EMA
EUROPEAN MEDICINES AGENCY

Updates on CTIS Programme

CTIS Info Day

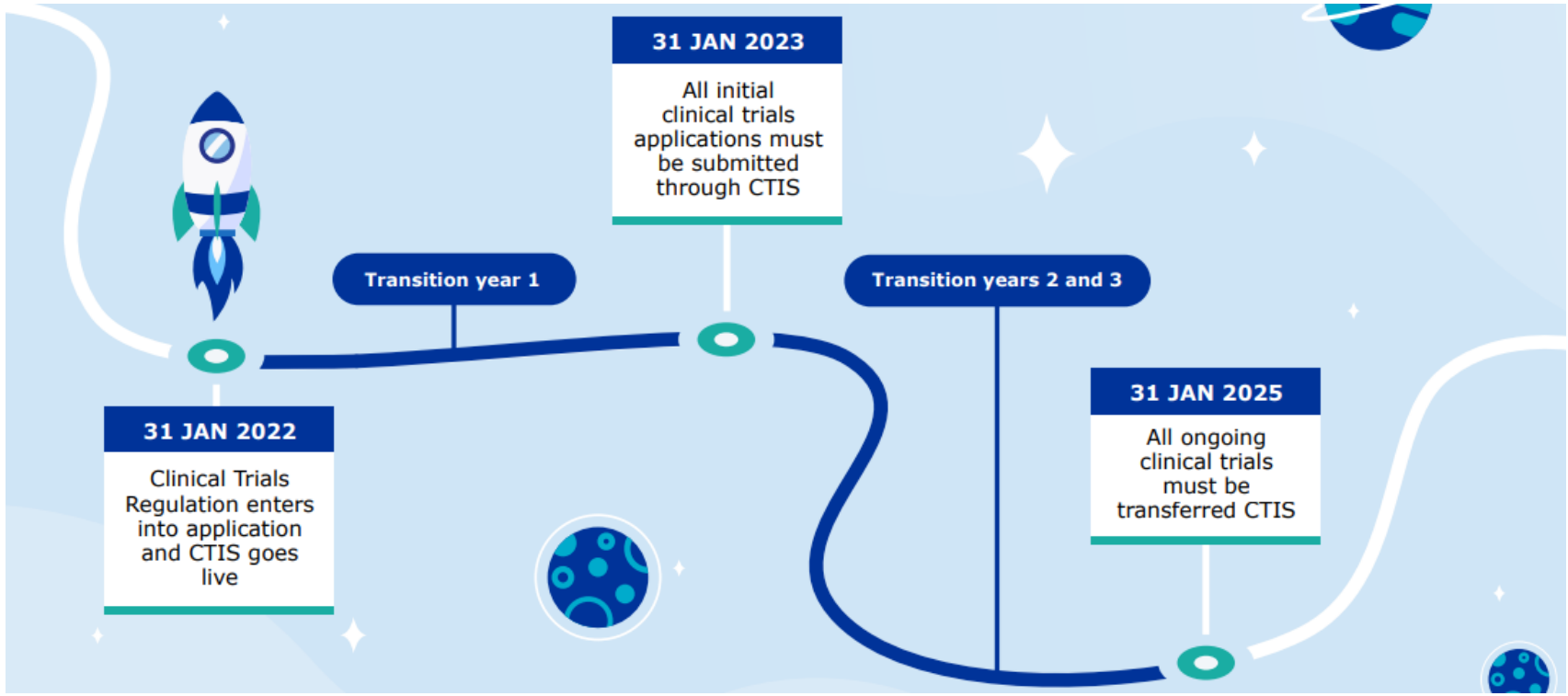
22 May 2025

Presenter: Mumtaz Sultani

Data Analytics and Methods Task Force (TDA)

