EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

How to manage a CT – Trial results

CTIS Training Programme – Module 05

Version 1.0 – October 2021

Learning Objectives

- Understand how to submit clinical trial results.

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.

Introduction

The sponsors are responsible for compiling, recording and submitting data for clinical trials carried out in the EU, responding to RFIs sent by MSCs, and submitting notifications for relevant events occurred while the trial is being conducted. In this module (How to manage a clinical trial), we will address four system functionalities and processes that allow the sponsors to manage a clinical trial:

- **Notifications** (please, refer to the eLearning of this module).
- **RFIs raised in the context of an ad hoc assessment and corrective measure** (please, refer to the eLearning of this module).
- **Trial results** (focus of this Quick guide).

'Trial results' is a functionality that allows the sponsors to submit a summary of results, a summary that is understandable to a layperson, and the clinical study report.

The sponsor can submit the summary of results and the layperson summary within one year from the end of a clinical trial (in all EEA MSCs or globally, if applicable), and within 6 months in case of paediatric trials or if the clinical trial is part of a paediatric investigation plan.

For more information, see art. 37 and Annex IV and V of the CT Regulation[1]:

Sections of this quick guide

This quick guide is structured in four sections:

Access Trial results

Steps that users need to follow to access the 'Trial results' sub-tab.

Summary of results

Guide for users to be able to view and submit the summary of results.

Lay person summary of results

Guide for users to be able to view and submit the layperson summary of results.

Roles & permissions

This section provides an explanation of which roles can view, submit, update and withdraw the summary of results.

[1] 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/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

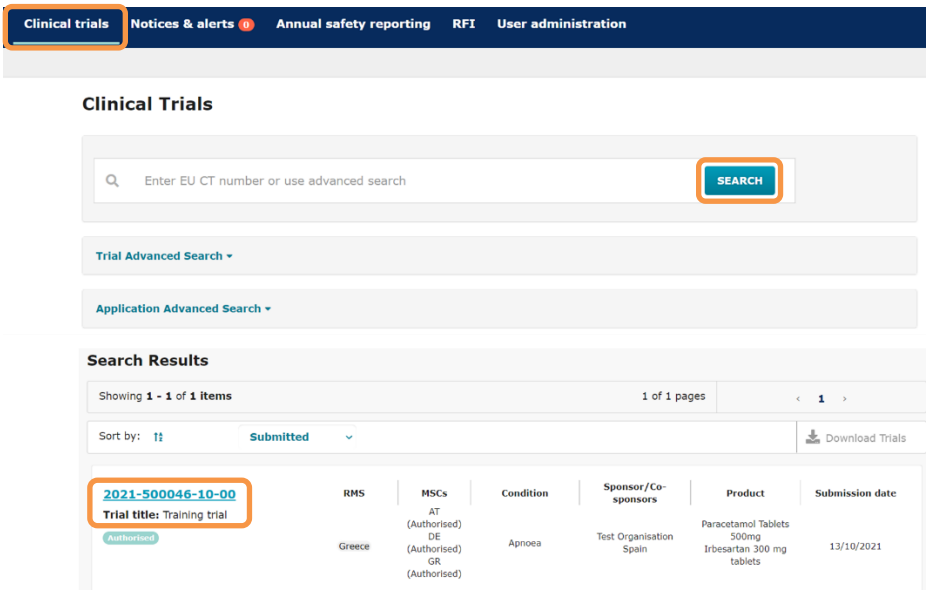
Access Trial results

The search functionality enables users to search for CTs and/or related CTAs matching a set of criteria.

