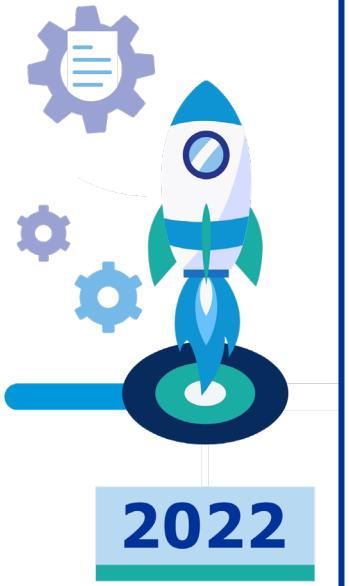
CTR implementation and ACT EU update

Industry Standing Group (ISG) meeting, 21 March 2023

Presented by Peter Arlett, Data Analytics and Methods Task Force.

1st year of CTR Implementation



- CTIS went live on 31 January 2022, kicking off the 1st year of transition of the Clinical Trials Regulation (CTR)
- A total of 552 initial clinical trial applications submitted and **201 clinical trials authorised** in CTIS in 2022 (31 January – 31 December)
- Intensive collaboration with Sponsors, MS to resolve challenges with a small number of trials
- Since 31 January 2023, **CTIS use mandatory for initial clinical trial applications**
- Over 190 initial CTs submitted since 31 January 2023: submissions increasing

CTR implementation survey follow-up actions

- Targeted consultation on the implementation of the Clinical Trials Regulation (EU) No 536/2014 - summary report (europa.eu)
- Solutions to the issues raised:
  - CTIS
  - Full implementation and enforcement of the CTR – monitoring through CTAG
  - Enhanced Member State coordination – assessors roundtable, ethics committee forum, best practices
  - Guidance: transition trials; Q&A on transparency
  - IMPD-Q when sponsor is not the same as the product owner: in EudraLex V 10 Q&A 2.5
- 2nd Survey for sponsors planned for **Q2 2023**

Recent Improvements in CTIS

- Process initiated for CTIS to become **WHO data provider**
- **Performance:** resolving database locks to enable small number of affected users to submit Requests for Information (RFI)
- **Backlog:** 3 out of 5 disaster recovery scenarios implemented; Anatomical Therapeutic Chemical Search enabled
- Improvements in **Member State API** (Application Programming Interface)

For more information, see Release Notes and Known Issues:
Website outages and system releases - EMA (euclinicaltrials.eu)

CTIS focus in 2023

2023 CTIS workplan focussed on:

- Enhancing the user experience by implementing improvement in most impactful functional areas of the system
- Future proofing and minimising risks to the technical core of CTIS

Multi-factor authentication (2FA) for CTIS from 1 June 2023

- **Multi-factor authentication (MFA) strategy for user logins in CTIS to be activated from 1 June 2023**, reinforcing security of user accounts
- Users will be asked to choose their preferred second factor method to verify their identity during log-in, via:
  - a token received in Microsoft Authenticator mobile app, or
  - an automated phone call or
  - a text to mobile phone, or a call to office phone
- To prepare, users should be equipped with a mobile phone, or an office phone that can be used for MFA
- Instructions on setting up the MFA for EMA systems are available here

Notices about MFA have been published in the EMA Clinical Trials Newsletter in July, October and December 2022, the CTIS Newsflash in March 2023, and communicated via email to CTIS Administrators in July 2022 and via stakeholder meetings incl. CTIS Forum in October 2022, ISG in December 2022

Reinforced transparency and stakeholder engagement

Regular Communications

- Weekly Newsflash to all users - link
- Clinical Trials Highlights Newsletter – link - *next in late-April 2023*

Regular Events

- CTIS Walk-in Clinics - link
- Bitesize talks - link
- Quarterly CTIS Forum with Stakeholders – *next on 25 April 2023*