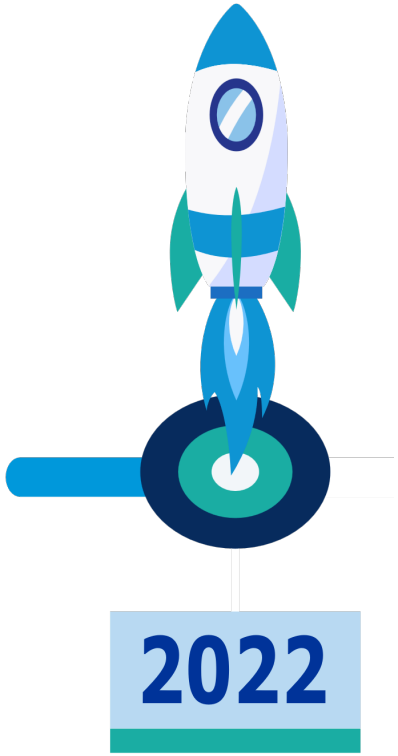
European Medicines Agency

CTIS and the End of the 3-year transition period



- CTIS went live on **31 January 2022** with 3 years of transition period
- **31 January 2023**, all initial applications have to be submitted through CTIS
- **31 January 2025:**
  - Ongoing trials under the CTD transitioned to CTIS
  - EudraCT continues to operate for results reporting of CTD trials and global end of trial.

CTIS Data- CTAs submitted vs decided



CTA Submissions

Initials
11,308

Substantial Modification
15,382

Additional MSC
1,641

Total
28,331

CTAs with a Decision

Initials
9,380

Substantial Modification (*)
13,238

Substantial Modification Transitional Trial (*)
4,552

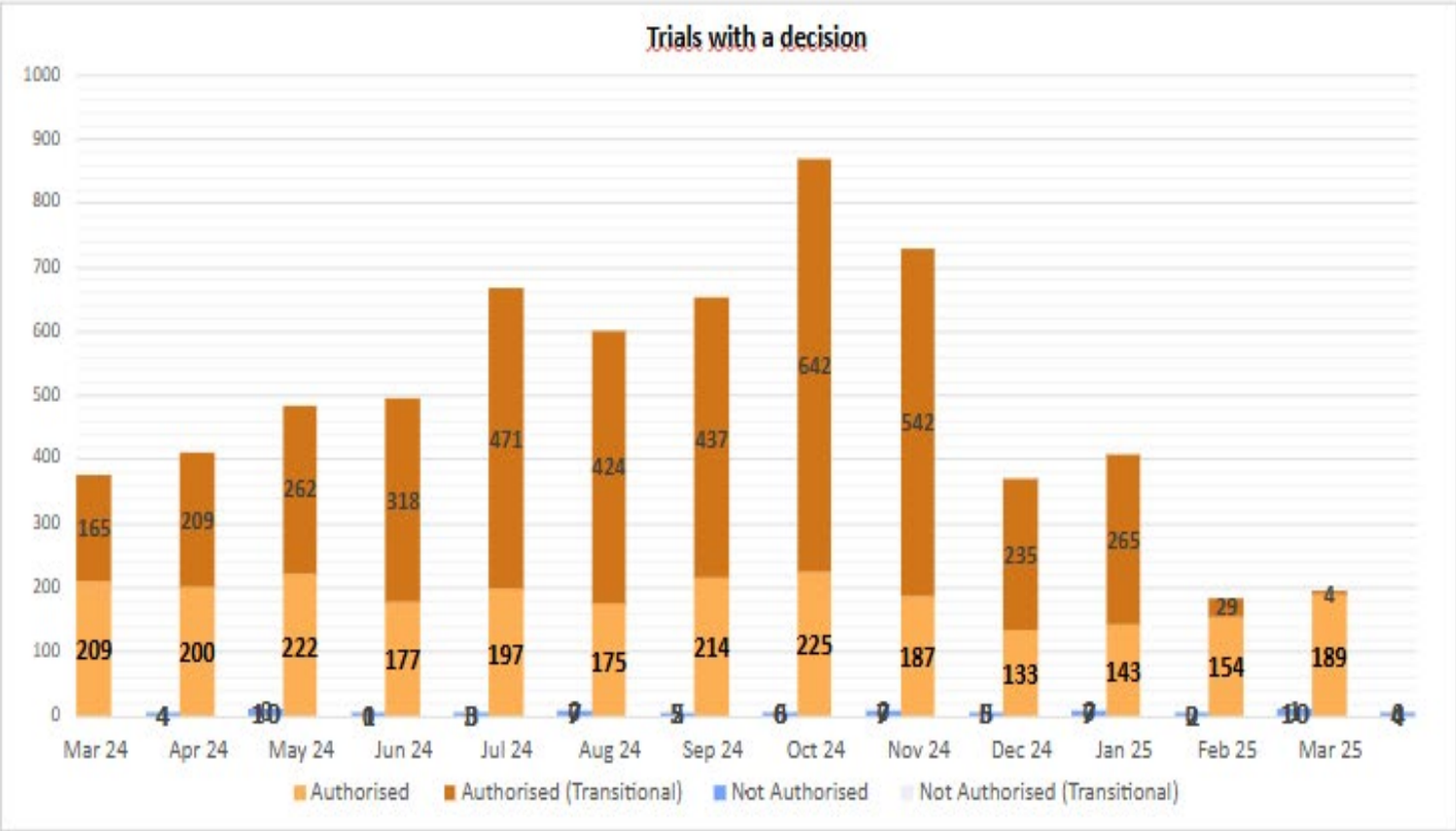
Substantial Modification NO Transitional Trial (*)
8,686

