

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Clinical Study Reports submission

CTIS Training Programme – Module 13
Version 1.0 – March 2021

Learning Objectives

- Remember what a Clinical Study Report (CSR) is
- Understand how to create and submit a CSR
- Understand how to view, download, update and withdraw a CSR
- Understand the roles and permissions involved in managing a CSR

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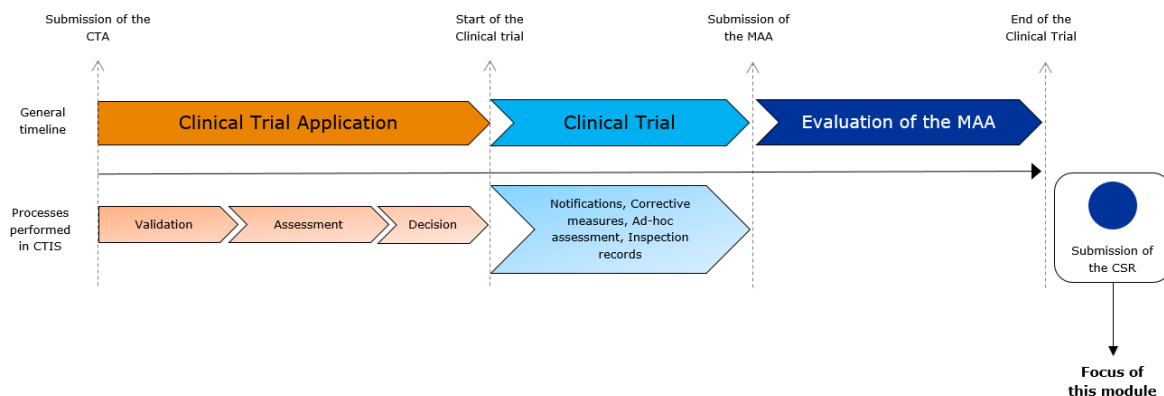
Introduction

Where a clinical trial is intended to be used for obtaining a marketing authorisation for an investigational medicinal product, the sponsor must submit a Marketing Authorisation Application (MAA). The European Regulatory Authorities are responsible for evaluating those applications in the European Union (EU). Once granted, the authorisation allows to commercialise a medicine and make it available to patients and healthcare professionals across the European Economic Area. The process for evaluation of the MAA is not performed in CTIS and therefore it will not be the focus of this module.

As per Article 37 of the CT Regulation, the marketing authorisation applicants/holders must submit a **'Clinical Study Report' (CSR)** to CTIS, within **30 days** after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for the marketing authorisation has withdrawn the application.

A CSR is a report of an individual study of an investigational medicinal product, in which the clinical and statistical description, presentations, and analyses are integrated¹. The CSR includes a title page; a synopsis; a table of contents for the individual clinical study report; a list of abbreviations and definitions of terms; the ethics of the clinical study; the investigators and study administrative structure; the study objectives; the investigational plan; the study patients; the efficacy evaluation; and the safety evaluation. **At the moment of the submission, the information contained in the CSR will become public.**

In CTIS, the users responsible for this action are the **Marketing Authorisation Holder users (MAH)** within the sponsor workspace.



Article 37(4) of the CT Regulation also describes that irrespective of the outcome of a clinical trial, the sponsor must submit to CTIS a summary of the results of the trial, within one year from the end of a clinical trial in all Member States concerned or within six months for a trial in paediatric population. The summary of results shall be accompanied by a summary written in a manner that is understandable to laypersons.

¹ ICH Topic E 3 Structure and Content of Clinical Study Reports, July 1996, European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf

It should be noted that while the summary of results and the layperson summary are to be provided by the sponsor users after the end of each clinical trial in the EU, the CSRs are to be submitted by the MAH users only, in the case that a clinical trial is intended to be used for obtaining a marketing authorisation for the investigational medicinal product. As these processes are independent and performed by different users, they are explained in dedicated modules: **the focus of this module is the submission of the CSR**, while for more information regarding the summary of results, users can refer to *Module 5: How to manage a CT (Notifications, Ad Hoc assessment, Corrective measures, and Trial results)*.

Sections of this quick guide

This quick guide is structured in four sections:



Create and submit a CSR

This section outlines the steps that users need to follow to create and submit new CSRs.



Search for a CSR

This section outlines the steps that users need to follow to search for a CSR (including an explanation of the different fields of search).



