



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Assess an annual safety report

CTIS Training Programme – Module 20
Version 1.1 – September 2021

Learning Objectives

- Understand the phases of the assessment of an Annual Safety Report (ASR).
- Understand how to search and view an ASR.
- Understand how to assess an ASR.
- Understand how to request additional information to the sponsor.

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Assess an annual safety report

CTIS allows Member States to **assess an Annual Safety Report (ASR)**, a document provided annually by the sponsors to the authorities for the **monitoring and evaluation of the evolving safety profile of the Investigational Medicinal Product (IMP) and the mitigation of potential risks**.

After the sponsor submits an ASR, the appointment of the safety assessing Member State (saMS) process starts (in case the ASR involves multiple MSCs). Once appointed, the MSCs can start the assessment tasks of the ASR.

This guide explains how to assess an ASR (from the point of view of the saMS), and how to create an RFI as part of the assessment of an ASR.



Appointment of the saMS

This section outlines the steps that MSCs should follow to appoint the saMS.



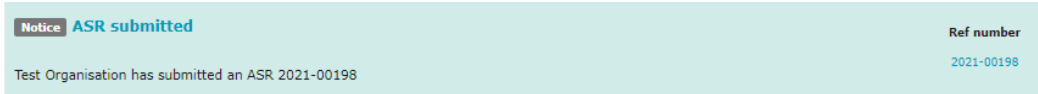
Assess an ASR

This section outlines the steps that the saMS and the rest of MSCs should follow to assess an ASR.

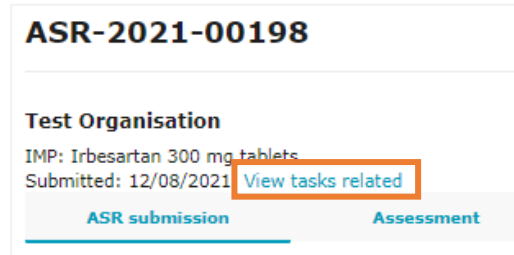
Appointment of the saMS

Express willingness/unwillingness to become the saMS (all MSCs)

- MSC users with specific roles for ASR will receive a notice in the **'Notices & alerts'** tab once the sponsor has submitted the ASR. They can **click** on the 'ASR submitted' notice.



- In the ASR page, users can click on the link **'View tasks related'**.



- Users can view the task **'Express willingness/unwillingness'** and select the **'Assign to me'** button.

Express willingness/unwillingness	saMS:	Application and Non-SM type:	Sponsor/Co-sponsors:	Evaluation process:	Created:	Due:	Remaining days:	Assignee:
Pending 2021-00198		ASR	Test Organisation	Assess ASR	12/08/2021	19/08/2021	7	

- Then, they can click on the corresponding **'Pending'** button.

Member states concerned
saMS selection for ASR-2021-00198 submitted on 12/08/2021 by Test Organisation for:
IMP1: Irbesartan 300 mg tablets
Candidate based on workload rules Austria

MSC	MS Role	Willingness	ASR workload in past 12 months	ASR as saMS in past 12 months	ASR as MSC in past 12 months	Justification
AT	Candidate saMS	Pending	0 %	0	5	
DE	MSC	Pending	19 %	8	42	

- Users can select **'Willing'** or **'Unwilling'**. Additionally, users can provide a justification and click on the **'Save'** button.

EXPRESS WILLINGNESS ✕

Select willingness to be saMS: Willing Unwilling

Justification:

- Finally, they can click on the **'Complete'** button at the bottom-right corner of the Express willingness/ unwillingness task page.



Assess an ASR

Circulate draft ASR-AR by the saMS and review by all MSCs

- Once the saMS is appointed, the saMS can view the 'Circulate draft ASR-AR' task in the 'Tasks' tab and then click on the 'Assign to me' button.

- The saMS can upload the **ASR-AR document** and click on the 'Share' and on the 'Complete task' buttons respectively. (saMS)

- All MSCs can view the 'Review ASR-AR' task in the 'Tasks' tab and click on the 'Assign to me' button.

- They can review the ASR-AR from the 'Assessment documents' of the 'Assessment' sub-tab in the ASR page.

Assess an ASR

Circulate draft ASR-AR by the saMS and review by all MSCs

5. Additionally, all MSCs (including the saMS) can document their consideration by clicking on the '**Considerations**' section and then on the '+ New' button. Finally, type the consideration and click on the 'Save' button.

