



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

Transitional trials from EudraCT to CTIS

CTIS Training Programme – Module 23

Version 1.4 – August 2024

What you will find

- Answers to general questions regarding Transitional trials.
- Answers to questions regarding how to create and submit Transitional trials.
- Answers to questions regarding how to submit notifications and clinical trial results.
- Answers to questions regarding how to complete the evaluation of a Transitional trial.
- Answers to questions regarding the roles and permissions involved in the Transitional trial processes.

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Record of updated version

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.4	New questions: 2.5 What should sponsors do if they forget to tick the "transitional trial" checkbox when drafting or submitting a trial? 2.10 Is it mandatory to register organisations in OMS prior to initiating transitional applications in CTIS? 2.11 Is it mandatory to register the investigational medicinal product (IMP) in XEVMPD for a trial approved as per CTD for transitional application in CTIS? Questions updated: 2.2, 2.6 and 4.1	August 2024
1.3	Question 1.2 updated – accurate phrasing of the Transition period	January 2023
1.2	Update European Commission reference link Update references to the Training materials	July 2022
1.1	Training material version published at CTIS go-live	January 2022

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FAQs



In this document, we list common questions regarding *Module 23: Transitional trials from EudraCT to CTIS*. They are categorised into questions regarding what Transitional trials are; questions regarding how to create and submit Transitional trials; questions regarding how to submit notifications and clinical trial results for Transitional trials; and questions regarding the completion of the evaluation of a Transitional trial. The specific learning objectives of this module are:

1. Remember what a Transitional trial is (common in both workspaces).
2. Understand how to submit a Transitional trial in the sponsor workspace.
3. Understand how to evaluate a Transitional trial in the authority workspace.
4. Understand how to submit notifications and clinical trial results for a Transitional trial (available for sponsor users).
5. Understand the roles and permissions involved (available for sponsor users).

We encourage you to read these questions and answers carefully. If you have any questions that are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the EMA experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

For more information, users can refer to the Quick guides of this module; practical and simple guides with images to prepare Sponsor and Authority users on how to submit, manage and evaluate Transitional trials, respectively. This will allow users to have useful information always at hand; both Quick guides are available on the EMA website¹. Another source of useful information is the Clinical Trials Information System (CTIS) – Sponsor Handbook² which compiles key guidance, technical information, recommendations and references to get ready for the use of CTIS.

¹ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

² European Medicines Agency: EMA/299895/2021 – Clinical Trials Information System (CTIS) – Sponsor Handbook. Available at: https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_.pdf

1. Transitional trials

1.1. What are Transitional trials?

Those trials that were authorised under the Clinical Trials Directive 2001/20/EC through EudraCT and are to be transitioned to CTIS are called Transitional trials. Refer to question 1.3 to know which are the EudraCT trials that need to be transitioned to CTIS. A 3-year transition period is foreseen from the implementation of the Clinical Trials Regulation (EU) No 536/2014. The sponsor should submit to CTIS any still ongoing trial by the end of the transition period, or any trial for which a new MSC need to be added. The transition can be enacted at any time during that period, however it is recommended perform the submission early enough before its end (i.e. 30 January 2025). Once a trial has been transitioned and authorised through CTIS, all the CT Regulation requirements apply. *For more information, users can refer to the Quick Guides of this module available for [sponsor](#) and [Member State users on the EMA website](#)³.*

1.2. When is a Transitional trial submitted in CTIS?

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 CT Regulation. During that period and at any time, the sponsor can transition clinical trials that are authorised under the 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 will have 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).

³ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

- **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.

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.

1.3. Which trials should be transitioned to CTIS?

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 authorised under the CT Directive that are foreseen not to end by 30 January 2025 and 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.

1.4. How can sponsor users inform that a trial is transitional in CTIS?

Various functionalities have been implemented in CTIS in order to allow the transition of trials to CTIS. When sponsor users are creating an Initial CTA in CTIS, a checkbox is available to indicate if a trial is a Transitional trial. If this checkbox is selected, users will be able to provide specific information about the trial being transitioned from EudraCT. In this sense, users will be able to populate the structured data and documents in the CTA entirely in CTIS. There is no automated migration of data between EudraCT and CTIS.

