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EUROPEAN MEDICINES AGENCY
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Clinical Trials HIGHLIGHTS

News, views and interviews for European Clinical Trials

An agency of the European Union

Welcome to Clinical Trials Highlights

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Welcome to the first Clinical Trials Highlights. With this edition, the CTIS Highlights has become the Clinical Trials Highlights. CTIS will continue to be covered in this newsletter alongside new topics, such as the business change programme Accelerating Clinical Trials in the European Union (ACT EU).

ACT EU was launched on 13 January 2022 by the European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA). ACT EU aims to transform how clinical trials are initiated, designed and run in the EU. The ACT EU strategy paper lists ten priority actions for 2022/2023, including enabling innovative trial methods, establishing a multi-stakeholder platform, and supporting the modernisation of good clinical practice.

ACT EU and its Steering Group will work in close collaboration with the newly established Clinical Trials Coordination Group (CTCG) to further develop the EU as a focal point for clinical research, to further promote the development of high quality, safe and effective medicines, and to better integrate clinical research in the European health system.

We hope you enjoy the Clinical Trials Highlights.

INSIDE THIS ISSUE

Clinical trials governance update

The governance of clinical trials at the European level has undergone recent developments with the establishment of the Clinical Trials Advisory Group (CTAG) the Clinical Trials Coordination Group (CTCG) and the ACT EU Steering Group.

The Clinical Trials Advisory Group (CTAG)

CTAG is established by Article 85 of the Clinical Trials Regulation (CTR). It is chaired by the European Commission (EC) and its members are the CTR National Contact Points (one representative per Member State). CTCG and EMA have observer status in CTAG.

The purpose of CTAG is to:

- support the exchange of information on the experience acquired with regard to the implementation of the CTR
- assist the EC in the preparation of delegated acts
- assist the EC in providing support on coordinated safety assessment
- prepare recommendations on criteria regarding the selection of a reporting Member State (RMS)

CTAG meets on a regular basis and ad-hoc when necessary.

Meeting agenda and minutes are publicly available here.

Clinical trials governance update (contd.)

The Clinical Trials Coordination Group (CTCG)

The CTCG is an HMA working group of experts from national agencies on the classification, assessment and oversight of clinical trials.

The objective of CTCG is to contribute to increasing the attractiveness of the EU/EEA for clinical trials by harmonisation and optimisation of the regulatory environment while assuring the protection of rights, safety and wellbeing of the subjects and the generation of robust data.

An increase in clinical trials in the EU/EEA is ultimately to the benefit of patients. It means receiving high quality treatment and having early access to new and innovative treatments, sometimes years before their introduction to the market.

EU/EEA trial sites are increasingly part of global multi-regional clinical trials. It is important to ensure EU/EEA remains an attractive partner in multinational projects. This implies the need for interaction with all relevant stakeholders involved in clinical trials regulation and conduct.

Early clinical trials are the first contact of regulators with innovation. CTCG will monitor these trends and evolutions in clinical trials and will develop and publish guidance documents at the HMA/CTCG website.

The ACT EU Steering Group

The ACT EU Steering Group is mandated by the EC, HMA and EMA and will oversee the clinical trials business transformation actions agreed for ACT EU. It will also take over the tasks formerly conducted by the EU CTR Coordination Group including oversight of the CTR and CTIS.

It is chaired by Andrzej Rys, Director for health systems, medical products and innovation at the European Commission and includes members appointed by the HMA, EC, EMA, the Network Portfolio Advisory Group (NPAG) and CTCG.

The mandate of the ACT EU Steering Group is to:

- Oversee programme management to achieve the ACT EU objectives and priority actions.
- Coordinate the governance of clinical trials at the EU level.
- Monitor the activities and deliverables from the different ACT EU workstreams against the ACT EU objectives.
- Identify and make recommendations on critical issues related to the broad environment of clinical research.
- Oversee the CTIS project.

The ACT EU Steering Group has a decision-making role and reports to the EMA Management Board and HMA.

