Transition:

In accordance with the Directive, clinical trials with at least one active site after 30 January 2025 must be transferred as a transitional trial to the CTIS portal in accordance with the EU Regulation. If there are no active sites in Finland in the clinical trial, no transfer will be needed for Finland.

Active sites are those which are engaged in clinical trial interventions or are still being monitored in accordance with the clinical trial protocol.

Because a transition application is an administrative change resulting from changes in legislation, the documents attached to the application must have already been processed by the ethics committee and/or Fimea. No new or modified document may be placed in the transition application, but the sections that have not previously been required may or may not be entered with explanatory documents in the program. These sections can be completed in connection with the first substantial modification (SM).

The transition must be approved by 30 January 2025. Depending on the completeness of the documents, it will take 3-5 weeks to process the application if the application is available in the CTIS portal by no later than 16 October 2024. After this, the processing may take a normal amount of time for assessment. It should also be noted here that there is a Christmas break in official proceedings, usually lasting from Christmas Eve to Epiphany (6 January), depending on where the days in question fall on the calendar.

How to get started

First, create a new EMEA account, if no there is no existing account:

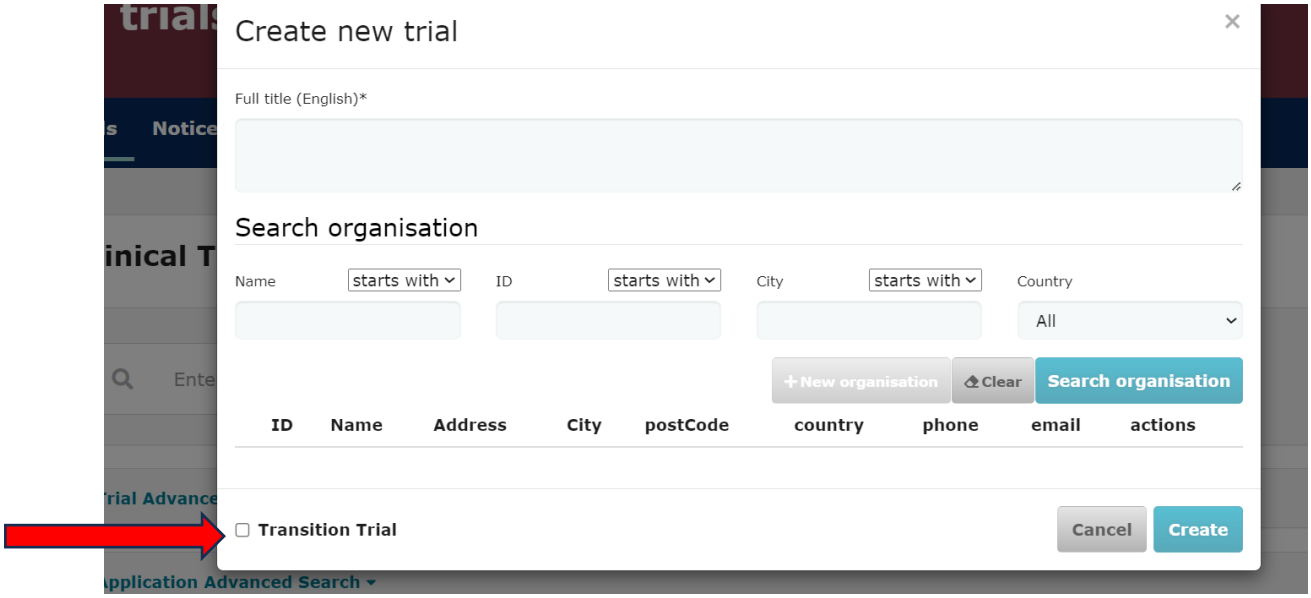
Then, ensure that your organisation can be found on Organisation Management System (OMS). That is the organisational management system of the European Medicines Agency (EMA). The sponsors of a trial, sites, and key service providers are registered in the OMS where the applicant can choose from among them in the CTIS system for their clinical trial application. For example, you can search a locality under Organisations. The OMS can be, for example, a social welfare and health care area.

If the organisation cannot be found, it must be reported there according to the EMEA guidelines. Further instructions can be found at:

CTIS Q&A Page "My organisation is new to CTIS, how can we get started?"

