able to submit their questions in advance from 18 August to 11 September 2024.

Sponsors can also register to the upcoming CTIS user training on 23-26 September 2024, 09:00-13:30 CEST. For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

## Tips for CTIS users

- For applications or Non-Substantial Modifications that can be submitted in parallel within a clinical trial, users are advised to wait a few minutes between each submission. It is not recommended for different users to submit applications or Non-Substantial Modifications for the same clinical trial simultaneously, as it may result in different applications sharing the same ID.
- After a 'Sponsor Admin' or 'MS Admin' role is revoked in IAM, the revoked user needs to log into CTIS at least once to complete the revocation process.

## System improvements

The CTIS release on 18 July 2024 introduced several improvements:

- Sponsors can now use a new type of Substantial Modification (SM) called 'Part I only – Change of Sponsor' to transfer ownership of the trial to a different sponsor. More details on this new feature are available in the annex.
- Sponsors can now indicate that a trial is transitional even after the creation of the clinical trial application, while drafting the initial application or after resubmission. More details on this new feature are available in the annex.
- When a corrective measure is applied and the overall status of a clinical trial changes to 'Revoked', a new 'Revocation' section is now displayed in both the sponsor and authority workspaces, containing the following:

  - The field 'Revocation EEA', which is automatically populated with the date of revocation in the last MSC;
  - The field 'Anticipated date of summary of results from Revocation', which is populated with a date set to either: a) 12 months after the revocation of the trial in the last MSC for adult trials or b) 6 months for paediatric trials;
  - The 'Update results date' button, allowing sponsors to update the 'Anticipated date for summary of results from Revocation', if required.

  More details on this new feature are available in the annex.

- The Start of Recruitment date is now displayed in the Notifications tab only if the start of recruitment notification has been submitted.
- When the Safety assessing Member State (saMS) finalises the Annual Safety Report (ASR) Assessment, the task 'Finalise assessment' is now displayed as completed in the task list.
- When an ASR is created, if a Member State Concerned (MSC) or the Reference Member State (RMS) did not authorise the initial application and then authorised it through an Additional MSC application, this MSC/RMS is now correctly displayed in the MSC section of the ASR.
- In subsequent applications submitted for a clinical trial that has been restarted through a Substantial Modification after a temporary halt due to safety, sponsors can now respond to a validation Requests for Information (RFI) and change the application.
- System performance has been improved to facilitate the 'change of application' as part of the response to RFIs in multinational clinical trials involving many Member States.

More information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users.

EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

## Latest publications

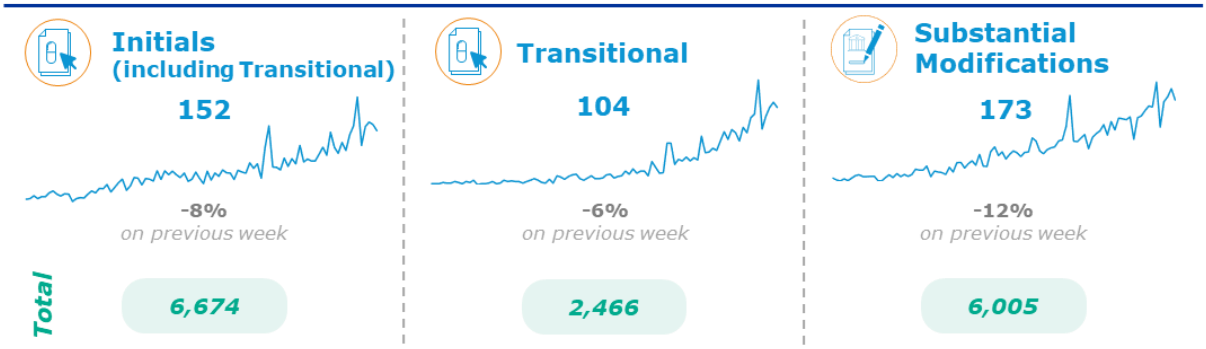
- The European Commission has published a new version of the Q&A on the Clinical Trials Regulation.
- CTCG has published new templates to support sponsors with their clinical trial applications: cover letter for initial applications, cover letter and modification description for Substantial Modifications, and an RFI response list of changes to the application.

## Current operational experience with CTIS

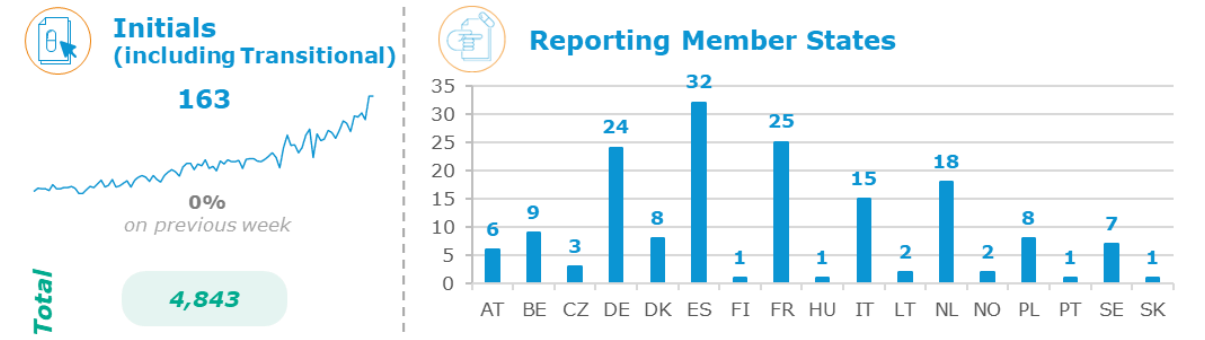
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 16 to 22 July 2024.