Clinical Trials Regulation & CTIS go-live communications

The European Commission, EMA and the Heads of Medicines Agencies (HMA) communicated widely to various audiences in support of the entry into application of the Clinical Trials Regulation and the go-live of CTIS. The communications included a press release and press briefing, a statement by European Commissioner for Health and Food Safety Stella Kyriakides, an update of the Clinical Trials Regulation and CTIS pages on the EMA website, the launch of the Clinical Trials website, and the publication of the CTR/CTIS promotional video and a sponsor infographic. These communication materials were supported by a social media campaign (see European Commission and EMA's tweets here and LinkedIn posts here, and join the conversation with #EUClinicalTrials).

Image 1.
Snapshot from the infographic "Key Information for Sponsors on CTIS"

Following the go-live of CTIS, EMA continues to communicate regularly via the CTIS newsflash, which provides updates on key facts and figures regarding CTIS usage, as well as links to useful reference materials. Interested parties can sign up to the CTIS newsflash and the Clinical Trials newsletter by e-mailing CT.NewsletterSubscriptions@ema.europa.eu.

CTIS 20 January 2022 demonstration video recording

A CTIS demonstration was held on 20 January 2022 for stakeholders involved in the CTIS project. The demonstration, attended by over 1800 participants, aimed to showcase system functionalities by walking the audience through the workflow of a typical clinical trial in CTIS. The presentations used during the event as well as video recordings of the event are now available to all on the EMA website.

EMA plans to hold further system demonstrations to showcase new CTIS functionalities on a regular basis, starting in the second half of 2022. Information on future system demonstrations will be shared in subsequent editions of the Clinical Trials Newsletter.

CTIS events for clinical trial sponsors

EMA provides events for clinical trial sponsors to ensure they understand and receive practical guidance on CTIS.

The CTIS sponsor end user programme will run monthly until June 2022. The January, February and March course have been completed and positive feedback has been received. Places are available in the April, May and June courses.

The CTIS bitesize talks will run on a monthly basis in the first half of 2022 and allow sponsors to learn about a dedicated CTIS functionality through a short presentation and demonstration, while also providing time to ask practical questions. The first CTIS bitesize talk in February had over 900 attendees and answered various audience questions about user access and role management. A further CTIS bitesize talk was held on 23 March and covered the initial clinical trial application. And the next event is planned for 28 April.

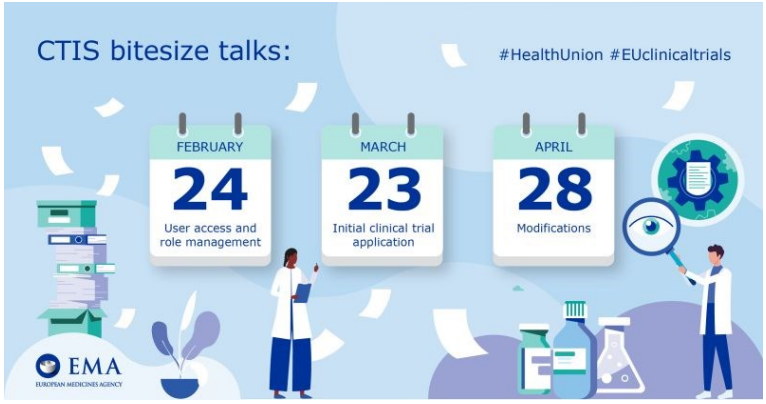

Image 3.
CTIS bitesize talks offer the opportunity to ask questions live to experts.

Additionally, the CTIS walk-in clinics are a new series of events launched on 28 March. The walk-in clinics provide users with the opportunity to ask questions on any aspect of CTIS functionality and use and to receive an answer from CTIS experts. The clinics provide an opportunity to learn from the questions raised by other users. EMA plans to host two walk-in clinics a month, with the next events planned for 4 April and 22 April.

