EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Transitional trials from EudraCT to CTIS (authority users)

CTIS Training Programme – Module 23

Version 1.3 – January 2023

Learning Objectives

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

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
1.3	Minor changes applied: • Clarification on transition period and date when CTIS becomes mandatory	January 2023
1.2	Minor changes applied: • European Commission reference link • New content in the Transitional trial section	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Since January 31st, 2022, the Clinical Trials Regulation (EU) No 536/2014 repealed the Clinical Trials Directive 2001/20/EC; a **3-year transition period** is foreseen from the implementation of the Clinical Trials Regulation (CT Regulation).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 EU/EEA CTAs need to be submitted through CTIS. The latest date for submission of an Initial EU/EEA CTA under the CT Directive is 30 January 2023. From 31 January 2023, clinical trial sponsors need to use CTIS to apply to start a new clinical trial in the EU/EEA. 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. 30 January 2025), unless a new EU/EEA member state is added to the trial (this is considered a new trial application for this member state, and needs to be done through CTIS).
- **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

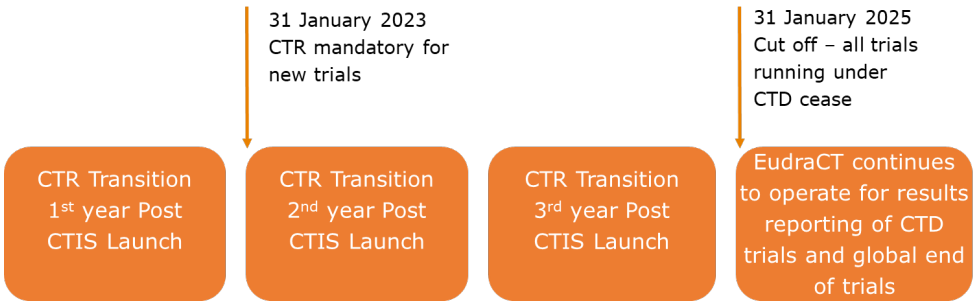
Steps to search a Transitional trial.

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**. Sponsors must transition a trial from EudraCT to CTIS if at least one of the following conditions is fulfilled:

- the EudraCT trial is going to be conducted in additional EU/EEA member state(s), to which a EudraCT CTA was not submitted before 31 January 2023 (this is considered a new trial application for this member state)
- the EudraCT trial completion date is expected to be after 30 January 2025

In addition, only trials that meet the following criteria can 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

Trials that are foreseen to be completed by 30 January 2025, and that are not including additional EU/EEA Member States after 30 January 2023, remain in the EudraCT database, and do not need to be transitioned to CTIS. 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.

#CTIS insights

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.

#CTIS insights

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

Evaluation of a Transitional trial

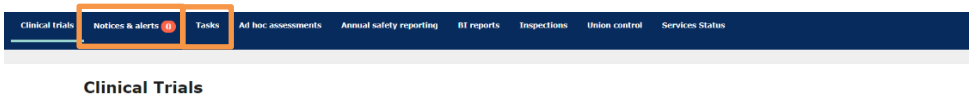
The process to evaluate a Transitional trial starts once the sponsor has submitted an Initial CTA marked as a Transitional trial. The MSCs can start with the evaluation of the documentation provided by the sponsor to ensure compliance with the CT Regulation.

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.



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.

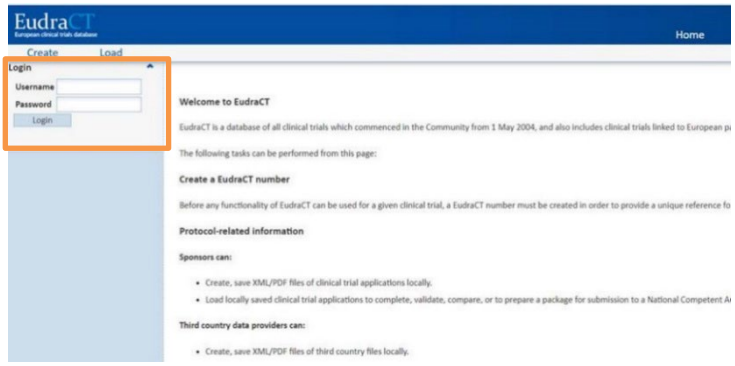
Once a trial has been transitioned to CTIS, **all the CT Regulation requirements will apply from the date of authorisation** of the transition application under the CT Regulation.

Update status of a Transitional trial in EudraCT

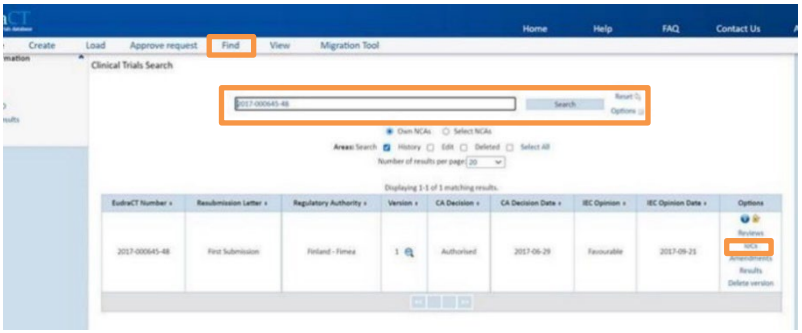
Member State users need to update in EudraCT the latest status of a transitioned trial submitted to CTIS, which is only possible once the Transitional trial is authorised in CTIS. To do so, users need to access the EudraCT platform and click on the 'EudraCT tools & Login' section and log in with their EMA credentials.

