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.

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.

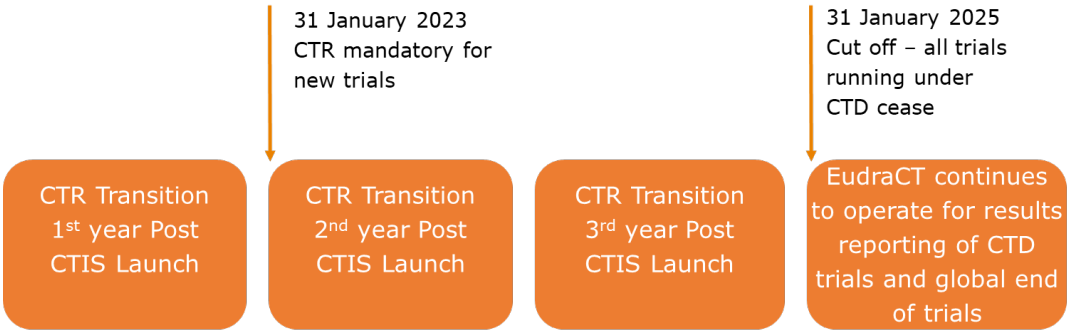
Record of updated versions

Version	Version description	Date
1.4	Minor changes applied: • 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: • Clarification on transition period and date when CTIS becomes mandatory	January 2023
1.2	Minor changes applied: • European Commission reference link • Part I 'Estimated Start of Recruitment' information for transitional trials • Information about the EudraCT number for transition trials New content: • 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 As of January 31st, 2022, the Clinical Trials Regulation (EU) No 536/2014 (CT Regulation) repealed the Clinical Trials Directive 2001/20/EC (CT Directive), initiating a 3-year transition period ending on 30 January 2025.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.

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).

#CTIS insights

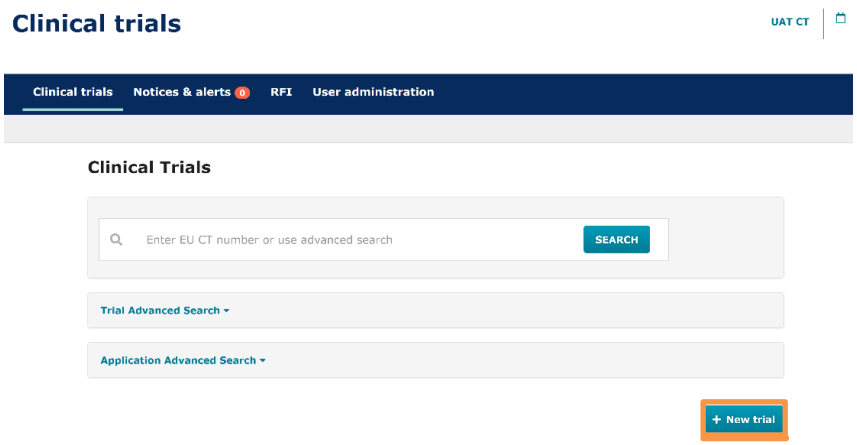
Three types of applications are available for the submission process for trials conducted in the EU.

Create, submit, and search Transitional trials

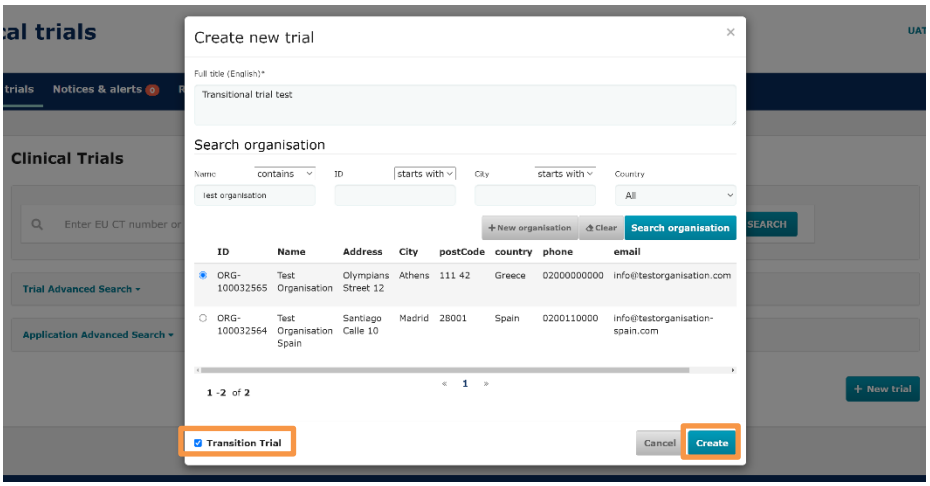
A set of buttons and tabs are available on CTIS allowing the sponsors' workspace users to create and submit transitional trials.

