Clinical Trial Information System: Metrics & Looking forward

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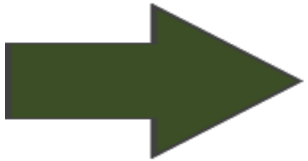
The European Clinical Trials Regulation



Before the Clinical Trials Regulation

Clinical trial applications were submitted separately to regulators and ethics committees in each EU Member State

After the Clinical Trials Regulation

Single clinical trial application covering regulatory and ethics submission in up to 27 Member States

Applies as of **31 January 2022**

CTIS is the business tool of the Clinical Trials Regulation

The Clinical Trials Information System (CTIS) is the single submission portal which **harmonises the submission, assessment and supervision of clinical trials** in the EU/EEA.

Public health

Facilitates multinational trials to address key health issues, increase transparency & enables patient enrolment

Research and innovation

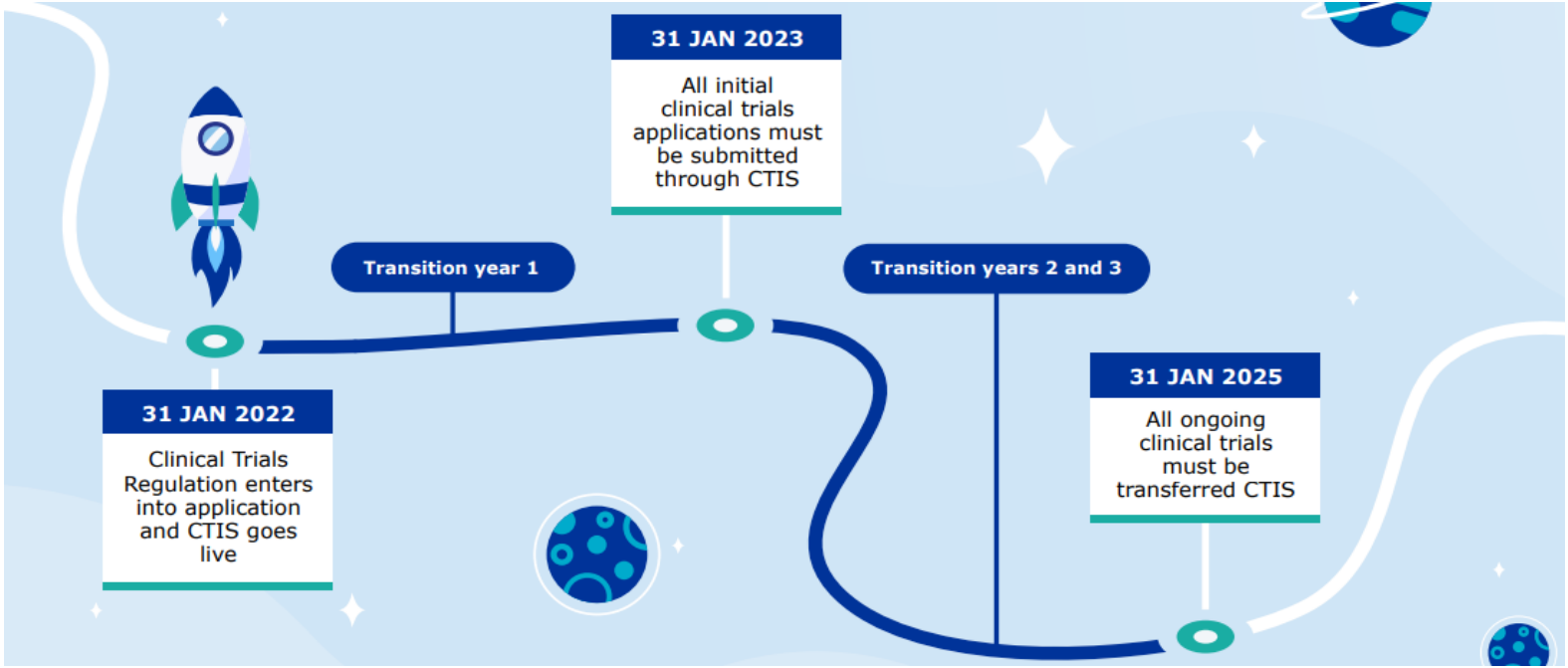
Enables medical innovation through collaboration and access to clinical research data.