## CTA Submissions

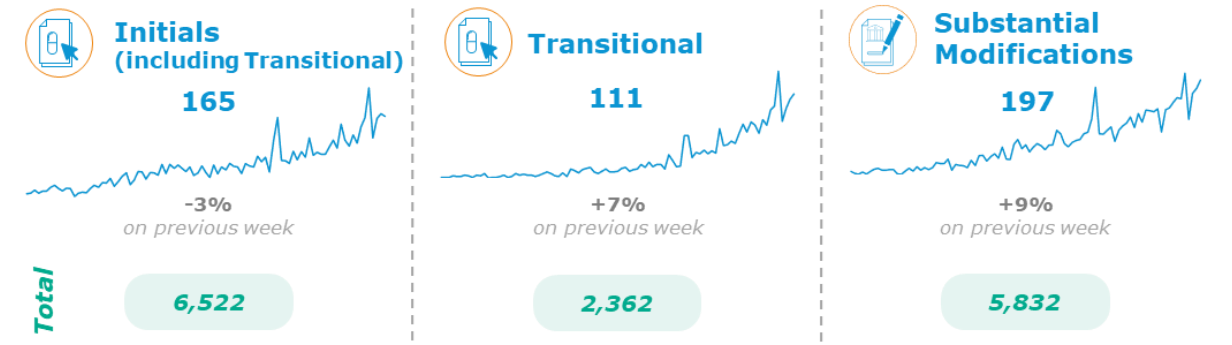



## CTAs with a Decision

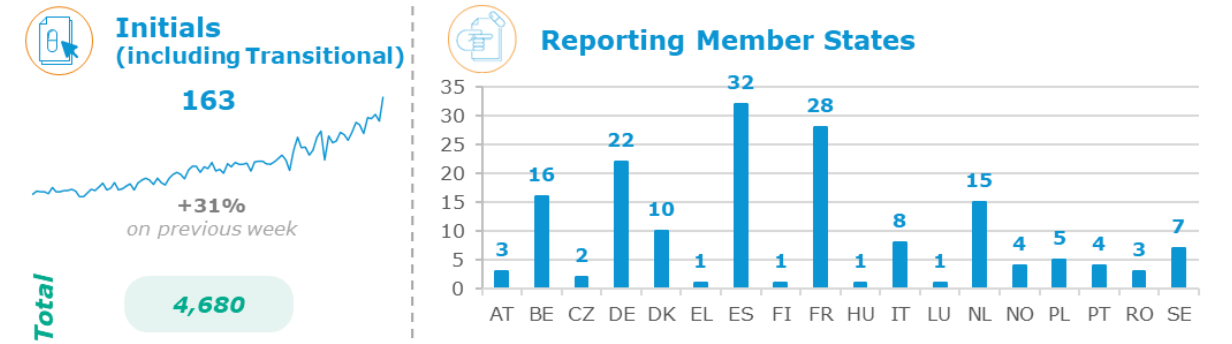



The data presented below refer to the period from 9 to 15 July 2024.

## CTA Submissions




## CTAs with a Decision



### Requesting access to the CTIS Training Environment

Sponsors can 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.

## 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 latest 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.

Information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users. Resources to support sponsors transitioning trials from the Clinical Trials Directive (CTD) to the CTR are available on the CTIS website.

# Annex: New features in CTIS release 18 July 2024

## 1. Substantial Modification to change sponsor Org-ID

*Minor edits made after the communication to all users on 19 July 2024*

Sponsor users can now submit a new type of Substantial Modification (SM) Part I to request a change of the sponsor Org-ID, in order to transfer the ownership of the trial to a different sponsor with a different legal entity. This type of SM can only be submitted after the initial application has been authorised by all Member States Concerned (MSCs). All MSCs must authorise the SM, for the change of sponsor to come into effect.

**Warning:** This SM change of sponsor triggers the publication of part I documents in line with timelines of the revised transparency rules. For trials submitted before 18 June 2024, if their part I documents 'for publication' contain commercially confidential information or personal data, refer to slide 17 of the quick guide on the revised CTIS transparency rules and historical trials.

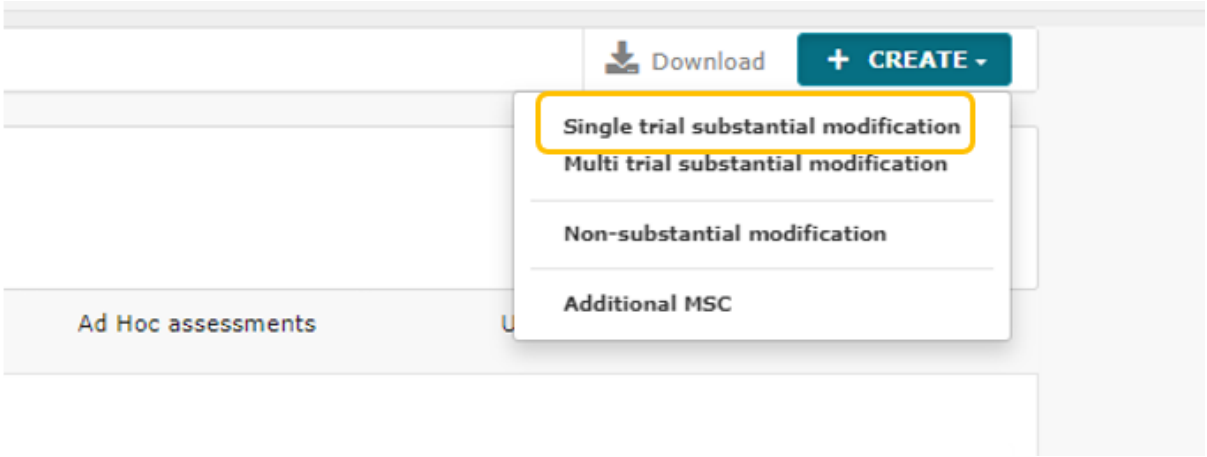
### *Step-by-step instructions: how to submit an SM to change sponsor Org-ID*

After the authorisation of the initial application by all MSCs, sponsor users can request the change of the Org-ID of the trial sponsor through the submission of a specific Part I SM. Once the SM gets authorised by all MSCs, the transfer of the ownership of the trial to the new sponsor will take place.

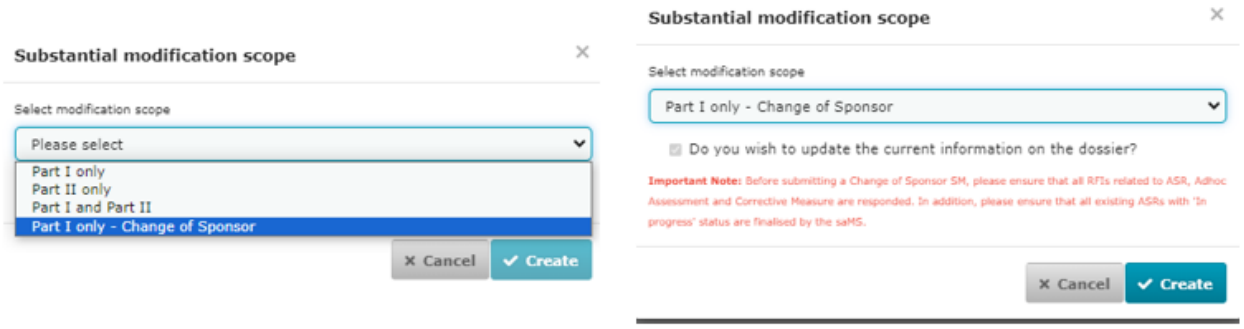
Before requesting a change of sponsor org-ID, users should ensure that the new sponsor is registered in the Organisation Management Service (OMS), i.e. the request for OMS registration has been submitted and approved. See the Quick guide: How to use the Organisation Management Service for instructions.

