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.

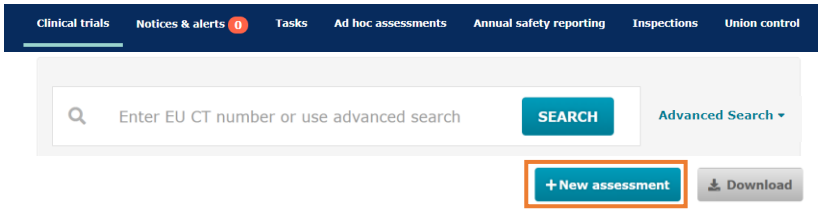
How to search and view an ad hoc assessment

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

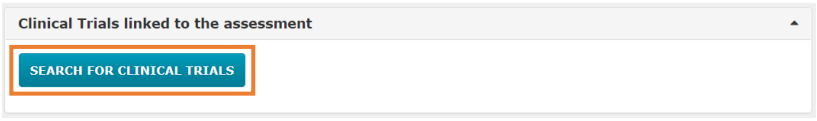
How to create and complete an ad hoc assessment

How to create and complete an ad hoc assessment

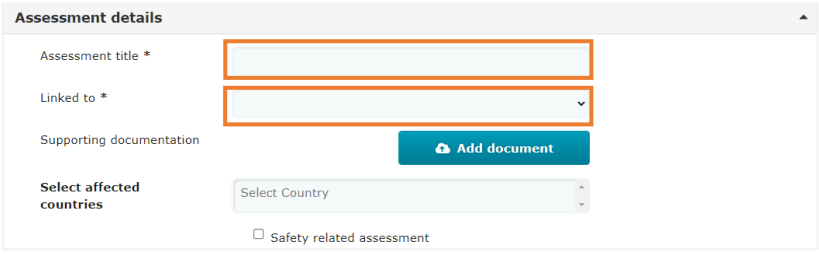
1. Open the **'Ad hoc assessment' tab** on a CT page and click on the '**New assessment**' button.



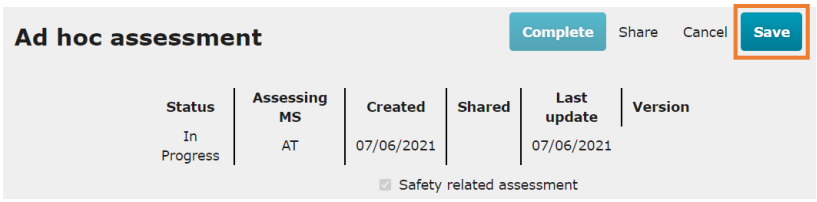
2. Populate the '**Clinical Trials linked to the assessment'** section by clicking on the 'Search for clinical trials' button and selecting one or more CTs from the same sponsor in which the assessment is to be made. Additionally, the corresponding Investigational Medical Products (IMPs) need to be selected.



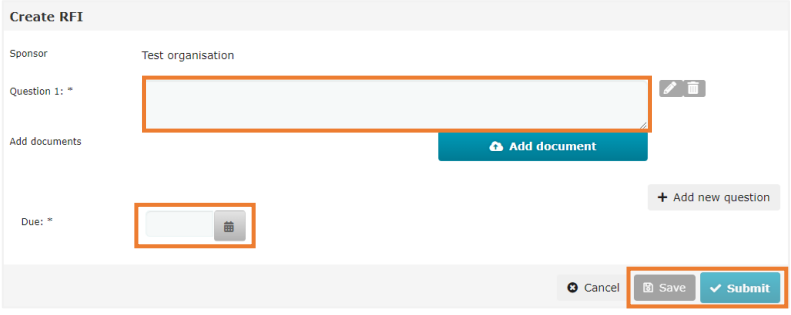
3. Populate the **'Assessment details'** section including the title and the reasons for creating an ad hoc assessment (user also may populate the optional fields).



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



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.



#CTIS insights

Member States can link the assessment to the **appropriate type of notification or event**. The notifications need to be previously submitted in the trial.

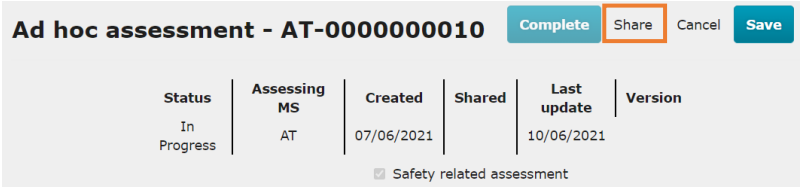
Once sponsors **have provided a response to the RFI,** the assessing Member State receives a notice and can then **assess the sponsor's answer.**

Only the MSC can submit RFIs to the sponsor.