Update, download and withdraw a CSR

This section outlines the steps that users need to follow to update, download or withdraw a CSR.



Roles and permissions

This section provides an explanation of which roles can view, submit, update and withdraw a CSR.

Create and submit a CSR



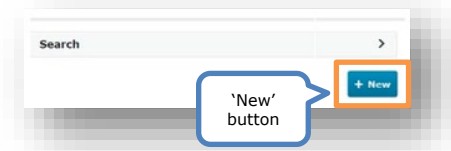
A new CSR for an already existing Clinical Trial can be created and uploaded from the Clinical study reports tab using the '+ New' button.

If users want to cancel the submission they need to select the button 'Close'.

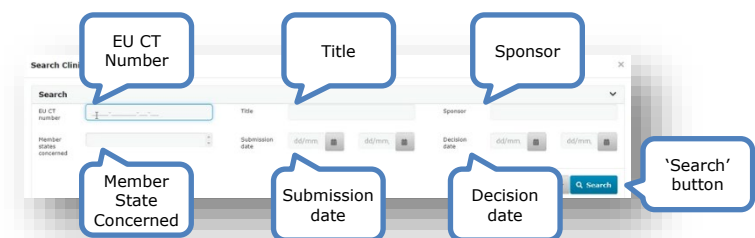
Create and submit a CSR

MAH users can access the Clinical study reports tab from the sponsor workspace. Within this tab, users with specific roles (see section 4: Roles and permissions) can **create and submit** a new CSR.

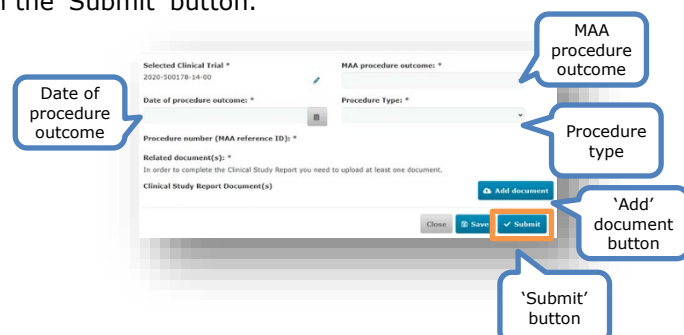
1. To do so, they need to select the 'New' button displayed on the left of the screen.



2. After users have clicked on the 'New' button, a **search** interface is displayed where users can search for the **Clinical Trial (CT)** for which they intend to submit the CSR. This search functionality allows users to find the CT by populating one or more of the following fields:
 - **EU CT Number:** Number assigned by the system to a specific CT.
 - **Member State Concerned:** Member State of the European Union in which the CT was carried out.
 - **Title:** Title of the CT.
 - **Submission date:** Date of submission of the Initial application dossier.
 - **Sponsor:** Organisation submitting the Initial application dossier.
 - **Decision date:** Date in which the MSCs provided a decision on the authorisation of the CT in question.



3. After the search is launched, users are able to select one trial and then click on the '**Confirm**' button at the end of the results page.
4. Once confirmed, a pop-up window is displayed in which users can populate the CSR form (including the fields MAA procedure outcome, procedure type, date of the outcome, and MAA reference ID), upload the appropriate document(s) and click on the 'Submit' button.



Users can create a CSR for authorised Clinical Trials only.

Search for a CSR



MAH users can search for a specific CSR managed by their organisation, from the Clinical study reports tab.



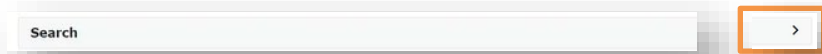
The search interface of the CSR differs from the search interphases of other tabs as it only includes an Advanced search functionality.

Search for a CSR

MAH users of the sponsor workspace have the **Clinical study reports tab available** in CTIS.



1. From the Clinical study reports tab, users can open the search functionality by clicking on the **drop-down** button displayed on the right side of the 'Search' field.



2. Once the search functionality is opened, users can search for a specific CSR that has been already submitted, withdrawn or that is in draft status, by populating one or more of the available search fields. The fields include:

- **EU CT Number:** Unique identifier of the clinical trial to which the CSR corresponds to.
- **Title:** Trial title.
- **Procedure number (MAA reference ID):** MAA procedure number.
- **MAA procedure outcome:** Decision that the awarding body has provided to the applicant for the application. These can be: MA granted, Procedure for MA completed, and MA withdrawn by the applicant (*see section 3: Update and withdraw a CSR for more information*).
- **Submission date:** Date when CSR was submitted, as applicable.
- **Status:** This shows the status of a given CSR. These can be submitted, draft, or withdrawn.