Sponsor users then need to follow the following steps to submit a request for sponsor org-ID change.

1. Sponsor users need to select 'Create' and choose "Single trial Substantial Modification".



2. Users should then select 'Part I only – Change of Sponsor'. After selecting the type of SM, a red warning message appears.




**NOTE**: Users should *not* proceed with SM draft/submission if there are pending Requests for Information (RFIs) for Annual Safety Reports (ASRs), Ad hoc assessments, Corrective measures or if there are ongoing evaluations for ASRs or other applications. Users should not have any draft ASR, application or non-SM during this process. Warning messages will appear during the SM creation and submission that need to be considered by users (step 2). The tick in box regarding the change of dossier appears checked by default and cannot be unticked (since the structured data for Part I / sponsor section will be modified).

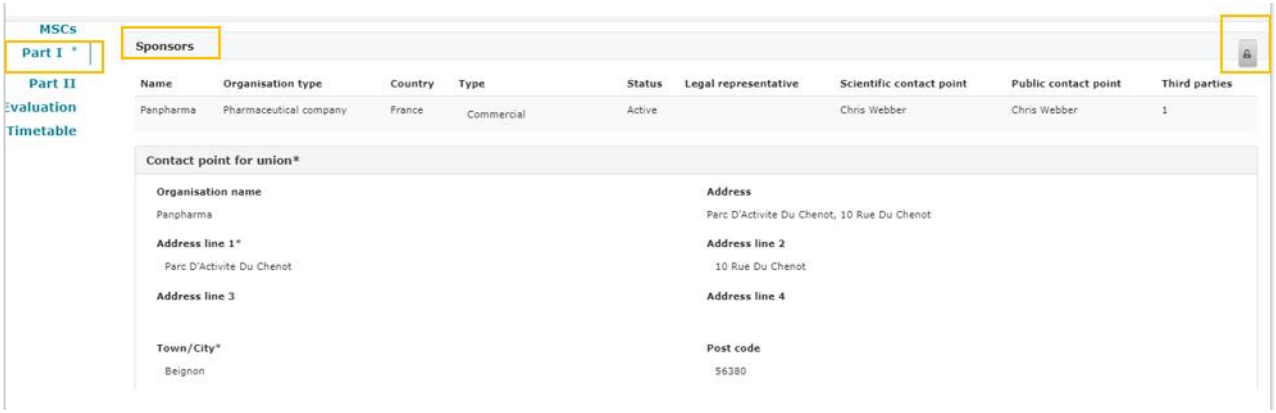
3. Once users click the 'Create' button, a draft of the SM application will be created.
4. Users need to use the common functionalities to complete the draft application before submitting it.

**NOTE:** This SM application type differs from the other SM types. Very few sections can be modified. The 'Part I only – Change of Sponsor' is only intended to be used for the change of sponsor Org-ID and not for other reasons. Below, the sections of the dossier that can be modified (or completed) are listed:

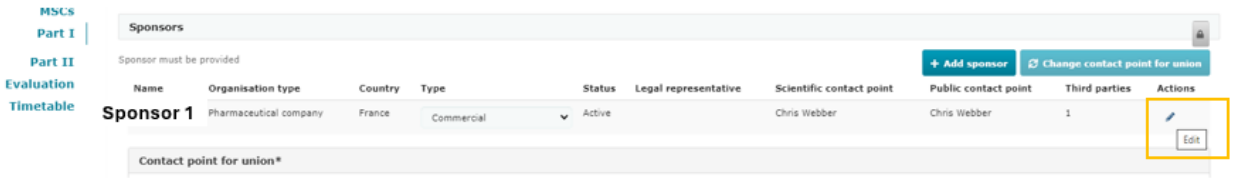
- FORM page: There are padlocks in two sections: 'SM details' and 'proof of payment fee'.
  - Document placeholders: 'Cover letter', 'Modification description', 'Supporting information documents', 'Proof of payment of fee'. Note: 'Cover letter' & 'Modification description' are mandatory fields. In case the Initial application of the relevant trial was submitted before 18 June 2024, specific content needs to be inserted in the cover letter; please refer to slide 17 of the quick guide on the revised CTIS transparency rules and historical trials.
  - Structured data: 'Supporting information'.

  The fields SM reason and scope have been pre-populated and cannot be modified.


- Part I page: The 'Sponsors' section has a padlock. All the structured data fields in this section can be modified, including those dedicated to contact points.

