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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS HIGHLIGHTS

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

An agency of the European Union

Welcome to CTIS Highlights

The go-live of CTIS on 31 January 2022 is now less than two months away, and organisations throughout Europe and beyond are undergoing preparations for CTIS. Future users of CTIS are again reminded of the available training and support materials, including the recently updated CTIS Sponsor Handbook, the principles for sponsor organisation modelling and personas documents, and the online modular training programme. The EMA CTIS team continues to work in collaboration with the European Commission, Member States and sponsors to ensure a smooth launch of CTIS. We wish all our readers a very happy holiday period and look forward to more engagement with the CTIS user community to close out 2021 and in the new year.

- **The CTIS team (pictured on the last page)**

INSIDE THIS ISSUE

Reminder for sponsors: register your organisation and administrator!

Users are reminded that certain preparatory steps must be taken before it is possible to use CTIS.

Sponsor organisations opting for the organisation-centric approach that are not yet registered in EMA's Organisation Management System (OMS) must do so before using CTIS.

Registration in OMS can be done by visiting the OMS webpage of the Substances, Products, Organisations and Referentials (SPOR) portal. An EMA account with a SPOR user role is required in order to register an organisation in OMS. Training materials for OMS can be found on the OMS webpage on the EMA website. It is recommended to register in OMS as early as possible. Sponsors can consult the Help section of the SPOR portal for details on guidance and support for OMS.

Once registered in OMS, sponsor organisations opting for the organisation-centric approach must register their first high-level administrator, the Sponsor Administrator, via EMA Account Management prior to using CTIS. More information on registration can be found on the EMA Account Management home page.

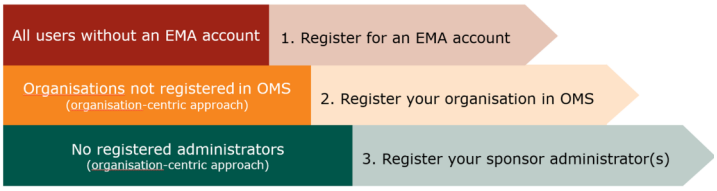

Image 1. Sponsor preparatory steps before using CTIS

Clinical trial site registration in OMS

Clinical trial sites that routinely participate in clinical trials are advised to register in OMS to facilitate the submission of clinical trial applications. Registration in OMS is less relevant for those sites that participate in clinical trials only once or very infrequently.

Registration in OMS can be done by visiting the OMS webpage.

XEVMPD guidance on registration of IMPs

EMA has published new guidance on how to register investigational medicinal products (IMPs) in the Extended EudraVigilance medicinal product dictionary (XEVMPD) for clinical trial sponsors. The IMP must be registered in XEVMPD before clinical trial sponsors can complete a clinical trial application in CTIS.

A new webpage has been created to outline the steps needed to register an IMP in XEVMPD, including detailed guidance documents.

Training material update

20 CTIS training modules are now available for use on the CTIS online modular training programme page. More modules are currently under development, including an introduction to CTIS for public users, and the management of Union Controls by the European Commission. A module on transition of clinical trials from Directive to Regulation is also foreseen.

In addition, existing online training modules are undergoing revision. The revision will include the creation of new materials to describe specific processes in further detail and the update of existing materials to match current system functionalities. In early 2022, new content will be available for sponsors on how to populate authorised and unauthorised products in clinical trial applications as part of Module 10 (Create, submit and withdraw a clinical trial).

More detailed content will also be made available on how to submit notifications as part of Module 5 (Manage a clinical trial through CTIS). More detail will be available for authorities on how to evaluate substantial modifications and additional Member State Concerned (MSC) applications.

The content, when published, will be available here.

Image 2.
CTIS online training material

Confirmation of simplified reporting of SUSARs

The European Commission Expert Group on Clinical Trials (CTEG) have announced that new arrangements for Suspected Unexpected Adverse Reactions (SUSAR) reporting will apply for all trials approved under the Clinical Trial Directive and the Clinical Trials Regulation from 31 January 2022, the same date that CTIS goes live.

Under the new arrangements sponsors will report SUSARs only to EudraVigilance, bringing the benefit of a single submission process and harmonised procedures to the area of SUSAR reporting. Member States will have the ability to set up SUSAR rerouting rules in EudraVigilance if they wish to receive copies of SUSARs for their national systems.

CTIS events 2021 and 2022

On 26th October 2021, EMA hosted a CTIS virtual information day on how users can prepare for CTIS with the support of DIA. The presentations from the information day and a video recording of the event can be found on the EMA event page.

On 29th November, EMA hosted a training webinar for SMEs and academia on key aspects of the Clinical Trials Regulation and CTIS. A video recording of the event will be made available on the EMA event page in due course.

In 2022, EMA plans to host regular 'CTIS Talks'. The CTIS Talks will include a short presentation about a key CTIS functionality area, e.g. user management, initial applications, modifications, and will also provide an opportunity for users to ask questions about this functionality area to CTIS experts. Details of the CTIS Talks will be provided on the EMA events listing in due course and in forthcoming issues of this newsletter.

