17 May 2024
EMA/162262/2024
European Medicines Agency

CTIS newsflash – 17 May 2024

Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 31 May 2024.

Previous issues of the CTIS Newsflash are available on the EMA website.

Reminder: Transition ongoing trials from CTD to the Clinical Trials Regulation

Sponsors are advised to transition any trials that are expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR).

Sponsors should take into account the time necessary for completion of the Member State(s) evaluation procedure, which can take up to 3 months. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

Further resources to support sponsors transitioning trials are available on the CTIS website.

Reminder: Launch of revised CTIS transparency rules on 18 June 2024

The revised CTIS transparency rules will become applicable on 18 June 2024, with the launch of an updated version of the CTIS public portal. Sponsors are advised to adapt their business processes accordingly, and can refer to the quick guide for users for an overview of the changes.

For all clinical trial applications submitted on or after 18 June 2024:

- it will no longer be possible to defer the publication of data and documents;
- data and documents will be published according to the established timelines for the trial category, population age and trial phase;
- publication of documents will be focused on key documents of interest.

Data on all clinical trial applications submitted before 18 June 2024 will be made publicly available in line with the principles and timelines defined in the revised transparency rules. Please note that existing CTIS documents of these trials will not be published. Documents included in subsequent applications of these trials submitted after 18 June 2024 will be published in line with the revised rules[1]: more details are available in the quick guide for users.

[1] This applies to documents of all types of applications, with the exception of part I documents of Non Substantial Modifications and Additional Member State applications.

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In the interim period until 18 June 2024, sponsors may already follow the principles of the revised CTIS transparency rules, as defined in section 4 of the ACT EU Q&A.

More information and resources are available on the ACT EU website and on the CTIS website.

Report on combined studies: Analysis phase and ways forward

In a recently published report, the European Commission, national authorities, ethics committees, EMA and stakeholders analyse the current challenges faced when conducting combined studies and possible ways forward to streamline the regulatory landscape.

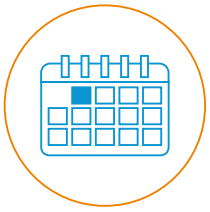
The report was delivered by the COMBINE project, which aims to address the issues linked to the interface between three EU regulations: the Clinical Trials Regulation (CTR), the Medical Devices Regulation, and the In vitro Diagnostic Medical Devices Regulation.

The next steps of this project will investigate developing some of the solutions proposed in the report.

Tip for sponsors

When submitting an application in CTIS, sponsors need to provide the full IMPD (Investigational Medicinal Product Dossier) document. Sponsors are reminded that they should submit:

- A version of the IMPD document with all edits visible in "Track changes";
- The final version of the entire IMPD document, with track changes accepted (clean version).



Save the date: Upcoming events

Sponsors can still register to the upcoming CTIS user training on 10-13 June 2024, 09:00-13:30 CEST.

On 20 June 2024, EMA is hosting a CTIS Bitesize talk on the revised transparency rules and the new version of the CTIS public portal at 15:30-17:00 CEST. Participants can submit their questions in advance from 20 May until 13 June via Slido with the code #bt20jun. An event page with more information will be available soon.

The next CTIS Walk-in Clinic will take place on 10 July 2024 at 16:00 – 17:00 CEST. Participants are able to submit their questions via Slido from 20 June to 3 July 2024, with the code #clinic246. More information is available on the event page.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

System improvements

A CTIS release on 16 May 2024 introduced several improvements:

- Users are now able to submit Part I only applications where validation requirements for Part II are not fulfilled, as long as the requirements have been fulfilled for Part I.
- When creating new draft applications which have two or more Product Role Groups with the same name, documents are no longer duplicated between the groups.
- When adding multiple documents at once, users can now select one of these documents and then delete / edit only the selected document.