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.



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.



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.

#CTIS insights

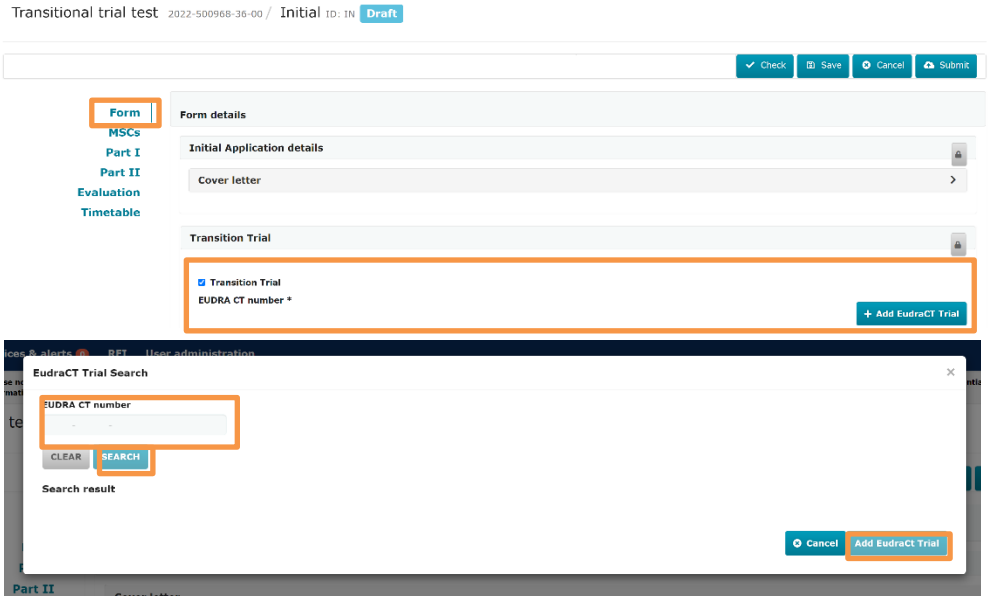
The 'Create new trial' pop-up window includes the option to indicate that it is a Transitional trial.

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.



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.

#CTIS insights

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.

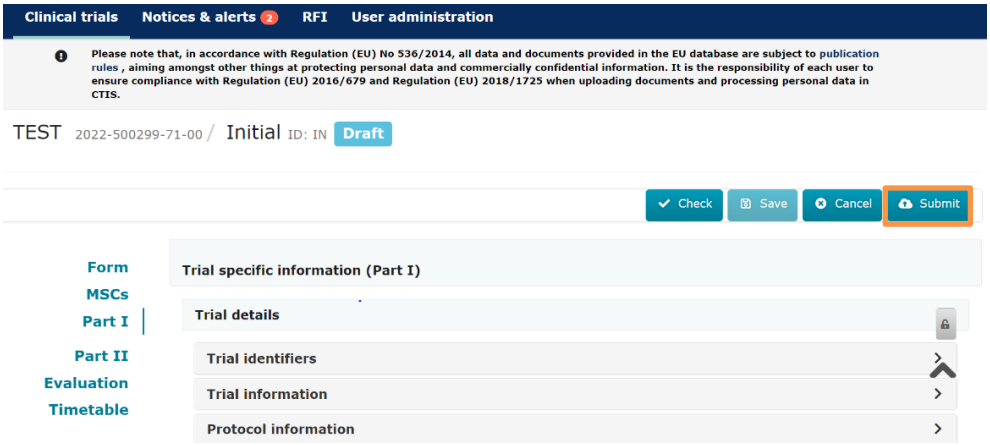
For more information on how to submit trials, users can refer to the eLearning material of Module 10 (Create, submit and withdraw a clinical trial) available on the EMA website.

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.

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.