Global hub for clinical trials

Ensures the EU/EEA remains an attractive clinical research hub globally.

A 3-year transition period

The Clinical Trials Regulation foresees a 3-year transition period to CTIS:



Transition period for trials authorised before the CTR

How to manage trials authorised under the previous legislative framework:

31 January 2023
CTR Mandatory for new trials and addition of MS

Submission **as per the CTCG guidance*** earlier than 30/01/2025**

31 January 2025 cut off
all trials running under CTD cease

CTR Transition 2nd year Post CTIS Launch

CTR Transition 3rd year Post CTIS Launch

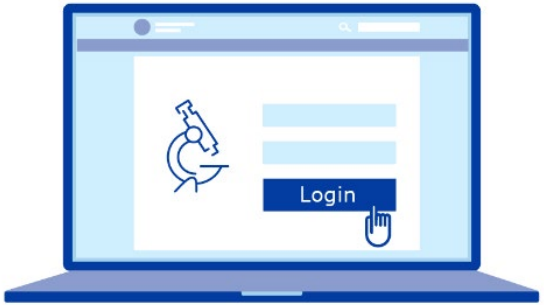
EudraCT continues to operate for results reporting of CTD trials and global end of trial

***CTCG published updated guidance for sponsors on transition of multinational trials at the HMA website (https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html, under key documents)**
****Sponsors need to take into account the time for the finalisation of the application procedure**

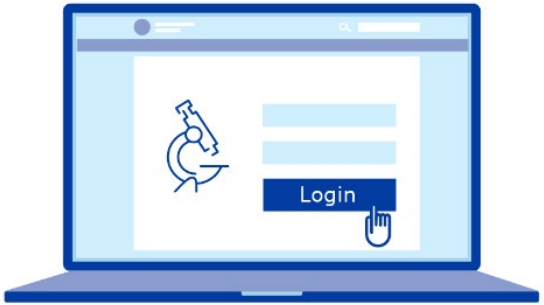
CTIS public website & secure domains

A **public website** where anyone can search for information on clinical trials
https://euclinicaltrials.eu

Open access



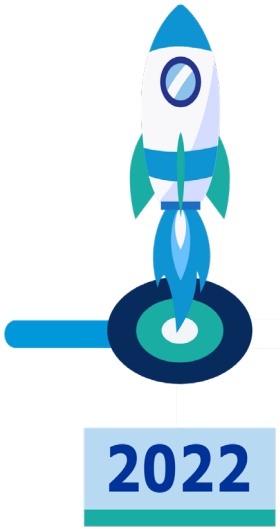
A **Sponsor workspace** where clinical trial sponsors and the organisations that work with them can apply for and manage a clinical trial in up to 30 EU/EEA countries



An **Authority workspace** for EU Member States, EEA countries and the European Commission to assess, authorise and oversee clinical trials

