

CTIS HIGHLIGHTS

News, views and interviews for the Clinical Trials Information System (CTIS)

An agency of the European Union



Welcome to CTIS



Pieter Vankeerberghen, Programme Manager for delivery of the Clinical Trials Information System (CTIS) and Head of Clinical Trials Workstream at the European Medicines Agency

"The Clinical Trials Information System (CTIS) is a corner stone of the Clinical Trials Regulation (EU) No 536/2014. It provides a paperless and integrated system which covers the full life cycle of a clinical trial application, from initial submission to authorisation, conduct, corrective measures, inspection information, and publication of relevant documents for the general public as well as substantial modifications over time. CTIS will achieve all of this for the sponsor and the Member States through one collaborative, consistent approach and technology. The harmonised submission procedure (single submission) will improve information-sharing between NCAs and Ethics Committees and will bring time and cost savings to sponsors by removing the need for country-specific submission. An increased transparency of CT information, improved research & development and facilitated access to clinical trials data, as well as enhanced patient safety, will be achieved in Europe with this new way of working. All users of CTIS will benefit from the integration of the different modules of the system in terms of efficiency and increased data quality".

CTIS Benefits

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The adoption of the Clinical Trials Regulation (EC) 536/2014 has laid down the basis for the development of the Clinical Trials Information System, facilitating an increased public availability of trial data in a central European repository and implementing the Regulation's transparency rules.

The picture below shows the main key benefits of the Clinical Trials Information System (CTIS) that includes:

Digitalisation and improved efficiency by:

- * Being the single EU entry point for clinical trial application submissions for sponsors (e-dossier);
- * Harmonising and simplifying the end-to-end application process over the life-cycle of clinical trials;
- * Coordinating the evaluation and supervision of clinical trials for Member States;
- * Being the electronic exchange of information between sponsors and Member States and being digital secured archive of

documents, decisions and information on clinical trials.

Increased transparency by:

- * Offering searchable clinical trial information to the patient, healthcare professional and the general public;
- * Sharing results available in lay language and accessing clinical trial or investigational medicinal products information across trials.

Enhanced patient safety providing:

- * End-to-end electronic solution for safety reporting of trials;
- * Harmonised assessment in Europe, accessing electronic reporting of SUSARs by Sponsors and re-routing to Member States, providing one single decision.

Support innovation and research by:

- * Being a unique intuitive tool facilitating submission of clinical trial applications;
- * Offering structured data to allow efficient reporting for scientists;
- * Enhancing recruitment rates without resubmission/reassessment of the clinical trial application.

*Digitalisation
& Improved
Efficiency*

*Increased
Transparency*

*Enhanced
Patient
Safety*

*Support to
Innovation &
Research*

CTIS features—User Administrator & roles

CTIS is a role-based system where users can perform actions depending on the roles assigned to them. Before accessing CTIS for the first time, users will first need to self-register via EMA Account Management Portal to obtain user credentials. This is regardless of whether their organisation represents a Member State or a Sponsor. Once users have an EMA account, they will be able to log directly into CTIS as of Go-Live.

The initial role received by the user in CTIS, once the user has an EMA Account, is a default role which enables users to access the system and perform a limited number of actions. To perform additional actions, users need to be assigned to specific CTIS roles by the user administrator.

The **role classification** below applies to Member State and Sponsor users:

⇒ **High-level administrators (Sponsor, Member State, European Commission Administrators):** these roles are assigned outside of CTIS, except the MAH (Marketing Authorisation Holder) Administrator, and must be validated/approved by EMA following the submission of specific documentation. These roles can manage all users within their own organisation or Member State, as applicable and are purely administrators, so-called *Organisation Administrators*. They cannot perform any business activity in the system unless they assign a business role to themselves.

⇒ **Medium-level administrators:** These roles are assigned within CTIS and they can assign different roles to as many users as needed within their organisation:

- * *CT Administrator (Sponsor only)*– Besides the assignment of roles to other users, the CT Administrator can also perform all sponsor business activities in CTIS. The role has permission to assign, amend, or revoke roles/CT access for other users;
- * *National Organisation Administrator (Member State only)* – This role operates as the administrator of a Member State organisation.

