



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Step-by-step guide

## Supervise a CT – Corrective measures

CTIS Training Programme – Module 14  
Version 1.1 – December 2021

### Learning Objectives

- Understand what a corrective measure is, and how to create one.
- Understand how to consult other MSCs on an intended corrective measure.
- Understand how to request the sponsor's opinion.
- Understand how to submit corrective measure and how to update and revert an existing one.

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# How to create and submit a corrective measure

The **corrective measure** is a process that allows the **Member State Concerned** (MSC) to **request a modification of a Clinical Trial** (CT) or to **modify its status** if the MSC considers that the requirements of the Clinical Trials Regulation (CT Regulation) are no longer met.

MSCs may apply measures such as the request for modification of the CT, the revocation of an authorisation, or the suspension of the CT. The CT Regulation foresees that the MSC shall request the sponsor's opinion before applying the corrective measure, except where immediate action is required.



## How create a corrective measure

- This section outlines the steps that MSCs need to follow to create a corrective measure and populate its form.



## How to submit, update and revert a corrective measure

- This section outlines the steps that MSCs need to follow to finalise a corrective measure, and update and revert if necessary.

# Corrective measures

## How to create a corrective measure

1. Open the 'Corrective measure' sub-tab on a CT page and click on the 'New' button.

CTIS Training Programme test CT for Demo - change for test

Summary Full Trial Information Notifications Trial results **Corrective measures** Ad hoc assessments Users Amend Inspections

Corrective measures

Corrective Measure ID	Member State Concerned	Submission date	Type	Notes	Actions
					<b>+ New</b>

2. Select the type and reason of corrective measure and indicate if immediate action is required.

Type \*

Suspend  
 Revoke  
 Require modification  
 No further action needed  
 Suspend & Require Modification

Reason \* Reason

Justification  
 Either justification or justification documents must be provided.

Justification documents  
 Either justification or justification documents must be provided.

**+ Add document**

Immediate action \* No

3. Consult with other MSCs by updating the necessary fields and clicking on the 'Submit request for consultation' button.

Consultation with MSCs **ASSESSOR: Austria**

Reason for consultation

Related documents

**+ Add document**

Requested response date 15-03-2021

**Submit request for consultation**

4. Request sponsor's opinion by updating the necessary fields and clicking on the 'Submit request for opinion' button. Finally, assess the response.

Sponsor opinion request

**+ Add**

Request

Question1

**+ Add question**

Related documents

**+ Add document**

Response opinion documents

**Submit request for opinion**

# Corrective measures

## How to submit, update and revert a corrective measure

1. Click on the **'Submit'** button to finalise the corrective measure.

A screenshot of a form's bottom right corner. It contains four buttons: a grey 'Close' button, a blue 'X Cancel CM' button, a blue 'Save' button with a floppy disk icon, and a blue 'Submit' button with a checkmark icon. The 'Submit' button is highlighted with an orange rectangular box.

2. Select the corrective measure, click on the **'Update'** icon (pencil) and confirm the update.

A screenshot of a table titled 'Corrective measures'. The table has columns: 'Corrective Measure ID', 'Member State Concerned', 'Submission date', 'Type', 'Notes', and 'Actions'. A single row is visible with ID 'CM-AT-0001', Member State 'Austria', Submission date '04/03/2021', and Type 'Suspend'. In the 'Actions' column, there are three icons: an eye, a pencil, and a refresh arrow. The pencil icon is highlighted with an orange box. Below the table, a large grey arrow points down to another screenshot.

A screenshot of a form's bottom right corner. It contains two buttons: a grey 'Close' button and a blue 'Update' button with a refresh arrow icon. The 'Update' button is highlighted with an orange rectangular box.

3. Select the corrective measure, click on the **'Revert'** button (arrow) and update the necessary fields. Finally, confirm the changes with the **'Revert'** button.

A screenshot of a table titled 'Corrective measures', identical to the one in step 2. The 'Revert' icon (a circular arrow) in the 'Actions' column is highlighted with an orange box. Below the table, a large grey arrow points down to another screenshot.

A screenshot of a dialog box titled 'Revert corrective measure'. It contains the following fields:
 

- 'Revert trial decision' with a dropdown menu set to 'Authorised'.
- 'Revert corrective measure type' with a dropdown menu.
- 'Justification' with a text area.
- 'Supporting documents' with an 'Add document' button.

 At the bottom right, there are two buttons: a grey 'Close' button and a blue 'Revert' button with a checkmark icon. The 'Revert' button is highlighted with an orange rectangular box.

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