Additional MSC (*)
1,368

Total
23,986

*Status 01 May 2025

CTIS Data: Monthly Evolution CT Authorisations



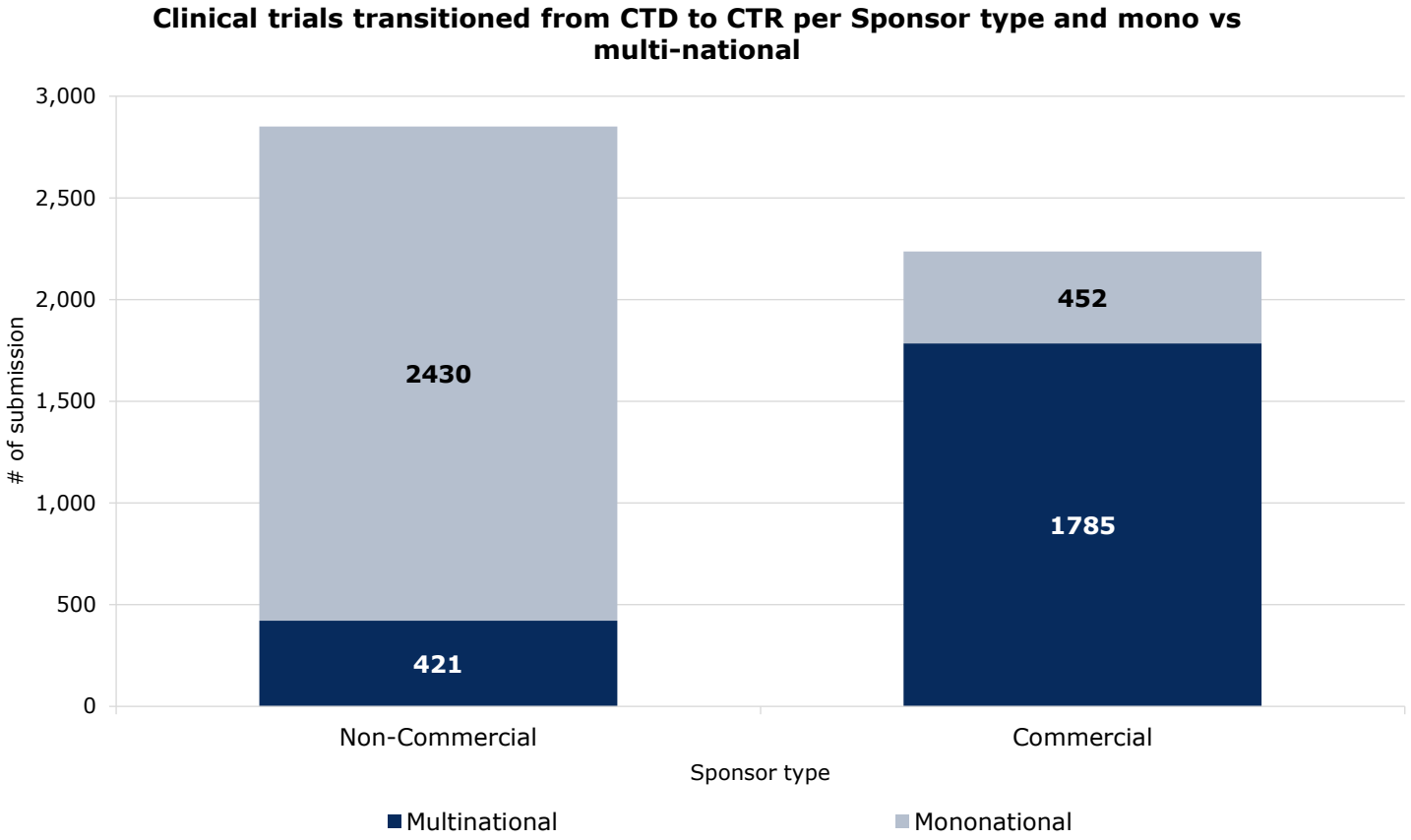
Total Authorised	Total Authorised - Transitional
8,921	4,646