- EMA Administrators can now correctly delete and replace documents when using the GDPR functionality for Requests for Information, Ad-hoc assessments, Inspections and Annual Safety Reports (ASR). New and replaced documents now also appear correctly in the download folder.
- Users with Supervisor Submitter and Supervisor Preparer roles (for all trials or for specific trials) can now navigate through all sections of a Clinical Trial Application (CTA), including the Evaluation folder.
- While the "Authorise" task is pending, all Member States Concerned (MSC) that need to submit a decision on a Substantial Modification application (all types) now receive the alert "There are 2 days remaining to submit a decision on the trial".
- The workflow for ad-hoc assessments has been improved:
  - When an Ad-hoc assessment is linked to a previously created event notification (Serious breach, Unexpected event or Urgent safety measure), sponsors receive the alert "Assessment of additional information" only after the assessing MSC submits the outcome of the Ad-hoc assessment. For this alert, the columns "IMP" (Investigational Medicinal Product) and "Sponsor" are now populated and display the correct information;
  - When sponsors click on the title of the above alert, they are redirected to the Notifications tab;
  - When MS users submit the assessment conclusion and navigate to the "Notices and Alerts" tab, the columns 'IMP' and 'Sponsor' in the 'Notification assessment outcome submitted' notice are populated and display the correct information.

More information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users.

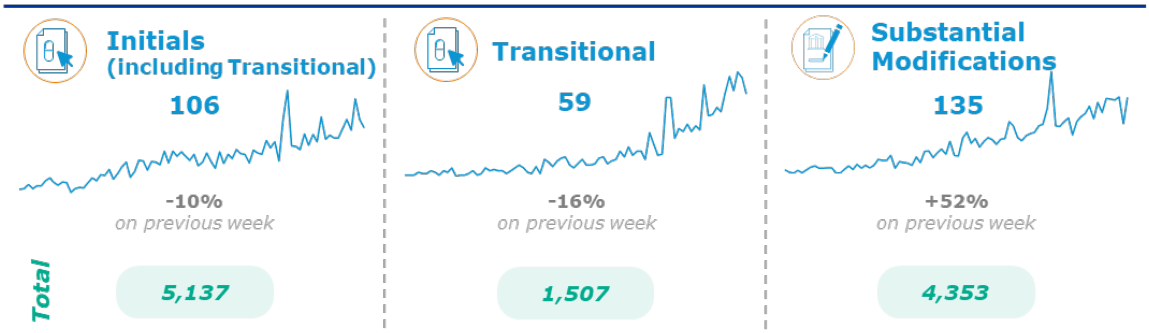
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

Current operational experience with CTIS

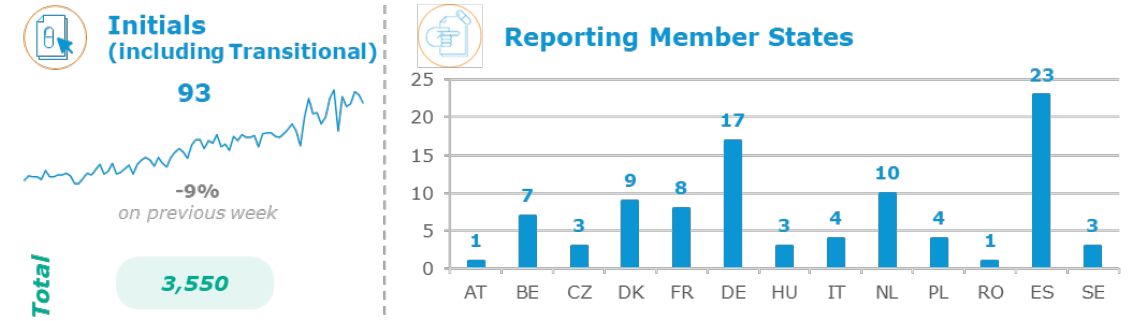
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 7 to 13 May 2024.