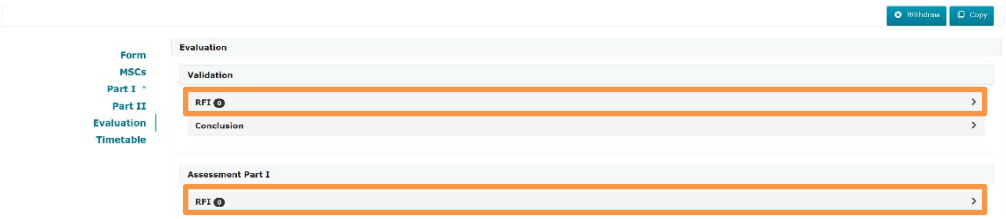


The trials that are transitioned to CTIS have already been authorised under the CT Directive. Member States Concerned (MSCs) may therefore choose to authorise the trials within or in less than 60 days. However, **MSCs can create Requests for Information (RFIs)** on the transitional application (leading 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.*

#CTIS insights

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



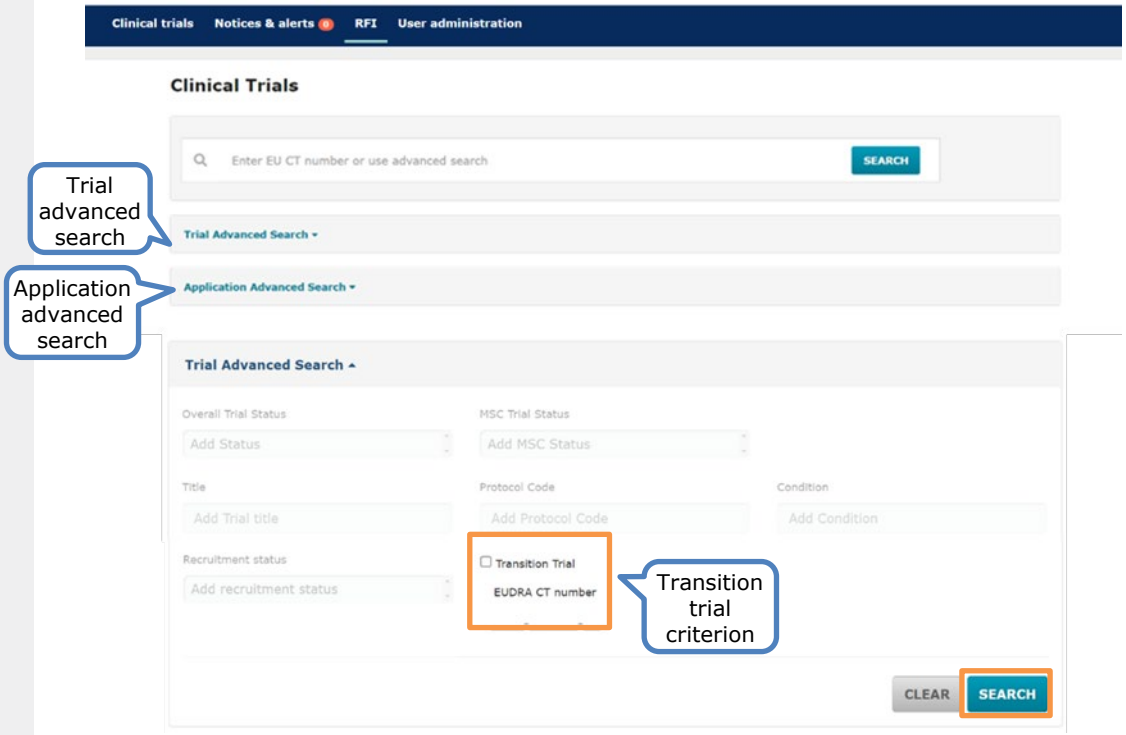
After a decision has been issued upon by the MSCs, **all publication rules of the CTIS documents are applicable,** including the deferrals. Sponsors are advised to monitor whether the EudraCT trial status has been marked as 'Trial now transitioned', through checking the relevant EU Clinical Trial Register 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

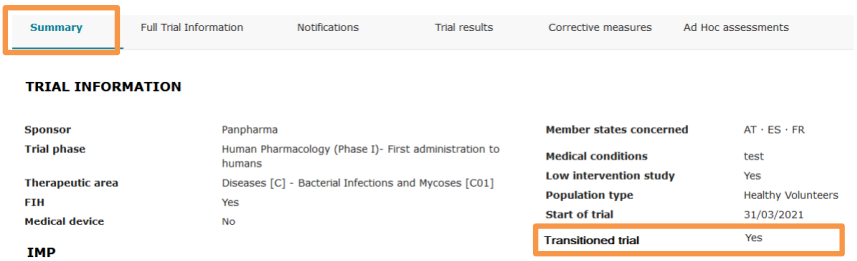
Users can search a Transitional trial directly with the EudraCT number using any of the Advanced searches.