Trainings & related materials

- Sponsor end user trainings – link - *next in May 2023*
- CTIS Training environment – survey link to request access
- Q&A on protection of personal data & CCI in CTIS – link
- Query Management Working Group Q&A on CTR and CTIS – link
- Step by step guide on registering organisations locally in CTIS - link

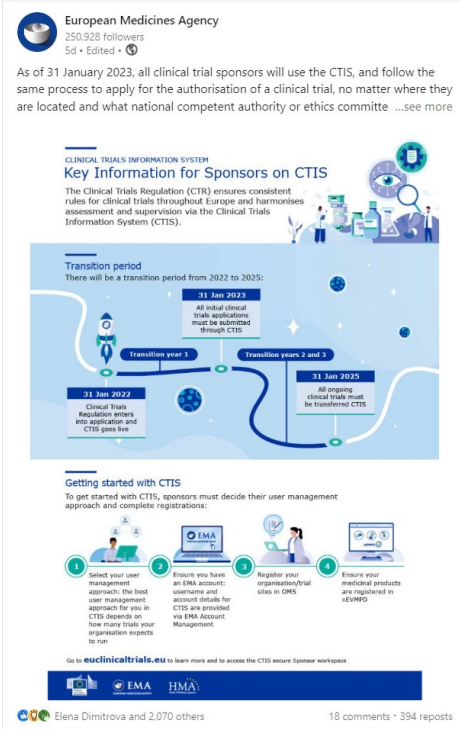
Impact of multi-lingual digital campaign to promote CTR/CTIS

- EMA ran an intensive campaign on Linkedin, a suitable platform for audiences interested in CTIS
- WGCP/Member States supported the campaign through further dissemination

Impact

The campaign had 2 components:

- organic (zero budget): 25 November 2022 - 31 January 2023 **>560,000 impressions** leading to almost **14,000 clicks**
- paid (paid ads campaign):
  - 19-30 December 2022 - **24 ads** leading to more than **410,000 impressions, 42,600 video views** and **2,633 clicks**
  - 9-31 January 2023 - **17 ads** that hit **more than 2,000,000 impressions, 285,000 video views** and **16,000 clicks**
- Increase of **10,000 unique visitors** to CTIS public portal since the start of the campaign (+60%)



