



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Quick guide

## Transitional trials from EudraCT to CTIS (authority users)

CTIS Training Programme – Module 23  
Version 1.2 – August 2022

### Learning Objectives

- Remember what a Transitional trial is.
- Understand how to evaluate a Transitional trial in the authority workspace.

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## Record of updated versions

Version	Version description	Date
1.2	Minor changes applied: <ul style="list-style-type: none"><li data-bbox="432 443 874 472">• European Commission reference link</li><li data-bbox="432 465 951 495">• New content in the Transitional trial section</li></ul>	July 2022
1.1	Training material version published at CTIS go-live	January 2022

# Introduction

Since January 31st 2022, the Clinical Trials Regulation (EU) No 536/2014 repealed the Clinical Trials Directive 2001/20/EC; a **3-year transition period** is foreseen from the implementation of the Clinical Trials Regulation (CT Regulation).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.

**The evaluation process of Transitional trials** established in the CT Regulation starts once the sponsor has submitted an Initial CTA marked as a Transitional trial. MSCs can evaluate the documentation provided by the sponsor to ensure compliance with the CT Regulation.

## Sections of this quick guide

This quick guide is structured in two sections:



### Overview of Transitional trials

Guide for authority users on the management of Transitional trials.



### Evaluation of Transitional trials

Steps to complete the evaluation of a Transitional trial in CTIS and update the status in EudraCT.



### Search Transitional trials

Steps to search a Transitional trial.

# Overview of Transitional trials



Various functionalities have been implemented in CTIS to allow the transition of trials.

## 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 ongoing trial by the end of the transition period. The transition can be enacted at any time during that period.



In order for the Member states to evaluate a transition a trial, sponsor need to transition from EudraCT to CTIS.

### 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:

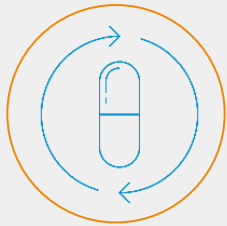
- Interventional clinical trials in humans.
- Involve at least one site in the EU/EEA where the trial is still ongoing.
- Not on hold, and no notification has been submitted regarding whether the trial has ended in the EU/EEA

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 by the sponsors via EudraCT under the CT Directive.



In order for the Member states to evaluate a transition a trial, sponsor need to transition from EudraCT to CTIS.

# Evaluation of Transitional trials



The evaluation process of a Transitional trial starts once the sponsor has submitted an Initial CTA marked as a Transitional trial.

## Evaluation of a Transitional trial

The process to evaluate a Transitional trial starts once the sponsor has submitted an Initial CTA marked as a Transitional trial. The MSCs can start with the evaluation of the documentation provided by the sponsor to ensure compliance with the CT Regulation.

CTAs to be transitioned have already been authorised under the CT Directive, **MSCs may therefore choose to authorise Transitional trials within or in less than 60 days.** However, **MSCs can create Requests for Information (RFIs)** on the transitional application, if necessary (leading to a maximum period of 106 days, or further in the case of some types of investigational medicinal products).

The **evaluation process** of an Initial CTA for a transitioned trial includes the same three main phases as any other application submitted under the regime of the CT Regulation, namely: Validation (including Reporting Member State selection for multinational applications), Assessment, and Decision.

Regarding the Assessment phase, in order to have tacit approval for each of the MSCs, there should be an 'acceptable' conclusion on Part I documented by the Reporting Member State (RMS).

The evaluation process can start once sponsors submit a transitional trial. Member states will receive an alert in the 'Notices & alerts' tab and new tasks in the 'Tasks' tab.



### Clinical Trials

For more information on the evaluation process of CTAs by the Member States, users can refer to the materials of [Module 06 \(Selection of RMS and validation\)](#) and [Module 08 \(Assessment and decision-making\)](#), available on the EMA website.

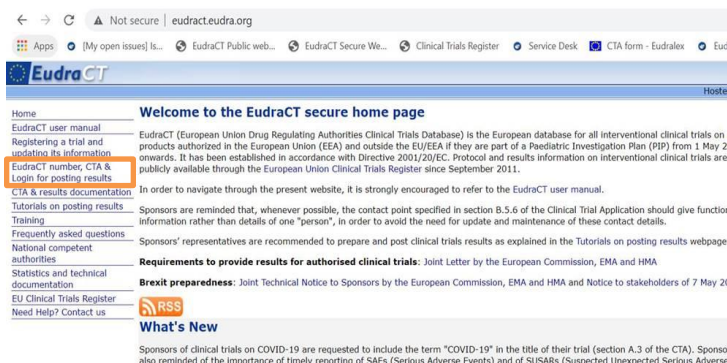
Once a trial has been transitioned to CTIS, **all the CT Regulation requirements will apply from the date of authorisation** of the transition application under the CT Regulation.

