

GCP | ENHEDERNE

God klinisk forskning ✓✓✓

The Danish GCP Units guide - Submission of Annual Safety Report (ASR) in CTIS

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1 Abbreviations

ASR = Annual Safety Report

AR = Assessment Report

AxMP = Auxiliary Medicinal Products

CT = Clinical Trial

CTR = Clinical Trial Regulation

DLP = Data Lock Point

EMA = European Medicines Agency

IMPD = Investigational Medicinal Product Dossier

NCA = National Competent Authorities

MSC = Member States Concerned

RFI = Request for information

RMS = Reference member states

RSI = Reference Safety Information

SM = Substantial modification

SmPC = Summary of Product Characteristics

SAE = Serious Adverse Event

SAR = Serious Adverse Reaction

saMS = safety assessing Member States

2 Introduction

2.1 What is an Annual Safety Report?

The Annual Safety Report (ASR) is 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. Sponsors must each year submit a report on the safety of each IMP or a combination of IMPs used in a clinical trial. This obligation starts with the first authorisation of the trial and finalises with the end of the trial. Submission of an ASR is not required in case the sponsor is conducting a trial less than one year long.

The ASR must conclude and evaluate the risk/benefit of the trial, based on all SAEs and SARs observed in the period of reporting, and include a line listing of any SARs observed.

A single ASR for the trial can be prepared for multi-drug therapy using authorised/ marketed drugs as an investigational drug combination. See also section 2.5 of the [ICH E2F](#).

A separate ASR of the Auxiliary Medicinal Products (AxMPs) is not required. However, any information relating to (authorised or non-authorised) AxMPs which are relevant to the IMP may be included in the ASR. All SARs to a non-authorised AxMP(s) should be included in the line listing of SARs.

A template for an ASR and line listing of SARs can be found on the GCP unit's Danish webpage: [Hændelser og bivirkninger vejledninger og skabeloner - GCP-Enhederne](#)

2.2 How to assign the business role; ASR submitter

The CT Admin can assign the ASR submitter business role for the specific trial. The CT Administrator user does not have ASR permissions to its role. In order to be able to perform ASR related activities; the CT administrator, should assign the ASR submitter role to him/herself.

Info box:

For more detailed information please refer to [Module19 - Step-by-step guide - User access management and user administration \(europa.eu\)](#)

Refer and "Roles and permissions matrix summary Sponsors Workspace CTIS Training Programme – Module 7" [Sponsor workspace - Roles and permissions summary \(europa.eu\)](#)

1. The CT Admin can log in to CTIS and click the User administration tab.

Clinical trials

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2. Click on the 'Assign new role' button.

Administration of users

Advanced search ▾

Search Results

Showing 1 - 1 of 1 items 1 of 1 pages < 1 >

Sort by: **Creation Dat** ▾

Approve Reject Revoke

3. Select the ASR submitter role to be assigned to the CT Administrator or other users within the organisation.

Role

▾
Select from list
Application Submitter
ASR Submitter
CT Admin
CT Results Submitter
CT Results Viewer
Notifications Viewer
Notification Preparer
Notification Submitter
Part II Preparer
Part II Viewer
Part I Preparer (exc Q-IMP)
Part I Viewer (exc Q-IMP)
Q-IMP Preparer
Q-IMP Viewer

Select 'Specific trial' in the 'Scope' field, fill in EU CT number and click on the 'Assign' button.

Assign role(s)

User Id: EU CT number:

Organisation name: Organisation Id:

Role: Scope:

Authorised date:

3 Create and submit an Annual Safety Report (ASR)

Video and Step-by-step guide on this topic in EMA training Module 18:

[Training Video: How to create, cancel or clear and submit an Annual Safety Report](#)

Info box:

Make sure to have the ASR document in PDF prepared before you start the completion of the ASR form.

