



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# 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.

© European Medicines Agency, 2021



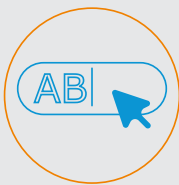
Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

# 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

## How to create and submit an annual safety report 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.



#CTIS  
insights

The ASR submission form **cannot be saved**.

The **'Clear'** 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.

# 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).

**REQUEST FOR INFORMATION - RFI-ASR-2021-00179-003** Pending

saMS	Submitted	Due	Responded	Reason:
Austria	07/06/2021	21/06/2021		Regular RFI

**ID: RFI-ASR-2021-00179-003-01**

New consideration for ASR RFI to the sponsor

RESPOND

**Sponsor response:**

**DOCUMENTS**

MS Documents

**Supporting document**

English · ASR Document · **System version 1.00**  
**submission date** 07/06/2021  
 · **Version 1** · 07/06/2021

Sponsor Documents

Add document

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

**I, on behalf of the sponsor, confirm that the:**

- a) Information provided is complete
- b) Attached documents contain an accurate account of the information available
- c) No personal data included

\*I agree with the above statements

Submit

**European Medicines Agency**

Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**Telephone** +31 (0)88 781 6000

**Send a question**

[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Clinical Trials Information System (CTIS)

Step-by-step guide: How to submit an annual safety report and respond to related RFIs

© European Medicines Agency, 2021.

Reproduction is authorised provided the source is acknowledged.