



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Transitional trials from EudraCT to CTIS (sponsor users)

CTIS Training Programme – Module 23
Version 1.4 – May 2024

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.

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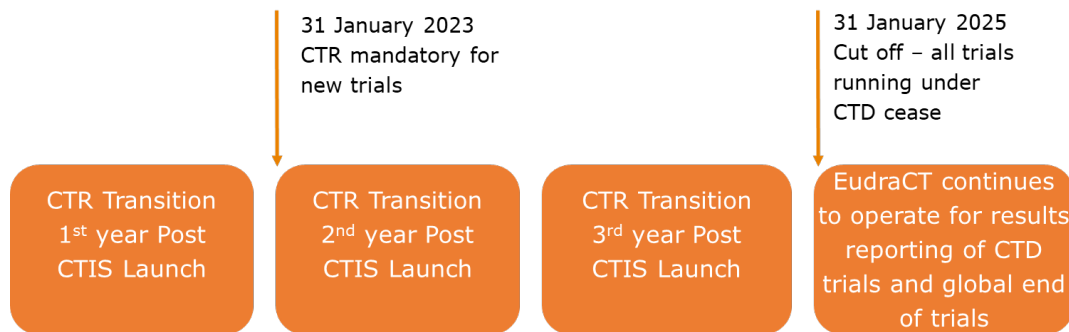
Record of updated versions

| Version | Version description | Date |
|---------|--|--------------|
| 1.4 | Minor changes applied: <ul style="list-style-type: none">• Minor update to the introduction and overview of transitional trials• CTIS: how to get started and how to transition a trial reference link added | May 2024 |
| 1.3 | Minor changes applied: <ul style="list-style-type: none">• Clarification on transition period and date when CTIS becomes mandatory | January 2023 |
| 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. As of January 31st, 2022, the Clinical Trials Regulation (EU) No 536/2014 (CT Regulation) repealed the Clinical Trials Directive 2001/20/EC (CT Directive), initiating a 3-year transition period ending on 30 January 2025.

Clinical trials authorised under the CT directive, foreseen to be ongoing in at least one EU/EEA Member State beyond 30 January 2025, should be transitioned to CTIS.



Sections of this quick guide

This quick guide is structured in three 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.



Roles and permissions

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

Overview of Transitional trials



Sponsors are advised to schedule their transition application submission early enough, in order to ensure continuity of the trial beyond January 31, 2025, taking into account the 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 that will not end by 31 January 2025 are to be submitted on CTIS as Transitional trials.

On January 31, 2025, the sponsor should have transitioned to CTIS any ongoing trial authorised under CT directive.

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 trial authorised under the CT directive is going to be submitted to an additional EU/EEA member state(s).
- 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.
- 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 via EudraCT. *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 and assessment of CTAs. The sponsor can request to conduct a clinical trial by submitting an **Initial CTA**. Once authorised by the Member State Concerned (MSC), the sponsor can submit **an additional MSC** and/or a **substantial modification** applications.

In order to transition a trial from EudraCT to CTIS, an **Initial CTA marked as a Transitional trial must be submitted**. When preparing a transition application, sponsors may consult the document [CTIS: how to get started and how to transition a trial](#) to retrieve a useful collection of training and reference documents.

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



A set of buttons and tabs are available on CTIS allowing the sponsors' workspace users to create and submit transitional trials.

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.

Clinical trials

UAT CT

The screenshot shows the 'Clinical trials' section of the CTIS interface. At the top, there are navigation tabs: 'Clinical trials', 'Notices & alerts', 'RFI', and 'User administration'. Below the tabs is a search bar with the placeholder text 'Enter EU CT number or use advanced search' and a 'SEARCH' button. Underneath the search bar are two dropdown menus: 'Trial Advanced Search' and 'Application Advanced Search'. At the bottom right of the section, there is a blue button labeled '+ New trial'.

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 trail. 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.

The screenshot shows the 'Create new trial' pop-up window. It has a 'Full title (English)*' field with the text 'Transitional trial test'. Below this is a 'Search organisation' section with search criteria: Name (contains), ID (starts with), City (starts with), and Country (All). A search bar contains 'test organisation'. Below the search bar is a table of search results:

| ID | Name | Address | City | postCode | country | phone | email |
|--|-------------------------|---------------------|--------|----------|---------|-------------|---------------------------------|
| <input checked="" type="radio"/> ORG-100032565 | Test Organisation | Olympians Street 12 | Athens | 111 42 | Greece | 02000000000 | info@testorganisation.com |
| <input type="radio"/> ORG-100032564 | Test Organisation Spain | Santiago Calle 10 | Madrid | 28001 | Spain | 0200110000 | info@testorganisation-spain.com |

At the bottom of the window, there is a 'Transition Trial' checkbox which is checked, and a 'Create' button.