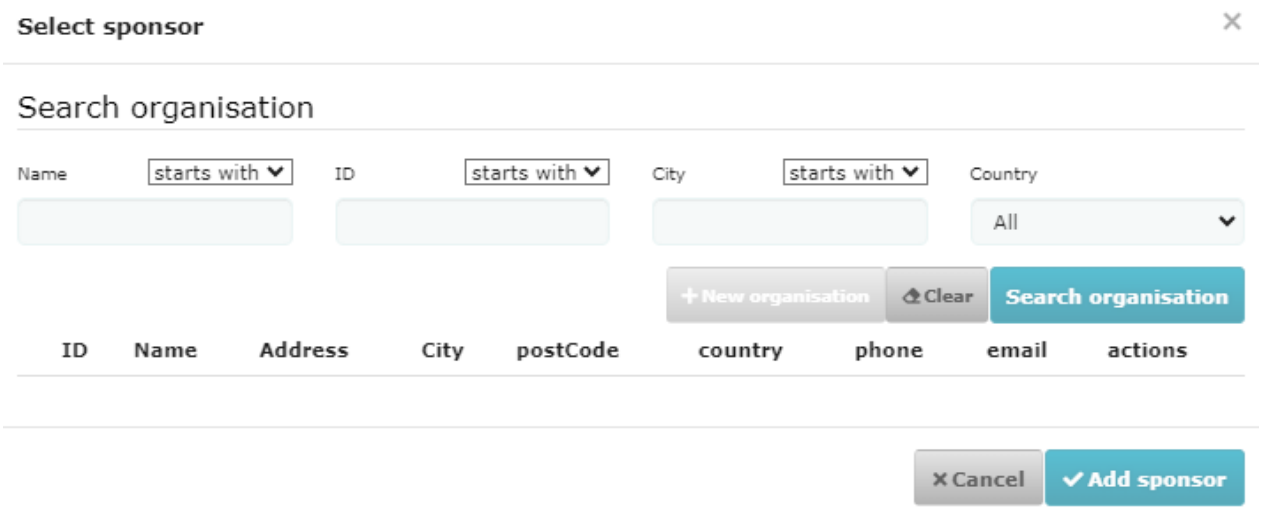



5. After uploading the documents for the mandatory document placeholder fields in the FORM page, users can move to the Part I section to change the sponsor Org-ID.
6. By using the padlock in the 'Sponsors' section, users can edit the fields of the section. An edit button (pencil icon) appears on the right side of the ribbon that includes the main sponsor details.

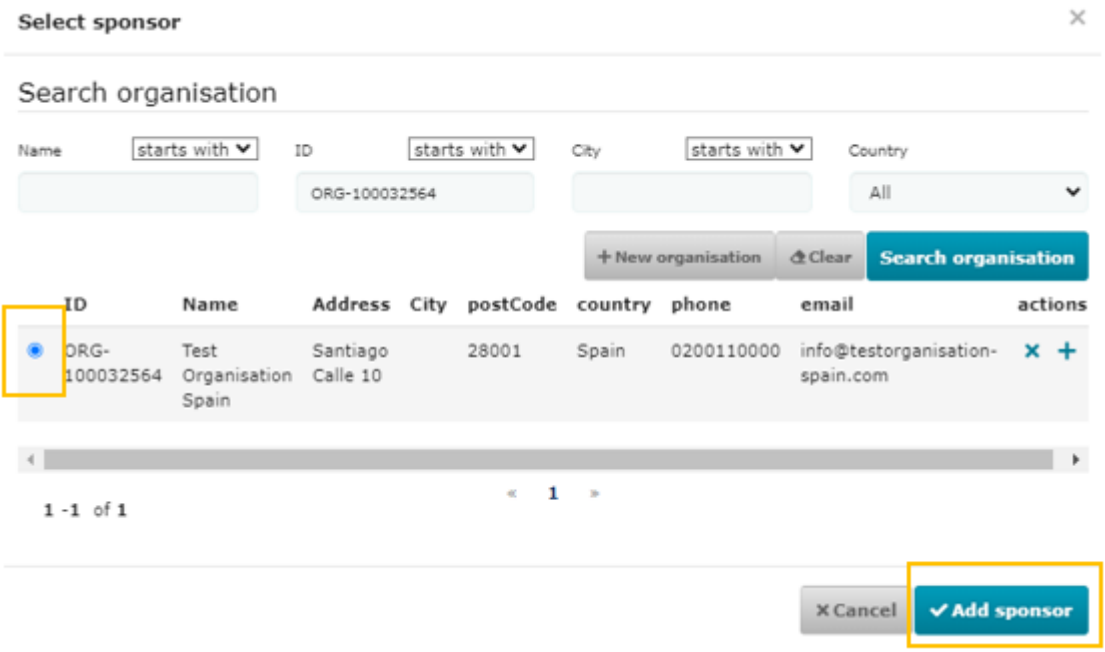



7. After clicking the pencil icon, users can see a pop-up menu that allows them to search for other organisations.

**NOTE:** The organisation functionality search works as in other cases. Users need to populate at least three letters in the 'Name' field or one character in the ID field to activate the 'Search' button. Additional fields can be used to narrow down the scope of the search.

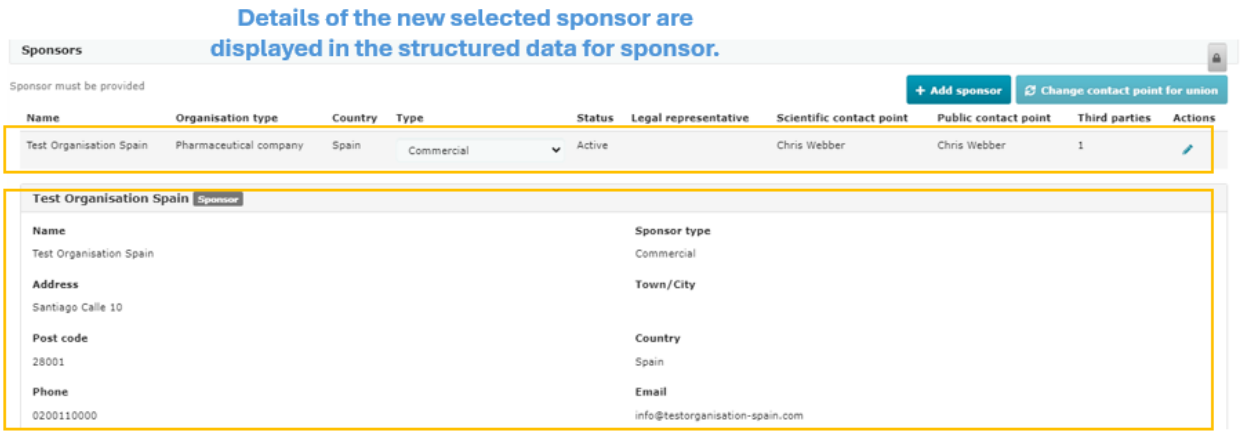



8. Sponsor users select the correct organisation from the search results, by using the radio button on the left side. The 'Add sponsor' button is activated.