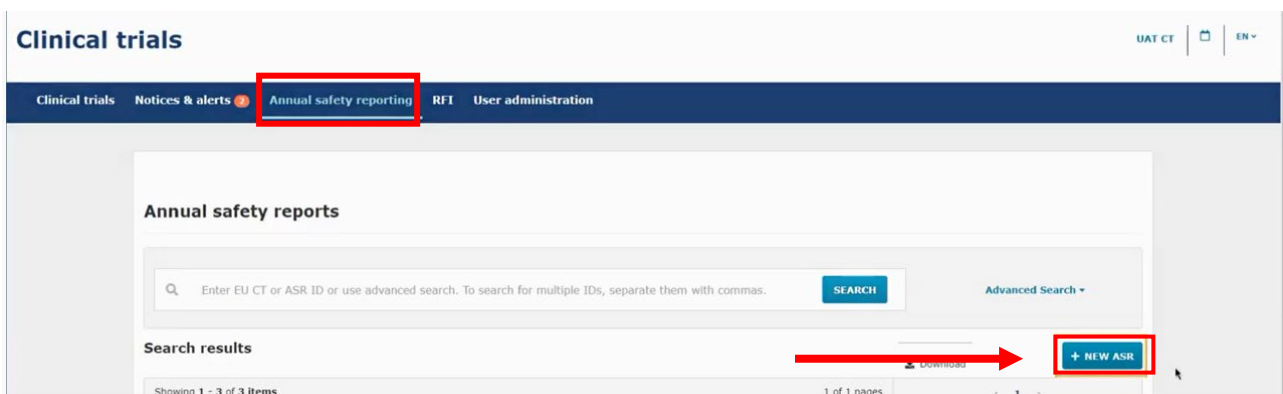
The ASR form cannot be saved, but has to be completed and submitted in one go!

You also need to have all the relevant information ready (e.g. Reference Safety Information on Investigational medicinal products, relevant events that occurred (incl. SAR line listing), reporting period, etc.) before you start.

In the 'Annual safety reporting' tab, users of the sponsor workspace with the role of 'ASR submitter', are able to complete and submit new Annual Safety Reports (ASRs). Sponsor users can only view ASRs for the clinical trials they have a role in.

Information entered in the ASR form cannot be saved. The form has to be completed in one go and submitted, or the entered information will be lost.

To create and submit an Annual Safety Report users can open 'the Annual Safety Reporting form' by clicking on the **'+New ASR' button**.



An ASR form opens:

The screenshot shows the 'Submit ASR' form in the 'Clinical trials' system. The form is titled 'Submit ASR' and has a progress bar with four steps: 1. Sponsor information, 2. Clinical Trial detail, 3. ASR reporting period details, and 4. Supporting documents and submit. The 'SUBMIT' button is highlighted in blue. The form is currently on Step 1.

Fill in the information for the four steps (**Sponsor information**, **Clinical Trial Detail**, **ASR Reporting Period details** and **Supporting Documents**) and submit by clicking the 'Submit' button.

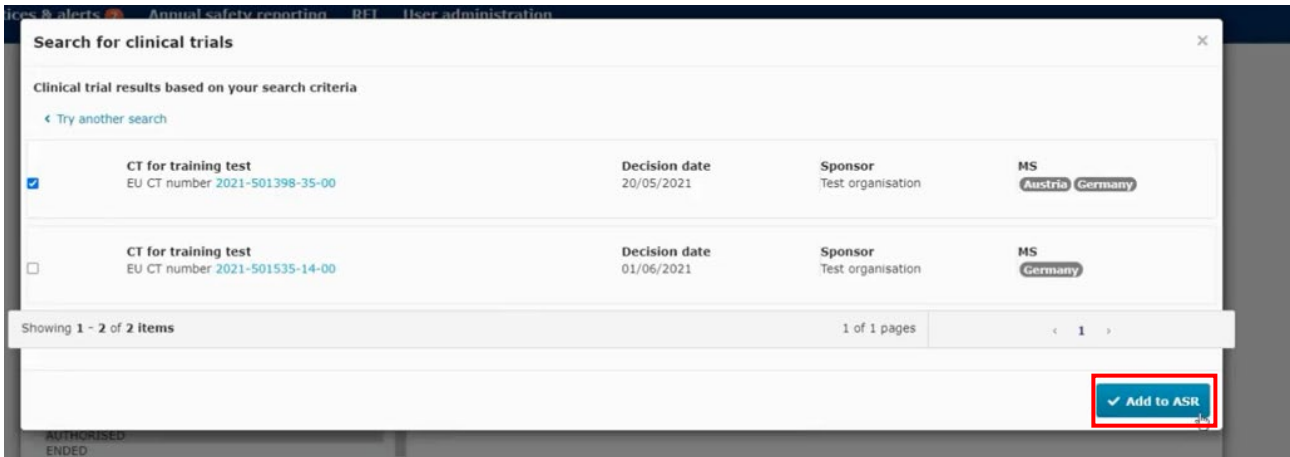
Step 1: Sponsor information

The screenshot shows the 'Sponsor information' step of the ASR form. The form is titled 'Sponsor information' and has two sections: 'Organisation details of the selected sponsor' and 'Contact details for ASR submission'. The 'Next' button is highlighted in blue.

Fill in Organisation details of the sponsor and the contact details for the person who is responsible for the submission and can be contacted with an email address and a phone number. Click 'Next'.

Step 2: Clinical trial details

Search for the Clinical Trial (CT) to which you want to submit an ASR. You search for clinical trials that are authorised for the sponsor organisation and select the trial for which you want to submit an ASR.