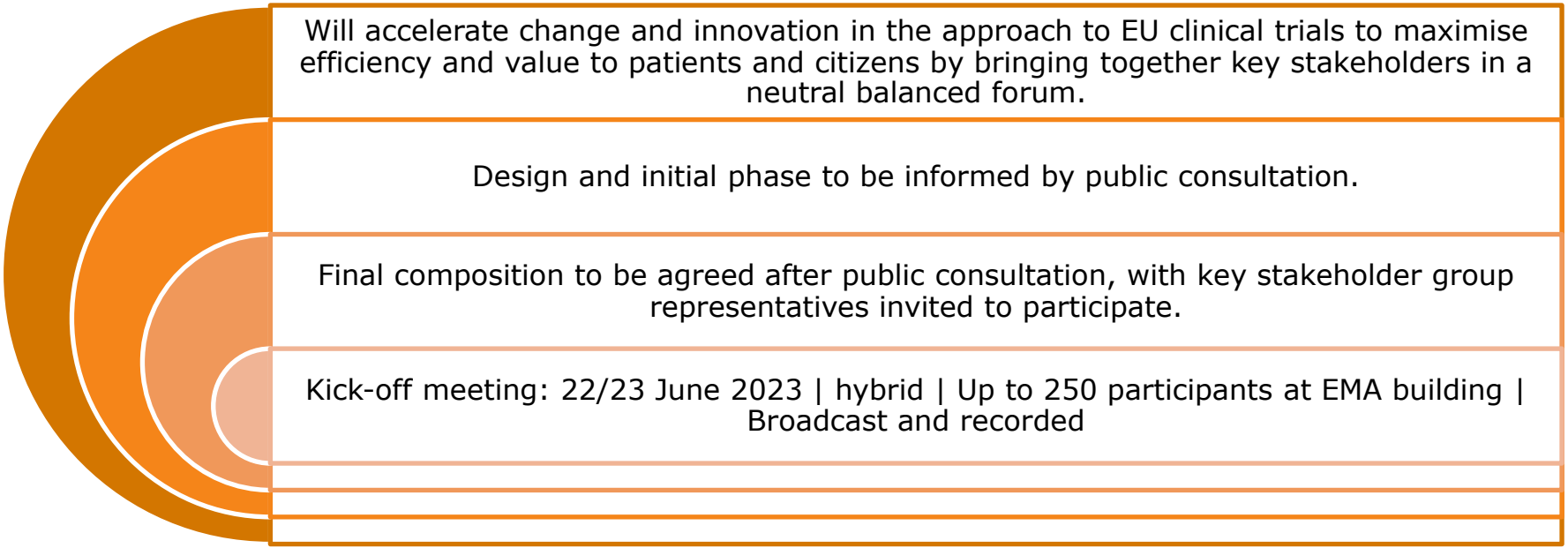
ACT EU 2023 focus

- Reinforced focus on successful **implementation of the Clinical Trials Regulation**, including use of Clinical Trials Information System (CTIS): change management including stakeholder engagement, surveys, training, communication
- Launch a scheme to **support academic sponsors** conducting large multi-national clinical trials
- **Creation of the Multi-stakeholder platform**
  - A sustainable platform that enables all stakeholders to collaborate for better clinical trials
  - Kick-off meeting: **Q2 2023**
- **Revise workplan** informed by learnings and Network needs and priorities (CTR)

ACT EU Stakeholder engagement

Priority action	Key activities
PA2 CTR implementation	• 2nd sponsor survey on CTR implementation Q3 2023
PA3 Multi-stakeholder platform	• Public consultation concluded 3 March 2023 • Kick-off meeting planned Q2 2023
PA4 GCP modernisation	• ICH E6 (R3) public consultation multi-stakeholder meeting: Q3 2023
PA5 Clinical trials data analytics	• Multi-stakeholder event to identify stakeholder research priorities on clinical trials data, and develop research agenda Q4 2023
PA8 Methodologies	• Multi-stakeholder event on clinical trial methodologies Q3 2023

Multi-stakeholder platform



Key messages

- CTR implementation progresses and closely monitored
- CTIS use is now mandatory for new CT applications and user experience much improved
- Over 190 initial CTs submitted since 31 January 2023: submissions increasing
- Further improvements in CTIS with releases planned through-out 2023 to enhance user experience
- Intensified communication and stakeholder engagement continues
- ACT EU launch of Multi-Stakeholder Platform 22/23 June 2023

Any questions?

Further information

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CTIS in 2023: Focus and System Improvements

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

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 NextPage, LastPage and total items attributes
- Enabling multiple MS APIs to coexist allowing Member States to adopt changes at their own pace

Public Portal

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

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

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

Stakeholder requests

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

- Process initiated for CTIS to become a WHO data provider

Immediate planned releases

28 March

- Implementing **2 remaining Disaster Recovery scenarios** enabling extension of start of recruitment via a SM and 'Temporary halt of a trial'
- **Enabling RMS to create considerations** in SM containing Part I, even if they did not authorise the Initial Application
- **Implementing performance improvements** for Notices & Alerts
- Enabling MS roles with quality-restricted rights to **create/edit/delete non-IMPDQ considerations**
- **Restricting the access view of the co-sponsor**
- Enabling the **extension of the "Authorise" task for Additional MSC** for RFIs in Part I when Part II is completed

TBC

- Enabling correction of **the sorting of considerations in** the RFI
- **Allowing number of subjects to be edited** through an RFI
- Allowing **role assignment for organisations with special characters** in their name
- Implementing **performance improvements in the upload and download of documents**