EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Clinical Study Reports submission

CTIS Training Programme – Module 13

Version 1.0 – April 2021

Learning Objectives

- Remember what is the Clinical Study Report (CSR)
- Understand how to submit a CSR
- Understand how to update a CSR

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Create and submit a CSR

A CSR is a report of an individual study of an investigational medicinal product, in which the clinical and statistical description, presentations, and analyses are integrated.

The CSR must be submitted within **30 days** after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for the marketing authorisation has withdrawn the application. It is considered the end of the clinical trial life-cycle in CTIS.

This step-by-step guide aims at explaining how to submit and update a CSR in CTIS. This material serves as support documentation for Module 13: Clinical study reports submission.

Submit a CSR

- This section outlines the steps that users need to follow to submit new CSRs.

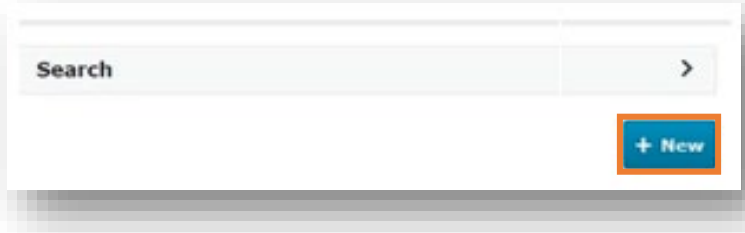
Update a CSR

- This section outlines the steps that users need to follow to update a CSR.

Submit a CSR

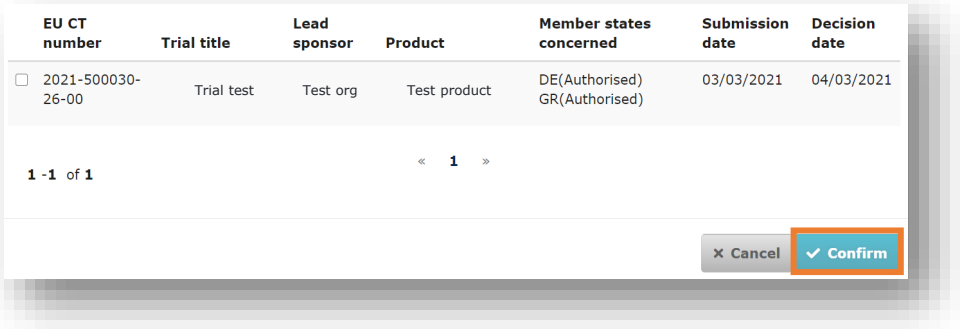
Submit a CSR

1. Select the **'New'** button displayed on the left of the screen.

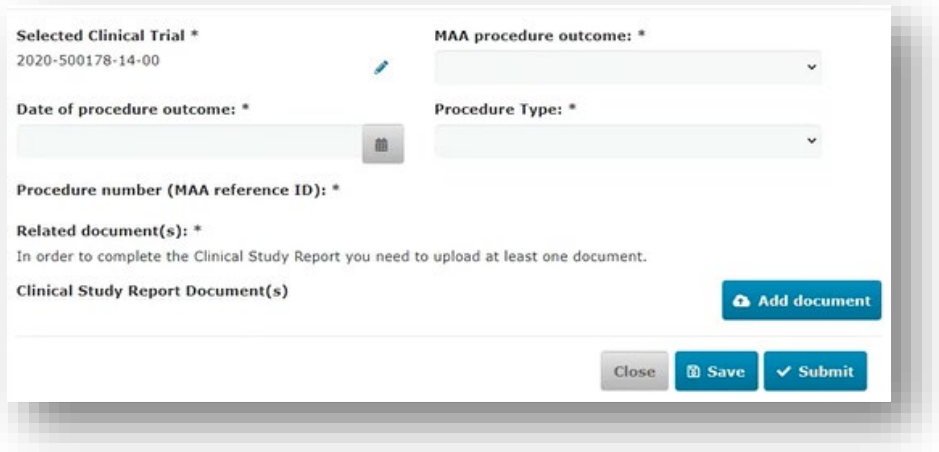


2. Search the Clinical Trial (CT) to which the CSR corresponds.

3. Select a CT from the results page and click on the '**Confirm'** button.



4. Enter the trial number, populate the CSR form, upload the appropriate document(s) and select the '**Submit**' button.



#CTIS insights

A new CSRs corresponding to an already existing trial can be created and submitted from the Clinical study reports tab using the '+ New' button.