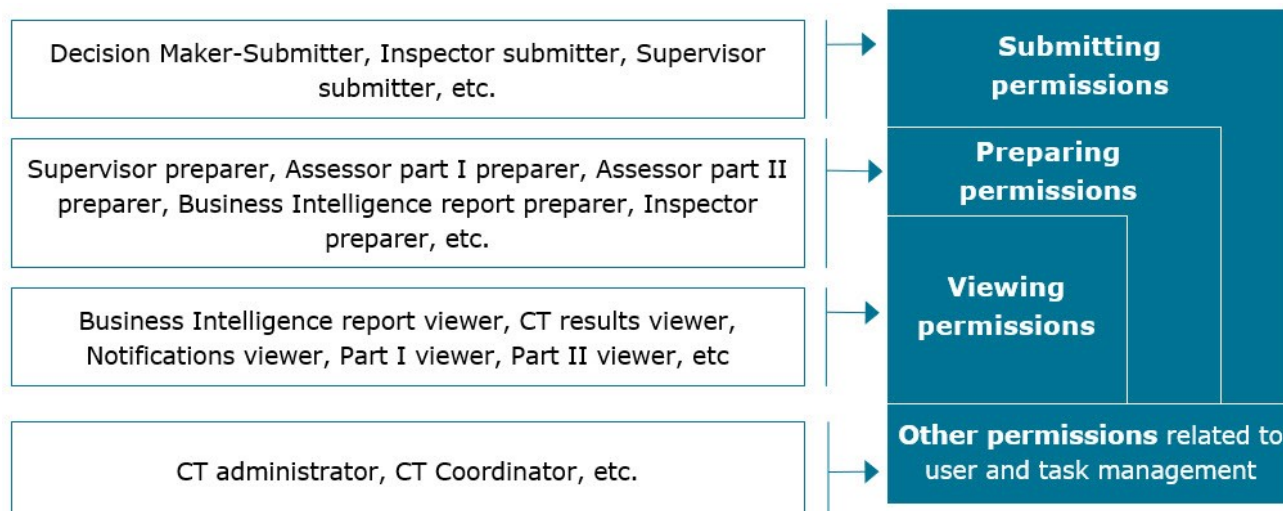
⇒ **Business roles:** These roles reflect the responsibilities and permissions of users during the lifecycle of a clinical trial. These are assigned by an administrator and have specific permissions (view, prepare, submit). They can be classified into two sub-types:

- * *CT coordinator role (Member State only):* This role is only available in the authority workspace and is responsible for the administration of tasks (view, assign or release tasks to/from users);
- * *Other business roles:* These are Member State and Sponsor roles with specific permissions (view, prepare, submit) related to their activities in the system (e.g. Part I preparer, Assessor Part I submitter etc).

More information will follow about the registration process, timing and about Member State/Sponsor business roles in a forthcoming CTIS Highlights Newsletter and in the Training

Snapshot below shows the business roles and their related permissions.

Image 2



On 21 September 2020 EMA organised a **CTIS webinar including presentations on user management and roles, clinical trial application process and also a demo of the Sponsor workspace.**

A recording of the webinar is available [here](#) under the section "External links".

Interaction Member States - Sponsors

The sponsor user community interacting with CTIS will include commercial sponsors, SMEs as well as non-commercial Sponsors including academic ones.

Except for the general public, all users will access the CTIS functionalities via the two restricted dedicated workspaces: the Sponsor workspace and the Authority workspace. CTIS provides harmonised and simplified end-to-end electronic application procedures over the life-cycle of clinical trials across the EU.

The interaction between Member States and Sponsors during the submission and management of a clinical trial application is shown on image 3 below right.

Sponsors can:

- * submit an initial application;
- * submit substantial and non-substantial modifications;
- * add a new Member State to an existing clinical trial application via the system;
- * propose a Member State Concerned who will be the key authority responsible for the assessment and approval of the CT application.

Member States will be able to:

- * agree on Reporting Member State (RMS) for a multinational trial;
- * validate and assess clinical trial applications;
- * request additional information from Sponsors;
- * issue a decision on a clinical trial application;
- * supervise the conduct of the clinical trials.

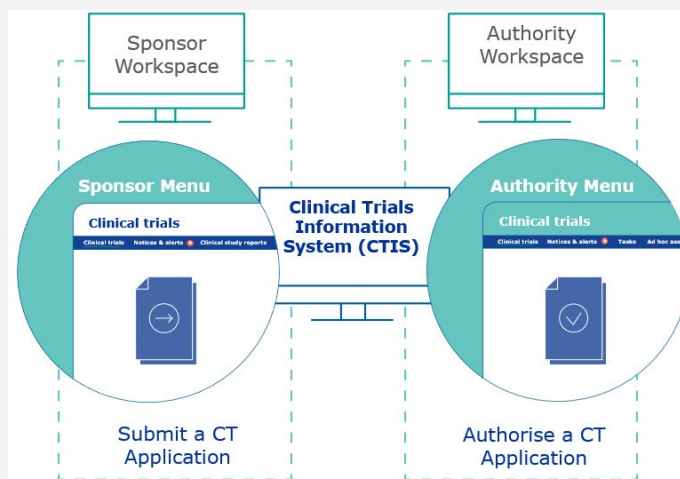


Image 3

The Sponsors and Authority Workspaces have different functionalities to enable and support the respective responsibilities, however there is a set of functionalities common between the workspaces and related to notices and alerts and user administration.