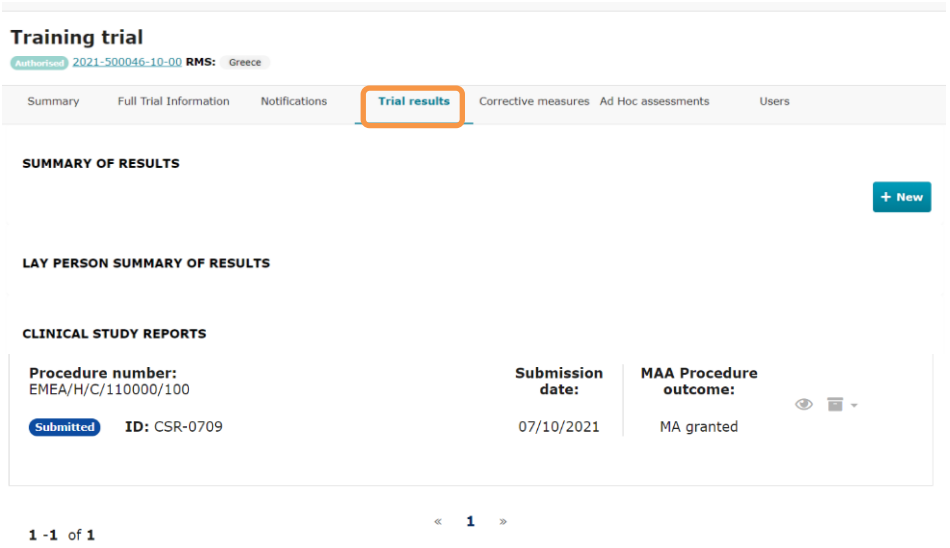
Users are able to see trials in which they are involved and for which they have been assigned a role by an administrator user.

Access Trial results

To access the 'Trial results' functionality, users need to search for **an authorised clinical trial.** To do so, users can click on the **'Clinical trials' tab** and use the search functionality. Once they have found the related clinical trial, they can click on it and navigate to the CT page.



Once in the CT page of a clinical trial, sponsors can access the **'Trial results'** sub-tab. Within this sub-tab, sponsors can view three different documents: Summary of results, Layperson summary of results and Clinical study reports. *For more information regarding the Clinical study reports, please refer to module 13 (access to the Quick Guide).*



#CTIS insights

In both advanced searches, users can specify multiple values for most criteria. For example, users can search for trials in status 'under evaluation' and 'authorised' and select two therapeutic areas.

The advanced search will look for trials in either of these statuses, with either of the two therapeutic areas.

Summary of results

The summary of results is classified in six categories of information the sponsors need to follow.

#CTIS insights

The sponsor can submit the summary of results within one year from the end of a clinical trial (in all EEA MSCs or globally, if applicable), and within 6 months in case of paediatric trials

Summary of results

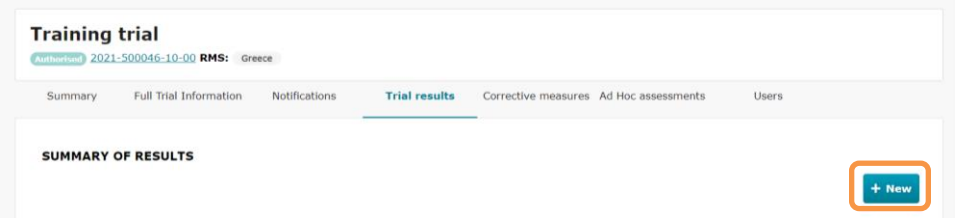
The system allows the user to submit a version of the summary of results for an intermediate data analysis (if applicable), and a version of the final clinical trial results at a later stage.
When for scientific reasons it is not possible to submit the final clinical trial results within the periods established, it shall be submitted as soon as it is available.

According to the Annex IV of the CT regulation[2], the summary of results is classified in six categories of information:

- **CT information:** Clinical trial identification; identifiers; sponsors details; paediatric regulatory details; results analysis stage; general information about the clinical trial; population of subjects.
- **Subject disposition:** Recruitment; pre-assignment period; post assignment periods.
- **Baseline characteristics:** Age and gender (required); study specific characteristic (optional).
- **End points:** End point definitions; end point #1: statistical analyses; end point #2: statistical analyses.
- **Adverse events:** Adverse events information; adverse events reporting group; serious adverse event; non-serious adverse event.
- **Additional information:** Global substantial modifications; global interruptions and re-starts; limitations, addressing sources of potential bias and imprecision and caveats; declaration by the submitting party on the accuracy of the submitted information.