Total Ended
6

Total Not Authorised
171

*Status 01 April 2025

CTIS Data: Transitional Trials



Non-commercial sponsor:

2,430 - Mono-national trials
421 - Multinational trials

Commercial sponsor:

452 – Mono-national trials
1,785 - Multinational trials

*Status 01 May 2025

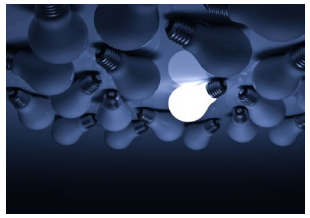
CTIS Key Milestones 2024-2025 ROADMAP

CTIS Maintenance

- Service Desk Support- User Incidents
- Problem resolution- code fixing
- Technical enables (Performance, Security etc.)

CTIS Enhancements

- New improvements/features



Simplification Taskforce

- Simplification of Business Rules towards modernization

Change of vendor

- Knowledge Transfer activities

CTIS Modernisation

- New Public Portal (2024)
- CTIS Secure Workspaces (2025)

Change Management

- Training
- Communication

World Health Organization

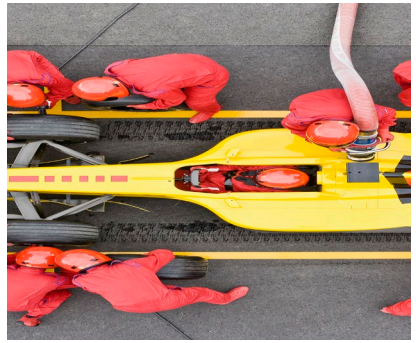
WHO ICTR Contribution

- CTIS became the WHO primary registry

EMA

CTIS Maintenance- Service Desk support

- If a CTIS user experiences an issue or has a question regarding CTIS functionality, various guidance and support materials are available, including:
    - **Sponsor quick guide: Getting started with CTIS**
    - **CTIS training material**
    - **CTIS Handbook for clinical trial sponsors**
    - **List of known issues and proposed workarounds**
    - **CTIS newsflash**
    - **CTIS Support Page with tips for users**



- If the answer to the question is not included in the guidance and support materials, users can open a ServiceNow ticket.
- EMA ServiceDesk provides support to end users, where possible, with prioritisation depending on:
    - whether the user is blocked from continuing or not with the business workflow
    - whether or not a workaround is available
- Problems will be created based on incidents reported and prioritised involving Subject Matter Experts representing MSs and sponsors (commercial and non-commercial)
- **Problem resolution:** addresses the root cause of an incident in CTIS, preventing future incidents.

CTIS Maintenance- Problem Resolution 1/3

CTA SUBMISSION:

- ✓ Sponsor users can now submit **Part I only applications** when **Part II** validation requirements are **not met/required** (e.g, Q-IMPD)
- ✓ **Clinical trial sites** are now **saved** immediately when **added** and not when saving the CTA, **preventing their disappearance** from the Clinical Trial Site list during “time out” situations.
- ✓ **Draft Substantial Modification (SM) or Additional Member States Concerned (AMS)** applications are now cancelled without errors when a sponsor cancels them under specific circumstances.
- ✓ In clinical trials with **ongoing AMS applications**, sponsors creating a new draft of a **subsequent application can now view all Part I translations** (data and documents) from **previous authorised AMS** applications. Authority users receiving this subsequent application can also see all translations.

CTIS Maintenance- Problem Resolution 2/3

NOTIFICATIONS:

- ✓ Users can now **submit the End of trial Notification** without experiencing page loading issues.

RFI REQUEST/RESPONSE ISSUES:

- ✓ Sponsors can **respond to validation RFIs** for subsequent applications submitted **for a clinical trial restarted** after a temporary halt due to safety.

