



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Transitional trials from EudraCT to CTIS (sponsor users)

CTIS Training Programme – Module 23

Version 1.2 – August 2022

Learning Objectives

- Remember what a Transitional trial is.
- Understand how to submit a Transitional trial.
- Understand how to submit notifications and clinical trial results for a Transitional trial.
- Understand the roles and permissions involved.

© European Medicines Agency, 2022

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.

Record of updated versions

Version	Version description	Date
1.2	Minor changes applied: <ul style="list-style-type: none">• European Commission reference link• Part I 'Estimated Start of Recruitment' information for transitional trials• Information about the EudraCT number for transition trials New content: <ul style="list-style-type: none">• Search Functionality	July 2022
1.1	Training material version published at CTIS go-live	January 2022

Introduction

CTIS enables sponsors to fulfil their responsibilities for collecting, recording and submitting data for **Transitional trials** conducted in the EU/EEA. Since January 31st 2022, the Clinical Trials Regulation (EU) No 536/2014 repealed the Clinical Trials Directive 2001/20/EC; a **3-year transition period** is foreseen from the implementation of the Clinical Trials Regulation (CT Regulation). During that period and at any time, the sponsor can transition clinical trials that are authorised under the Clinical Trials Directive (CT Directive) and are ongoing. Its purpose is to enable sponsors to prepare the trials to be transitioned. The 3-year period is articulated according to the following schedule and rules:

- **In the first year** of application of the CT Regulation, sponsors are able to choose to submit new Initial Clinical Trial Applications (CTAs) under the regime of the CT Directive or the CT Regulation.
- **In the second and third years** following the application of the CT Regulation, all new Initial CTAs will have to be submitted through CTIS. The latest date for submission of an Initial CTA under the CT Directive is 31 January 2023. However, trials authorised under the CT Directive regime can remain in EudraCT and continue to run under the requirements of the CT Directive until the end of the 3-year transition period (i.e. January 2025).
- **From the end of the third year** following the application of the CT Regulation, all trials that are still ongoing in at least one EU/EEA Member State will have to be transitioned to CTIS.

Sections of this quick guide

This quick guide is structured in four sections:



Overview of Transitional trials

Guide sponsor users on the management of Transitional trials and the process of creating and submitting a Transitional trial.



Create, submit and search Transitional trials

Steps to create, submit and search a Transitional trial.



Submit notifications and summary of results

Steps to create and submit notifications for Transitional trials and how to submit the summary of results.



Roles and permissions

Overview of the roles and permissions involved in the Transitional trial processes.

Overview of Transitional trials



Transitional trials can be submitted at any time during the 3-year transition period and sponsors are advised to complete the process early enough in the transition period to ensure continuity of the trial beyond 31 January 2025, taking account of statutory holidays and the two-week winter clock stop.



Three types of applications are available for the submission process for trials conducted in the EU.

Transitional trials

Trials authorised under the CT Directive are to be transitioned to CTIS as Transitional trials. A 3-year transition period is foreseen from the implementation of the CT Regulation. The sponsor should submit to CTIS any still on-going trial by the end of the transition period. The transition can be enacted at any time during that period.



What to do before transitioning a trial

Sponsor organisations are advised to **consider whether a trial needs to be transitioned**. Only trials that are **still running under the CT Directive by 30 January 2025** that meet the following criteria need to be transitioned:

- Interventional clinical trials in humans.
- Involve at least one site in the EU/EEA where the trial is still ongoing.
- Not on hold, and no notification has been submitted regarding whether the trial has ended in the EU/EEA.

If an end of trial notification has been submitted in all EU/EEA member states, but the global end of the trial has not been notified, **the trial does not need to be transitioned**. Global end of the trial and trial summary results should be uploaded via EudraCT under the CT Directive. *For more information on **other cases where trials do not have to be transitioned**, users can refer to the [FAQs document of this module](#) available on the EMA website.*

Types of Clinical trial applications

The CT Regulation introduced a harmonised procedure for the submission of CTAs regarding trials to be conducted in the EU. Three types of applications are defined:

- **Initial CTA:** Request to conduct a Clinical trial (CT) that includes comprehensive information about the CT for the evaluation by the Member State Concerned (MSC).
- **Additional MSC:** Request by the sponsor for extending an authorised CT to another MSC.
- **Substantial modification:** Request by the sponsor for a change of a CT that is likely to have a substantial impact on the subject's safety or rights or on the reliability/robustness of the generated data.