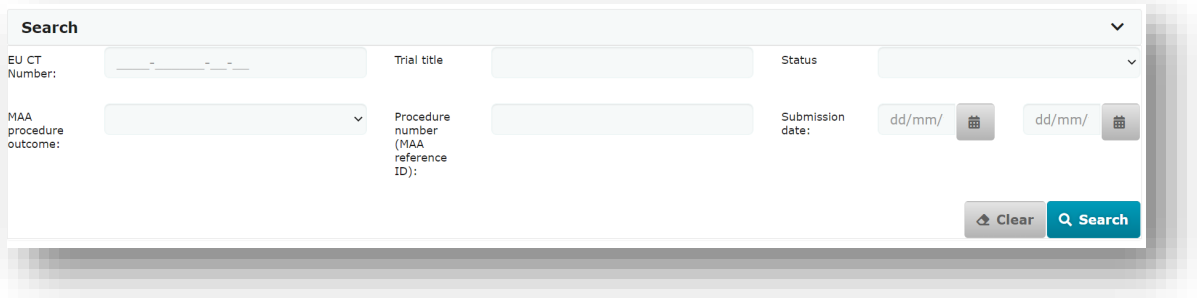
If the users want to cancel the submission, they need to select the button 'Close'.

Users can create CSR for authorised trials only.

Update a CSR

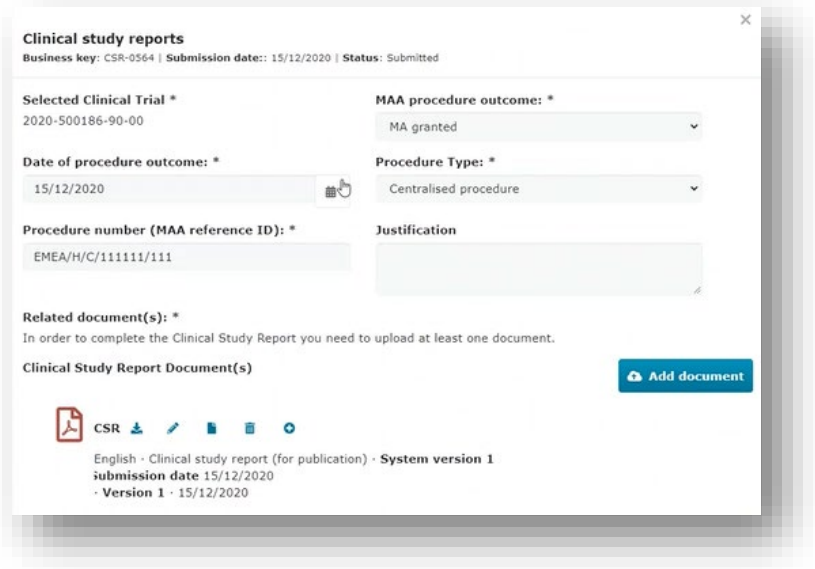
Update a CSR

1. Search the CSR to be updated.

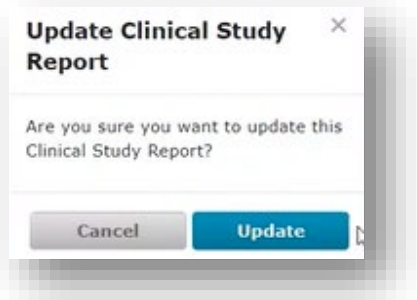


2. Select the CSR and click on the '**Update**' icon (pencil).

3. Update the necessary fields (the fields marked with an asterisk (*) are required).



4. Click on the '**Update**' button and confirm the update.



#CTIS insights

CSRs data can be updated from the Clinical study reports tab using the 'Update' icon (pencil).

Users can save drafts of uncompleted CSRs by selecting the 'Save' button. They can access those draft versions and complete them via the Clinical study reports tab or the Trial results sub-tab of the CT Page.

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Clinical Trials Information System (CTIS)
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