Secure access

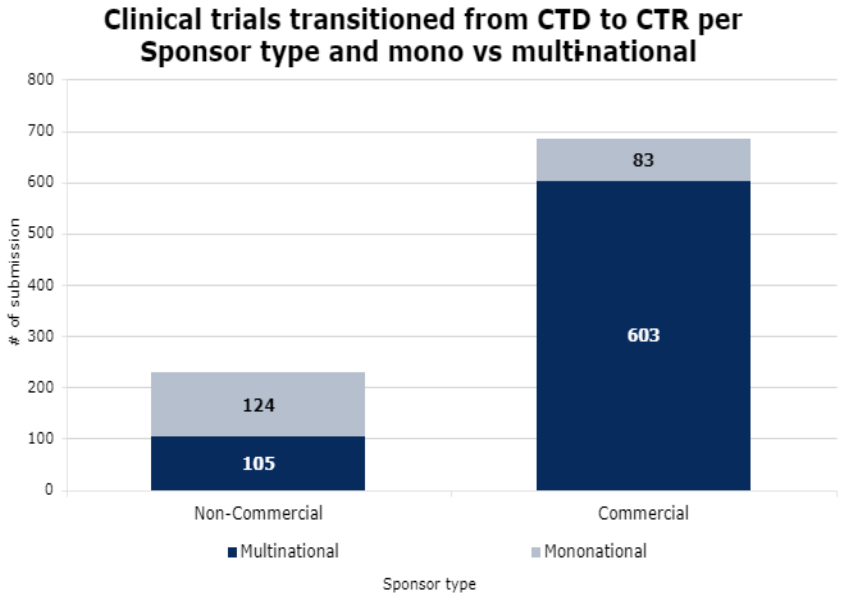
CTIS Overview: 2022 - now



- CTIS went live on **31 January 2022**, kicking off the 1st year of transition of the Clinical Trials Regulation (CTR)
- Since 31 January 2022 a total of **4,046*** initial clinical trials, **3,083** Substantial Modifications affecting 1,338 trials and **533** additional MSC applications were submitted affecting 210 trials have been submitted on CTIS of which:
- **2,582** clinical trials with a decision
- **915 transitional trials** submitted of which, **672** with decision, **516** Substantial Modifications submitted affecting 286 transitional trials.

*Status as of 29/02/2024

CTIS Overview: Transitional trials



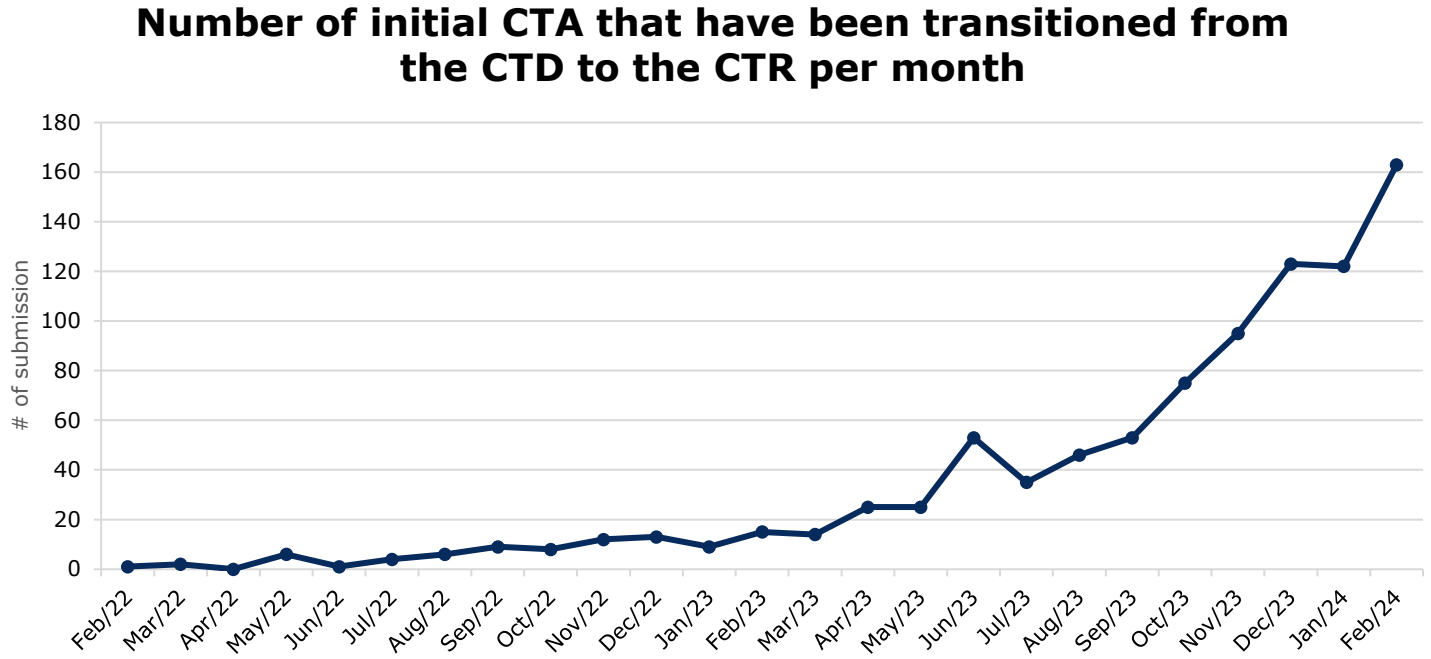
Non-commercial sponsor:

