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.
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)**

1. 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.

2. In the ASR page, users can click on the link ‘View tasks related’.

3. Users can view the task ‘Express willingness/unwillingness’ and select the ‘Assign to me’ button.

4. Then, they can click on the corresponding ‘Pending’ button.

5. Users can select ‘Willing’ or ‘Unwilling’. Additionally, users can provide a justification and click on the ‘Save’ button.

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

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**CTIS insights**

Users can also access the ASR through the ‘Annual safety reporting’ or ‘Tasks’ tabs. If none of the MSCs are willing, and the Candidate saMS is not willing to be saMS, the candidate saMS can appoint another MSC as saMS.
Assess an ASR

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

1. 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.

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

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

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

The saMS can generate a template of the draft ASR-AR with specific information of the ASR pre-filled. The document can only be uploaded as a Word file. The saMS can provide considerations before and after the draft ASR-AR is updated.
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.

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.

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.

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.

Users can comment the shared considerations by selecting the three dots button (under the ‘Expand all’ button) or selecting the ‘Comment’ button.
Assess an ASR

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

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.

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.

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.
Clinical Trials Information System (CTIS)
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