When the form opens you click on the related IMP or IMP's for the clinical trial you want to submit an ASR.

Step 3: ASR reporting period details

In this section you need to select and fill in the **data lock point (DLP)**. This is the cut-off date of selecting data for the ASR. The DLP must be as close as possible to the approval date.

If this is the first ASR in the clinical trial the **ASR reporting period** starts with the date where the clinical trial is first authorised and ends with the selected DLP (approximately after one year).

The deadline for submission of ASR is every year 60 calendar days after the DLP.

The following must be answered:

- Has the RSI (reference safety information) been updated during the reporting period?

- Has a Substantial modification on the RSI been submitted and approved during the reporting period?

In most cases the answers would be **No**.

‘*During the reporting period the ASR includes*’ must be answered by selection of one or more items from the drop down menu.

Step 4: Supporting documents and submit

Step 4
Supporting Documents and Submit

ASR Document * Add document

SmPC Add document
(if the SmPC includes RSI and not submitted as part of the ASR document)

Investigator's Brochure Add document
(if the Investigator's Brochure includes RSI and not submitted as part of the ASR document)

Other Add document

Submit

In step 4 you add the ASR report document and you can also add other supporting documents. The ASR report should be uploaded as a PDF.

Now scroll to the top of the form and check if all information is valid or anything is missing by using the ‘**Check**’ button and submit the ASR by clicking the ‘**Submit**’ button.

Once submitted you see this page where all the information that was populated will appear.

Clinical trials Notices & alerts Annual safety reporting RFI User administration

< Go to search

ASR-2021-00183

Test organisation IMP: Paracetamol 500 mg Soluble Tablets Submitted: 11/06/2021	MSC AT, DE	saMS	ASR reporting period 01/04/2020 - 30/04/2021	Submitted 11/06/2021
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[ASR Submission](#) [Assessment](#)

SPONSOR DETAILS

ORGANISATION DETAILS FOR SPONSOR Test organisation Dun Karm Street, 2 Floor, Orange Point Building, BKR 9037, Birkirkara, Malta	CONTACT FOR ASR SUBMISSION Full name test Test organisation Dun Karm Street, 2 Floor, Orange Point Building, BKR 9037, Birkirkara, Malta 123123123 testmail@mail.com
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If requests for information (RFI) are received during the safety assessing Member States (saMS) evaluation of an ASR, please refer to the Step-by-step guide and video found in the **EMA training Module 18**.

4 After submission of Annual Safety Report (ASR)

The ASR will not be available in the public CTIS database.

After submission you will get a screen showing “in progress”, which you can print and use as documentation for your Trial Master File (TMF). See example of screen print below.

Clinical trials

Clinical trials Notices & alerts Annual safety reporting RFI User administration

ASR-2023-

Submitted: 01/06/2023

ASR Submission () Assessment ()

SPONSOR DETAILS

ORGANISATION DETAILS FOR SPONSOR

CONTACT FOR ASR SUBMISSION

MSC DK saMS Denmark ASR reporting period **In progress 01/06/2023**

CLINICAL TRIAL DETAILS

Expand all

"Titel of trial"

- IMP1: , injektionsvæske, suspension i fyldt injektionssprøjte / Role: Comparator ()
- IMP2: injektionsvæske, suspension i fyldt injektionssprøjte / Role: Test ()

Annual safety report details

This is the first sponsor's ASR for any of the IMP(s) selected Yes

If yes, indicate which IMPs , injektionsvæske, suspension i fyldt injektionssprøjte, injektionsvæske, suspension i fyldt injektionssprøjte

Data lock point /2023

ASR reporting period /2023

RSI Updated during the reporting period No

Substantial modification on RSI submitted and approved during the reporting period No

During the reporting period ASR includes None

Submission documents

- Annual safety report season 1
 English · ASR Document · System version 1.00
 submission date 01/06/2023
 · Version 1 · 01/06/2023
- SmPC
 English · Summary of Product Characteristics (SmPC) · System version 1.00
 submission date 01/06/2023
 · Version 1 · 01/06/2023
- SmPC
 English · Summary of Product Characteristics (SmPC) · System version 1.00
 submission date 01/06/2023
 · Version 1 · 01/06/2023

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

- Information provided is complete
 - Attached documents contain an accurate account of the information available
 - The Sponsor, declares that the Annual Safety Report is prepared and hereby submitted to the Agency in accordance with Article 43 of Regulation (EU) No 536/2014 and all other applicable legal provisions.
- RSI Document/s (Old and new version where applicable)
- I agree with the above statements

5 Changes log

Version 1.0

Version 1.2: Updated with section 4.