EMA IDs are used in the CTIS portal to apply for trial-centric applications

For a transitional trial, remember to tick the Transition section at the beginning of the first page and enter the EudraCT number of the trial in accordance with the Directive. This cannot be entered later.



It is a good idea to keep a record of the portal number given by the trial. The application does not need to be completed in one session. It can be more easily found later by searching with the portal number. The portal number is the new identification number of the trial. The old EudraCT number will no longer be used after the trial has been transferred to the CTIS portal.

All mandatory fields (marked with an *) must contain some information/attachment, otherwise the user cannot advance in the program. If there is no document in a Directive-compliant trial, a free-form document stating that it is a transitional trial must be added to the mandatory section in question.

In the future, a clinical trial that has been transferred in accordance with the Regulation will only be processed in the portal, i.e. once the application has been processed as a transition, a decision on it will be issued in the CTIS program. After the decision, the applicant must enter the start date of the clinical trial in the program (see below in this section). In the future, any substantial modifications (SM), annual report, termination notification and results will also be processed in the portal. The old EudraCT program no longer updates any of the clinical trials transferred. Fimea records data on the transfer of approved transfer trials made to EudraCT to the CTIS portal.

Entering a start date: Fimea's website contains instructions (in English) on the trial-centric application procedure, page 32 (Section 5 Notifications after Authorisation). It explains, for example, how to enter a start date after a clinical trial has been approved..

Submitting an annual report: Fimea's website contains instructions (in English) on the trial-centric application procedure, page 38 (Section 9 Create and submit an Annual Safety Report (ASR)). It explains how to submit an annual report after a clinical trial has been approved.

Documents required for transition:

Part I:

1. **Cover letter**
2. **Protocol under the Directive**
3. **IMPD/IB and GMP certificates, if applicable**

Part II:

1. **Patient information and consent forms approved by the ethics committee**

Cover letter:

The cover letter must contain the EudraCT number and information on the ethics committee that issued the favourable opinion on the Directive-compliant clinical trial. The statement that the clinical drug trial complies with the approval and that it meets the requirements for clinical trials transferred to the EU portal and database (active site in Finland) must also be mentioned, as well as that all documents in the transition application have already been processed by Fimea and/or the ethics committee. The documentation cannot therefore be changed from a Directive-compliant notification.

If desired, a model for commercial sponsors **template** (PDF, in English) is available for use in the cover letter of the transitional trial.

Organization information:

When entering an application, the CTIS program will first request the organisation's OMS information. For more detailed information, see the first page of the guide.

How to upload the application to the CTIS portal:

Fimea's website contains instructions (in English) on the trial-centric application procedure, page 12 (Section 4 How to Create, Submit and Withdraw an initial Clinical Trial Application (CTA). It explains how to start filling in the application.

Time limits:

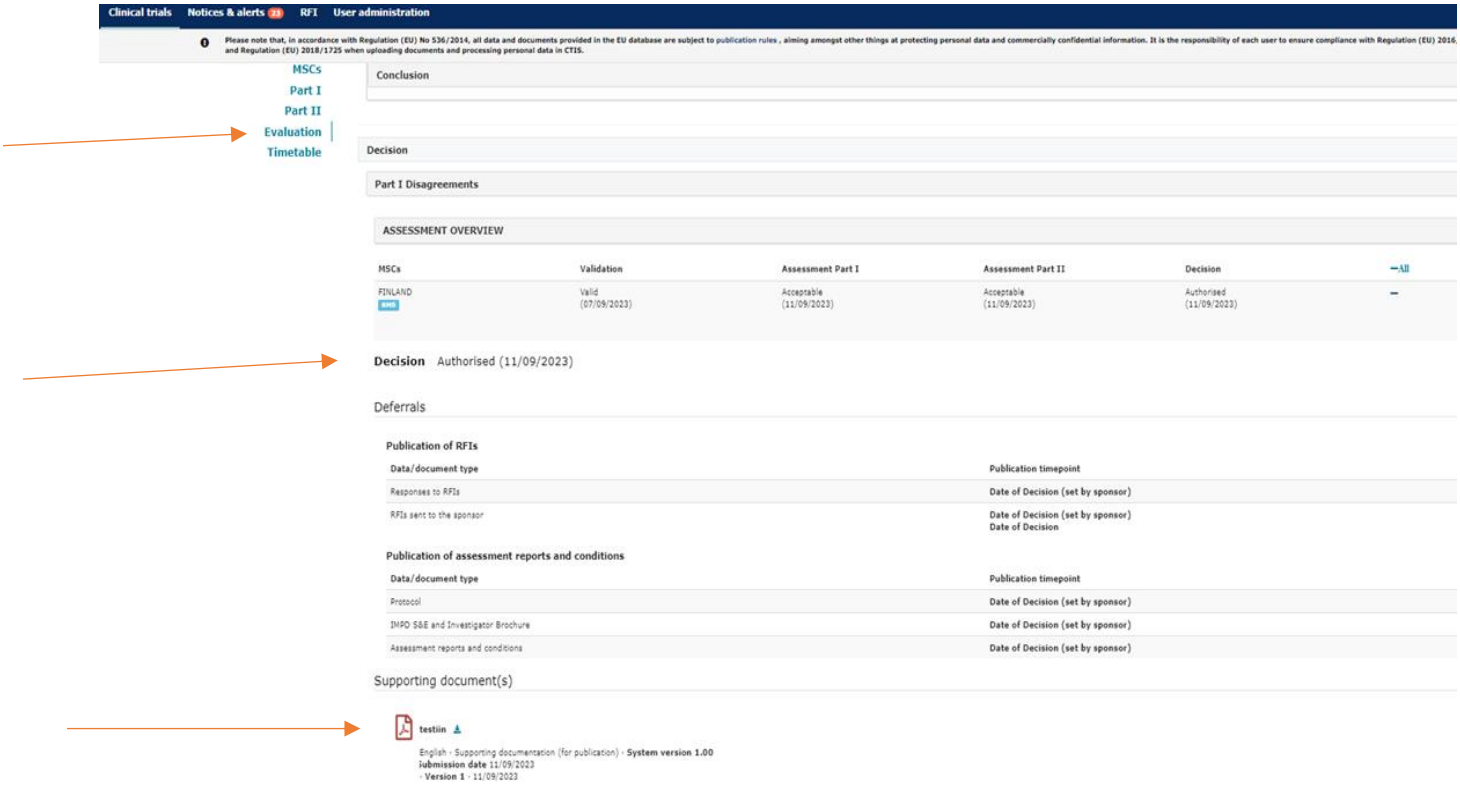
The maximum time limit for transition processing is estimated to be 22 days if no additional questions are required: 10 days (validation phase without RFI, + 7 days (evaluation phase if RFI is not required) + 5 days (decision)). All phases of the application take place in the CTIS portal, from which no separate e-mail prompts or other equivalent notifications are sent. The stages of one's own clinical trial must be monitored in the program: whether a request for further information should be submitted and within what time limits in order to ensure that the application does not expire.

How to answer any questions on the application:

Fimea's website contains instructions (in English) on the trial-centric application procedure, page 26 (Section 5 Validation, Request for Further Information (RFI) and Authorisation) on how to find and respond to requests for further information.

Where to find the decision:

The decision is not sent to the applicant, but can be found on the CTIS portal under Evaluation and under Decision and Supporting document, from which the applicant can download it:



For multinational clinical trials, the following should be taken into account:

Further information on the transition period and transferring a clinical trial to conform with the Regulation can be found in European Commission **EudraLex - Volume 10 - website** document CLINICAL TRIALS REGULATION (EU) NO 536/2014 QUESTIONS & ANSWERS. The Clinical Trials Coordination Group (CTCG) has also compiled a **Best Practice Guide** in accordance with the Directive on making an international clinical trial conform with the Regulation. In multinational trials, only one transition application is made, which is processed simultaneously in all countries.

- a harmonised protocol, IB and/or IMPD means that the respective document(s) is identical and includes the same trial procedures in all countries approved across all EU Member States under the CTD.
- a consolidated protocol, IB and/or IMPD means that there are some substantial differences in the respective document(s) in different Member States, but the document itself is

identical, i.e. Member State-specific issues are outlined within the document text or in an appendix to the respective document. The consolidated protocol, IB and/or IMPD do not need prior approval under CTD before the transition.