EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

FAQs

Clinical Study Report submission

CTIS Training Programme – Module 13
Version 1.1 – October 2022

What you will find

- Answers to questions regarding general information and timelines of the CSR.

- Answers to questions regarding the management of the CSR.

- Answers to questions regarding the publication of the CSR.

- Answers to questions regarding the roles and permissions involved in the management of a CSR.

Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.1	**Updated questions:** 2.1, 2.3, 2.4, 2.11. Mistyping errors and rephrasing of minor parts. 4.2. Add details for the tasks of CSR related roles. 4.3. Add details on how to request MAH Admin role.	March 2022

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FAQs

In this document, we list common questions regarding *Module 13: Clinical Study Reports submissions*. They are categorised into: Questions of a general nature regarding information and timelines of the CSR; questions on the management of the CSR; questions on the publication of the CSR; questions on the roles and permissions involved in the management of the CSRs. The specific learning objectives of this module are:

1. Remember what a Clinical Study Report (CSR) is.

2. Understand how to create and submit a CSR.

3. Understand how to view, download, update and withdraw a CSR.

4. Understand the roles and permissions involved in managing a CSR.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1.   General information

1.1. What is a Marketing Authorisation Application (MAA)?

A Marketing Authorisation Application is a request submitted to a European regulatory authority for approval to commercialise a medicinal product, and it is based on a dossier which includes data of clinical trials carried out in the EU and/or third countries, as applicable.

1.2. Is the Marketing Authorisation Application submitted to CTIS?

No, the process to obtain a marketing authorisation is performed outside of CTIS.

What is performed in CTIS is the submission of the Clinical Study Report (CSR) when the medicinal product has been tested in a clinical trial conducted in the EU and/or third countries.

1.3. What is a Clinical Study Report (CSR)?

A CSR is a report of an individual study of an investigational medicinal product conducted in trial subjects, in which the clinical and statistical description, presentations, and analyses are integrated[1].

1.4. What is the aim of a CSR?

A CSR describes the outcomes of the clinical trials carried out in the EU and/or third countries, as applicable. Moreover, it provides details on how the data were collected and analysed.

1.5. What does a CSR?

The CSR includes a title page; a synopsis; a table of contents for the CSR; 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[2].

1.6. When should users submit a CSR?

Regarding the clinical trial life-cycle, the marketing authorisation application will be sent once the clinical trial with a medicinal product is performed (*see the diagram below*). As per Article

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[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
[2] Idem.

37(4) of the CT Regulation[3], the Marketing Authorisation Holders (MAH) users must submit a CSR through 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.
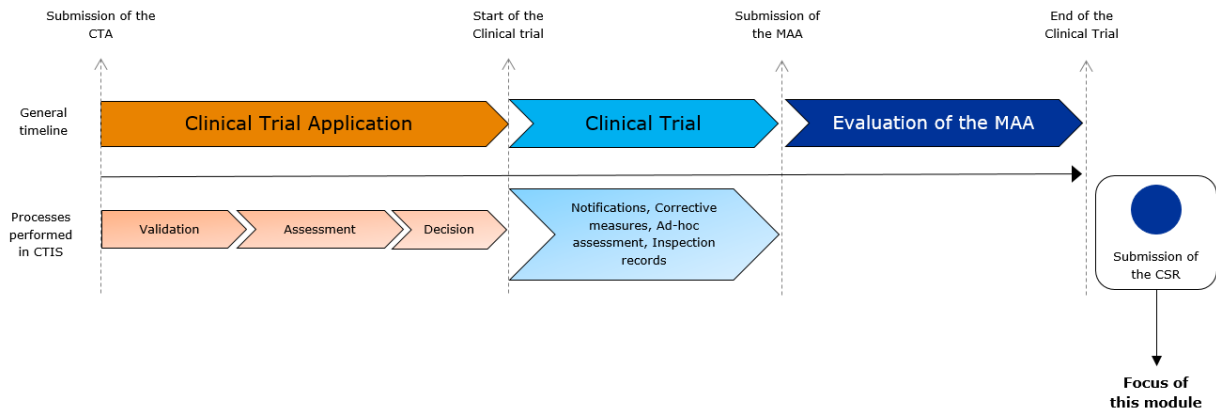
1.7. Is there any relation between the CSR and the summary of results of a clinical trial?

Article 37(4) of the CT Regulation[4] also describes that irrespective of the outcome of a clinical trial, the sponsor will have to submit 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, a summary of the results of the clinical trial. The summary of results shall be accompanied by a summary written in a manner that is understandable to laypersons.

