EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

How to manage a clinical trial

CTIS Training Programme – Module 05
Version 1.0 – October 2021

Learning Objective

- Remember the responsibilities of the sponsors from the submission of a clinical trial application until the submission of trial results.
- Understand the use of notifications.
- Understand the processes of ad hoc assessment and corrective measure, and how to respond Request for Information (RFI) related to them.
- Understand how to prepare and submit CT results.

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How to manage a clinical trial from the Sponsor workspace

CTIS allows sponsors **to meet their responsibilities in terms of compiling, recording and submitting data for clinical trials conducted in the EU/EEA**, responding to RFIs sent by RMS/MSC, and submitting notifications for relevant events occurred while the trial is being conducted.

This guide explains how to manage the events that might occur during the conduct of a clinical trial.

This step-by-step guide includes:

Notifications

This section outlines the steps that sponsor users should follow to create 'Trial & Recruitment Periods' notifications and other types of notifications.

Ad hoc assessments

This section outlines the steps that sponsor users should follow to respond to the RFIs received in the context of ad hoc assessments.

Corrective measures

This section outlines the steps that sponsor users should follow to respond to requests for opinion received in the context of corrective measures, as well as how to access corrective measures that have already been applied.

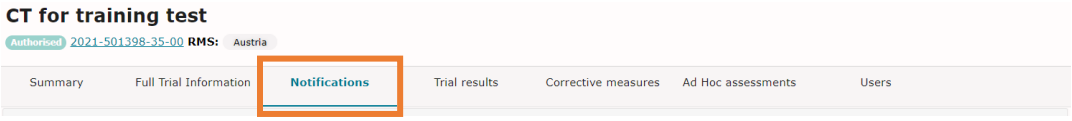
Trial results

This section outlines the steps that sponsor users should follow to submit the trial results and the lay person summary of results.

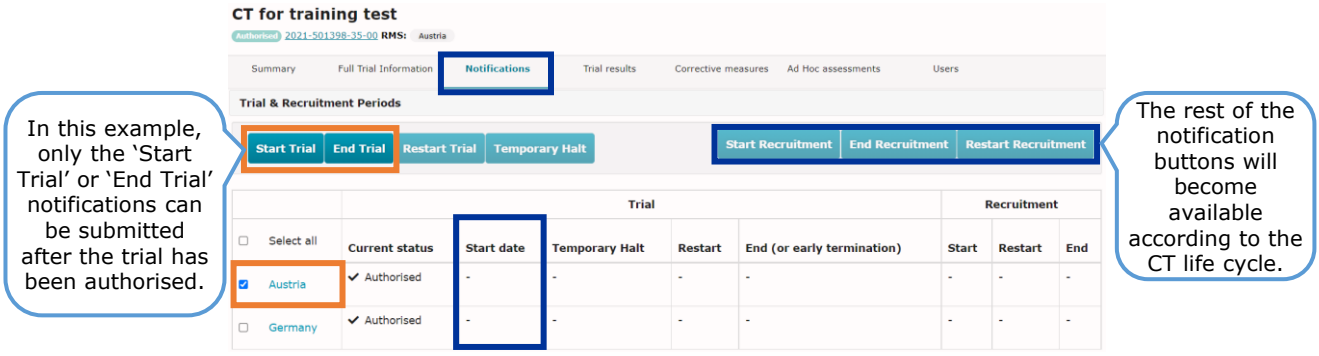
Notifications

How to create 'Trial & Recruitment Periods' notifications

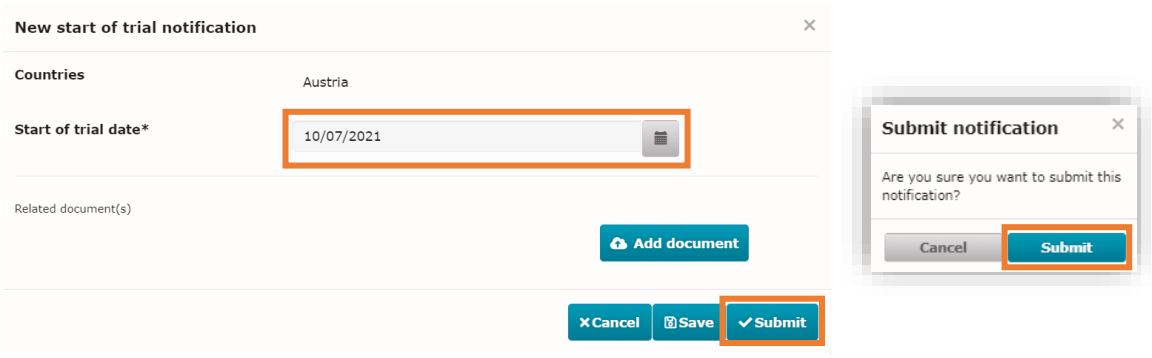
1. In a **clinical trial page**, users can click on the **'Notifications' sub-tab**.