3. Once the search is launched, a list of the CSRs matching the populated fields is displayed. Users can select a specific CSR from the results page by clicking on the checkbox located on the left of each CSR.

EU CT number	Trial title	Lead sponsor	Product	Member states concerned	Submission date	Decision date
<input type="checkbox"/> 2020-500199-32-00	CTIS Training 1	Test	Test product	AT(Ended) RO(Ended) ES(Ended)	31/10/2020	31/10/2020

Update a CSR



CSRs data can be updated from the Clinical study reports tab using the 'Update' icon (pencil).

Update a CSR

MAH users (with specific roles) can also **update** an existing CSR.

1. To do so, they need to search for a CSR (see section 2: Search for a CSR). Once the search is launched, the CSR matching the data populated in the search fields is displayed.
2. Once users have identified the CSR to be updated, they can click on the 'Update' icon (pencil) on the right side of the CSR.

EU CT number	Trial title	Procedure number:	Procedure outcome	Submission date:	Status	Action
2020-500186-90-00	CTIS Training 1	EMA/H/C/111111/111	MA granted	15/12/2020	Submitted	

'Update' button

3. After users click on the update icon, a pop-up window is displayed where the fields that are required to complete are marked with an asterisk (*). These fields include:

- Date of procedure outcome
- Procedure number (MAA reference ID)
- MAA procedure outcome
- Procedure type
- Related documents

Submission date: 15/12/2020 | Status: Submitted

MAA procedure outcome: *

MAA procedure outcome: MA granted

Date of procedure outcome: *

Date of procedure outcome: 15/12/2020

Procedure Type: *

Procedure Type: Centralised procedure

Procedure number (MAA reference ID): *

Procedure number (MAA reference ID): EMA/H/C/111111/111

Justification

Related document(s): *

In order to complete the Clinical Study Report you need to upload at least one document.

Clinical Study Report Document(s)

Add document

Related document

English - Clinical study report (for publication)
Submission date: 15/12/2020
Version 1 - 15/12/2020

4. After users have updated the necessary fields, they can click on the 'Update' button on the bottom left corner of the pop-up window.



5. The system will display a message requesting active confirmation of the update of the CSR.

Update Clinical Study Report

Are you sure you want to update this Clinical Study Report?

Cancel Update



Users can save drafts of uncompleted CSRs by selecting the 'Save' button. They can access those draft versions and complete them via the 'Clinical study reports' tab.

Download a CSR



CSRs data can be downloaded through three paths:

- 1) From the overview page of the CSR
- 2) From the Trial results sub-tab of the Clinical trial page
- 3) Downloading all the documentation from the CT





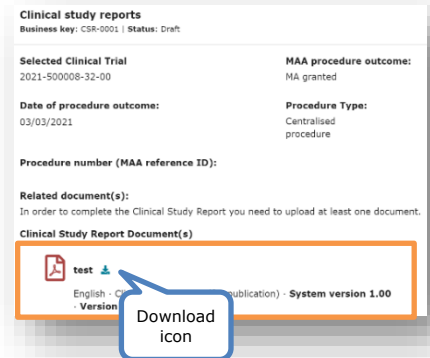
Users can download a specific CSR from the Trial summary sub-tab of the CT page, by clicking on the EU CT number listed on the search results from the Clinical trials tab.

Download a CSR


Users have three options to download a CSR:

I. From the overview page of the CSR:


1. Search the CSR from the search functionality of the Clinical study reports tab.
2. Select the 'View'  icon on the right side of the CSR.
3. After selecting the 'View' icon, a pop-up window is displayed with all the information of the CSR included the uploaded document(s).
4. Users can download the documents by selecting the 'Download'  icon.