CTA Submissions

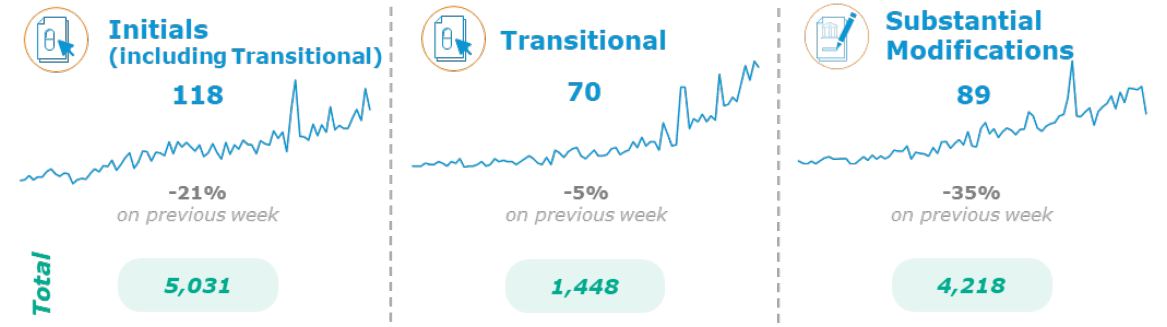


CTAs with a Decision

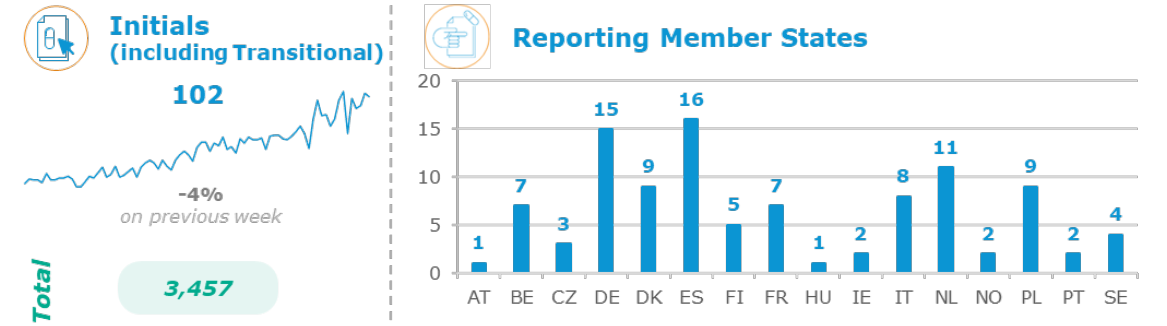


The data presented below refer to the period from 30 April to 6 May 2024.