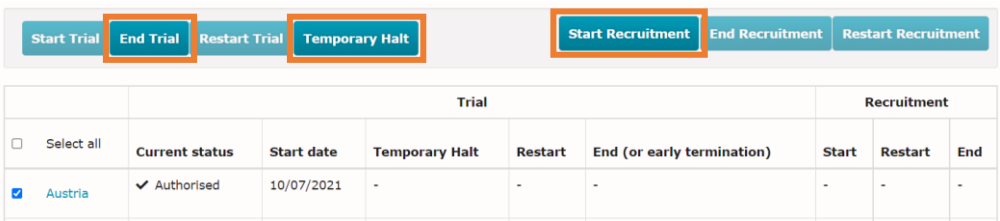
2. On the list, users can **select the Member State Concerned (MSC)** that they want to submit a notification to, and the click on the notifications buttons displayed at the top of the '**Notifications'** sub-tab.



3. By selecting **'Start Trial'**, users need to **fill in the details,** such as the start of trial date or **add supporting documents** in the pop-up window and **click on the 'Submit'** button and the 'Confirm' button.



4. Once **the trial has started**, other notifications can be submitted, such as a **temporary halt** or the **start of recruitment** of a trial.



#CTIS insights

Notifications can be created once the CT is authorised.

'Trial and Recruitment periods' notifications **enable sponsors to inform MSC of relevant moments** during the conduction of a CT.

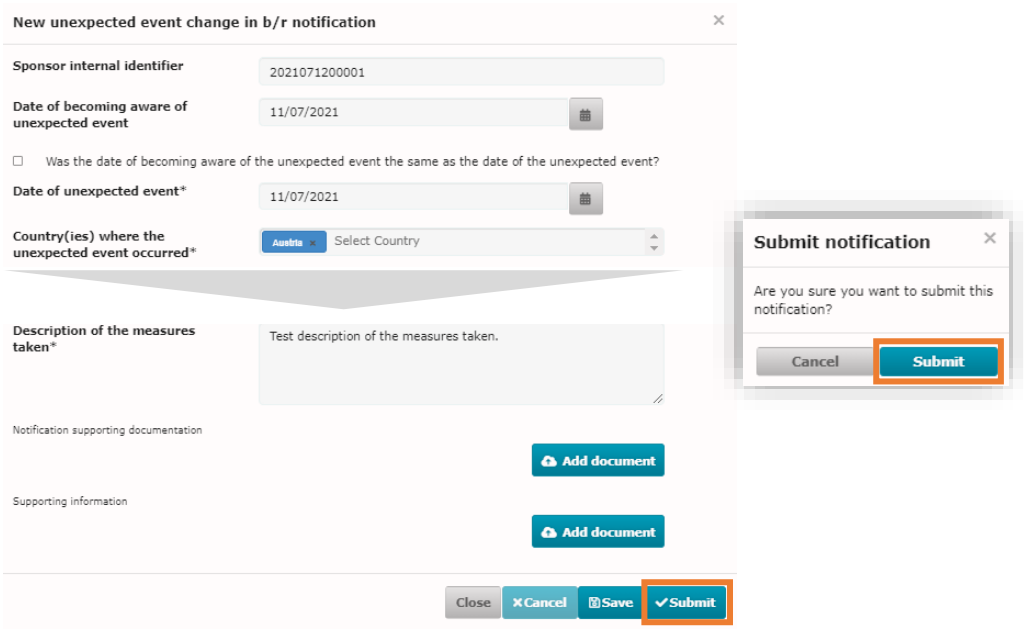
To be able to notify the **start of a trial**, an MSC **must be selected**.

