



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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.

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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.

The screenshot shows the top navigation bar with tabs: Clinical trials, Notices & alerts (6), Tasks, Ad hoc assessments, Annual safety reporting, Inspections, and Union control. Below the navigation bar is a search bar with the placeholder text 'Enter EU CT number or use advanced search' and a 'SEARCH' button. To the right of the search bar is an 'Advanced Search' dropdown. Below the search bar is a '+ New assessment' button, which is highlighted with an orange box, and a 'Download' 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.

The screenshot shows a section titled 'Clinical Trials linked to the assessment'. Inside this section, there is a button labeled 'SEARCH FOR CLINICAL TRIALS', which is highlighted with an orange box.

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).

The screenshot shows the 'Assessment details' form. It includes the following fields and controls:

- 'Assessment title *': A text input field, highlighted with an orange box.
- 'Linked to *': A dropdown menu, highlighted with an orange box.
- 'Supporting documentation': A section with an 'Add document' button.
- 'Select affected countries': A dropdown menu labeled 'Select Country'.
- 'Safety related assessment': A checkbox.

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

The screenshot shows a summary card for an 'Ad hoc assessment'. At the top right, there are buttons for 'Complete', 'Share', 'Cancel', and 'Save'. The 'Save' button is highlighted with an orange box. Below the buttons is a table with the following data:

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

At the bottom of the card, there is a checkbox for 'Safety related assessment' which is checked.

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.

The screenshot shows the 'Create RFI' form. It includes the following fields and controls:

- 'Sponsor': A dropdown menu with 'Test organisation' selected.
- 'Question 1 *': A large text area, highlighted with an orange box.
- 'Add documents': A section with an 'Add document' button.
- 'Due *': A date picker, highlighted with an orange box.
- 'Add new question': A button.
- At the bottom right, there are buttons for 'Cancel', 'Save', and 'Submit'. The 'Save' and 'Submit' buttons are highlighted with an orange box.

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 Padlock

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 *

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

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.

The screenshot shows a navigation bar with tabs: Clinical trials, Notices & alerts (with a red notification icon), Tasks, Ad hoc assessments (underlined), Annual safety reporting, Inspections, and Union control. Below the navigation bar is a search area with a search bar containing the placeholder text "Enter EU CT or ASSESSMENT ID or use advanced search." To the right of the search bar are two buttons: "SEARCH" and "Advanced Search". Both buttons are highlighted with orange boxes.

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

Sort by: **Id**

Title	Sponsor	MSC	RMS	Assessing MS	Shared	Assessment Type
New Ad Hoc Completed GR-0000000006 Safety Related	Panpharma	Greece France	Greece France	GR	15/05/2021	Other
New Ad Hoc 1 In progress 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 Assessment - AT-0000000008 Complete Share Close Save

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

Clinical Trials linked to the assessment

Assessment details

Versions Expand all

- 3 | 03/06/2021
- 2 | 03/06/2021
- 1 | 02/06/2021

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Clinical Trials Information System (CTIS)

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