124- Mononational trials
105- Multinational trials

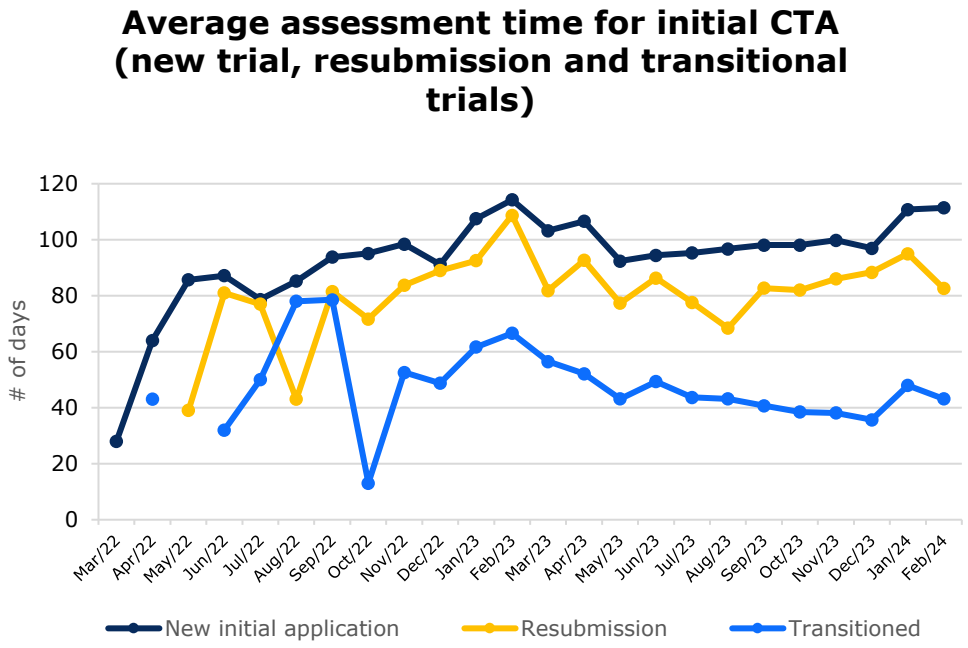
Commercial sponsor:

83- Mononational trials
603- Multinational trials

CTIS Overview: Transitional trials



CTIS Overview: Transitional trials



February 2024: The average assessment time was 43 days while an initial clinical trial is 111.

Accelerating Clinical Trials in the EU (ACT EU)

ACT EU is a business change initiative to **transform the EU clinical research environment** in support of medical innovation and better patient outcomes.

- Builds on the momentum of the Clinical Trials Regulation and CTIS
- Driven by the Network Strategy to 2025 and the EU Pharmaceutical Strategy
- Launched 13 January 2022 and includes 11 priority actions with a focus on:
  - **EU as an attractive region for clinical research**
  - **Enabling larger and more impactful CTs,** with seamless coordination among regulators and stakeholders
  - Smart CTs through **regulatory, technological and process innovation**
  - Empowering, engaging and supporting **stakeholders**

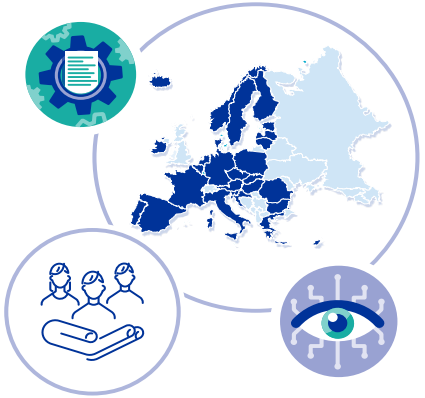
Over the next 4 years ACT EU aims to

- Ensure **effective operation** of the clinical trials regulation
- **Simplify governance** and **align CT approval** with scientific advice
- Support academic sponsors to conduct **impactful clinical trials**
- Establish the place of **novel methodologies**
- Enable **decentralised approaches**
- Training: create an **educational "ecosystem"** (leveraging existing initiatives)
- **Align internationally** (including GCP)
- **Optimise the use of data** about clinical trials for better research and decision-making
- Empower the **Multi-Stakeholder Platform (MSP)** and its **Advisory Group** to foster dialogue and collaboration with stakeholders
- Enable CTs in **public health emergencies**