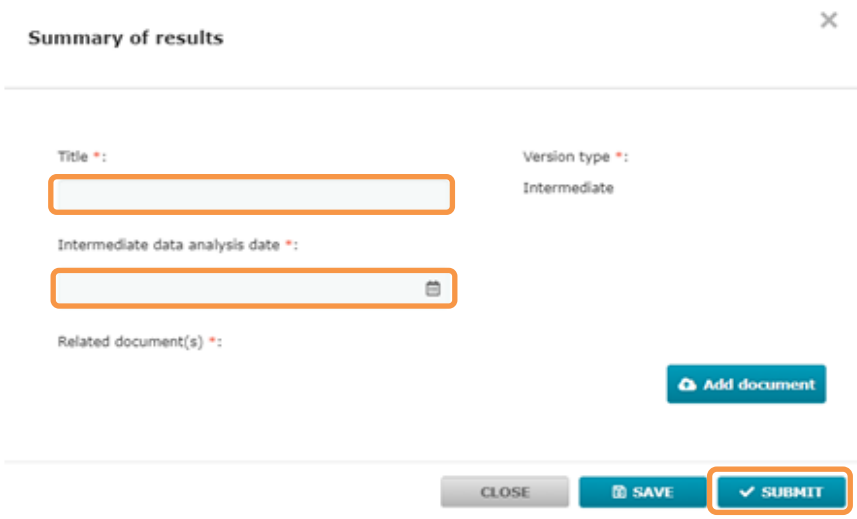
If the CT has not ended in all MSCs, sponsors have the option to submit an intermediate summary of results. In that case, the layperson summary of results cannot be uploaded.

Sponsors can upload the intermediate summary of results by clicking on the **'+ New'** button and adding the information in the requested fields.

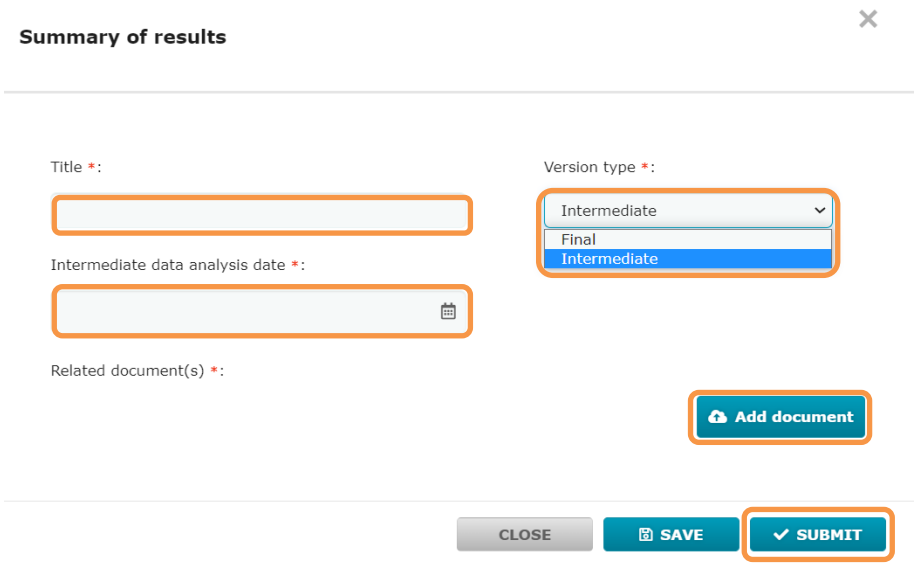


[2] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_e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

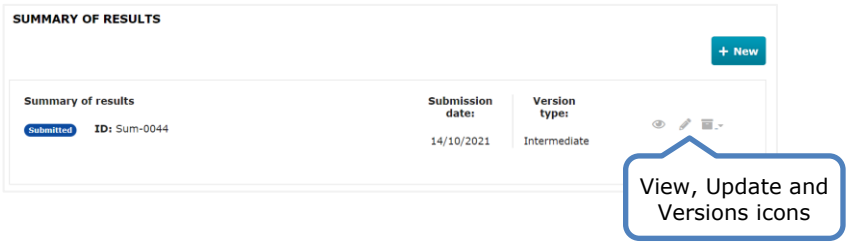
When updating a summary of results, the system allows the users to view the different versions.



Once the CT has ended in all the MSCs, sponsors are able to submit the final summary of results.



Once the summary of results is submitted, sponsors can view it under the **'Trial result'** sub-tab. The sponsors can view and update a previously submitted summary of results.



Layperson Summary of results

The sponsor can submit the layperson summary of results within one year from the end of a clinical trial (in all EEA MSCs or globally, if applicable), and within 6 months in case of paediatric trials.

#CTIS insights

When updating a summary of results, the system allows the users to view the different versions.