CTA Submissions



CTAs with a Decision

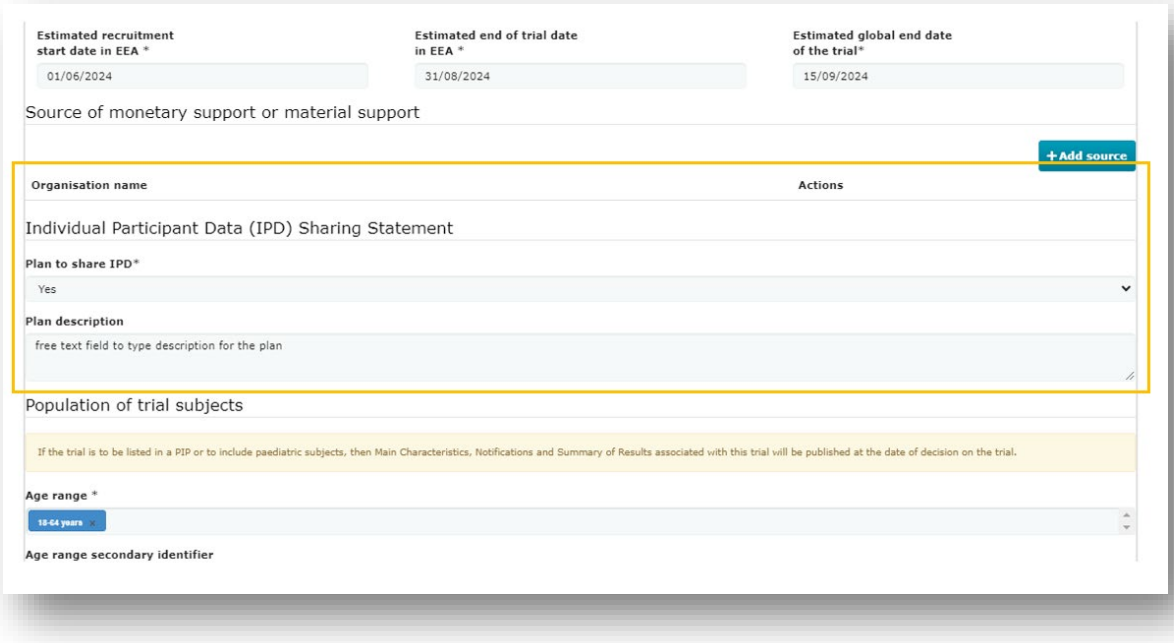


New CTIS feature: Field on Individual Participant Data

As required in the WHO Trial Registration Data Set, the field 'Individual Participant Data (IPD) Sharing Statement' collects information on how this data will be made available to other researchers. Sponsor users in CTIS can now record in a structured way how IPD will be shared in the future.

Two new fields have been added in the Part I section of the application form in CTIS, above the fields for the population of trial subjects. The first new field, 'Plan to share IPD', is mandatory. Users need to select a response from a drop-down list of pre-defined values (Yes/No/Undefined). We recommend that sponsor users select "Yes" or "No", to meet the requirements of the International Committee of Medical Journals Editors (ICJME).

The second field, 'Plan description', is optional. It allows users to describe the plan in detail, in free text, using up to 1000 characters.



Important note: If you are working on a draft application (initial, SM, NSM, RFI response) with Part I in scope, please ensure that you populate the mandatory field "Plan to share IPD" before submitting, otherwise the technical validation will flag this field and prevent the submission.

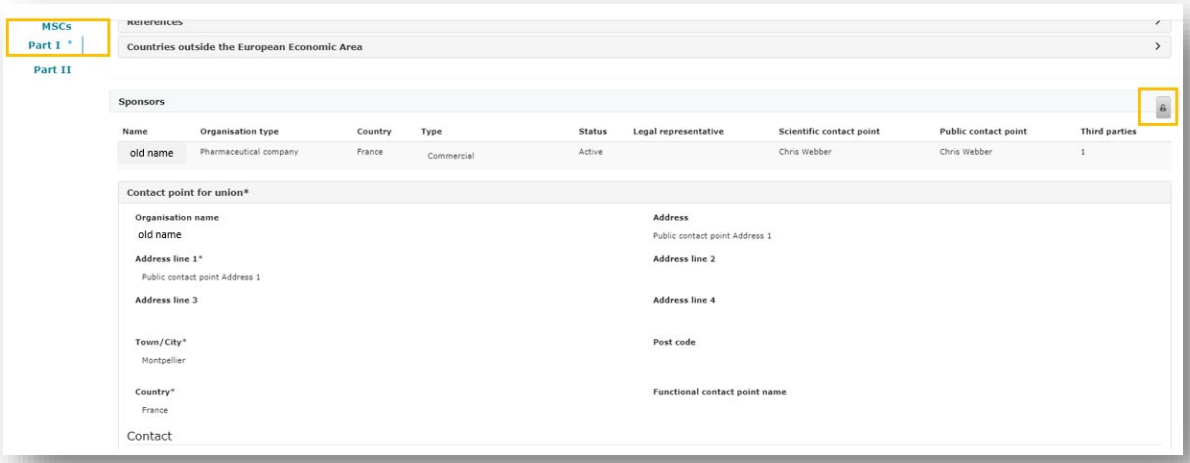
New CTIS feature: Updating sponsor information via a Non-Substantial Modification

A new feature now allows sponsor users to update the details of the sponsor of their trial.