It should be noted that while the summary of results and layperson summary are to be provided by the sponsors after the end of each clinical trial in the EU, the CSRs are to be submitted by the MAH in case the clinical trial was intended to be used for obtaining a marketing authorisation for the investigational medicinal product. The focus of this module is the submission of the CSR. *However, for more information regarding the summary of results, please refer to Module 5: How to manage a CT - Notifications, Ad Hoc assessment, Corrective measures, and Trial results.*

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3 European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
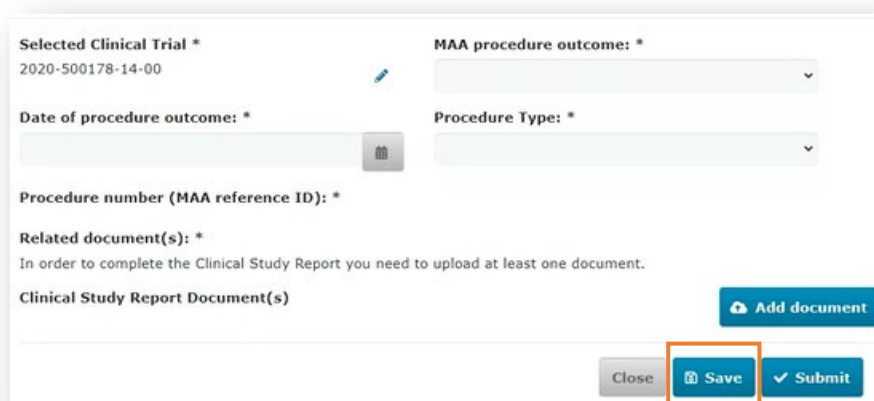
4 Idem

2. Management of a CSR

2.1. How can MAH users manage CSRs in CTIS?

MAH users have the possibility to manage a CSR through the Clinical Study Reports tab, in the sponsor workspace. From this tab, MAH users (*see section 4: Roles and permissions for CSR in CTIS*) can upload, submit, update and withdraw the CSR for which they have been given CSR related roles.

2.2. Can users save a draft version of a CSR?

Yes. Users can save a draft CSR before submitting it. In order to do so, users can click on the 'Save' button on the bottom right corner of the pop-up window that will be displayed when creating a new CSR (CSR form).

2.3. Where can users view and edit the draft CSR?

MAH users can view the draft CSR in the Clinical Study Report tab and the Trial results sub-tab of the Clinical trial page. To edit the details (Selected clinical trial, Date, Procedure number, etc.) pertaining to a CSR still in draft, they need to access it from the Clinical Study Report tab, as in the Clinical trial page users can only view the draft CSR.

2.4. Is it possible to create more than one CSR for a clinical trial?

No, users cannot create (still in draft) or submit multiple CSRs for the same trial. Each CSR corresponds to a specific clinical trial. However, when a CSR is updated a new version of that CSR will be created. If a CSR is withdrawn, users may submit a new CSR for that trial.

2.5. Is it possible to submit the same CSR for more than one clinical trial?

No. Each CSR corresponds to a specific clinical trial. The system will allow users to select only one trial when creating a new CSR.

2.6. How can users download a CSR?

Users have three options to download a CSR:

- From the Clinical Study Reports tab:

    1) Users can search the CSR using the search functionality of the Clinical Study Reports tab and select the 'View' icon on the right side 👁 of the CSR.

    2) After selecting the 'View' icon, a pop-up window will be displayed with all the information of the CSR, including the uploaded document(s).

    3) Users can download the documents by selecting the 'Download' ⬇ icon.

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

    1) Users can select the 'View' 👁 icon.

    2) Afterwards, a pop-up window will be displayed with all the information of the CSR, including the uploaded document(s).

    3) Users can download the documents by selecting the 'Download' ⬇ icon.

- From the CT page:

    1) Users can select the 'Download' ⬇ Download button in the upper-right corner of a Clinical trial page.

    2) Afterwards, they can select the Clinical Study Report checkbox, and then click on the start 'Download' ⬇ Start Download button.

2.7. Where can sponsor users view the CSR?

Sponsor users (who are not MAH users) can view the CSRs in the Trial Results sub-tab of a Clinical trial page. They cannot see the Clinical Study Report sub-tab as it is meant for the MAH users to manage the application.

2.8. What information of the CSR can sponsor users view?

Sponsor users can view the structured data of the submitted and withdrawn CSRs (EU CT Number, MAA procedure outcome, date of procedure outcome, procedure type) and the related documents.

2.9. Where can Member States users view the CSR?

Member States users can view the CSRs in the 'Trial results' tab of the Clinical trial page.