The screenshot shows the 'Assessment' sub-tab of the ASR submission interface. Under the 'saMS selection' section, there is a text input field labeled 'Considerations'. To the right of this field, there are two buttons: 'Download' and '+ New'. The '+ New' button is highlighted with an orange box.

6. Then they can select the **considerations**, click on the '**Actions**' button and select the '**Share**' button from the drop-down list so that other MSCs (including the saMS) can view the considerations.

The screenshot displays a table of 'Considerations'. The table has columns for 'ID', 'MSC', 'Status', 'Consolidated', and 'Shared'. Two rows are visible: ID: AT002 (Test) and ID: AT001. The 'Actions' button for the first row is highlighted with an orange box, and its dropdown menu is open, showing options like 'Edit', 'Comment', 'Share', and 'Remove'. The 'Share' option is highlighted with an orange box.

7. After the considerations are shared (by the MSCs), the saMS can check them, select the appropriate **consolidation actions** (Accept, Adapt, Merge and Not included), and share them again with the other MSCs.

The screenshot shows the 'Considerations' table with two rows: ID: ASR-AT002 and ID: ASR-AT001. The 'Status' for both is 'Accepted'. The 'Actions' menu for the first row is open, showing options like 'Accept', 'Adapt', 'Merge', and 'Not included'. The 'Accept' option is highlighted with an orange box.

8. Additionally, the saMS can **raise an RFI** in case additional information must be provided by the sponsor through the '**Create RFI**' button available on the '**Consolidated considerations**' sub-tab.

The screenshot shows the 'Consolidated considerations' sub-tab. It displays a table with one row: ID: ASR-GR004, Consideration N°: ASR-GR001, Status: Adapted, Consolidated: 08/09/2021, and Shared: 08/09/2021. At the bottom right of the table, there is a 'CREATE RFI' button highlighted with an orange box.

Assess an ASR

Finalise assessment (saMS)

1. The saMS can view the 'Finalise assessment' task in the 'Tasks' tab and click on the 'Assign to me' button.

Finalise assessment	saMS:	Application and Non-SM type:	Sponsor/Co-sponsors:	Evaluation process:	Created:	Due:	Remaining days:	Assignee:
Pending 2021-00197	GERMANY	ASR	Test Organisation	Assess ASR	03/08/2021	12/10/2021	60	

2. saMS users can provide answers to specific **questions regarding the ASR and include additional information**, if applicable. If the saMS responds positively to any question, additional information must be provided.

Summary and Conclusion for Member States (can be seen only by MSCs)

SUMMARY AND CONCLUSION FOR MEMBER STATES

Are there any safety issues to be aware of and/or to follow up? Yes No

Safety issue*
 Specific safety issue (new or ongoing)
 Extra monitoring required
 SII issue
 Studies halted / suspended due to safety

Comments:

Do there any action required to follow up and/or to take? Yes No

Requested action to sponsor to follow up?
 Yes No

Requested action to sponsor?
 Protocol
 RSI during ID update
 ID
 RIF

Corrective measure required? Yes No

Corrective measure*
 If request not fulfilled by sponsor in time set
 Request change most immediately
 Suspend
 Revoke

Comments:

Is the ASR compliant with ASR (DCH E2F) format? Yes No

Summary and Conclusion for Sponsors (can be seen by sponsors and MSCs)

SUMMARY AND CONCLUSION FOR SPONSOR

Are there any new issues? Yes No

Acceptable action is taken by sponsor? Yes No

Specific action is required by sponsor? Yes No

Due date for specific action? Yes No

Requested action? Yes No

3. Users can click on the 'Add document' button and upload a **Final ASR-AR document** (PDF file). This document shall be created considering the draft ASR-AR in order to preserve the information. Then click on the 'Share' button to share it with the rest of the MSCs.

In order to finalise the ASR assessment report and complete the task you need to upload at least one document.

ASR-AR document*

test

English · Final ASR Assessment Report · System version 1.00
 · Version 1 · 13/08/2021

Add more documents

4. Lastly, they can click on the 'Complete task' button and then click on the 'Confirm' button of the pop-up window. The ASR-AR is **not subject to the publication** rules of CTIS.



The saMS will **not be able to finalise the assessment** if:

- There are any outstanding RFI awaiting a response.
- The due date for MSCs to finalise the Review ASR-AR task has not expired (14 days for multinational trials).
- There are any considerations received which have not been consolidated.
- The final ASR-AR document has not been uploaded.

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Send a question

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Clinical Trials Information System (CTIS)

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