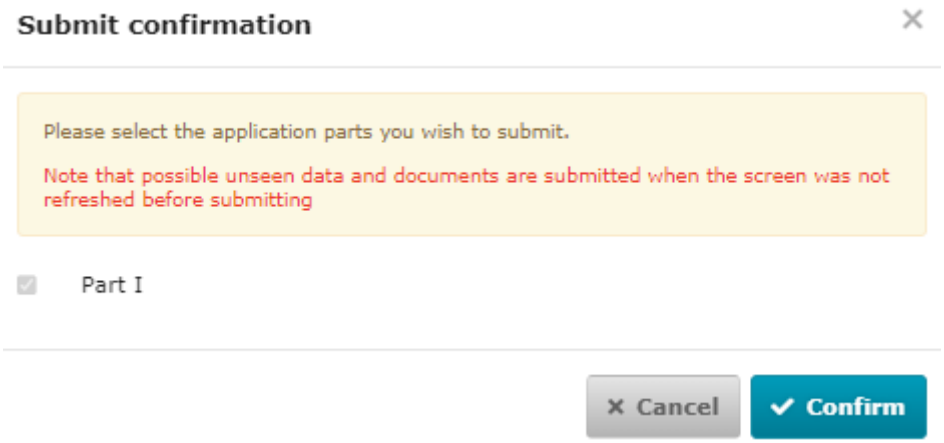



9. After clicking on the 'Add sponsor' button, sponsor users overwrite the details of the initial sponsor with those of the new selected organisation (intended to be the new sponsor of the trial after the authorisation of the SM by all MSCs).

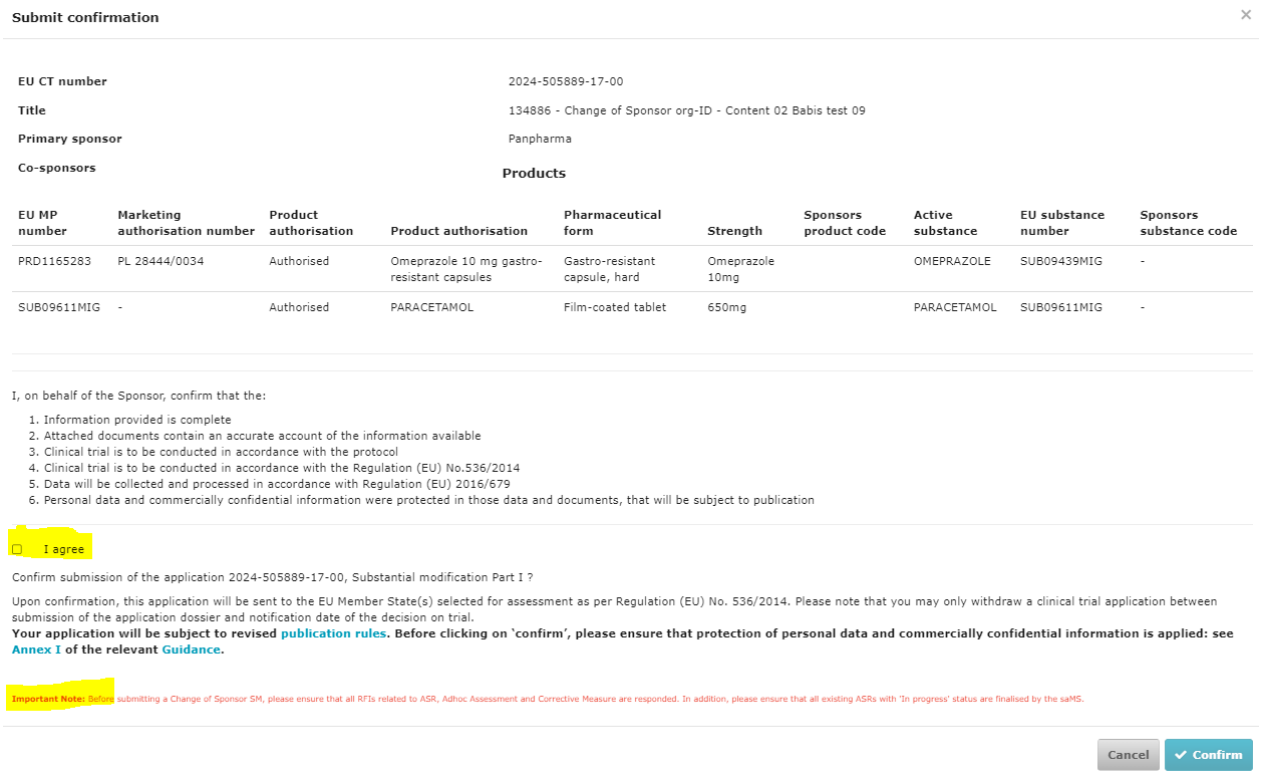
**NOTE:** Multiple changes can be done during the drafting of the SM, in addition to the change of sponsor Org-ID. When responding to a Validation/Part I RFI during the SM evaluation, sponsor users may change their selection of Org-ID and/or the structured data fields for the contact points, as required.




10. Sponsor users may proceed with submission of the SM, requesting the change of the sponsor Org-ID of the trial. After using the 'Submit' button, users will see a pop-up window to confirm the submission.