Contributions from Academia/SMEs & National Competent Authorities

Stéphanie Kromar, European Organisation for Research and Treatment of Cancer (EORTC) CTIS product owner representing non-commercial sponsors

"In view of the upcoming CTR and in order to continue its mission, the European Organisation for Research and Treatment of Cancer (EORTC) will have to adapt. In this regard, a cross-department working group was put in place in order to:

- identify the impacts induced by the implementation of the CTR;
- decide and implement all the adaptations needed on our workflows, processes, work instructions and standard operating procedures;
- assess the resources needed for implementing the CTR.

Moreover, EORTC has been involved in the CTIS development since the first User Acceptance Testing and is now part of the new CTIS delivery model. We believe that although there is still time, the changes that the CTR will bring, need an in-depth assessment in order to ensure being ready once it enters into force."

Maria Elgaard Sørensen, Special Adviser and Project Manager at DKMA (Danish Medicines Agency)

"In Denmark a national law describes the future roles and responsibilities in the collaboration between the Danish Medicines Agency and the Medicinal Research Ethic Committees. Although the authorities remain independent, a much closer collaboration is warranted in the future and a mutual process has been agreed upon. Both authorities will have access to CTIS and analysis are in progress on how to best support the MS interfaces within the CTIS. In addition, it is planned to integrate the respective national systems to CTIS to ensure adequate overview and timely contribution in accordance with the regulation."

Stefan Strasser, MD—Head of Clinical Trials, Institute Surveillance at the Austrian Medicines Agency

"The overall objective for the preparation for the CTR in Austria is to maintain the high standards for clinical studies and to actively participate as Reporting Member State (RMS) for multinational trials. The Austrian Agency and Austrian Ethics Committees together have adapted and finalised the necessary processes. A national IT project to connect to CTIS via Application Programming Interface (API) is ongoing in parallel with CTIS development. Drafts for the national law are ready to be implemented by the Ministry of Health next year (2021)."

CTIS Training focusing on online materials

The CTIS training programme is an important part of successful implementation of CTIS as it aims to facilitate user and organisation preparation for CTIS. The training strategy was revised in early 2020 with the aim to provide the CTIS users with the skills, capabilities and knowledge they need for a successful adoption of CTIS.

A strong online presence of training modules is foreseen for all user groups to ensure equal access for all. The production of training materials started in March 2020 and is progressing as planned. Quick guides, Frequently Asked Question sheets, e-learning materials, infographics and short videos will be gradually available as of January 2021.

The CTIS users will be able to follow the online training at their convenience and own pace and search materials to fulfil their training needs concerning specific CTIS functionalities when needed. (Image 4 below describes the variety of training materials available).

For Member States, a network of Master Trainers has been formed in 2020 representing the National Competent Authorities and the Ethics Committees that will take responsibility for dissemination of training to Member State users.

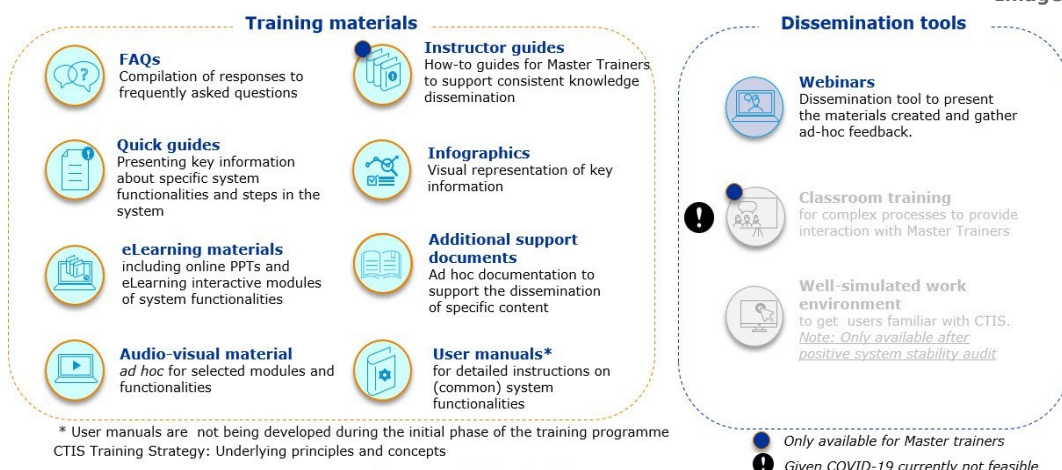
The training of MS Master Trainers has started in December 2020, in which material from the first introductory CTIS training modules will be presented. Member State Master Trainers will be disseminating this knowledge by organising training sessions within their organisations for the CTIS end-users.

