CTIS newsflash – 9 June 2023

Introduction

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

The next issue will be circulated on 23 June 2023.

Save the date: CTIS events in June

On 14 June 2023, EMA with the support of national competent authority representatives is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST. Participants are able to submit their questions in advance starting 1 June or during the event via Slido with the event code #clinic236.

On 21 June 2023, a CTIS Bitesize talk is planned at 15:30-17:00 CEST. The talk will focus on transitional trials and the event will be supported by national competent authority and ethics committee representatives.
Participants will be able to submit their questions in advance between 1-14 June or during the event via Slido with the event code #bt21jun.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support.

Spotlight: Can a Sponsor Administrator create a CTA?

The Sponsor Administrator role has only permissions to manage users' access (e.g. assign/amend/revoke roles or approve role requests). This role needs to be combined with the CT Admin role for the creation of initial CTAs or, for the creation of subsequent CTAs (e.g. SM, AMS and NSM), with the CT Admin or Application submitter role. More information is available in Module 7 of the CTIS online modular training programme on "Management of registered users and role matrix" and specifically in the Sponsors Business Processes and Roles (slides 8, 35-41)and role matrix for sponsors.

Key updates

- Dates for the Extended EudraVigilance medicinal product dictionary (XEVMPD) sponsor training courses in Q4 2023 are now available on the XEVMPD Training webpage.
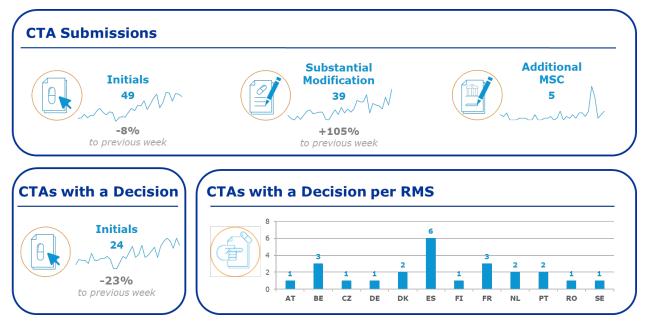
- The draft ICH E6 (R3) scientific guideline on good clinical practice has been published for open consultation. The guideline aims to provide a unified standard to facilitate the mutual acceptance of clinical trial data for ICH member countries and regions by applicable regulatory authorities. Stakeholders are invited to submit their comments by 26 September 2023.

  A fully virtual multi-stakeholder workshop on ICH E6 R3 public consultation is being organised by ACT EU Priority Action 4 (PA4) on 13 – 14 Jul 2023.

- Following the end of the public consultation period on the ICH M11 scientific guideline in the EU, an overview of comments received has been published. The purpose of this draft ICH guideline is to introduce a clinical protocol template and a technical specification to ensure that protocols are prepared in a consistent fashion and enable an harmonised data exchange format acceptable to the regulatory authorities. More information is available on the ICH website.

Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends compared to the previous week.
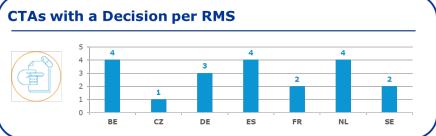
The data presented below refers to the period from 23 to 29 May 2023.

The data presented below refers to the period from 30 May to 5 June 2023.

CTA Submissions

Initials
70

+43%
to previous week

Substantial Modification
40

+3%
to previous week

Additional MSC
3

CTAs with a Decision

Initials
20

-17%
to previous week

CTAs with a Decision per RMS

	BE	CZ	DE	ES	FR	NL	SE
Value	4	1	3	4	2	4	2

System improvements

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

The dashboard below summarises the main improvement areas of focus for 2023 and improvements implemented.

Performance

- Resolve timeouts for large, complex trials
- Improve transaction inefficiencies through code improvements and enable asynchronous processing
- Transition to a high-availability infrastructure

- Lock removed in database enabling RFI submission
- Lock modified enabling submission of large initial clinical trial applications
- Improved processing of high demanding functionalities such as creating SM and resubmission of trial

Member State API

- Implement versioning to allow MS to adopt changes at their own pace
- Resolve current defects and resolve workarounds
- Improvements to add additional information

- Correct setting of notifications for Next Page, Last Page and total items attributes
- Enabling multiple MS APIs to coexist allowing Member States to adopt changes at their own pace
- Correct sorting of notifications

Public Portal

- Public Portal Refactoring Assessment
- Resolve known problems with the deferral functionality
- Schedule publication of trials with deferrals

- Public consultation on CTIS Transparency rules launched

Information Security

- Implement a 24/7 security monitoring of CTIS through EMA's Security Operations Center
- Develop plans for the implementation of multi-factor authentication

- Multifactor authentication implemented

Backlog

- Implement remaining 2 disaster recovery scenarios
- Reducing Data fixes required for users to progress with applications

- 3 out of 5 disaster recovery scenarios implemented
- Anatomical Therapeutic Chemical Search enabled
- Improved generic organisation search

Stakeholder requests

- Strengthening Service Desk operations
- Connectivity to WHO registry
- Improve download and sorting of documents
- Launch business intelligence for MS

- CTIS is a registered data provider for World Health Organization (WHO)
- Download of documents improved
- Enabling selection of 'Start recruitment' date prior to 'Start of trial' date in each MSC for multinational and transitional trials

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.

Reminders

- Resubscribe here to receive the Clinical Trials Highlights Newsletter. The next issue will be circulated in mid-July 2023 only to the resubscribers.

- CTIS is now a registered data provider for the World Health Organization (WHO). More information is available in the Introduction section of the CTIS website.

- Due to the planned migration of EMA applications to high availability data centres, users are advised to take note of below downtime windows which may impact their use of the system:

  - On Saturday 10 June 2023 from 08.00 to 12.00 CEST, the CTIS website (both the secure workspaces and public search portal) will be unavailable.

  - On Saturday 17 June 2023 from 08.00 to 12.00 CEST, the CTIS website and CTIS MS API will be unavailable.

  - On Saturday 24 June 2023 from 08.00 to 12.00 CEST, users will be unable to search and select authorised or not-authorised medicinal products, ACT codes or active substances in the CTIS website.

- A **public consultation on the CTIS transparency rules** has been launched on the [EMA website](). The review aims at simplification to improve user experience while also reducing the risk of data breaches and maintaining high levels of transparency. Stakeholders are invited to provide their comments **by 28 June 2023**.

- In addition to the public consultation, [an interim guidance document (and its annex)]() on the current transparency rules has also been published. The documents are intended for CTIS users and have been revised following the public consultation in 2022.

- 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.

- The revised [Questions and Answers document]() for the Clinical Trials Regulation (EU) No 536/2014, Version 6.4, published by the European Commission in [EudraLex Volume 10]() includes a dedicated item to provide guidance on how a third party other than the sponsor can submit an IMPD-Q-only application in CTIS.

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 new 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.

Annex: ServiceNow mobile app QR codes

QR code for Android :

QR code for iOS :