- ✓ For **partially submitted initial CTAs** for all or some MSCs, sponsors can now **change the application and submit a validation RFI** response **without** receiving **an error** message due to the Part II not being submitted.

NOTICES & ALERTS:

- ✓ When an MS involved in a trial is **withdrawn and re-added through an Additional Member State** application, **notices & alerts** are **now correctly generated** and displayed for that Member State across all application types.

ANNUAL SAFETY REPORTS (ASR):

- ✓ It is now possible to **search for clinical trials to be linked to an ASR** under preparation.

CTIS Maintenance- Problem Resolution 3/3

WORKFLOW AND TASKS:

- ✓ **Substantial Modifications (SM)** applications **no longer include MSCs with an "Ended" status,** and these MSCs do not receive any related tasks.
- ✓ When the **"Submit Validation" task expires** in an SM Part II-only application, the **application is tacitly validated,** and the assessment workflow continues.
- ✓ The status of **Part II-only SMs,** submitted after an initial application with no conclusion in the assessment phase or tacit decision, **is now correctly set to 'tacitly authorised'** when the Part II conclusion is acceptable and the **'Authorise' task has expired.**
- ✓ When an RMS submits Part I and/or Part II Conclusion tasks as "Acceptable with conditions" or "Acceptable", the RMS decision section in the "Assessment Overview" table **no longer displays any decision or assessment condition if the "Authorise" task remains pending.**
- ✓ **Withdrawn SM** applications now **appear with the status "Withdrawn"** instead of "Under Evaluation".

PERFORMANCE:

- ✓ **Users are unblocked during the creation of SM** for very large trials, resulting in a sixfold improvement in average performance/100% success rate in creating SMs.
- ✓ Sponsors can now **submit SM** applications **without experiencing timeouts during the generation of "Notices & Alerts" and "Tasks".**

CTIS Enhancements- improvements/features (1/2)

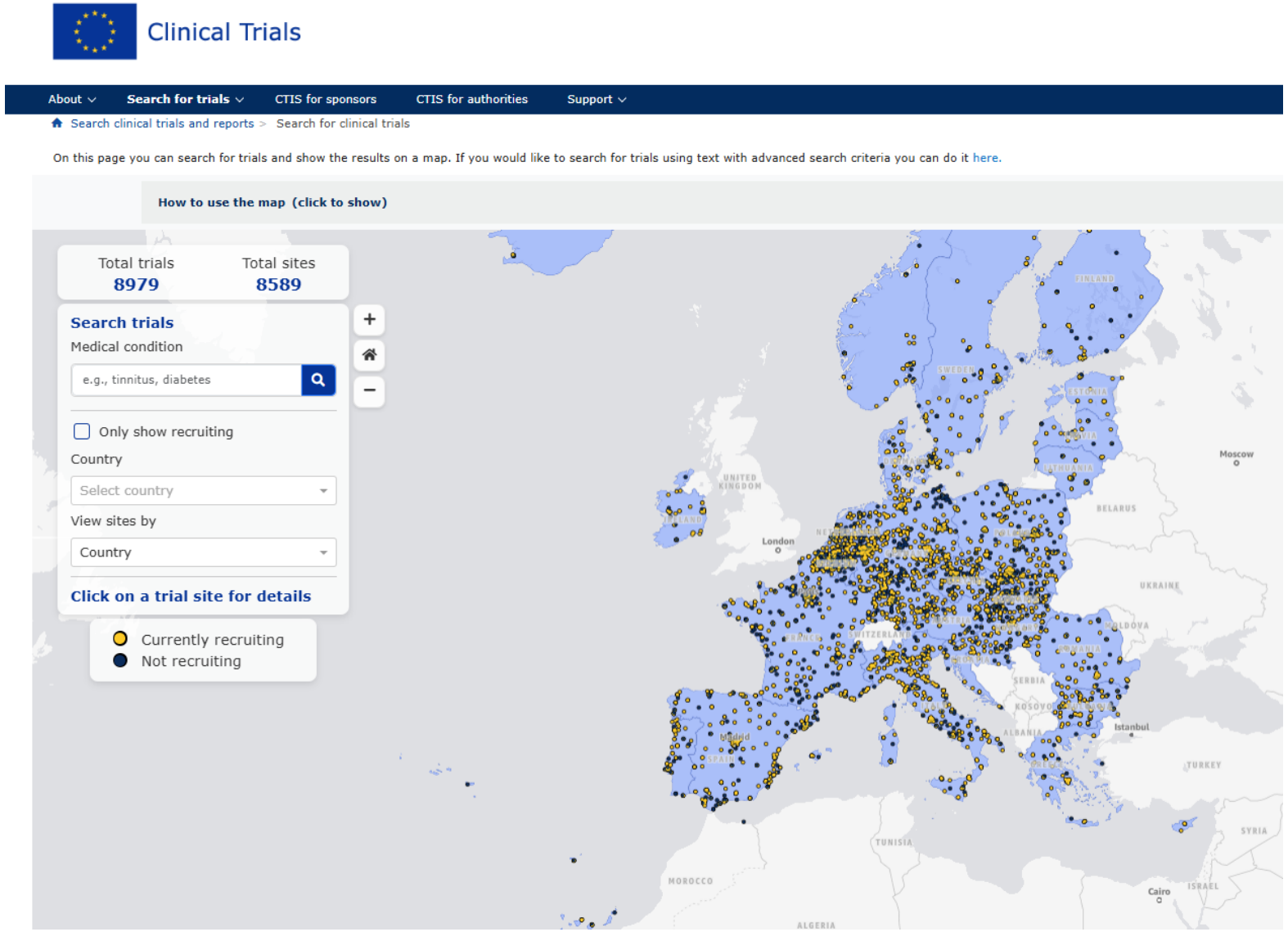
- **Change of Sponsor:**
  - ✓ **updating sponsor** (transfer ownership) or **sponsor information** (no ownership change) **via** Substantial Modification **(SM) or** Non-Substantial Modification **(NSM),** respectively
- **WHO requirements:**
  - ✓ **Field on Individual Participant Data (IPD):** As required in the WHO Trial Registration Data Set, the field 'IPD Sharing Statement' can now be recorded in a structured way.
  - ✓ **New WHO API** connected to the new Public Portal
- **Alignment with the CTIS revised transparency rules :**
  - ✓ CTIS **secure workspaces** and the **new Public Portal (PP)**
  - ✓ The **submit CTA pop-up window** in the sponsor workspace
  - ✓ The **publication rules banners** displayed in the **Authority** and **Sponsor workspaces**
  - ✓ The wording of **warning messages related to the CTIS transparency rules** have been clarified:
    - In the confirmation message after submitting a response to a Request for Information
    - In the section "Trial Category"