ACT EU, CTR and CTIS – Sponsors, Regulators, Patients and R&D

➢**ACT EU:**

- **Ensures the voice of patients is heard**
- Builds engagement with all stakeholders to improve EU as a **global centre for bigger and faster clinical trials**
- Revision of the **transparency rules** to deliver faster access to CT information
- Addresses health needs **by facilitating innovation in CT methods, data insights and multinational trials**



➢**The Clinical Trial Regulation and CTIS:**

- Find clinical trials
- Trial results in lay language
- Medical innovation and support patient safety

CTIS 2024-2026 roadmap

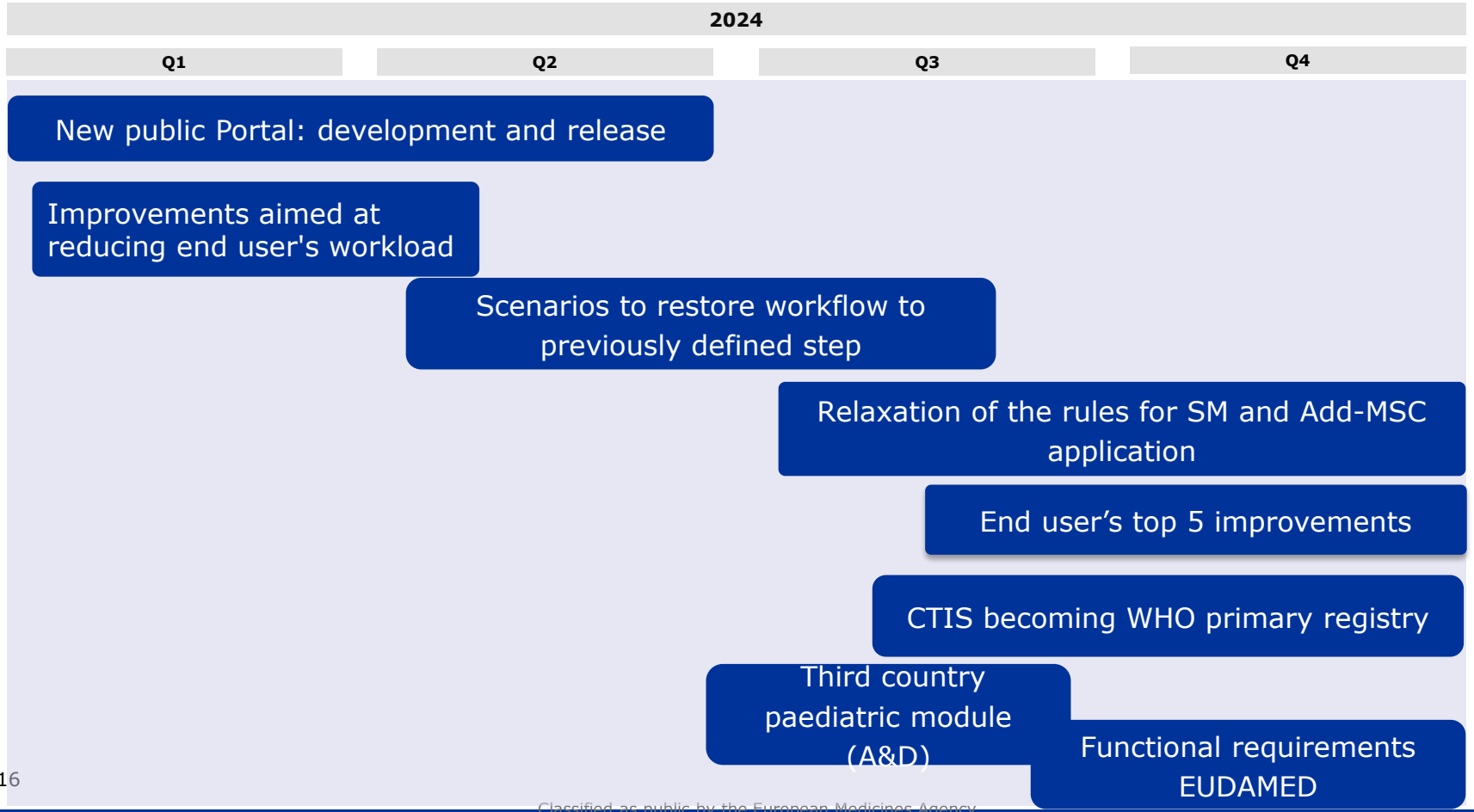
CTIS improvements in 2024 (1/2)