Notifications

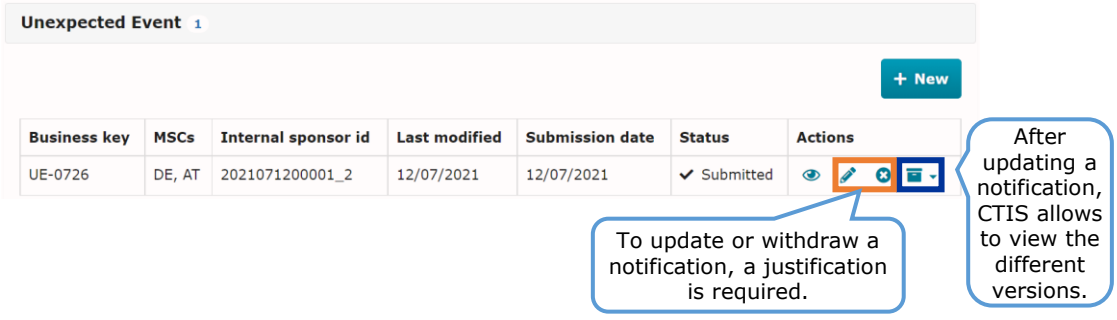
How to create other types of notifications

1. Users can scroll **below the trial and recruitment periods** notifications and click on the '**+ New**' button in the respective notification to be submitted.

2. Users can fill in the **respective details of the notification** to be submitted. In the example below, a notification of an **unexpected event** is shown. Users can click on '**Submit**' and then confirm it in the pop-up.



3. Once submitted, **users can use the icons to perform various actions**: The ***eye* icon** to view the information of the notification, the ***pencil* icon** to update data (e.g. to correct errors, provide additional information, etc.) and the ***cancel* icon** to withdraw the notification.



#CTIS insights

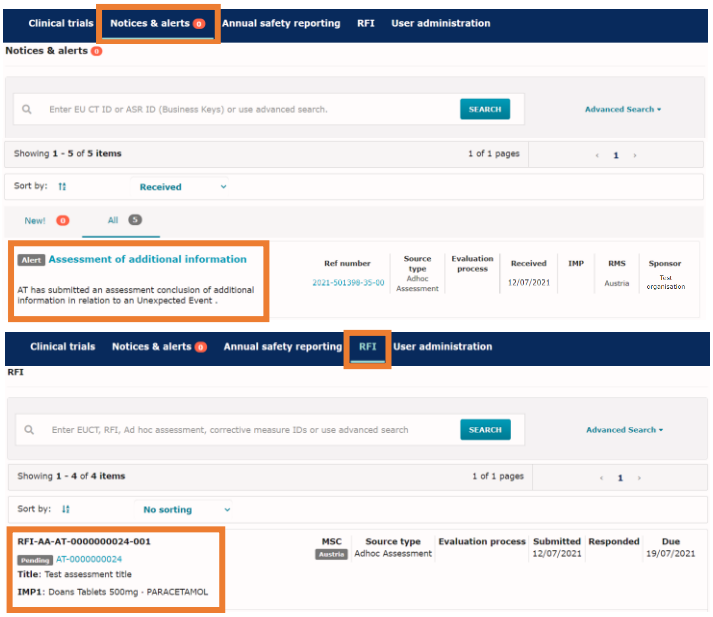
These notifications are only needed in **certain circumstances** that were **not foreseen** in the protocol.

Before **withdrawal**, sponsors need to request EMA for the removal from the public website of information regarding data privacy or disclosure point of view.

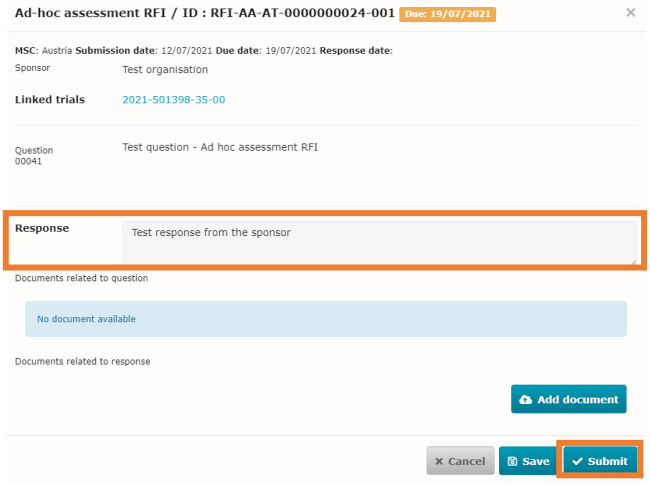
Ad hoc assessments

How to respond to ad hoc assessments Requests for Information (RFIs)

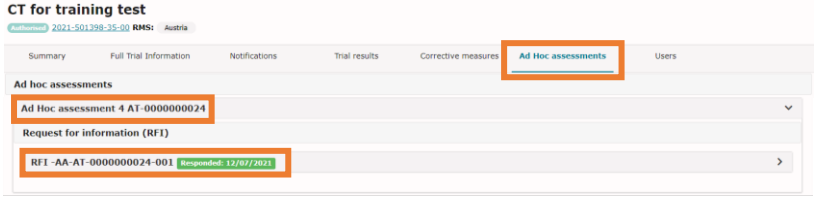
1. Users can access the RFI raised by the MSC(s) as part of an ad hoc assessment via the alert received on the '**Notices & alerts**' tab, or in the '**RFI**' tab.