2. Create and submit a Transitional trial

2.1. How can users search and view a Transitional trial?

Once a Transitional trial has been submitted to CTIS, users can search for them similarly to any other trial in the system. To perform a search, users can access the 'Clinical trials' tab, and use any of the two Advanced Searches. Users can search by Transitional trials; they can click on the 'Transition trial' criterion, they can insert the EudraCT number, and then click on the 'Search' button. *For more information on how to search for CTs and access them, users can refer to the Quick guide of [Module 09 \(Search, view and download information on clinical trials and clinical trial applications\)](#) for sponsor users, and [Module 15 \(Search, view and download a clinical trial and a clinical trial application\)](#) for authority users, available on the EMA website⁴.*

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'.

2.2. How can sponsor users create a Transitional trial?

The sponsor shall submit an Initial CTA marked as a Transitional trial to CTIS, but relying, in principle, on the existing dossier already assessed by the Member States under the CT Directive. In the CTIS 'Clinical trials' tab, sponsor users can create a Transitional trial by selecting 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 can click on the 'Transitional trial' checkbox and then click on the 'Create' button to create a draft Transitional trial. Clicking on the 'Transitional trial' checkbox enables a new field in the form section that allows users to link the EudraCT number data to the trial.

2.3. How can sponsor users populate a Transitional trial?

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. On the Form section of the CTA page, in the Transition trial sub-section, 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

⁴ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

'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. The system will highlight the sections where mandatory data or documents are missing.

2.4. How can sponsor users submit a Transitional trial?

Once the users have populated all the sections and checked everything is correct, the CTA can be saved and then submitted. The draft Transitional trial cannot be submitted if any mandatory fields or documents are not filled in or uploaded.

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. *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 website⁵.*

2.5. What should sponsors do if they forget to tick the "transitional trial" checkbox when drafting or submitting a trial?

If the initial application has not yet been submitted and is still in draft form, sponsors can edit the transition trial section and select the "transition trial" checkbox, even if it was not selected during the creation of the new clinical trial.

⁵ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

Create new trial

Full title (English)*

Search organisation

Name

starts with

ID

starts with

City

starts with

Country

All

+ New organisation

Clear

Search organisation

ID

Name

Address

City

postCode

country

phone

email

actions

☐ Transition Trial

Cancel

Create

In order to edit the transition trial section, sponsor users need to use the relevant padlock:

✓ Check

Save

Cancel

Submit

Form

MSCs

Part I

Part II

Evaluation

Timetable

Form details

Initial Application details

Cover letter

Transition Trial

☐ Transition Trial

If a trial was submitted without selecting the "transition trial" checkbox, sponsors may withdraw the application. They will then be able to edit the transition trial section. After the CTA is in Draft, sponsor can select the "transition trial" checkbox to resubmit the initial application.