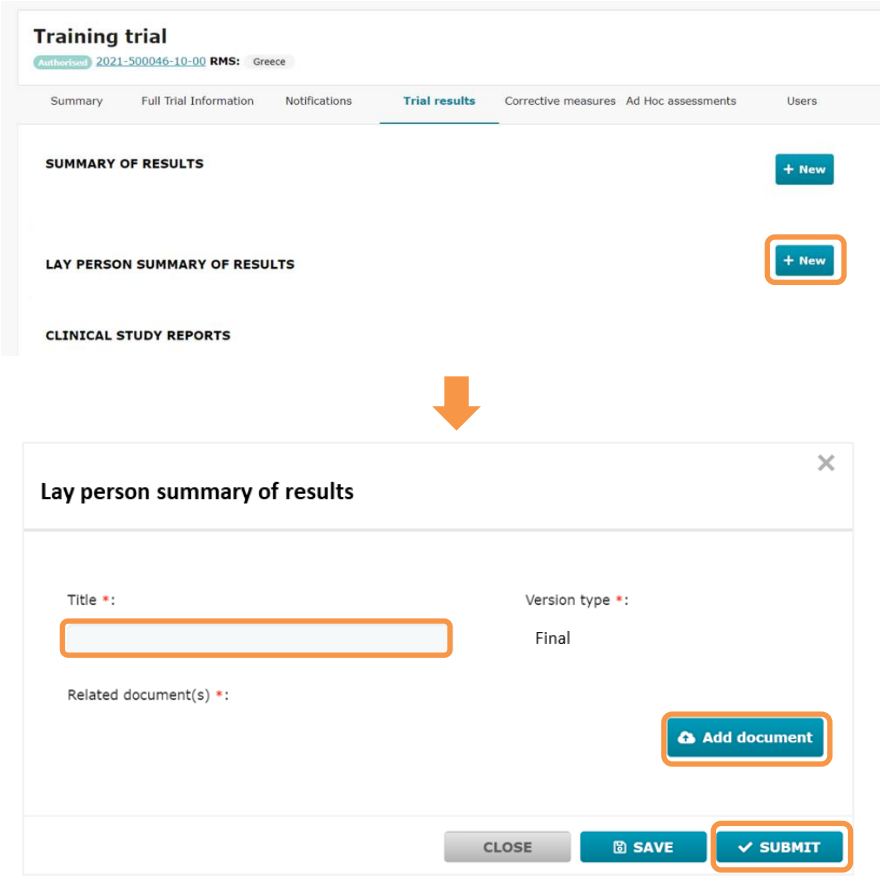
Layperson summary of results

The system allows the user to submit a summary of the trial results that is understandable to a layperson, namely someone who is not an expert. This document may only be submitted as a version of the final results.

According to the Annex V of the CT regulation, the summary of results for laypersons must include the following elements:

- CT information
- Sponsors name and contact details
- General information about the CT
- Population of subjects
- Investigational medicinal products
- Description of adverse reactions and their frequency
- Overall results
- Comments on the outcome
- Indication if follow up CTs are foreseen
- Indication where additional information could be found

Sponsors can upload the layperson summary of results by clicking on the **'+ New'** button and adding the information in the requested fields.



Roles and permissions

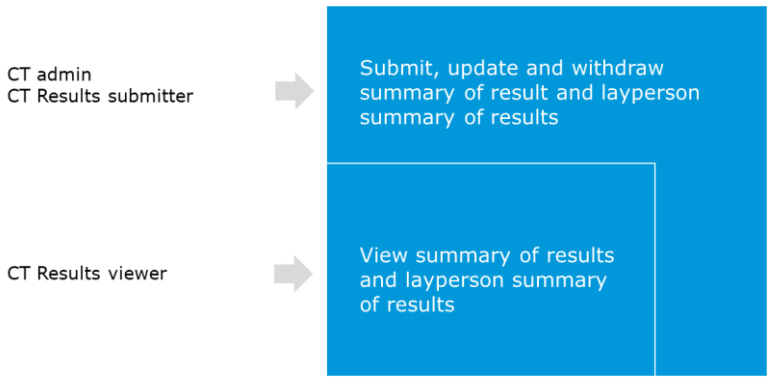
The permission levels are structured in a cascade system where the lowest level is viewing permissions, and the highest level is submitting permissions.

There are three roles involves the submission of the summary of results:

1) CT admin
2) CT Results submitter
3) CT results 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.
Only certain roles may view, update or submit clinical trial.



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Clinical Trials Information System (CTIS).

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