

# 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:





How to create 'Trial & Recruitment Periods' notifications

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

CT for trai	ning test	ia					
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users	

 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.

		T for traini	ng test 98-35-00 RMS: Austria Full Trial Information	Notifications	Trial results	Corrective me	casures Ad Hoc assessments	Users			
	Т	rial & Recruitme	ent Periods								The rest of the
In this example, only the 'Start Trial' or 'End Trial'	X	Start Trial	End Trial Restart 1	Trial Tempora	ary Halt	S	tart Recruitment   End Recruitme	ent Res	tart Recruit	ment	notification buttons will
notifications can	( _	Trial Recruitment							become		
be submitted after the trial has		Select all	Current status	Start date	Temporary Halt	Restart	End (or early termination)	Start	Restart	End	according to the
been authorised.		Austria	✓ Authorised	-			-			•	CT life Cycle.
		Germany	✓ Authorised	-		-	-	-	-	-	

 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.

New start of trial notification			×	
Countries	Austria			
Start of trial date*	10/07/2021	=		Submit notification ×
Related document(s)				Are you sure you want to submit this notification?
		Add document		Cancel Submit
	1	×Cancel Save ✓Subm	it	

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

Start Trial End Trial Restart Trial Temporary Halt Start Recruitment End Recruitment Restart F									art Recruiti	ment
Trial Recruitment										:
0	Select all	Current status	Start date	Temporary Halt	Restart	End (or early ter	mination)	Start	Restart	End
	Austria	✓ Authorised	10/07/2021	-	-	-		-	-	-



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**.

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#### How to create other types of notifications

#### **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.



 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.

New unexpected event change in	b/r notification		×	
Sponsor internal identifier	2021071200001			
Date of becoming aware of unexpected event	11/07/2021	曲		
<ul> <li>Was the date of becoming aware of</li> </ul>	the unexpected event the same as the date	of the unexpected event?		
Date of unexpected event*	11/07/2021	*		
Country(ies) where the unexpected event occurred*	Austria × Select Country	* *		Submit notification ×
				Are you sure you want to submit this notification?
taken*	Test description of the measures taken.			Cancel Submit
Notification supporting documentation		li .		
		Add document		
Supporting information		Add document		
	Close	×Cancel ⊠Save ✓S	Submit	

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.

Unexpected E	vent 1							
							+ New	
Business key	MSCs	Internal sponsor id	Last modified	Submission date	Status	Actions		After
UE-0726	DE, AT	2021071200001_2	12/07/2021	12/07/2021	✓ Submitted	۲	8 🖬 -	updating a notification.
				To u notifi	pdate or wi cation, a ju is require	ithdraw a stificatio ed.	a n	CTIS allows to view the different versions.



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.

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## Ad hoc assessments

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

 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.

Clinical trials	Notices & alerts 👩	Annual safety reporting	RFI User adm	inistration	
Notices & alerts 👩					
Q Enter EU CT	ID or ASR ID (Business Ke	ys) or use advanced search.		SEARCH	Advanced Search •
Showing 1 - 5 of 5 if	tems			1 of 1 pages	< 1 >
Sort by: 11	Received	~			
New!	All 🚯				
Alert Assessme AT has submitted ar information in relati	nt of additional infor assessment conclusion of on to an Unexpected Event	mation Ref m additional	amber Source type 398-35-00 Adhoc Assessment	Evaluation process Received 12/07/202	IMP RMS Sponsor Austria Toxi Austria creentation
Clinical trials	Notices & alerts 🧿	Annual safety reporting	RFI User adm	hinistration	
Q, Enter EUCT,	RFI, Ad hoc assessment,	corrective measure IDs or use ac	lvanced search	SEARCH	Advanced Search •
Showing 1 - 4 of 4	items			1 of 1 pages	$\langle 1 \rangle$
Sort by: 11	No sorting	¥			
RFI-AA-AT-00000 Periodise AT-000000 Title: Test assessm IMP1: Doans Tablet	00024-001 0024 ent title ts 500mg - PARACETAMOL	MSC Austria	Source type Adhoc Assessment	Evaluation process Su 12/	bmitted Responded Due 19/07/2021 19/07/2021

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.

Ad-hoc asses	sment RFI / ID : RFI-AA-AT-0000000024-001 Due: 19/07/2021	×	
MSC: Austria Subm Sponsor	nission date: 12/07/2021 Due date: 19/07/2021 Response date: Test organisation		
Linked trials	2021-501398-35-00		
Question 00041	Test question - Ad hoc assessment RFI		Confirm Submission ×
			Please confirm that you wish to
Response	Test response from the sponsor		submit the response of rfi with id:407 to Austria.
Documents related t	to question		Cancel Confirm
No document a	available		
Documents related t	to response		
		Add document	
	× Cancel	🕅 Save 🗸 Submit	

 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.