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.



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

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)

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.

Transitional trial test 2022-500968-36-00 / Initial ID: IN Draft

Form details

Initial Application details

Cover letter

Transition Trial

Transition Trial

EUDRA CT number *

+ Add EudraCT Trial

EudraCT Trial Search

EUDRA CT number

CLEAR SEARCH

Search result

Cancel Add EudraCT Trial

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.

Test trial 2022-500981-83-00 / Initial ID: IN Draft

Required sections

Form details

Initial Application details

Cover letter

Transition Trial

Transition Trial

EUDRA CT number *

EUDRA CT number may not be empty.

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



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.

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 is 'TEST 2022-500299-71-00 / Initial ID: IN' and the status is 'Draft'. At the bottom right, there are buttons for 'Check', 'Save', 'Cancel', and 'Submit' (highlighted in orange). On the left, a sidebar menu shows 'Form', 'MSCs', 'Part I' (highlighted), 'Part II', 'Evaluation', and 'Timetable'. The main content area shows 'Trial specific information (Part I)' with a sub-section 'Trial details' containing 'Trial identifiers', 'Trial information', and 'Protocol information'.

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. At the top right, there are 'Withdraw' and 'Copy' buttons. On the left, the sidebar menu shows 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation' (highlighted), and 'Timetable'. The main content area shows 'Evaluation' with a sub-section 'Validation' containing 'RFI' (highlighted in orange) and 'Conclusion'. Below this, there is a sub-section 'Assessment Part I' containing 'RFI' (highlighted in orange).

After a decision has been issued upon by the MSCs, **all publication rules of the CTIS documents are applicable**, including the deferrals. Sponsors are advised to monitor whether the EudraCT trial status has been marked as 'Trial now transitioned', through checking the relevant [EU Clinical Trial Register](#) trial page and liaising with the relevant Member States where the trial was authorised under the CT Directive. *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.

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.*

The screenshot shows the 'Clinical Trials' search interface. At the top, there is a navigation bar with 'Clinical trials', 'Notices & alerts', 'RFI', and 'User administration'. Below this is a search bar with the placeholder text 'Enter EU CT number or use advanced search' and a 'SEARCH' button. There are two main search options: 'Trial Advanced Search' and 'Application Advanced Search'. The 'Trial Advanced Search' form includes fields for 'Overall Trial Status', 'MSC Trial Status', 'Title', 'Protocol Code', 'Condition', and 'Recruitment status'. A callout box points to a checkbox labeled 'Transition Trial' with the sub-label 'EUDRA CT number'. Another callout box points to the 'SEARCH' button. A third callout box points to the 'SEARCH' button in the top search bar.

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'**.

The screenshot shows the 'Summary' tab of a trial page. The 'Summary' tab is highlighted with an orange box. Below the tabs, there is a table of trial information. The 'Transitional trial' label is highlighted with an orange box and shows 'Yes'.

| 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 |
| FTI | Yes | Population type | Healthy Volunteers |
| Medical device | No | Start of trial | 31/03/2021 |
| IMP | | Transitional trial | Yes |



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

Submit notifications



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.

The screenshot shows the CTIS interface for a trial titled "Test for Training team". The "Notifications" tab is selected and highlighted. Below the navigation bar, there are buttons for "Start Trial", "End Trial", "Restart Trial", and "Temporary Halt". The "Start Trial" button is highlighted. Below these buttons is a table with columns for "Current status", "Start date", "Temporary Halt", "Restart", "End (or early termination)", "Start", "Restart", and "End". Below the table is a section for "EEA and Global" information, including "End of trial EEA", "Anticipated date of summary of results", "End of trial Global", "Submitted on", and "Submission of results".

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.



For trials already transitioned in CTIS, the sponsor users may submit a 'Start trial' notification with a trial start date in the past and prior to the authorisation date recorded in CTIS.

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.*

Administration of users

Search Results

| ctuat881 | UAT.CT8003f@ext-test.ema.europa.eu | Role: CT Admin | Creation date: 18/01/2022 | Assessment date: 18/01/2022 | Authorised from: 18/01/2022 | Authorised to: |
|--|------------------------------------|----------------|---------------------------|-----------------------------|-----------------------------|----------------|
| approved | EU CT Numbers: 2022-500301-41-00 | | | | | |
| Scope: Specific trial | | | | | | |
| Employer: | | | | | | |
| Organisation name: A&M Stabtest Labor Fur Analytik Und Stabilitatsprufung GmbH | | | | | | |
| Organisation Id: ORG-100011546 | | | | | | |

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.

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