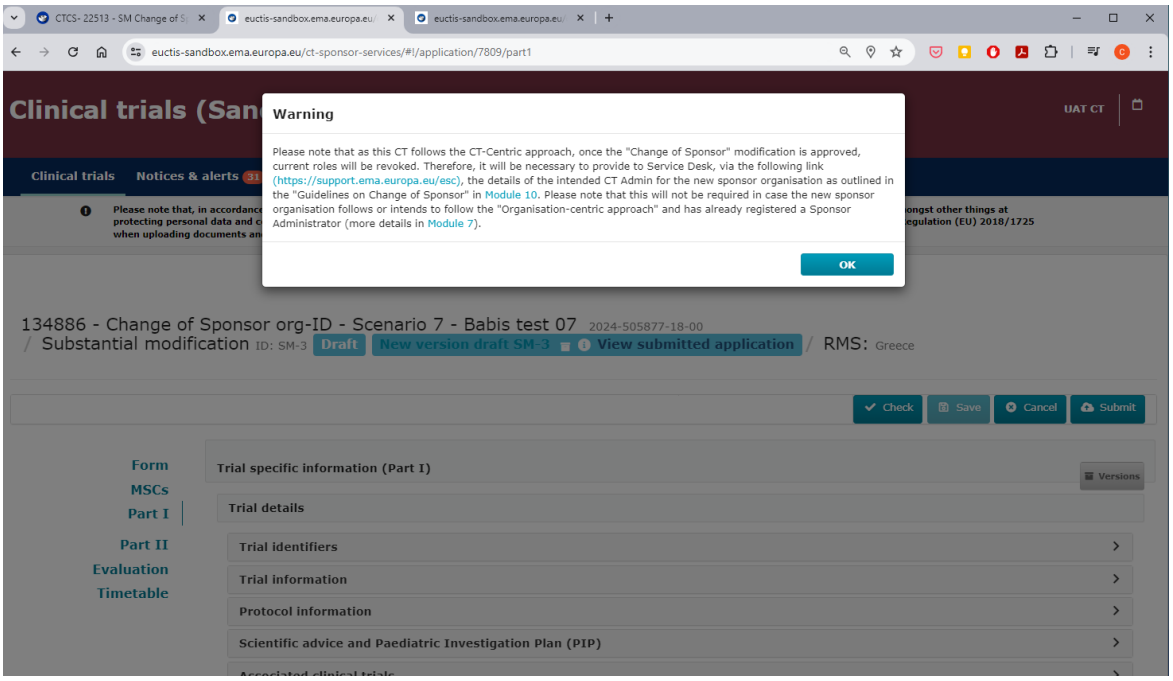

11. A second confirmation pop-up window will appear. Users need to agree on the terms mentioned in the pop-up window, using the tick-in box, to activate the 'Confirm' button. The warning message mentioned in the beginning is displayed again, in the end of the pop-up window.




12. The definite change of sponsor will occur only after the authorisation of the SM by all MSCs. Users need to take care of the role management prior the authorisation of the SM. Roles under the initial sponsor will be rendered obsolete after the authorisation of the MS by all MSCs.

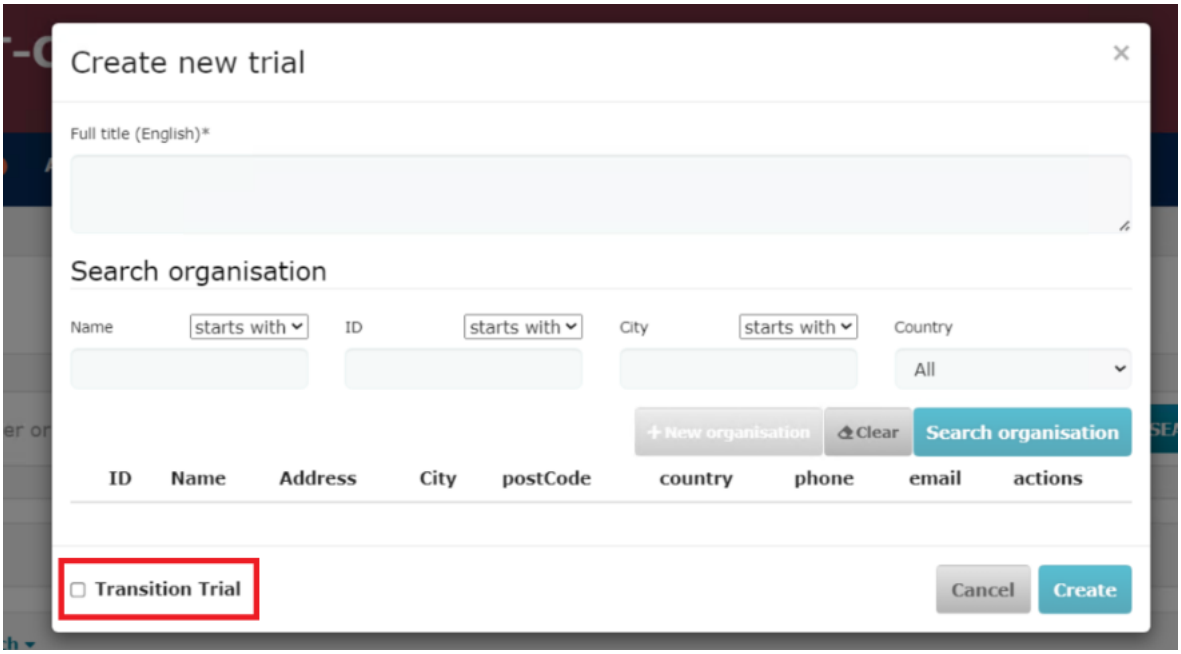
**NOTE:** If the new sponsor follows the organisation-centric approach, the Sponsor Admin will have access to the trial immediately after the authorisation of the SM by all MSCs. The Sponsor Admin should start assigning roles with scope "all trials" to other users in advance to the change of the sponsor so when the change become effective, these users will be automatically granted with access permissions to the trial without any further intervention of the Sponsor Admin.

If the new sponsor organisation follows the CT-centric approach (i.e. no Sponsor Admin has been delegated), the initial sponsor users will be informed accordingly, when they try to submit the SM-Change of sponsor. Users of the initial sponsor need to contact the EMA CTIS Service Desk and request that the CT Admin role is assigned to a user that represents the new sponsor organisation.

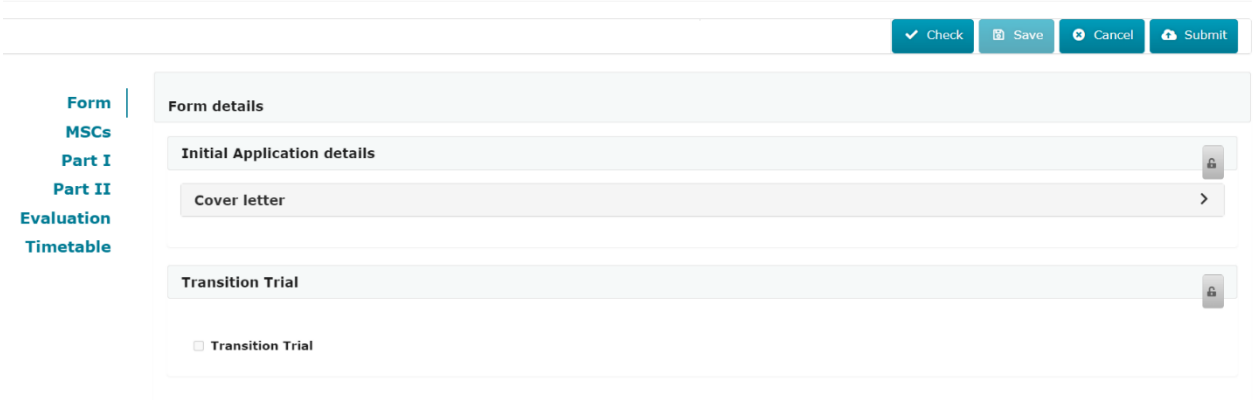



## 2. New functionality to edit the transition trial section during the preparation of a draft or resubmission of an initial application

The transition trial section is now visible and editable from the "Form" section during the preparation of a draft initial application even if the 'Transition trial' checkbox was not selected during the creation of a new clinical trial.