CT for training test											
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users					
Ad hoc assessm	nents										
Ad Hoc assess	ment 4 AT-0000000024						~				
Request for in	nformation (RFI)										
RFI -AA-AT-	0000000024-001 Respon	ded: 12/07/2021					>				



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

 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.

	Notices & alerts 🔘	Annual safety reporting	RFI	User admini	stration					
	Notices & alerts 🕦									
	Q, Enter EU CT ID	or ASR ID (Business Keys) or	use adva	anced search.		SEARCH		Advan	ced Sear	rch -
	Showing 1 - 1 of 1 items					1 of	1 pages		1	
	Sort by: 11	Received ~								
	New! 📵 All 🌘	205								
	Alext Sponsor opinion required There are 7 days remaining opinion on corrective measu	for the sponser to provide an ure CH-4T-0002	2	Ref number 101-501308-35-09	Source type Corrective measures	Evaluation process	Received	IMP Paraontamol Soluble Tableta	RMS Austria	Speesor Test organisation
Clinical trials	Notices & alerts (0)	Annual safety reporting	RFI	User admini	stration					
			_							
	RFI									
	RFI Q. Enter EUCT, RFI	, Ad hoc assessment, correcti	ve measu	are IDs or use	advance	SEARCH		Advan	ced Sear	rch *
	RFI Q Enter EUCT, RFI Showing 1 - 10 of 69 item	, Ad hoc assessment, correcti	ve measu	ire IDs or use	advance	SEARCH 1 of	7 pages	Advan	ced Sear	rch •
	RFI Q. Enter EUCT, RFI Showing 1 - 10 of 69 item Sort by: If	, Ad hoc assessment, correcti Mesorting v	ve measu	ure IDs or use	advance	SEARCH 1 of	7 pages	Advan < 1 :	ced Sear	rch •

 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.

prrective measure RFI / ID: 376 Due: 20/07/2021	×
3C: Austria Submission date: 13/07/2021 Due date: 20/07/2021 :	
This is a request for an opinion in the context of a potential corrective measure from Austria for trial 2021-501398-35-	00.
Please deliver your opinion for all questions within seven days of the first request for opinion.	
sposed corrective measure type Require modification	
sposed corrective measure reason Unexpected event	
stification Justification of CM	
dification documents	
CM justification 🛓	
English · Corrective Measure Justification (for publication) · System version 1.00 · Version 1 · 13/07/2021	Confirm submission
nked unexpected events	
D MSC Event date Description	
E-0726 DE, AT 12/07/2021 Test description of the unexpected event that occurred.	Please confirm that you wish to
onsor opinion request	submit your opinion on the correcti
uestion 1 Question 1 for the purpose of a corrective measure rec	uest for opinion. measure to Austria.
esponse 1 Sponsor response	
elated documents	Cancel Confirm
Supporting document	
Calify County and a later for the second sec	
Submission date 13/07/2021	
ocuments related to response	
<b>A</b>	Add document

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**.

CT for trai	01398-35-00 RMS: Austria						
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users	
Corrective Me	asures						
Only submitted Cl	M(s) is/are displayed on the Spon	ISOF.					
Corrective Mea	sure ID 👫	Member State Concerne	d	Submission date	Туре	Notes	Actions
CM-AT-0001		Austria		12/07/2021	Require modification		۲



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.

### 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.

ical trials	Notices & alerts	Annual safety reporting	RFI	User administration		
Clinica	Triele					
Clinica	ii i riais					
٩	Enter EU CT number or use a	advanced search			SEARCH	
Trial Adv	vanced Search <del>+</del>					
Applicat	ion Advanced Search +					

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

CT for training test								
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users		
SUMMARY OF	RESULTS					+ New		
LAY PERSON	SUMMARY OF RESULTS					+ New		
CLINICAL ST	UDY REPORTS							

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

Summary of results		×	La	y person summary of results	×	
Title *: Tittle of summary of results Intermediate data analysis date *: 14/07/2021	Version type *: Intermediate			Title *: Related document(s) *:	Version type: Final Add document	
Related document(s) *:		Add document			CLOSE SAVE SUBMIT	
Summary of results A P B English - Summary of results (for publication • Version 1 - 13/07/2021	) · System version 1.00 CLOSE 🕅 SA	VE SUBMIT				



**Trial results** 

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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European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands

Telephone +31 (0)88 781 6000

Send a question

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