II. From the Trial results sub-tab of the Clinical trial page:

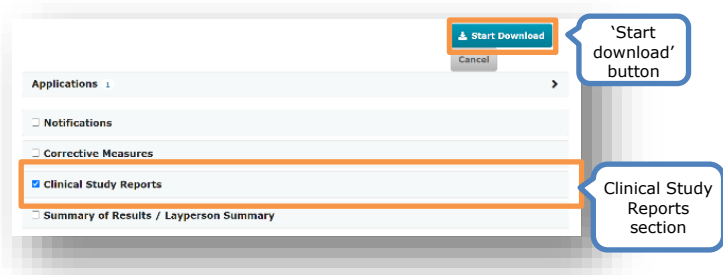
1. Search a specific CT from the Clinical trials tab and click on the EU CT number.
2. Select the Trial results sub-tab of the Clinical trial page.
3. Go to the section 'Clinical Study Reports'.
4. Select the 'View'  icon on the right side of the CSR.



5. After selecting the view icon, a pop-up window is displayed with all the information of the CSR, including the uploaded document(s).
6. Users can download the documents by selecting the 'Download'  icon.

III. Downloading the documentation from the CT:

1. Search a specific CT from the Clinical trials Tab and click on the EU CT number.
2. Select the download  button on the top-right corner of a Clinical trial page.
3. Select the 'Clinical Study Reports' section.
4. Click on the Start Download button.



Withdraw a CSR



Users can withdraw a submitted CSR. To do so, they are required to provide a suitable justification for the withdrawal.

Withdraw a CSR

MAH roles can also **withdraw** a CSR²:

1. To do so, they need to search for a CSR (see section 1: Search for a CSR). Once the search is launched, the CSR matching the data populated in the search fields is displayed.
2. Once users have identified the CSR to be withdrawn, they can click on the 'Update' icon on the right side of the CSR.
3. After users click on the update button, a pop-up window is displayed. In order to withdraw a CSR, a justification for its withdrawal is required.

4. After providing the justification users can click on the 'Withdraw' button at the bottom right corner of the pop-up window.



5. After users have clicked on the 'Withdraw' button, a message requesting the active confirmation for the withdrawal will appear.



A notice will be generated informing the sponsor responsible of the CT that a CSR corresponding to it has been submitted or withdrawn in CTIS.

² For more information on the implications of the withdrawal of a CSR, refer to the FAQs document of this module.

Roles and permissions



There are three roles in the MAH user group:

- 1) MAH Admin
- 2) CSR Submitter
- 3) CSR Viewer

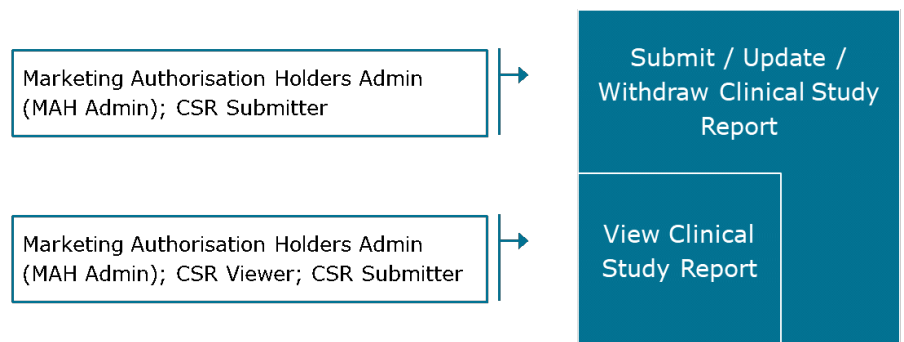
Roles and permissions

CTIS is a **role-based system** that enables users to perform different actions depending on the **permissions** attached to the **roles** assigned to them by a user from their organisation with administrator permissions.

In relation to the CSR process, three roles (from the MAH user group) are involved: Marketing Authorisation Holder Admin (MAH Admin), CSR Viewer, and CSR Submitter.

MAH Admin role needs to be assigned by the EMA Admin via CTIS. The MAH Admin user is able to assign the roles of CSR Submitter or Viewer to users within its organisation. This can be done for one or several trials.

The CSR Submitter can then submit the CSR for the trials for which the role has been granted as well as update or withdraw of the CSR(s) in question. The CSR Viewers can only view CSRs (including the drafts) but cannot submit, update or withdraw CSRs.



Matching of roles and permissions with the actions to be performed in CTIS



The permission levels are structured in a cascade system where the lowest level is viewing permissions, and the highest level is submitting permissions.

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Clinical Trials Information System (CTIS)

Quick guide: Clinical Study Report
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