Resubmit

Form

MSCs

Part I

Part II

Evaluation

Timetable

Form details

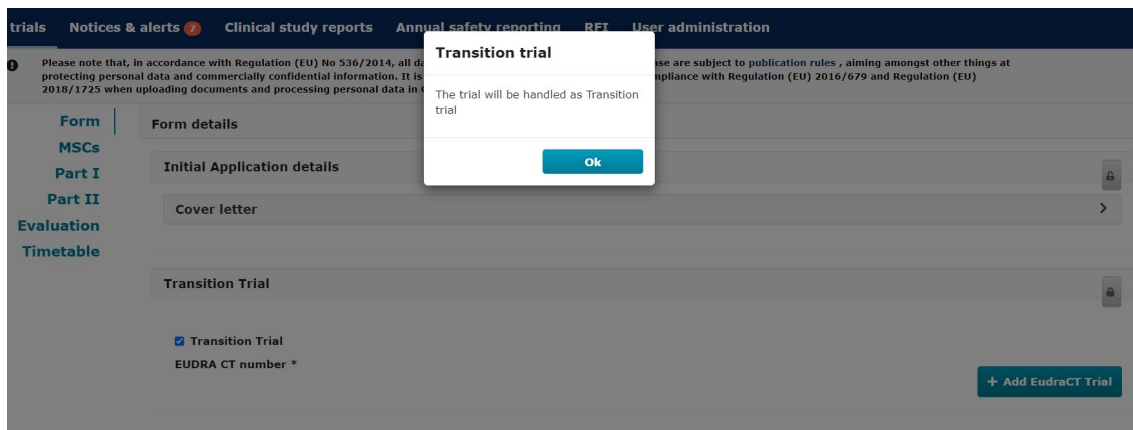
Initial Application details

Cover letter

Transition Trial

☐ Transition Trial

In a resubmission, if the sponsor user clicks on the relevant padlock, the section is editable and the trial is handled as a transition trial if the checkbox 'Transition trial' is selected.



2.6. Which differences are there when submitting a Transitional trial compared to a non-transitional trial?

Creating a Transitional trial implies that sponsor users have to proactively indicate that it is a Transitional application at the moment of creating the draft Initial CTA. A significant difference to highlight is that certain documents listed in Annex I of the CT Regulation are not required under the CT Directive. Sponsor users can upload a blank document to continue the creation of a Transitional trial application if a document was not a requirement under the CT Directive, but it is mandatory to be submitted for the application in CTIS.

For further clarification please refer to the Guidance for the Transition of Clinical Trials from the Clinical Trials Directive to the Clinical Trials Regulation available on Eudralex vol 10⁶.

2.7. How can sponsor users respond to Requests for Information and apply changes to the CTA of a Transitional trial?

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 trial application (leading to a maximum period of 106 days, or further in the case of some types of investigational medicinal products).

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, sponsor users can*

⁶ European Commission, Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation. Available at: https://health.ec.europa.eu/system/files/2023-12/transition_ct_dir-reg_guidance_en.pdf

refer to the materials of Module 11 (Respond to requests for information received during the evaluation of a CTA) available on the EMA website⁷.

2.8. What should sponsor users do in case a substantial modification is required after the submission of a Transitional trial?

According to the details provided on the Eudralex Volume 10 Q&A⁸, sponsors should take the necessary measures and inform the Reporting Member State (RMS) and other MSCs about the substantial modification. *For more information on how to submit substantial modifications, users can refer to the [eLearning material of Module 10 \(Create, submit and withdraw a clinical trial\)](#) available on the EMA website⁹.*

An RMS may decide to speed up the transitioning procedure to allow a sponsor to introduce a request for a substantial modification under the CT Regulation. The RMS may also advise the sponsor to withdraw the request for transitioning the trial and submit the request for substantial amendment under the CT Directive. The sponsor can then resubmit the Initial CTA for transitioning the trial once the decision on the substantial amendment is issued.

2.9. What should sponsor users do if a trial has ended in all of the MSCs of the trial?

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.

Details of the requirements for transitioning of single-country and multinational trials are provided in the Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation¹⁰. Multi-national CTs (trials conducted under the same EudraCT number in different Member States) should be transitioned as a single multi-country CTA under the CT Regulation, utilising a harmonised or at least consolidated protocol. Sponsors may need to consider harmonising the protocol by substantial amendments under the CT Directive before transitioning them as one trial under CT Regulation with one EU CT number.

⁷ CTIS online modular training European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system-training-support/clinical-trials-information-system-ctis-online-training-modules>

⁸ European Commission, Clinical Trials Regulation (EU) No 536/2014 Questions & Answers. Available at: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014

⁹ Idem⁸

¹⁰ European Commission, Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation. Available at: https://health.ec.europa.eu/system/files/2023-12/transition_ct_dir-reg_guidance_en.pdf

2.10. Is it mandatory to register organisations in OMS prior to initiating transitional applications in CTIS?

If users do not find an organization after searching in OMS or CTIS, they may proceed to register it before submitting the transition application. Although previous registration of organizations in OMS is not mandatory, it is highly recommended, as organizations created locally in CTIS are not validated by the EMA.

To create a new organization in CTIS, users can click the 'New Organisation' button. This functionality is available only for registering the following organizations:

- Part I Sponsor section – Third-party organizations
- Part II – Trial sites
- Serious Breach notifications – Details of the site where the serious breach occurred
- Third Country Inspectorate Inspection – Third country inspection site
- MS Inspections – Inspected site

Organizations registered through OMS adhere to a data quality standard, reducing the likelihood of receiving RFIs from assessing authorities regarding inaccurate data. For more information regarding how to register an organization in CTIS please refer to pages 11-13 of the CTIS Sponsor's Handbook¹¹.