In order to transition a trial from EudraCT to CTIS, **an Initial CTA marked as a Transitional trial must be submitted**. *For more information on how to manage other types of CTAs, users can refer to the [eLearning material of Module 10 \(Create, submit and withdraw a clinical trial\)](#).*

Create, submit and search Transitional trials



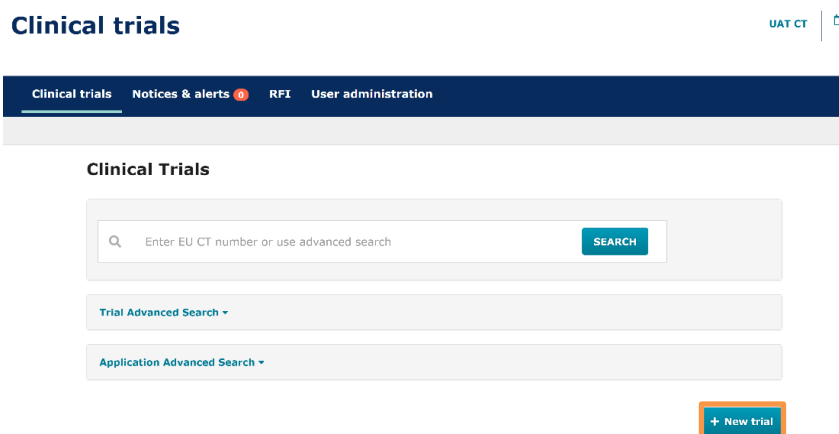
Various functionalities have been implemented in CTIS to allow the transition of trials. A set of buttons and tabs on the sponsors' workspace allow users to create and submit transitional trials.



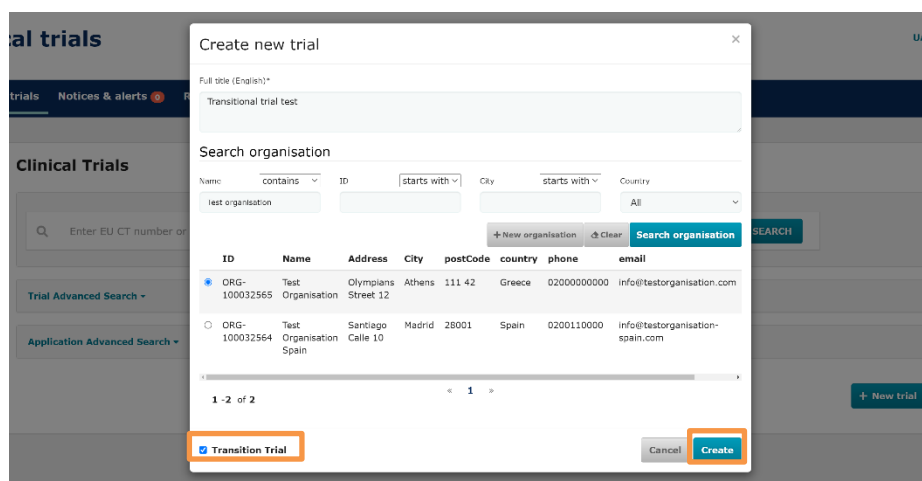
The 'Create new trial' pop-up window includes the option to indicate that it is a Transitional trial.

How to create a Transitional trial

In order to transition a trial from EudraCT to CTIS, an Initial CTA marked as a Transitional trial must be submitted. In the CTIS 'Clinical trials' tab, users can create a Transitional trial by clicking the 'New trial' button at the bottom-right corner.



A pop-up window opens and users can populate all the required fields, such as the trial 'Full title' and the organisation details, where users can search for the sponsor organisation or create a new one. **Once the required fields are populated**, users must click on the 'Transitional trial' checkbox and then on the 'Create' button to create a draft Transitional trial. This enables a new field in the form section that allows users to link the **EudraCT number data to the trial**. If users do not select the checkbox, they need to cancel the CTA and create a new one. The EudraCT number cannot change after the Transitional trial is submitted.



Once the **draft Transitional trial application** has been created, users can start populating the required fields of the sections 'Form', 'MSCs', 'Part I' and 'Part II'. In order to populate a field, users can **click on the 'Padlock' button** in each sub-section, and fill in the details.

Create, submit and search Transitional trials



Users must fill in all mandatory data and documents required in CTIS, even if those were not a requirement under the CT Directive.

In Part I, in the 'Estimated Start of Recruitment date' field, the user can select the start date of the trial (that can be in the past)



Users can upload a blank document to continue the creation of a Transitional trial application if a document was not a requisite under the CT Directive, but it is mandatory to be submitted for the application in CTIS.