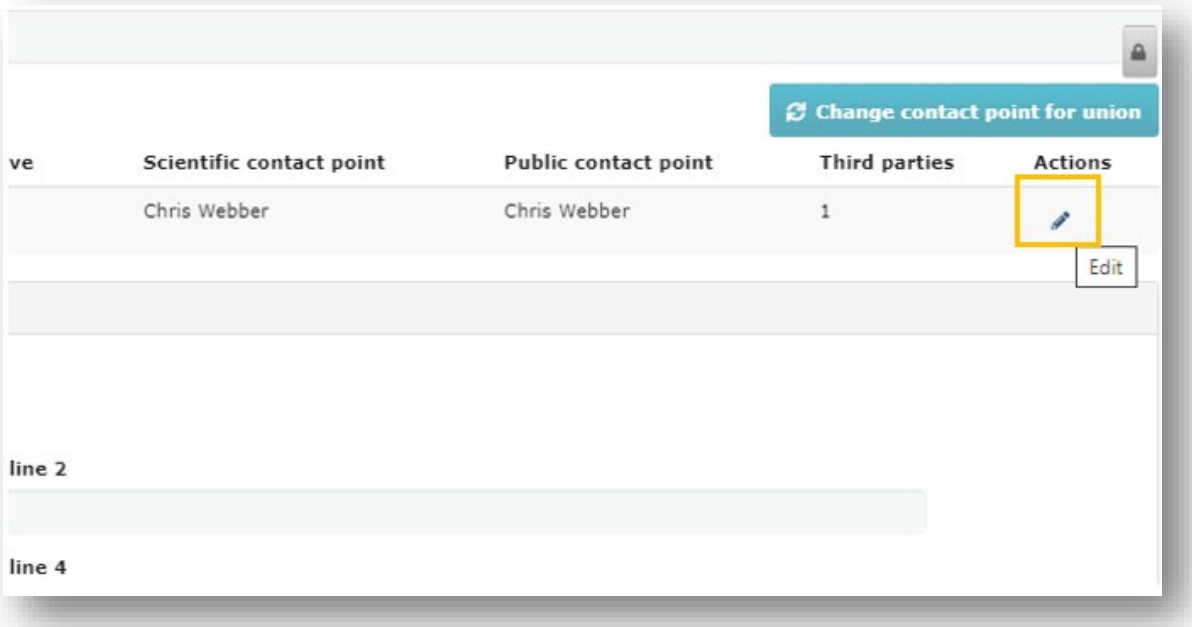
Users can submit a non-Substantial Modification (non-SM) to update the sponsor details recorded on an application form, such as the sponsor's name (without change of the legal entity), contact details, or address; see column 81.9NSM in Annex IV of the Q&A document on CTR.

Before recording the changes in CTIS, sponsor users need to update the OMS data. Users should submit a change request to update the organisation details in OMS (see document E - OMS Change Requests in OMS document repository), wait until their change request is validated and approved by the OMS team, and then apply the changes in CTIS by following the instructions below.

