



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
					+ New

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

Delete draft request for opinion

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.



Close X Cancel CM Save **Submit**





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

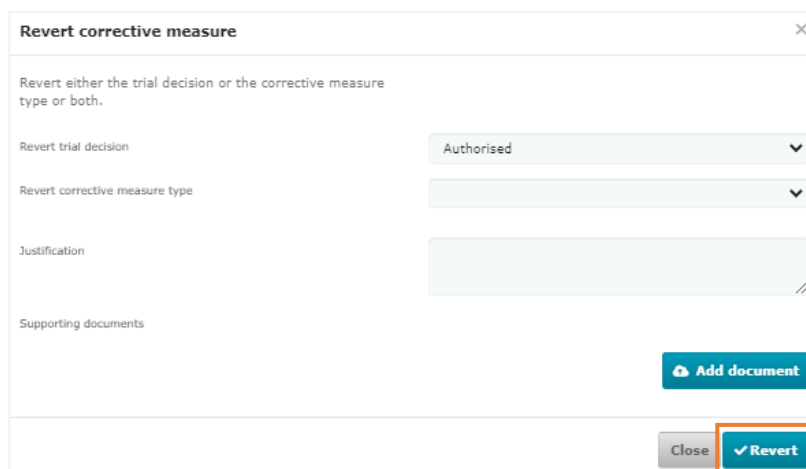
Corrective measures						+ New
Corrective Measure ID 	Member State Concerned	Submission date	Type	Notes	Actions	
CM-AT-0001	Austria	04/03/2021	Suspend		  	




Close **Update**

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

Corrective measures						+ New
Corrective Measure ID 	Member State Concerned	Submission date	Type	Notes	Actions	
CM-AT-0001	Austria	04/03/2021	Suspend		  	



Revert corrective measure 


Revert either the trial decision or the corrective measure type or both.

Revert trial decision

Revert corrective measure type

Justification

Supporting documents

 Add document

Close **Revert**

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Send a question

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Clinical Trials Information System (CTIS).

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