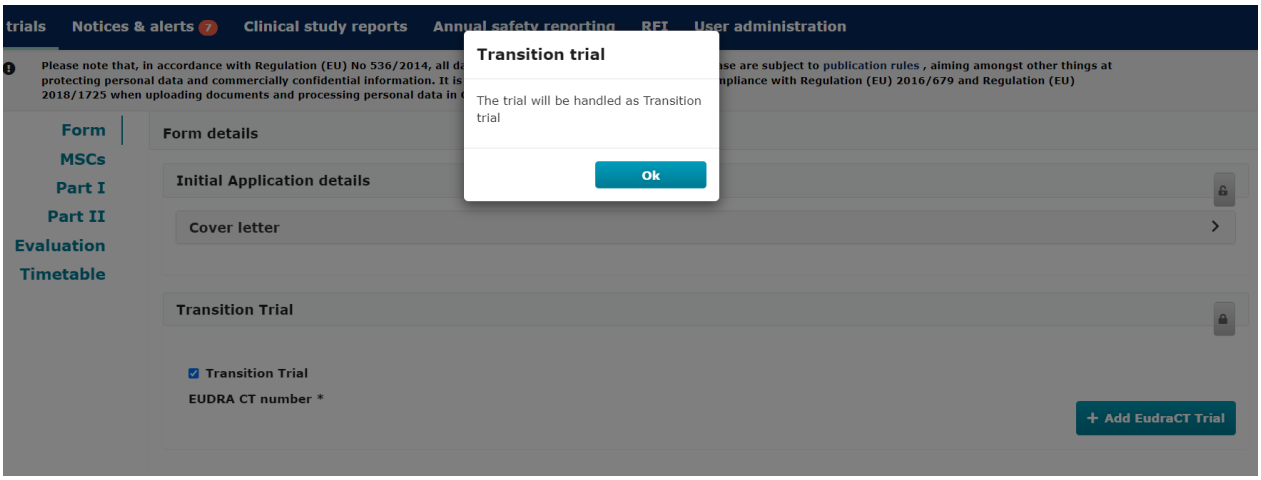



In order to edit the transition trial section, sponsor users need to use the relevant padlock:




In addition, the transition trial section is now editable when resubmitting the initial application.

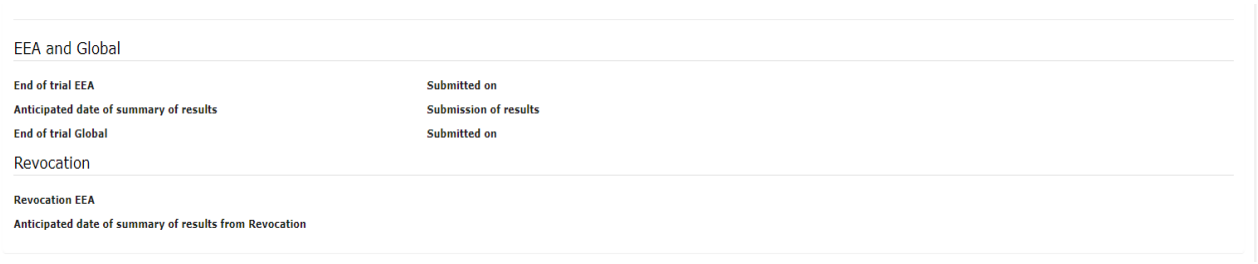

In a resubmission, if the sponsor user clicks on the relevant padlock, the section is now editable and the trial will be handled as transition trial if the checkbox 'Transition trial' is selected.



# 3. Population of the 'Anticipated summary of Results' date for a revoked trial

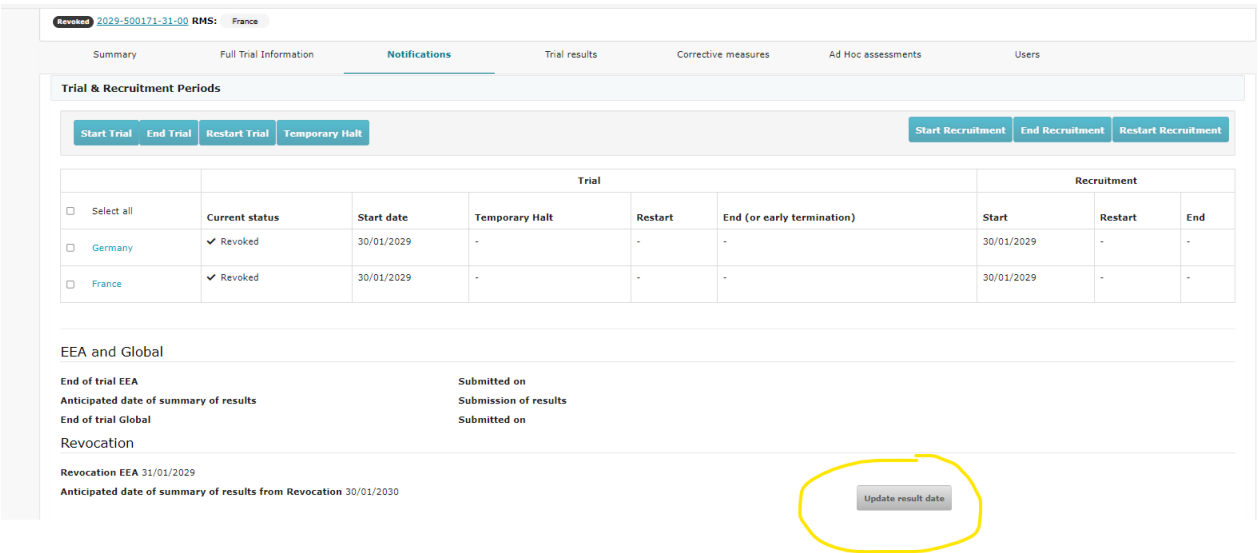
When the overall status of a clinical trial changes to 'Revoked' after a Corrective measure is applied, the system now populates the 'Anticipated date of summary of results' from the revocation date. This new feature enables the submission of the 'Summary of results' in this scenario.

For this purpose, a new section has been added under the 'EEA and Global' section with the title 'Revocation'.