- CTIS secure website and the new Public Portal in line with the revised transparency rules
- Enhancement aimed to reduce workload (change of sponsor and sponsor information, Ad hoc-assessment search improvements, recording IPD sharing)
- Delivery of technical solution to enable Application Workflow recovery in specific scenarios
- Relaxation of the rules regarding the submissions of SM part II and Add-MSC applications
- Preparation of the third country module (Article 46 of Regulation (EC) No 1901/2006)

CTIS improvements in 2024 (2/2)

- Implementation of the top 5 End users' improvements:
  - Increase flexibility for changes done via NSM
  - Allow the download of the list of user roles
  - Allow the download of the documents/list with metadata
  - Warning message for the creation of draft applications while others are under evaluation
  - Assess RFI task in subsequent RFIs
- CTIS becoming WHO primary registry with additional fields (e.g. IPD sharing)
- Prepare interoperability with Eudamed and establish the functional requirements

CTIS 2024 roadmap



CTIS 2024- 2026 Road Map

CTIS backlog and priorities will continue to evolve based on multiple factors (end user feedback, need for simplification and future proofing, etc..)

EMA team in collaboration with the network product owners will work on simplification following a Safe Agile methodology

CTIS modernisation focused on gradual replacement of obsolete components, simplifying business rules and reducing workarounds

Timeframe: 2024-2026

Support to CTIS Users

Regular Communications

- Clinical trials KPI reports are published as part of the ACT EU programme (link)
- Bi-weekly Newsflash to all users - link
- Clinical Trials Highlights Newsletter – link

Regular Events

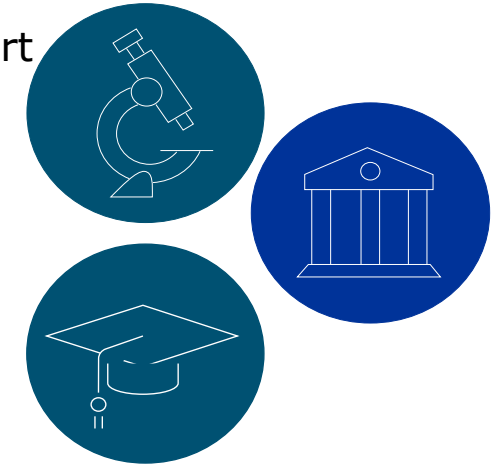
- CTIS Walk-in Clinics - link– *next on 15.05.2024*
- Bitesize talks – link *next on 24.04.2024*
- Quarterly CTIS Forum with Stakeholders – *next on 18-04-2024*

Trainings & related materials

- Sponsor end user trainings – *next on 8-11 April 2024*
- Revised Transparency rules and interim period approach - link
- CTIS Training environment – survey link to request access
- Query Management Working Group Q&A on CTR and CTIS – link
- Step by step guide on registering organisations locally in CTIS - link

Support to CTIS Users

- Strengthening collaboration with support to weekly CTCG Assessors Round Table
- Collaboration on the solutions to second survey results (as part of the ACT EU initiative)
- Hands-on support from EMA to sponsor users
- Publication of release notes/list of known issues documents
- Publication of MS calendars to EMA corporate website
- 23 online training modules published
- Update to the Evaluation Timelines document
- Sponsor Handbook available with link to training, guidance and Q&A documentation



Revised CTIS Transparency rules – useful material

The ACT EU – Implementation of clinical trial regulation website has a section dedicated to the revised transparency rules, to allow sponsors to familiarise with them during the interim period until the revised version of the public portal is launched:

- Quick guide for users
- ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS
- CTIS Bitesize talk on the transparency rules

Details are provided on data and documents that will be published, on the interim period and on all those trials submitted before the launch ('historical trials').