On the **Form section** of the CTA page, in the 'Transition trial' sub-section, **sponsor users can include the relevant EudraCT number for that respective Transitional trial. This sub-section is only available when a user has marked the 'Transitional trial' checkbox** when creating the CTA. To add the EudraCT number, users can click on the '+ Add EudraCT Trial' button, then search the respective trial via the search bar, select the EudraCT trial number, and then click on the 'Add EudraCT Trial' button. The EudraCT number cannot change after the Transitional trial is submitted.

On top of the EudraCT number, a **checkbox** indicating that the **trial is Transitional** is ticked by **default**. Users can **untick** it and the 'Confirmation' button to make the trial no longer treated as a Transition trial. This action **cannot be undone** and will make the 'Transitional trial' section no longer available within the 'Form' section, and all possible data uploaded within that section will be erased.

Users can populate the rest of the CTA sections and check that **all information has been populated correctly** by clicking on the 'Check' button. If everything is correct, it can be saved and then submitted. **The system will highlight** the sections where mandatory data or documents are missing. The draft Transitional trial cannot be submitted if any mandatory fields or documents are not filled in or uploaded.

For more information on how to submit trials, users can refer to the [eLearning material of Module 10 \(Create, submit and withdraw a clinical trial\)](#) available on the EMA website.

Create, submit and search Transitional trials



The trials that are transitioned to CTIS have already been authorised under the CT Directive. MSCs may therefore choose to authorise the trials within or in less than 60 days.



Users can also access RFIs through the 'Notices & alerts' tab and the 'RFI' tab.

How to submit a Transitional trial

Once users fill in all mandatory fields and upload documents as applicable, users can submit the **Transitional trial** by clicking on the 'Submit' button and the 'Confirmation' button.

The screenshot shows the top navigation bar with 'Clinical trials', 'Notices & alerts' (with a red notification icon), 'RFI', and 'User administration'. Below the navigation bar is a warning message: 'Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.' Below the warning, the trial ID 'TEST 2022-500299-71-00 / Initial ID: IN' is shown next to a 'Draft' button. At the bottom right, there are buttons for 'Check', 'Save', 'Cancel', and 'Submit' (highlighted with an orange border).

The trials that are transitioned to CTIS have already been authorised under the CT Directive. Member States Concerned (MSCs) may therefore choose to authorise the trials within or in less than 60 days. However, **MSCs can create Requests for Information (RFIs)** on the transitional application (leading to a maximum period of 106 days, or further in the case of some types of investigational medicinal products). Therefore, **sponsors are advised to submit their Transitional trials to CTIS early enough** before the end of the transition period. Once a trial has transitioned to CTIS, all the CT Regulation requirements will apply from the date of authorisation of the transition application under the CT Regulation.

Sponsors can access the **'Evaluation' section** of a CTA page to access possible RFIs from MSCs about information that needs to be clarified in the context of the Transitional trial or other types of CTAs. *For more information on how to respond to RFIs, users can refer to the [materials of Module 11 \(Respond to requests for information received during the evaluation of a CTA\)](#) available on the EMA website.*

The screenshot shows the 'Evaluation' section of the CTIS interface. The left sidebar has 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation' (highlighted), and 'Timetable'. The main content area shows 'Validation' with 'RFI' (highlighted with an orange border) and 'Conclusion'. Below that is 'Assessment Part I' with 'RFI' (highlighted with an orange border). At the top right, there are 'Withdraw' and 'Copy' buttons.

After a decision has been issued upon by the MSCs, **all publication rules of the CTIS documents are applicable**, including the deferrals. *For more information, users can refer to the [FAQs document of Module 10 \(Create, submit and withdraw a clinical trial\)](#) available on the EMA website.*

Create, submit and search Transitional trials



Users can search a Transitional trial directly with the EudraCT number using any of the Advanced searches.

Trial advanced search

Application advanced search

Search Transitional trials

There are two **advanced search functionalities** that allow users to search for **Transitional trials**. In the 'Clinical trials' tab users can open any of the searches, click on the 'Transition trial' criterion, insert the EudraCT number, and click on the 'Search' button. *For more information on how to search for clinical trials and access them, users can refer to the [Quick guide of Module 9 \(Search, view and download a clinical trial and a clinical trial application\)](#) available on the EMA website.*

Once users **access a Transitional trial**, in the summary sub-tab of a Transitional trial page, there is a label on the trial information outlining **'Yes'** when it is a Transitional trial. If the trial is not a transitioned trial, the label shown is **'No'**.

Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments
TRIAL INFORMATION					
Sponsor	Panpharma	Member states concerned	AT · ES · FR		
Trial phase	Human Pharmacology (Phase I)- First administration to humans	Medical conditions	test		
Therapeutic area	Diseases [C] - Bacterial Infections and Mycoses [C01]	Low intervention study	Yes		
FIH	Yes	Start of trial	31/03/2021		
Medical device	No	Transitioned trial	Yes		
IMP					



Users can check if the trial is transitioned by viewing the label on the summary page.

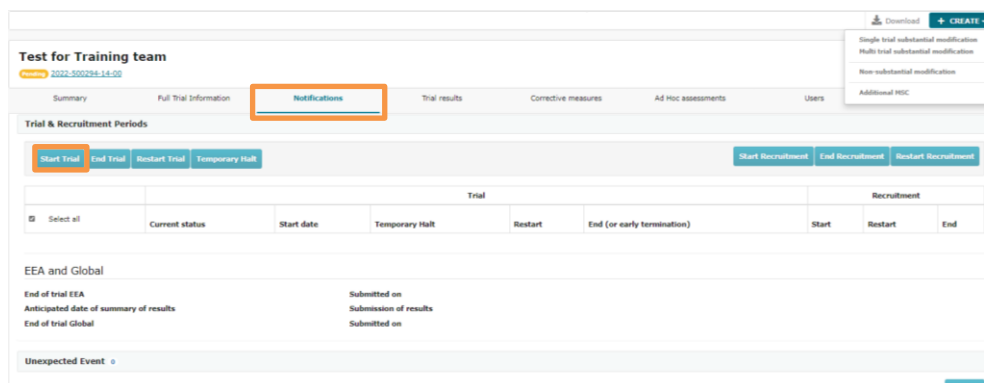
Submit notifications and summary of results



Trial and Recruitment period notifications enable sponsors to inform MSCs of relevant moments during the conduction of a CT.

Submit notifications

Users can submit **trial and recruitment period notifications** through the 'Notifications' tab on a clinical trial page **once the Transitional trial has been authorised by the MSCs**. For Transitional trials, **unlike non-Transitional Initial CTAs**, the sponsor users may submit a 'Start trial' notification with a trial start date in the past and prior to the authorisation date documented in CTIS, as in fact the application was already previously authorised under the regime of CT Directive.

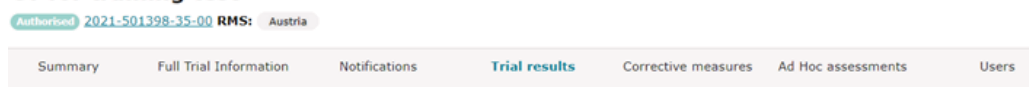


For more information on how to submit notifications; and the differences between trial submission date, authorisation date, trial start date, and notification submission date, users can refer to the [eLearning material of Module 05 \(Manage a clinical trial through CTIS\)](#) available on the EMA website.

Submit the summary of results

CTIS allows the user to **submit the trial results** after the authorisation of the Transitional trial in the 'Trial results' tab of a clinical trial page. The sponsor can submit the layperson summary within one year from the end of a clinical trial (in all EEA MSCs, 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, refer to the [Quick guide of Module 05 \(Manage a clinical trial\)](#) available on the EMA website.*

CT for training test



SUMMARY OF RESULTS

+ New

LAY PERSON SUMMARY OF RESULTS

+ New

CLINICAL STUDY REPORTS



Sponsors have the possibility of submitting an intermediate summary of results, prior to the summary of results if the CT protocol provides for an intermediate data analysis.

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.

Roles and permissions

From the CTIS 'User administration' tab, users can **manage the roles and permissions assigned**. Users can search for users with already assigned roles by using the basic and advanced searches. Users can assign new roles by clicking the 'Assign new role' button on the right side of the page. *For more information, users can refer to the [materials of Module 07 \(Management of registered users and role matrix\)](#) available on the EMA website.*

In relation to the Transitional trials processes, only **certain roles** may view, update or submit one. The CT Admin and Application Submitter are the only two roles that can create and submit a Transitional trial.

CT Admin
Application Submitter

Part I (exc. Q-IMPD)
Part II Preparer
Q-IMPD Preparer

Create and submit a Transitional trial; view form section; submit, update and withdraw summary of results and layperson summary of results.

Edit a draft CTA



Sponsors have the possibility to manage the roles and permissions for each Transitional trial.

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

Clinical Trials Information System (CTIS).

Quick guide: Transitional trials from EudraCT to CTIS (Sponsor users).

© European Medicines Agency, 2022.

Reproduction is authorised provided the source is acknowledged.