2.11. Is it mandatory to register the investigational medicinal product (IMP) in XEVMPD for a trial approved as per CTD for transitional application in CTIS?

Yes. If the IMP has not previously been registered in XEVMPD, the sponsor will not be successful populating the IMP information in the Clinical Trial Application (CTA) on CTIS. The information on the IMP to populate in the CTA in CTIS can only be retrieved from XEVMPD. For more information regarding how to register an organization in CTIS please refer to the pages 30-35 of the CTIS Sponsor's Handbook¹².

¹¹ European Medicines Agency, Clinical Trials Information System (CTIS) – Sponsor Handbook. Available at: https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_.pdf

¹² Idem¹¹

3. Submit notifications and clinical trial results

3.1. How can sponsor users submit notifications for a Transitional trial?

Sponsor users can submit trial and Recruitment periods 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 trials, 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 authorised under the regime of the 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 website¹³.*

3.2. How can sponsor users submit the results of a Transitional trial?

CTIS allows the sponsor users 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 summary of results and the layperson summary within one year from the end of a CT (in all EEA MSCs or globally, if applicable), and within 6 months in case of paediatric trials or if the CT is part of a paediatric investigation plan. *For more information, refer to Article 37 and Annex IV and V of the CT Regulation¹⁴, and the Quick guide of Module 05 (Manage a clinical trial through CTIS) available on the EMA website¹⁵.*

4. Complete the evaluation of a Transitional trial

4.1. How can Member State users evaluate 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 process is the same as the process to evaluate a non-transitional trial. MSCs can start with the evaluation of the documentation provided by the

¹³European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

¹⁴ European Commission, Clinical Trials Regulation (EU) No 536/2014, July 2024. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536>

¹⁵ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

sponsor to ensure compliance with the CT Regulation. CTAs to be transitioned have already been authorised under the CT Directive. MSCs may authorise Transitional trials within or in less than 60 days. The Guidance for the Transition of clinical trials from the CTD to the CTR¹⁶ available on Eudralex vol 10 sets an expedited timeline for the transition procedure of minimum dossiers for multinational trials restricted to documents already approved under the CTD estimated to be a maximum of 22 days provided that no Requests For Information have to be sent: 10 days (validation phase without Request For Information) + 7 days (assessment phase provided no Request For Information is needed) + 5 days (decision).

However, for the procedures assessed outside the expedited procedure, if MSCs create Requests for Information (RFIs) on the Transitional application this can lead to a procedure duration of a maximum period of 106 days, or further in the case of some types of investigational medicinal products.

The evaluation process of an Initial application 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). *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)¹⁷ and Module 08 (Assessment and decision-making)¹⁸.*

4.2. How can Member State users update the status of a Transitional trial in EudraCT?

Member State users need to update in EudraCT the latest status of a transitioned trial to CTIS, which is only possible once the Transitional trial is authorised in CTIS. Each MSC is expected to perform this update on the EudraCT platform¹⁹. The process that users need to follow is outlined below:

- Access the EudraCT platform and click on the 'EudraCT Tools & Login' section and login with their EMA credentials.
- 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.

¹⁶ European Commission, Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation version 4 May 2024. Available at: https://health.ec.europa.eu/system/files/2023-12/transition_ct_dir-reg_guidance_en.pdf

¹⁷ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

¹⁸ Idem¹⁷.

¹⁹ European Medicines Agency: EudraCT secure home page. Available at: <https://eudract.ema.europa.eu/>

- Once users click on 'Ioc', they can choose the status of the trial. For Transitional trials uploaded and authorised through CTIS, they need to select 'Trial now transitioned'.

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.

5. Roles and permissions

5.1. What roles and permissions are involved in the Transitional trial processes?

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 website²⁰.*

In relation to the Transitional trials processes, for sponsor users, 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.

²⁰ European Medicines Agency: Clinical Trials Information System (CTIS): online modular training programme. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme>

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