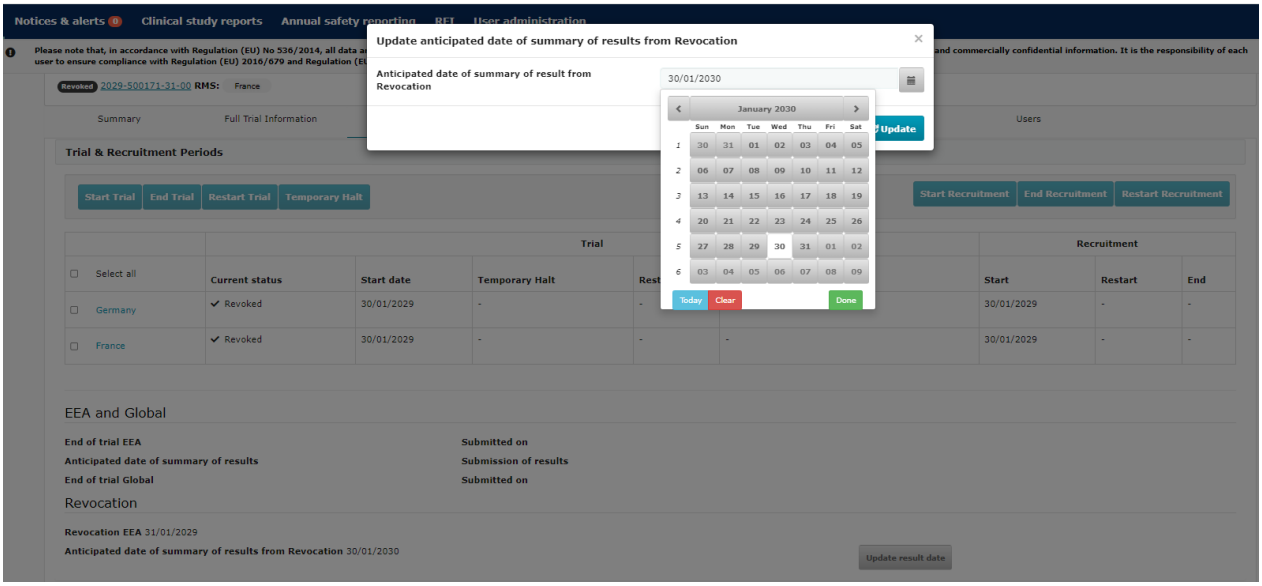



The field 'Revocation EEA' will be automatically populated with the date of revocation in the last MSC. The same will happen with the 'Anticipated date of summary of results from Revocation', which will be automatically populated with a date set to a) 12 months after the revocation of the trial in the last MSC for adult trials or b) 6 months for paediatric trials.

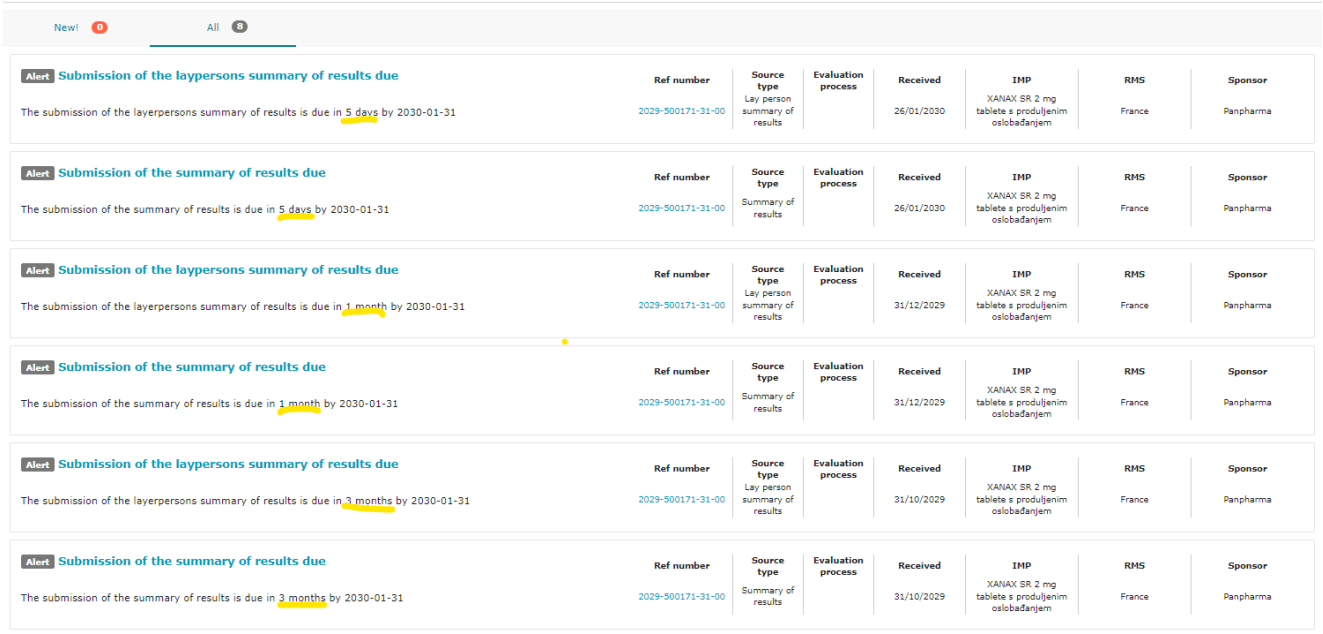
Sponsor users can select the '**Update results date'** button to **update** the 'Anticipated date for summary of results from Revocation', if required.




When clicking in this button, a date-picker will be displayed to update this date.




As a reminder for sponsor users to submit the summary of results/lay person summary within the legal framework, new alerts have been created (3 months, 1 month and 5 days) before this anticipated date.




When downloading the Corrective measures Form by using the 'Download' functionality, the 'Anticipated date of summary of result from revocation' will be displayed.

Corrective Measure

## Corrective Measure CM-DE-0001

**Corrective Measure ID:**

CM-DE-0001

**Version Number:**

1

**Submit Date:**

2029-01-31

**Status:**

Submitted

**Corrective Measure Type:**

Revoke

**Corrective measure reason:**

Result of inspection

**Justification:**

njnknj

**Anticipated date of summary of result from revocation:**

30/01/2030

**MSC:**

Germany

**EUCT Number:**

2029-500171-31-00

**Note:** If at least one MSC reverts the revoked trial status to the previous trial status (i.e. Authorised), the fields 'Revocation EEA' and 'Anticipated date of summary of results from Revocation' become blank again.