As a complement to the online self-paced training materials that will be made available in 2021, considering the high volume of end-users representing commercial Sponsors, SMEs and non-commercial Sponsors, three main programme streams are envisaged for sponsor users:

- * The first stream is a sponsor Master Trainers concept similar to the train-the-trainer approach now in place for Member State users. This training aims to provide training in the functionalities of the system for all CTIS roles available for Sponsors. It is primarily intended for commercial Sponsors and Contract Research Organisations (CROs) that are likely to submit several clinical trial applications;
- * The second stream will disseminate knowledge to SMEs and non-commercial sponsors (e.g. academic sponsors) adjusted to their needs. This will be done through compact and simplified materials about key CTIS functionalities and dedicated training events.;
- * The third stream will cater for the end-users from all sponsor groups to provide training in their role-specific functionalities (e.g. administrator, preparer, submitter). This stream will be initiated closer to CTIS Go-live.

The snapshot below describes the variety of training materials available

Image 4



Save the dates!

- A dedicated information/training event for **SMEs and non-commercial Sponsors** will be organised in two parts on **22 February** and on **4 March 2021**. More information will be available on the [Events](#) page.
 - **The CTIS Training programme** foresees a series of training events targeted at Master Trainers representing primarily commercial Sponsors and that will be organised by DIA on behalf of EMA starting in Q2 2021.
- Detailed information on training events will be available on the [Events](#) page.

The Clinical Trials Regulation

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC



Audit

The application of Regulation (EU) No. 536/2014 ("Clinical Trials Regulation") is conditional on the conduct of an independent audit to verify that the EU portal and EU database (EUPD) have achieved full functionality and the systems meet the functional specifications, as required by Article 82, paragraph 2 of the [Clinical Trials Regulation](#).

The audit of the EUPD has the following key objectives:

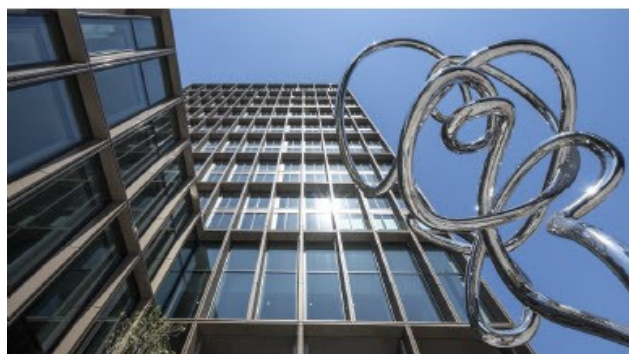
- * Confirm that the European Portal and Database (EUPD) meet the functional specifications agreed by the Member States and endorsed by the EMA Management Board and have achieved full functionality;
- * Report on the implementation of the functionalities agreed, which are subject to audit or not;
- * Report on the review of the Agency's project plan for the delivery of the go-live and post-go-live releases of the clinical trials EUPD.

The audit should furthermore include the Clinical Trial application programming interface (API) to allow Member States to interact with the Clinical Trials Information System (CTIS).

Highlights on activities that took place in Q4 2020:

The independent audit of the EU Portal and Database (EUPD) was initiated in September 2020, the first field work started on 18 November 2020 and ended on 8 December 2020 with the summary of preliminary findings expected in the 3rd week of December 2020.

- ⇒ If you want to give feedback on the CTIS Highlights Newsletter click [here](#)
- ⇒ If you want to subscribe/unsubscribe to the CTIS Highlights Newsletter write to this email: CT.Communication@ema.europa.eu
- ⇒ If you want to read the previous issue click [here](#)



CTIS current and future developments

The **Audit** version has been developed and the audit has started. Meanwhile, recent extended testing performed by experts and user representatives showed that thorough stabilization of the system is required to assure a smooth and timely Go-Live. This will be fixed alongside audit findings.

Go-Live is planned for **December 2021** and CTIS will be further developed to include:

- * The safety reporting module which will be fully combined with the CTIS components and other safety reporting features will be improved;
- * The sponsor workspace with enhanced functionalities;
- * Enhanced functionalities available for oversight, cooperation, supervision and visibility within and among Member States;
- * Improved users' navigation and experience.

After Go-Live more functionalities will be released such as:

- * The public register will be enhanced;
- * Reporting, cooperation, interoperability functionalities will be improved;
- * User experience features will be further strengthened.

In the next issue

- **CT application process and functionalities**
- **Sponsors' views on CTIS**
- **Audit outcome highlights**
- **Go-Live preparation**
- **Training programme update**

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