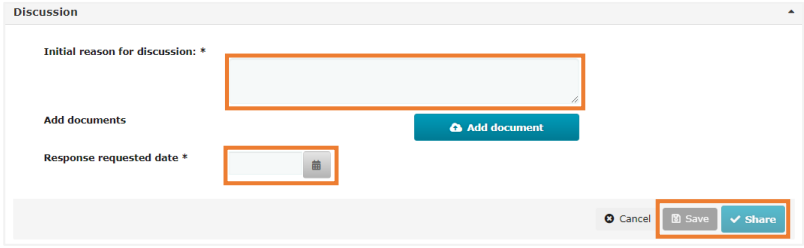
How to create and complete an ad hoc assessment

How to create and complete an ad hoc assessment

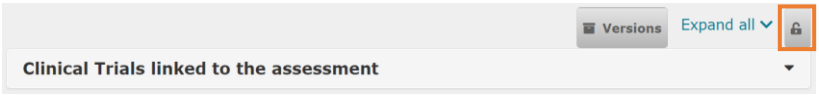
6. Click on the 'Share' button to **share the assessment with the other Member States**.



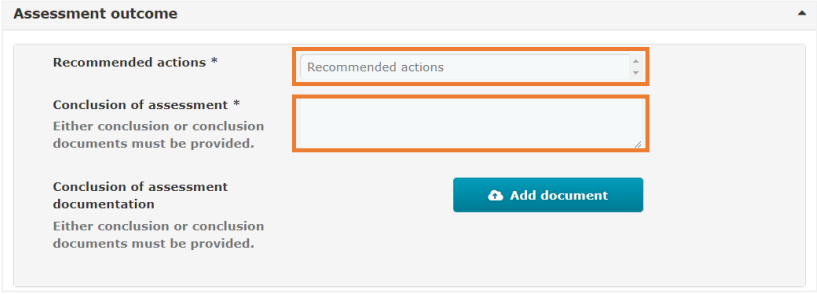
7. Additionally, the assessing Member State can **discuss the process with other Member States**. The user needs to fill in the fields with the discussion details and click on **the 'Save' and 'Share' buttons.**



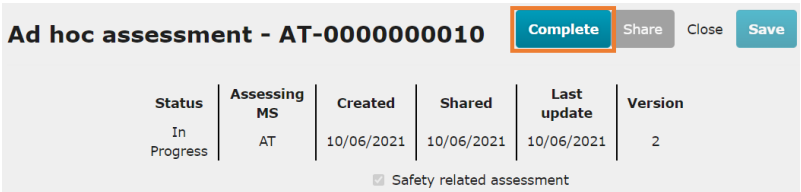
8. If necessary, **update** the information of an ad hoc assessment by clicking on the **'Padlock' button**.



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



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



#CTIS insights

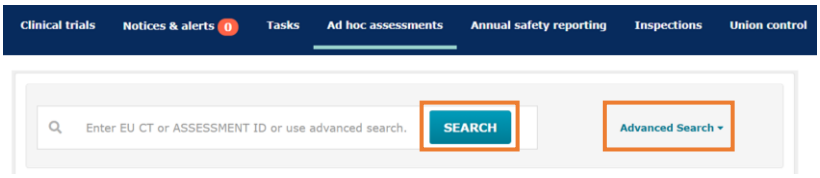
Once the ad hoc assessment **is shared**, the user is **not allowed to cancel the form.**

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.**

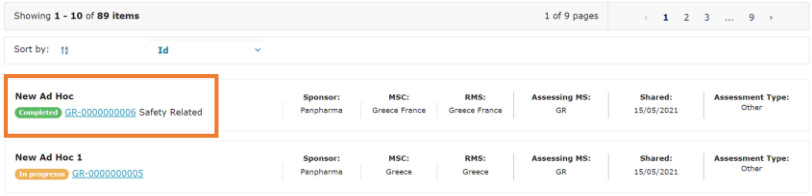
How to search and view an ad hoc assessment

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.



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



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.

#CTIS insights

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

All Member States can view the ad hoc assessment.

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Clinical Trials Information System (CTIS)
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