CTIS Training environment ('CTIS Sandbox') update

Access to the CTIS training environment (CTIS Sandbox) has been provided to clinical trial sponsors who expressed interest in a survey (Survey 1.0) conducted in October 2021. Access was provided to those organisations that had expressed their intention to submit clinical trial applications in the first quarter of 2022.

Sponsors who did not respond to Survey 1.0 can express interest in Survey 2.0, which includes a self-assessment of need and urgency for access to the CTIS training environment. Survey 2.0 closes on 31 March 2022. Sponsors who have already participated in Survey 1.0 do not need to participate in Survey 2.0 unless their clinical trial submission plans have changed.

Sponsors are reminded that currently no decision has been taken on whether additional access to the CTIS training environment will be granted and the survey responses will help inform that decision.

IT systems for the Safety Implementing Regulation

The Commission Implementing Regulation (EU) 2022/20 on the cooperation of Member States in the safety assessment of clinical trials sets up rules and procedures for harmonised safety assessments, as foreseen by the CTR.

The Implementing Regulation supports the aims of the CTR of protecting the safety and wellbeing of clinical trial participants and future patients, while ensuring that clinical trials data are reliable and robust. The Implementing Regulation entered into application on 31st January 2022, the same day as the entry into application of the CTR.

EMA, the European Commission and the Member States delivered three key IT tools to facilitate the application of the Implementing Regulation, which are now in use by Member States:

1. A **dedicated Clinical Trials monitoring dashboard for Member States** to support the screening of Suspected Unexpected Adverse Reactions (SUSARs) submitted to EudraVigilance.
2. A **document repository** for Member States to record information such as the safety assessing Member States (saMS) and SUSAR assessment reports.
3. A system **to facilitate Member State communication** for the selection of the saMS.

Protection of personal data and Commercially Confidential Information (CCI) in CTIS

To assist sponsors and authority CTIS users in fulfilling the transparency requirements set out in the CTR, EMA is preparing ~~a~~ dedicated guidance on the protection of personal data and CCI. EMA plans to publish a draft of the guidance for consultation in Q2 2022 to allow for wider stakeholder input and to account for experience gained in working with CTIS. A stakeholder workshop is being planned to coincide with the public consultation and further practical details will be made public once a date and outline agenda are agreed.

New External Organisation Administrator role in EMA Account Management

In 2022, updates will be made to EMA Account Management to allow for a new, streamlined way for organisations to manage their administrators for different EMA systems and business applications.

The update will introduce the role of External Organisation Administrator in EMA Account Management. This Administrator, once validated by EMA, can approve or reject requests to become an administrator for EMA-run systems for their organisation. For example, the External Organisation Administrator could approve requests to become a CTIS Sponsor Administrator from other users. The new process has the potential to reduce the number of administrators that need to be validated by EMA with a proof of affiliation letter, speeding up the process of administrator approval while ensuring organisations retain control over requests for administrator roles in EMA Account Management.

The new process is optional, and organisations can continue using the existing process, in which EMA assesses and approves requests for high-level administrators for EMA-run systems via the submission of an affiliation letter in EMA Account Management, if preferred.

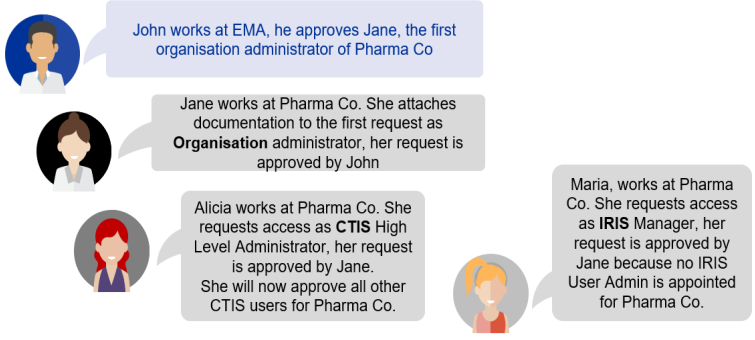

Image 3. Example of functioning of the External Organisation Administrator role