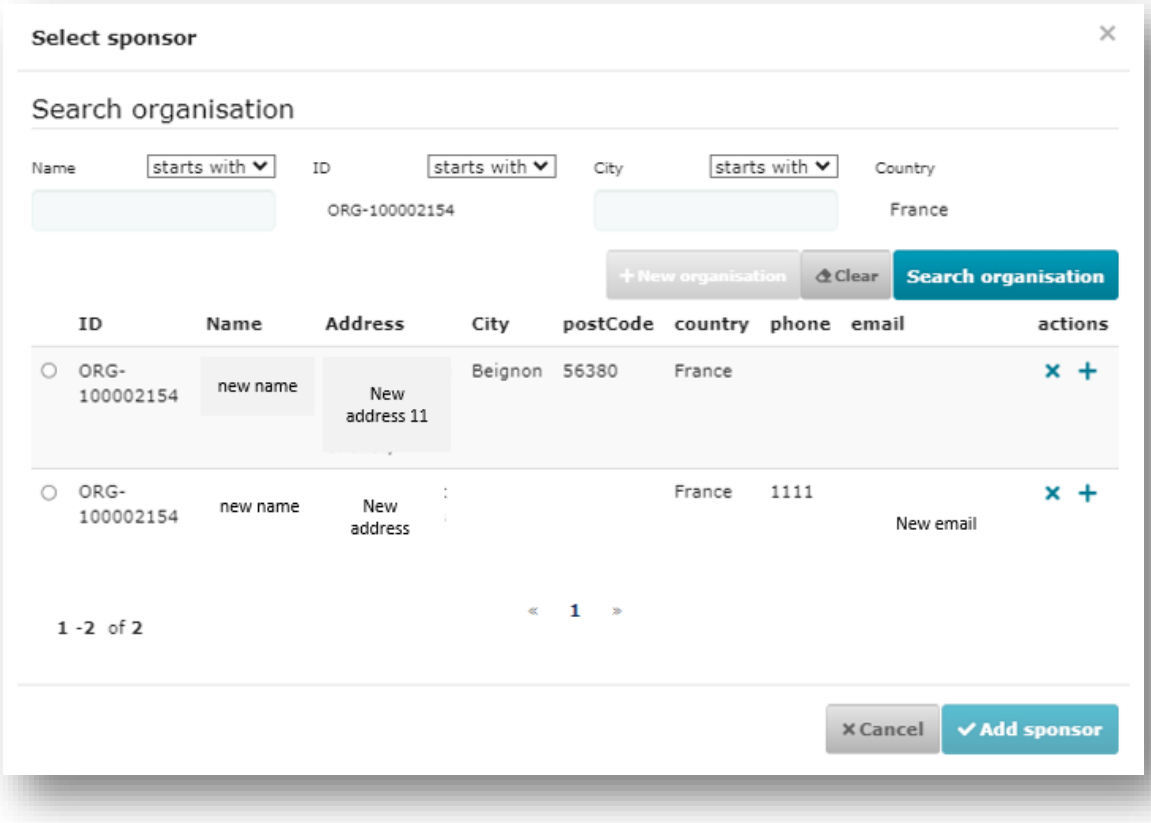
Sponsor details are captured in Part I; therefore, sponsor users need to submit a non-SM that affects Part I (Part I only or Part I & II). After creating the non-SM draft (Module 10), users can click on the Part I page and use the padlock of the 'Sponsors' section to edit the previously recorded details.



After selecting the padlock, users should see an edit button (right side).



After selecting the edit button, a pop-up window appears which allows users to search for organisations. The fields 'organisation ID' and 'country' are already populated and cannot be edited; changes to these fields imply a change of legal entity. Users can use the non-mandatory fields 'Name' or 'City' to search for the organisation. If the OMS change request has been approved, the new entry with the updated sponsor details will appear in the search results.



Users need to select the correct result (using the radio button on the left), to activate the 'Add sponsor button'. After clicking the 'Add sponsor' button, the updated sponsor details will overwrite the obsolete ones. Users may save the draft and submit it.

After the change of the sponsor details on CTIS, any new application, Annual Assessment Report (ASR), Ad hoc assessment or Inspection that is created will reflect the updated sponsor details. Previous applications (or ASRs or Ad-hoc assessments) submitted before the change of sponsor information in CTIS will keep the previous sponsor details and will not be impacted by the change.

Training materials are being updated to provide more information on this new feature. Users will be notified of the publication of revised training materials via the regular communication channels, including this newsflash.

Requesting access to the CTIS Training Environment

Sponsors can express their interest in gaining access to the CTIS Training Environment by filling in the ongoing survey. The training environment is a simulation of CTIS used in production and allows users to get familiar with system functionalities.

More information

Are you a sponsor user starting out with CTIS? Please consult the 'Sponsor quick guide: Getting started with CTIS' or refer to the CTIS training material, including the latest version of the 'CTIS Handbook for clinical trial sponsors'. The handbook provides useful information on how sponsors can navigate CTIS to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation (EU) No 536/2014.

Information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users.

Resources to support sponsors transitioning trials from the Clinical Trials Directive (CTD) to the CTR are available on the CTIS website.