Evaluation of Transitional trials

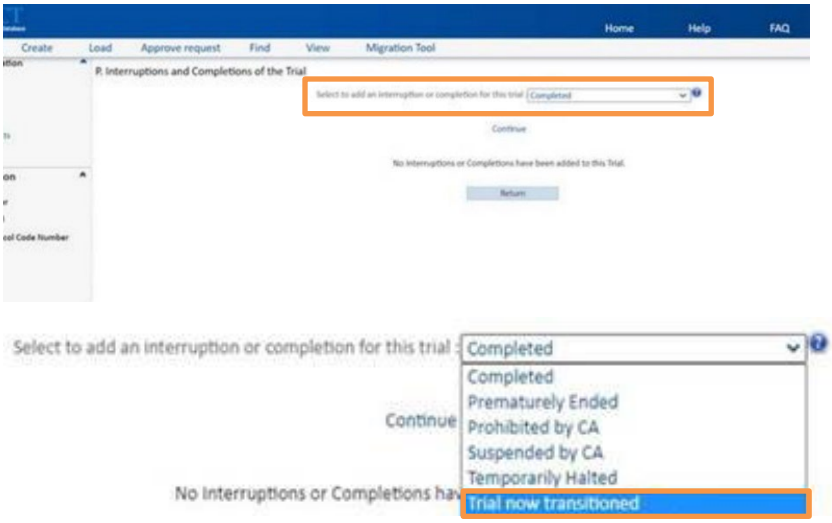
Each MSC is expected to update in the EudraCT platform the latest status of a Transitioned trial to CTIS.



Users 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 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 and authorised through CTIS, they need to select 'Trial now transitioned'.



#CTIS insights

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

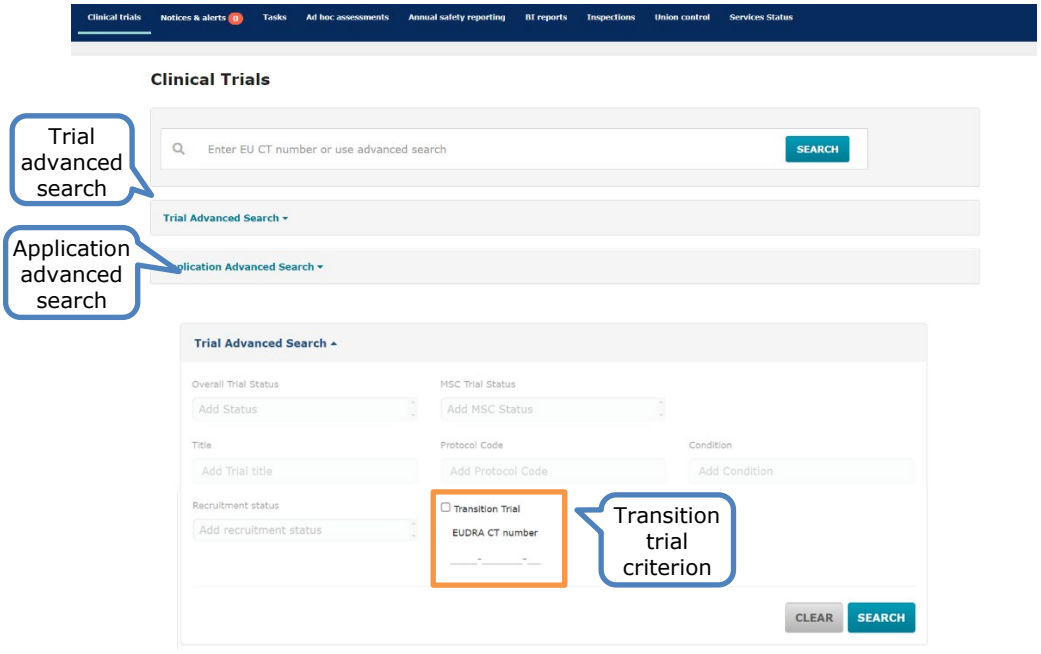
Once a trial is marked as 'Trial now transitioned' in EudraCT by the member states, it is expected that sponsors will follow up on the trial on CTIS, including the submission of results. For this reason, it is essential that the relevant Member State report the correct status of transitioned trials on the EudraCT database.

Search Transitional trials

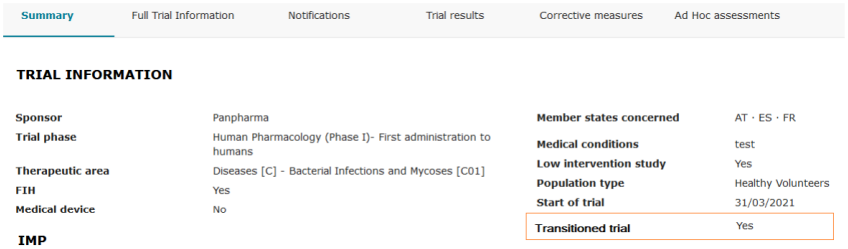
Users can search a Transitional trial directly with the EudraCT number using any of the Advanced searches.

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**'.



#CTIS insights

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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