



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Supervise a CT – Ad Hoc Assessment

CTIS Training Programme – Module 17
Version 1.3 – August 2024

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.

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Record of updated versions

Version	Version description	Date
1.3	Minor changes to the content: adding the 'Record of updated versions' table	August 2024
1.2	Training material version published at CTIS go-live.	January 2022

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.

2. 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.

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).

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

Status	Assessing MS	Created	Shared	Last update	Version
In Progress	AT	07/06/2021		07/06/2021	

☒ Safety related assessment

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.

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 assessment - AT-0000000010

Complete

Share

Cancel

Save

Status	Assessing MS	Created	Shared	Last update	Version
In Progress	AT	07/06/2021		10/06/2021	

☒ Safety related assessment

7. 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**.

Versions

Expand all

Clinical Trials linked to the assessment

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

Assessment outcome

Recommended actions *

Recommended actions

Conclusion of assessment *

Either conclusion or conclusion documents must be provided.

Conclusion of assessment documentation

Either conclusion or conclusion documents must be provided.

Add document

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

Ad hoc assessment - AT-0000000010

Complete

Share

Close

Save

Status	Assessing MS	Created	Shared	Last update	Version
In Progress	AT	10/06/2021	10/06/2021	10/06/2021	2

☒ Safety related assessment



#CTIS
insights

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.

Clinical trials

Notices & alerts 0

Tasks

Ad hoc assessments

Annual safety reporting

Inspections

Union control

Enter EU CT or ASSESSMENT ID or use advanced search.

SEARCH

Advanced Search +

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

Showing 1 - 10 of 89 items1 of 9 pages< 1 2 3 ... 9 >

Sort by: 11Id

New Ad Hoc Completed GR-0000000006 Safety Related	Sponsor: Panpharma	MSC: Greece France	RMS: Greece France	Assessing MS: GR	Shared: 15/05/2021	Assessment Type: Other
New Ad Hoc 1 In progress GR-0000000005	Sponsor: Panpharma	MSC: Greece	RMS: Greece	Assessing MS: GR	Shared: 19/05/2021	Assessment Type: 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 Assessment - AT-0000000008

CompleteShareCloseSave

Status	Assessing MS	Created	Shared	Last update	Completed	Version
Completed	AT	03/06/2021	03/06/2021	03/06/2021	03/06/2021	3

☒ Safety related assessment

VersionsExpand all

3 | 03/06/2021

2 | 03/06/2021

1 | 02/06/2021

Clinical Trials linked to the assessment

Assessment details



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)

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