CTIS Training environment update

As communicated in the October CTIS Highlights, a CTIS training environment ("CTIS Sandbox") has been made available progressively to different groups of future CTIS users starting from 15 October 2021.

In the last newsletter, a survey was made available for sponsors to provide self-assessment and express interest in accessing the training environment. Respondents will be contacted directly by EMA in December 2021.

The survey may reopen in the new year.

Sponsor end user training

EMA, with support from DIA, are planning a limited number of sponsor end user training courses starting 2022.

The programme will be focussed on explaining and demonstrating CTIS functionalities related to the use of CTIS by sponsors. More information will be published on EMA and DIA websites shortly.

CTIS Sponsor Handbook version 2

A new version of the CTIS Sponsor Handbook has been published on the EMA website.

Key changes include updates to the sections on the OMS registration process, product management in CTIS, the transition from the Clinical Trials Directive to the Clinical Trials Regulation and SUSAR reporting, and the addition of new sections on data fields and document specifications and the training environment.

Happy holidays from the CTIS team!

Pictured below: EMA staff, contractors and external experts of the CTIS governance groups working towards CTIS go-live, wishing season's greetings to all CTIS Highlights readers.

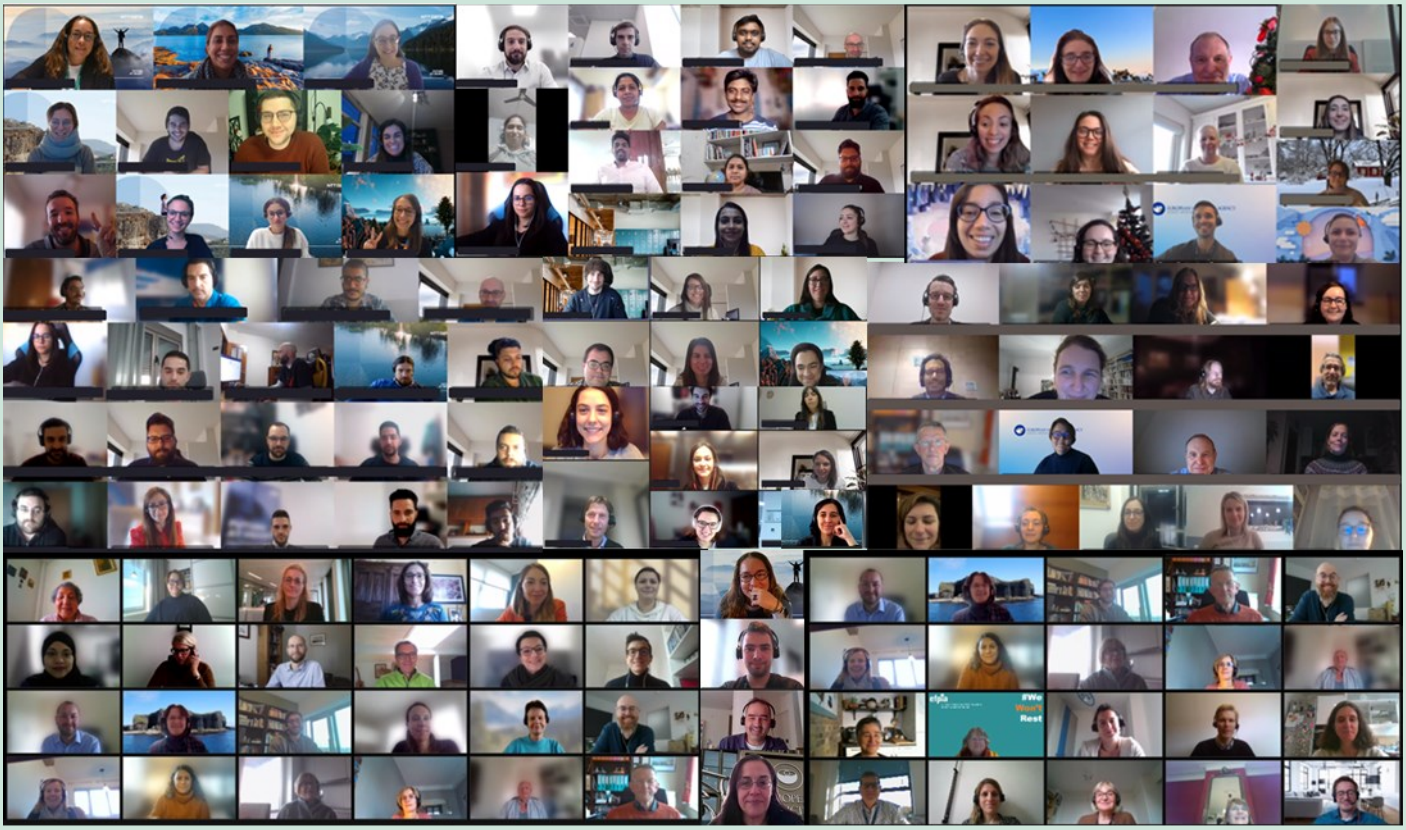

Image 3.
EMA staff, contractors and external expert members of CTIS governance groups working towards CTIS go-live

Read previous issues of CTIS Highlights

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