2. To answer the RFI, users can fill in the **respective details** in the pop-up window. They can click on '**Submit**' and then confirm it. Through the RFI responses provided as part of an ad hoc assessment it will not be possible for the sponsor to update the dossier. Supporting documentation can be provided in support to the responses.



3. To access the ad hoc assessments and responses to the respective RFIs, users can click on the '**Ad Hoc assessments**' **sub-tab on a clinical trial page** and scroll down to the Ad-hoc assessment.



#CTIS insights

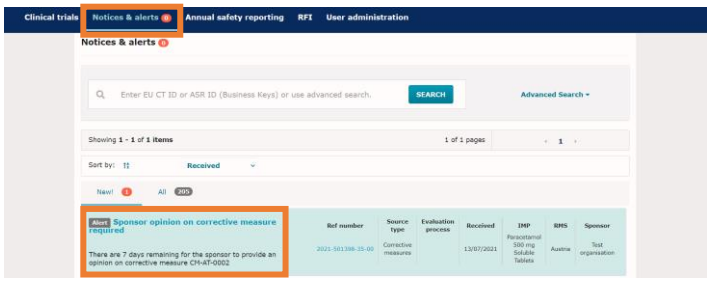
In the '**Ad Hoc assessments**' sub-tab of a **clinical trial page**, the sponsor can find the information related to **any ad hoc assessment** for a specific trial.

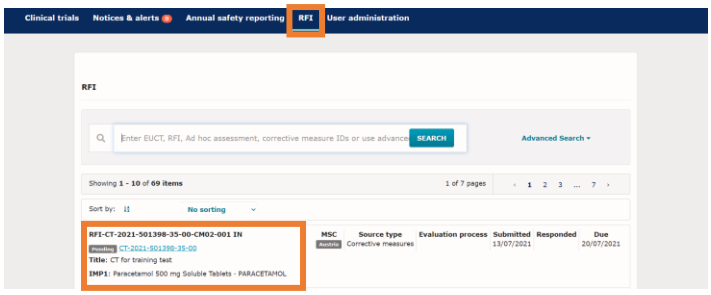
A **pop-up window** will allow the sponsor to answer the RFI related to the ad hoc assessment **regardless where the RFI is accessed from**.

Corrective measures

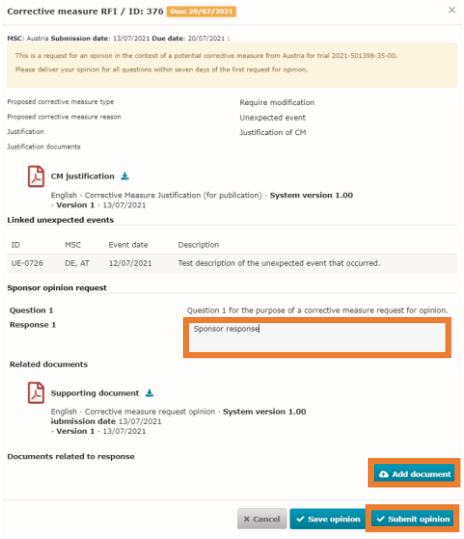
How to respond to requests for opinion regarding corrective measures

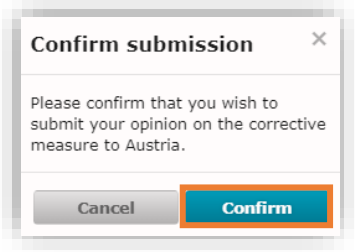
1. Users can access the requests for opinion sent by the MSC(s) regarding the corrective measures RFI via the alert received on the '**Notices & alerts**' tab, or in the '**RFI**' tab.





2. To answer the RFI, users can fill in the **respective details** in the pop-up window. Click on '**Submit opinion**' and then select the **'Confirm'** button. Supporting documentation can be provided in support to the responses.





3. To access the **corrective measures that have been already applied**, they will appear on the '**Corrective measures**' sub-tab **on a clinical trial page**.