## Update status of a Transitional trial in EudraCT

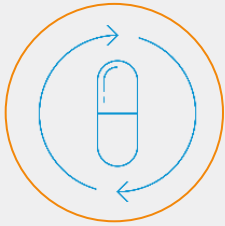
**Member State users can update in EudraCT** the latest status of a transitioned trial submitted to CTIS, which is only possible once the Transitional trial is authorised in CTIS. To do so, users can access the [EudraCT platform](#) and click on the 'EudraCT number, CTA & login for posting results' section and log in with their credentials.



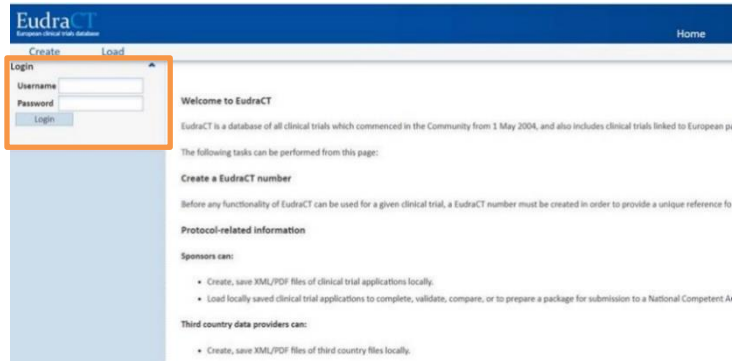
Member State users need to make sure all the evaluation steps are completed in order to authorise a Transitional trial in CTIS.



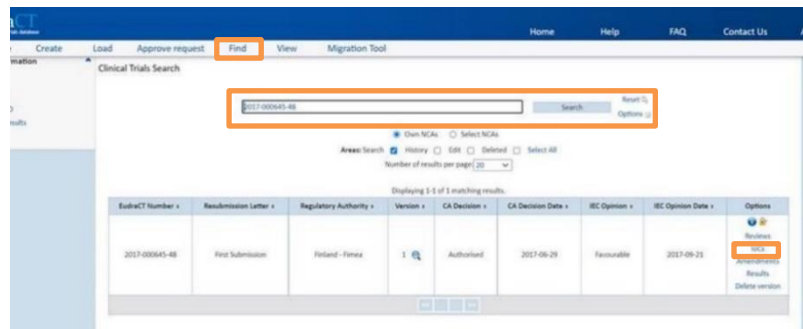
# Evaluation of Transitional trials



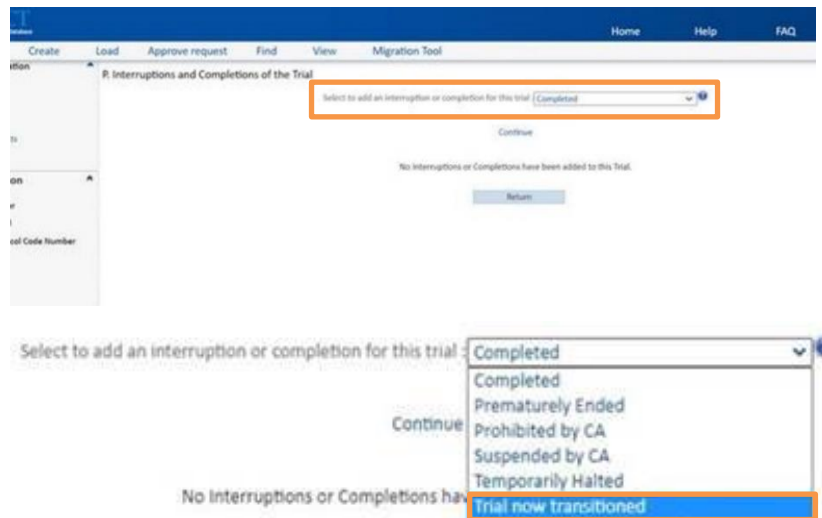
Each MSC is expected to update in the EudraCT platform the latest status of a Transitioned trial to CTIS.



Users can click on the 'Find' tab and search for a trial by using its EudraCT number in the search bar. Once the results are displayed, they can click on the 'IoC' button on the right-hand side of the page.



Once users click on the 'IoC' button, they can choose the status of the trial. For Transitional trials uploaded in CTIS, they need to select 'Trial now transitioned'.



It is only possible to update the latest status of a test in EudraCT when it is authorised in CTIS.

# Search Transitional trials



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

## Search Transitional

There are two **advanced search functionalities** that allow users to search for **Transitional trials in CTIS**. 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 15 \(Search, view and download a clinical trial and a clinical trial application\)](#) 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'**.

TRIAL INFORMATION			
<b>Sponsor</b>	Panpharma	<b>Member states concerned</b>	AT · ES · FR
<b>Trial phase</b>	Human Pharmacology (Phase I)- First administration to humans	<b>Medical conditions</b>	test
<b>Therapeutic area</b>	Diseases [C] - Bacterial Infections and Mycoses [C01]	<b>Low intervention study</b>	Yes
<b>FIH</b>	Yes	<b>Population type</b>	Healthy Volunteers
<b>Medical device</b>	No	<b>Start of trial</b>	31/03/2021
<b>IMP</b>		<b>Transitioned trial</b>	Yes



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

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Clinical Trials Information System (CTIS).

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