CTIS Enhancements-improvements/features (2/2)

- **Transitional Trials:**
  - ✓ Sponsors can now indicate that a trial is transitional even after the creation of the clinical trial application, while drafting the initial application or after resubmission.
- **Other improvements:**
  - ✓ **A warning message has been added** to prevent the creation of draft applications while others are under evaluation.
  - ✓ **"Anticipated date of summary of results"** is now **automatically populated** when the overall status of a clinical trial changes to "**Revoked" after a corrective measure** is applied.
  - ✓ **Email** notifications **when managing roles** to users have been updated to reflect the **Dutch address** instead of the UK address
  - ✓ The **drop-down list** for the **"Not Authorised" reasons** in the "Decision" task includes now a **new option**: "Part I conclusion by RMS: Not acceptable" for the MSC to clearly indicate the reason behind.

For updates on CTIS system functionalities, users can refer to the release notes and newsflash.

Trial Map



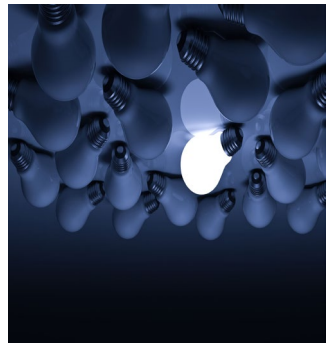
ACT EU Trial Map & Benefits

- Launched in March 2025
- Integrated with the CTIS public portal
- Empowers patients and healthcare professionals:
  - Provides easy **access to information** about clinical trials operating in a geographic area
  - Improves **access to trials** by making it easy to find the contact information for each clinical trial site
  - Increases **findability of trials** by allowing for medical condition searches in lay language (through the Consumer Health Vocabulary)

CTIS Simplification Taskforce

Objectives

- Keep the momentum following the successful simplification of the new CTIS Public Portal
- Simplify CTIS functionalities in preparation for CTIS modernisation in 2025 and beyond



Members: DG SANTE, Member States, sponsor, Subject Matter Experts (commercial and non-commercial), and EMA.

