Step-by-step guide

How to submit an annual safety report and respond to related RFIs
CTIS Training Programme – Module 18
Version 1.1 – July 2021

Learning Objectives

- Understand how to create, cancel and submit the ASR submission form.
- Understand how to respond to RFIs received during the assessment of an ASR.

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How to submit an ASR and respond to related RFIs

CTIS allows sponsors to submit an annual safety report (ASR), a document provided to the authorities regarding the monitoring and evaluation of the evolving safety profile of the Investigational Medicinal Product (IMP) and the mitigation of potential risks.

This guide explains how to create an ASR submission form and how to submit it, as well as how to respond to related Requests for Information (RFIs).

Create and submit an ASR submission form

This section outlines the steps that sponsor users should follow to create and submit the ASR submission form.

Respond to Requests for Information

This section outlines the steps that sponsor users should follow to access and respond to RFIs created by the safety assessing Member State (saMS) in the context of the ASR assessment.
Create and submit an ASR submission form

1. Make sure to have the ASR document in PDF prepared to be submitted, and know all the relevant information to populate the ASR submission form (e.g. Investigational medicinal products, relevant events that occurred, reporting period, etc).

2. Open the Annual safety reporting tab and click on the ‘+New ASR’ button.

3. Fill in step one of the ASR form: Include the sponsor information (Organisation details of the selected sponsor and Contact details for ASR submission).

4. Fill in step two of the ASR form: Include the clinical trial(s) involved in the ASR, the IMPs and the auxiliary medicinal product (if applicable).

5. Fill in step three of the ASR form: Include the ASR data lock point, the reporting period, what the ASR includes and other relevant reporting period details.

6. Fill in step four of the ASR form: Upload the ASR document and the supporting documents in the respective fields.

7. Scroll to the top of the form and click on the ‘check’ button to test if the form is complete and then click on the submit button.

The ‘Check’ button allows erasing the information populated on the form and start over without closing the form.

The ‘Cancel’ button allows you to erase the information populated on the form and go back to the Annual safety reporting tab.

#CTIS insights
The ASR submission form cannot be saved.
Respond to Requests for Information

How to submit responses to an RFI

1. Access the RFI through an alert in the Notices & alerts tab, the RFI tab, or the Assessment sub-tab of an ASR page of the Annual safety reporting tab.

2. Review the details of the ASR RFI and the documents submitted by the saMS (highlighted in blue below). Write a response to each consideration, and upload supporting documents if necessary (highlighted in orange).

3. Tick the checkbox to agree with the ASR RFI response submission statement and click on the 'Submit' button.

In the same way as the ASR form, the RFI responses cannot be saved before the submission. Submitting an ASR RFI including supporting documentation (e.g. a new ASR document) will not replace the original documents, neither create a new version of the ASR.
Clinical Trials Information System (CTIS)
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