#CTIS insights

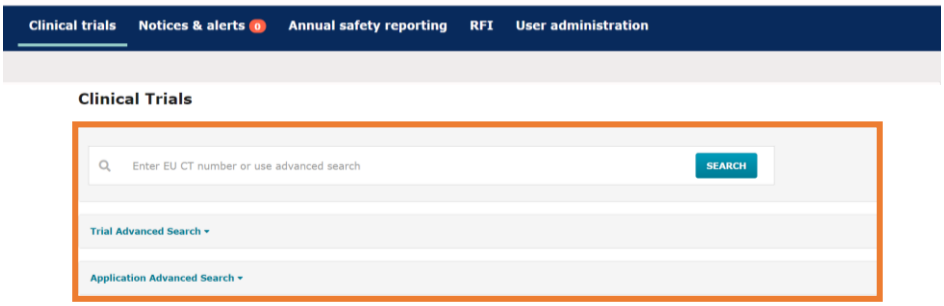
Generally, the **MSC must request the sponsor for their opinion** through an RFI before applying the corrective measure, **except where immediate action** is required.

When a **corrective measure is updated**, the system allows to view the previous version(s) via an icon next to the eye icon.

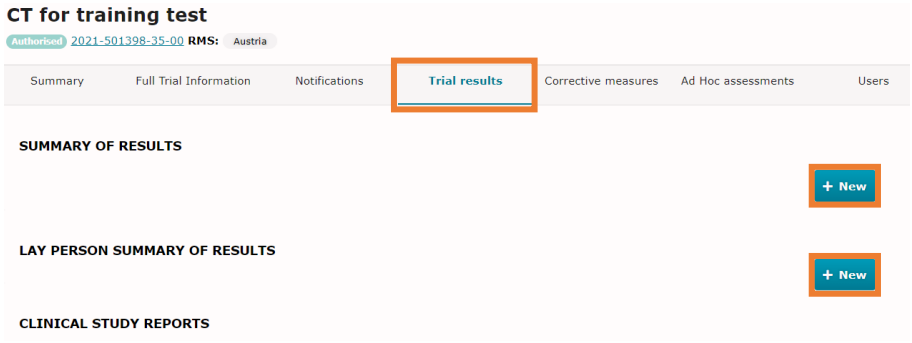
Trial results

How to submit trial results and lay person summary of results

1. Users can open the '**Clinical trials' tab** and search for the clinical trial using the **search functionality** that suits the best their need.

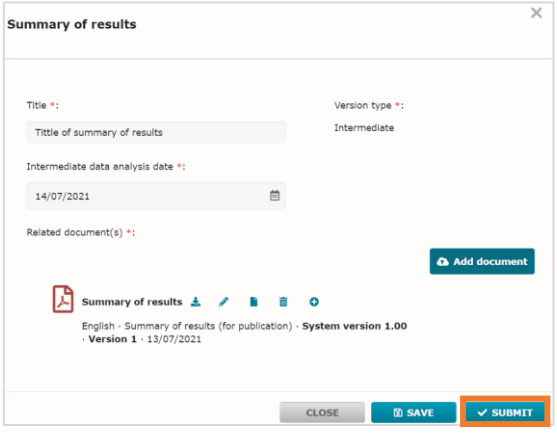


2. Users can access the '**Trial results**' sub-tab in a **CT page.** Then click on the **'+ New'** button.

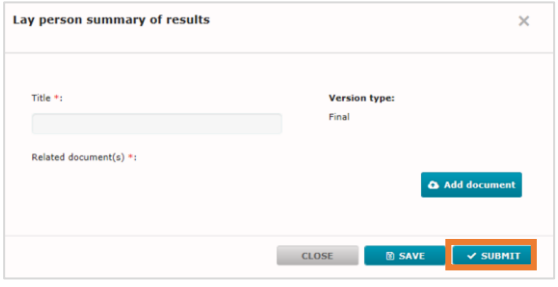


3. After populating the **details according to each case** (summary of results and lay person summary of results), users can click on '**Submit**' button and then confirm it in the pop-up.

Summary of result



Lay person summary of result



#CTIS insights

Sponsors must submit a **summary of results** and a **lay person summary** within **one year** from the end of a CT (in all EEA MSC or globally, if applicable), and within 6 months in case of paediatric trials.

Sponsors have the possibility of submitting an **intermediate summary of results**, prior to the **summary of results** if the CT protocol provides for an intermediate data analysis.

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