The launch of the revised public portal is foreseen on Q2, sponsors will be informed in advance.

CTIS Training Environment update

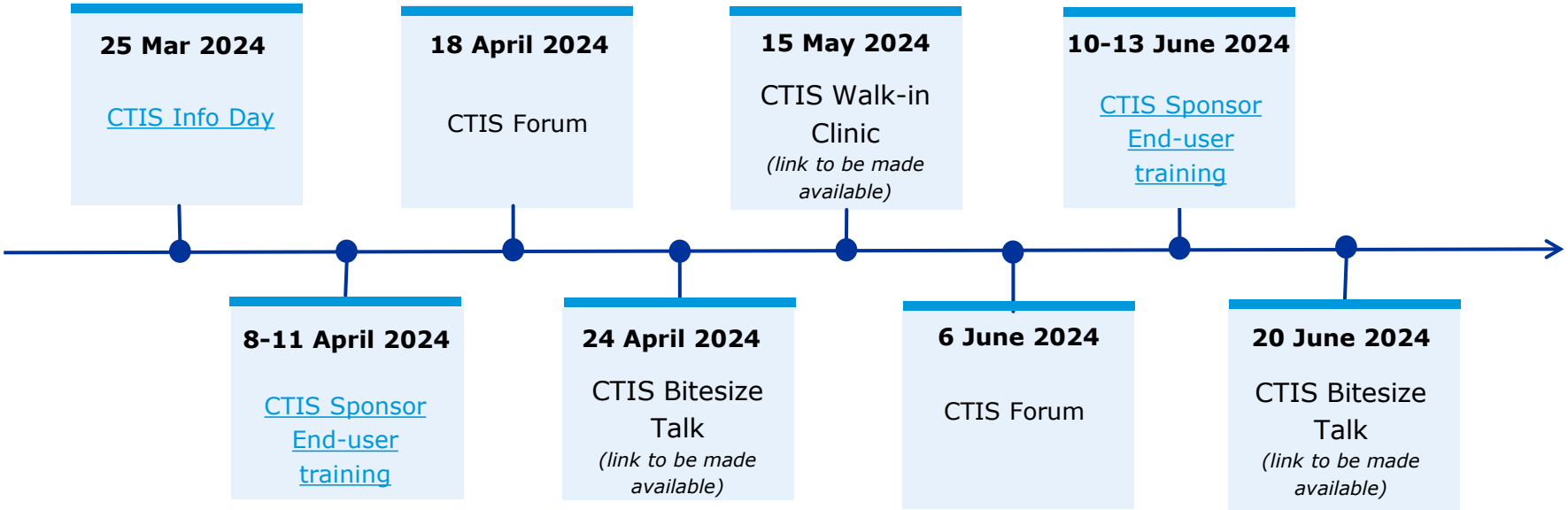
The CTIS Training environment survey (Survey 4.0) is reopened:

https://ec.europa.eu/eusurvey/runner/2abb5ba8-0ec4-9979-b692-0c63f4508b9b

This survey collects expressions of interest in accessing the CTIS training environment ('CTIS Sandbox'), information and contact details of representative individuals, the organisations that they represent and the planning for use of CTIS of these organisations is reopened.

All details will serve to proactively identify the needs and intention of use of CTIS and grant access accordingly.

Upcoming Meetings, Events, Communications



Reference list to Transition trials

Reference documents to Transition trials have been published in the EC website, EMA website and CTCG website:

- EC: Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation
- CTCG: CTCG Best Practice Guide for sponsors of multinational clinical trials (at the HMA webpage https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html), under key documents.
- EMA: BiteSize event June 2022 dedicated to Transitional trials (demo of functionality included).
- EMA: BiteSize event June 2023 dedicated to Transition trials (CTCG participation)
- EMA: Bitesize event February 2024 dedicated to Transition Trials (CTCG participation)
- EMA: Training for non-commercial sponsors event February 2024
- EMA: Sponsor Handbook / Chapter 05
- EMA: Training Module M23

Thank you for your attention

Further information

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