

Step-by-step guide

Supervise a CT – Ad Hoc Assessment

CTIS Training Programme – Module 17 Version 1.1 – June 2021

Learning Objectives

- · Understand how to create, cancel, save, and share an Ad hoc assessment.
- Understand how to raise a Request for Information, consult with other MSs, and how to update and complete an Ad hoc assessment.
- Understand how to search and view an Ad hoc assessment.



© European Medicines Agency, 2021

Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

Ad Hoc Assessment

An ad hoc assessment can be created by a Member State (MS) after a **Clinical Trial Application (CTA) has been authorised** and at least one of the following situations has occurred and need to be considered:

- An event has occurred during the trial.
- An event not directly related to the trial has occurred (e.g. a new IMP safety data).

The ad hoc assessment process enables the Member States to **assess information** related to a notification, an investigational medical product, or any other information relevant to the supervision of the trial.

Any Member State is able to create a new additional information assessment and consult with other MSs. The sponsors can be involved if a request for information is submitted.



How to create and complete an ad hoc assessment

 This section outlines the steps that Member States need to follow to create an ad hoc assessment and populate its sections.



How to search and view an ad hoc assessment

 This section outlines the steps that Member States need to follow to search and view an ad hoc assessment outcome.

How to create and complete an ad hoc assessment

How to create and complete an ad hoc assessment

1. Open the **'Ad hoc assessment' tab** on a CT page and click on the **'New assessment**' button.

Cli	nical trials	Notices & alerts 🕕	Tasks	Ad hoc assessments	Annual safety reporting	Inspections	Union control
	Q	Enter EU CT numbe	er or us	e advanced search	SEARCH	Advanc	ed Search •
					+ New asses	sment	🛓 Download

 Populate the 'Clinical Trials linked to the assessment' section by clicking on the 'Search for clinical trials' button and selecting one or more CTs from the same sponsor in which the assessment is to be made. Additionally, the corresponding Investigational Medical Products (IMPs) need to be selected.

Clinical Trials linked to the assessment	•
SEARCH FOR CLINICAL TRIALS	

3. Populate the **'Assessment details'** section including the title and the reasons for creating an ad hoc assessment (user also may populate the optional fields).

Assessment details		
Assessment title *		
Linked to *		~
Supporting documentation	Add document	Ī
Select affected countries	Select Country	▲ ▼
	□ Safety related assessment	

4. Save the form through the **'Save' button** available on the upper-right corner in order to continue the process.

Ad hoc assessment Complete Share Cancel Save									
Status In Progress	Assessing MS AT	Created 07/06/2021		update 07/06/2021	Versi	on			

5. In case MS need additional details from the sponsor, they can request information through the 'Request for information (RFI)' section. Once all the information is provided, MS can click on the 'Save' and 'Submit' buttons. Note that users have the flexibility to do the 'Discussion' section first.

Create RFI	
Sponsor	Test organisation
Question 1: *	
Add documents	🗅 Add document
Due: *	+ Add new question
	Cancel 🛛 Save 🗸 Submit



Member States can link the assessment to the **appropriate type of notification or event**. The notifications need to be previously submitted in the trial. Once sponsors have provided a response to the RFI, the assessing Member State receives a notice and can then assess the sponsor's answer.

Only the MSC can submit RFIs to the sponsor.

3

How to create and complete an ad hoc assessment

How to create and complete an ad hoc assessment

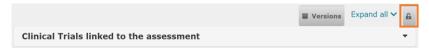
6. Click on the 'Share' button to **share the assessment with the other Member States**.

Ad hoc assessme	Share	Cancel	Save					
Status Assessin MS In AT Progress		Created Shared		d Last Version update 10/06/2021				
	Safety related assessment							

 Additionally, the assessing Member State can discuss the process with other Member States. The user needs to fill in the fields with the discussion details and click on the 'Save' and 'Share' buttons.

Discussion			*
Initial reason for discussion: *			
Add documents		Add document	
Response requested date *			
			Cancel Save Share

8. If necessary, **update** the information of an ad hoc assessment by clicking on the **'Padlock' button**.



9. Populate the 'Assessment outcome' section with the recommended actions and conclusions of the assessment.

Recommended actions *	Recommended actions	*
Conclusion of assessment *		
Either conclusion or conclusion documents must be provided.		<i>#</i>
Conclusion of assessment documentation	🗛 Ad	ld document
Either conclusion or conclusion documents must be provided.		

 Finalise the ad hoc assessment by clicking on the 'Complete' button. Once is completed, users are not able to update the form.

Ad hoc assessme	ent - AT	-000000	0010	Complete	Share	Close	Save
Status	Assessing MS	Created	Shared	Last update	Version		
In Progress	AT		10/06/2021		2		
		etv related ass	essment				

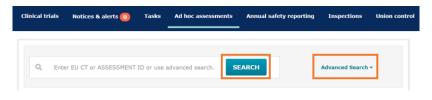


Once the ad hoc assessment **is shared**, the user is **not allowed to cancel the form.** Once the Member States have provided a response to the discussion, all MSs including the assessing MS receives an alert in the 'Notice & alerts' tab and can then assess the answer.

How to search and view an ad hoc assessment

How to search and view an ad hoc assessment

1. Search for an ad hoc assessment by indicating the **EU CT** number, **assessment ID** or, alternatively, using the **'Advanced Search'** button.



2. In order to view the details, select the ad hoc assessment by clicking on the title.

Showing 1 - 10 of 89 items					1 of 9 pages	< 1 2	3 9 >
Sort by: 11 Id	Ý						
New Ad Hoc	Related	Sponsor:	MSC:	RMS:	Assessing MS:	Shared:	Assessment Type:
Completed <u>GR-0000000006</u> Safety		Panpharma	Greece France	Greece France	GR	15/05/2021	Other
New Ad Hoc 1		Sponsor:	MSC:	RMS:	Assessing MS:	Shared:	Assessment Type:
In progresss GR-0000000005		Panpharma	Greece	Greece	GR	15/05/2021	Other

3. Member States can **view all the versions of the ad hoc assessment** after they have been updated. User can click on the versions icon and all the versions will be displayed.

Back to previous search							
Clinical Trial Assess	ment -	AT-000	000000	3	Complete	Share C	lose Save
Status Completed	Assessing MS AT	03/06/2021	Shared 03/06/2021 Safety related	•	Completed 03/06/2021	Version 3	
						Versions	Expand all 🗸
Clinical Trials linked to the	Clinical Trials linked to the assessment					/06/2021	-
Assessment details						/06/2021 /06/2021	-



Old versions of any section can be access in **Read-only mode**.

All Member States can view the ad hoc assessment.

European Medicines Agency

Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands **Telephone** +31 (0)88 781 6000 **Send a question** www.ema.europa.eu/contact

Clinical Trials Information System (CTIS) Step-by-step guide: Supervise a CT – Ad Hoc Assessment

© European Medicines Agency, 2021. Reproduction is authorised provided the source is acknowledged.