2.10. What information of the CSR can Member States users view?

Different from the sponsor users, Member states will not be able to see the draft or withdrawn CSR. Member States users will only be able to see the CSRs that are submitted.

2.11. How will users be notified when a CSR has been submitted, updated, or withdrawn?

A notice will be generated in the Notices & alerts tab informing the sponsor of the clinical trial (providing the user has been assigned CSR related roles) and Member State concerned of a clinical trial, that a CSR corresponding to it has been submitted or withdrawn in CTIS.

2.12. Will users receive an alert when the due date for submitting a CSR is approaching?

No. As the Marketing Authorisation Application process is performed outside of CTIS, the system cannot determine the deadline for the submission of a CSR. Therefore, the MAH users must take into account that the CSR must be submitted 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, as per Article 37(4) of the Clinical Trials Regulation[5].

2.13. What are the implications of submitting a CSR late?

There are no implications in the system if the CSR is submitted late. However, it is the responsibility of MAH users to comply with the timelines stipulated in the Clinical Trials Regulation.

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[5] European Commission, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

3.   Publication of CSR

3.1.   When is the CSR published?

The information contained in the CSR will be made public at the moment of the submission, 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.

3.2.   Can users upload a CSR not meant for publication?

Yes. By default, the first version of the CSR uploaded to the system will be published. Users can upload a CSR not for publication by selecting the 'Add' button next to the document uploaded for publication.

It is the responsibility of the MAH users to ensure that the principles of the GDPR are followed when processing personal data that might be available in these documents. *Please refer to Module 12: Data protection in CTIS to see the process of uploading versions of documents that will not be subject to publication.*
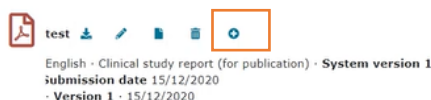
3.3.   What are the implications of a withdrawal?

If a CSR is withdrawn, the MAH users will have to submit a new CSR 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.

If a CSR is withdrawn, it will not be subject to publication. However, it will remain visible in the Clinical Study Report tab for MAH users and in the Trials results sub-tab of the Clinical trial page for sponsors users and flagged as withdrawn.

3.4.   Is it possible to withdraw a CSR once it is published?

CSRs cannot be withdrawn once they are published on the public website. If the MAH user wishes to remove it from the public website, a request will need to be provided to the European Medicines Agency (EMA), along with the justifications for this removal, which will be evaluated by the EMA.

The withdrawal of a CSR can only happen after it has been removed from public view by the EMA.

3.5. Can a CSR that has been removed from the public website be re-submitted?

Yes, the MAH users can resubmit a CSR if needed following the withdrawal of the previous CSR.

3.6. What happens when the CSR is published?

The submission of a CSR triggers the publication of certain documents of the clinical trial if these are not already published because a deferral has been applied. These documents are the Subject information sheet; the Protocol; Product safety documents; Responses to RFIs'; Clinical results summary for intermediate data analysis; Clinical results summary and the Layperson summary.

4. Roles and permissions for CSR in CTIS

4.1. What are MAH users?

MAH users are users within the sponsor workspace that are responsible for the management of the CSR. Three CTIS roles can be given to MAH users.

A MAH Admin needs to be appointed in CTIS by the EMA Admin. Once appointed this role, the user can assign the roles of CSR Viewer and CSR Submitter to other CTIS users. On how to assign CTIS roles to users, please view the training material of Module 07.

4.2. Which roles are involved in the management of CSR?

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. The MAH Admin can perform all the CSR related tasks (view, create, edit, submit, update, and withdraw a CSR), as well as assign business roles to other CTIS users to perform their activities. The CSR Submitter can perform all the tasks related to the management of CSRs, except for managing CSR related roles. However, CSR Viewers can only view CSRs that are in draft and submitted but cannot submit, update or withdraw CSRs.

4.3. How can a user be assigned the MAH Admin role?

CTIS users need to request the MAH Admin role by raising a ticket to User Support Service for CTIS users. In their request, users need to attach a filled affiliation letter (template provided

by EMA), signed by a representative of the MAA/MAH. Requesters will need to include in the affiliation letter the details of the users that need to be assigned the MAH Admin roles, as well as the EU CT numbers of the trials for which the MAH Admin role is assigned to abovementioned users. EMA, after receiving such requests, will validate them, and if no additional information is needed, EMA will assign the MAH Admin role for the EU CTs mentioned in the affiliation letter to the users. The MAH Admin users then can assign other CSR related roles for the trials that have been assigned the MAH Admin role (CSR Submitter/Viewer) to other CTIS users.