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.*



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

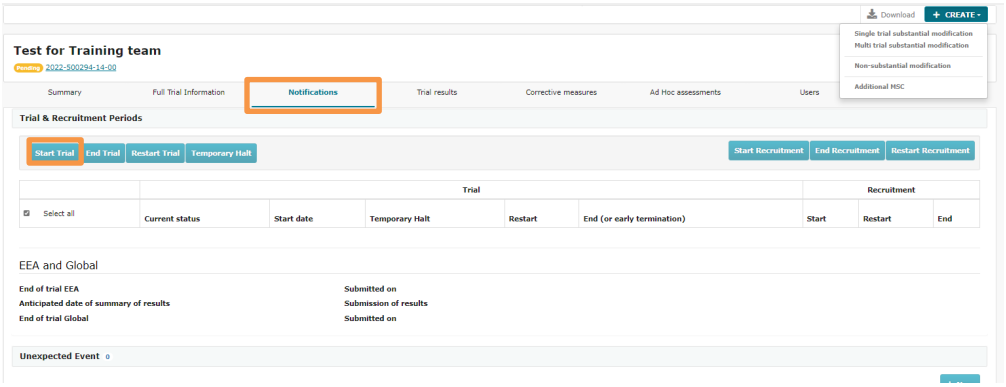
Users can check if the trial is transitioned by viewing the label on the summary page.

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.



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.

#CTIS insights

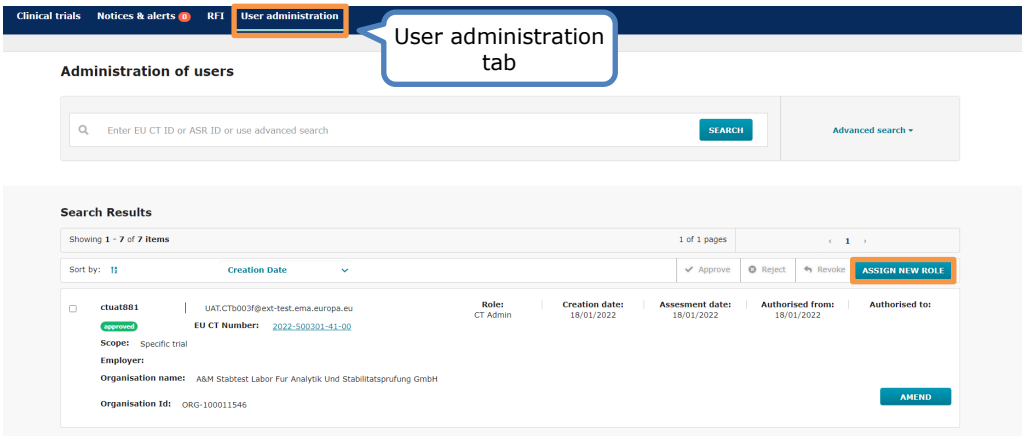
For trials already transitioned in CTIS, the sponsor users may submit a 'Start trial' notification with a trial start date in the past and prior to the authorisation date recorded in CTIS.

Roles and permissions

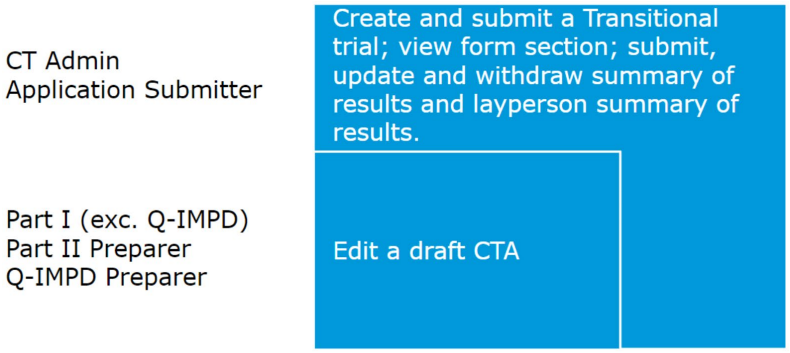
CTIS is a role-based system that enables users to perform different actions depending on the permissions attached to the roles assigned to them by a user from their organisation with administrator permissions.

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.*



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.



#CTIS insights

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

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