SCOPE

COMPLETED TOPICS	ONGOING TOPICS
• Safety (saMS and ASR)	• CTA Submission and Assessment Workflow
• Timetable visualisation	• Lock mechanism
• Role Matrix	• MS API
• User Management	
• IMPD-Q only CTAs	
• Ad hoc Assessment	

CTIS Change of Vendor- Knowledge Transfer

Q4 2024			Q1 2025			Q2 2025		
Oct 24	Nov 24	Dec 24	Jan 25	Feb 25	Mar 25	Apr 25	May 25	Jun 25
Contract Awarded	*Contract signed*	*Transition start*	*Hard Freeze*					*Transition end*

Operational services transitioned to the new provider

Handover Execution
Knowledge Transfer / Shadowing / Reverse Shadowing

CTIS Providers - NTT DATA

Resources off -boarding

Public Portal Provider - Accenture

Resources on-boarding

New Provider - Accenture B.V.

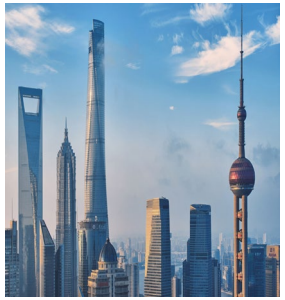
CTIS Modernisation- Secure Workspaces

WP1- Functional Improvement

Analyse the outputs of the STF and PIRQ[1] backlog. Participate in STF activities and define the Governance and collaboration process.

WP3- Transitional Architecture

Design transitional Architecture, prepare related materials and **create implementation backlog** for the next plan interval,



WP2- CTIS Modernisation

Define high-level technical architecture & implementation features and update the **Modernisation Roadmap**

WP4- Safety module prototype

Design, build, and test a **technical prototype** of a limited set of use cases of the CTIS **Safety Module** (If successful, this will be followed by the delivery of the new safety module- minimum viable product- possibly early 2026)

1- PIRQ- Problems , Incidents, Requests and Questions

CTIS Modernization- Improvements in the pipeline

- EMA has compiled a list of improvements based on feedback from different forums (CTIS Forum, ACT EU survey, Collaborate project, Combine project, etc.)
- Subject Matter Experts (MS/Sponsors) involved in their prioritisation from a business perspective
- Pre-defined prioritisation criteria applied: effort, risk, impact, reduce burden, importance

Prio order	High level issue descrition	No of related tickets	Implementation
1	Downloadof list of document s (with metadata) / list of users	2	Current system
2	N&A email alert	1	Current system
3	Safety	1	Modernisation
4	Must be possible to submit a non substantial modification part II for a memberstate that is not assessing a Part II substantial modification.	1	Current system
5	Improve the UX design for claiming tasks/identify MSC in AMS tasks and record considerations	3	Current system
6	Include additional fields/to be searchable for complex trial and related to Medical Devices	2	Current system
7	Increase flexibility for changes changes allowed via NSM	1	Current system
8	Improvment to facilitate the best practice for the tracking of conditions	1	Current system
~~9~~	~~Improve the Decision reason dropdown for Not Authorised CTs~~	~~1~~	~~Current system~~
10	Communication features to MS for general discussion	1	Modernisation-
11	Implementation of the new DAR	2	Current system
12	Generation of Assess RFI task not only fopr the first RFI	1	Modernisation- Workflow simplification topic
13	Relaxation of the rules for the submission of applications (SM PartII, SM Part I and AMS)	1	Modernisation- Workflow simplification topic
14	Timetable	1	Current system
15	Improve the document repository to include a section for Form and Decision	1	Modernisation- Workflow simplification topic
16	View access of inspections to all inspectors	1	Current system
17	Change the reference number format for Inspections and PIP (aligned with IRIS request)	2	Current system
18	Q-IMPD submission related issues	2	Modernisation- Q-IMPD topic
~~19~~	~~Assignation role email to include the Dutch address~~	~~1~~	~~Current system~~
20	Hide 'Application Status' UI Label inside the application/ Ful trial Info tab	2	Current system
20	Improve perfromance related to N&A and Tasks of Advanced search	1	Modernisation- Workflow simplification topic
21	Review workflow for SM Part II Only and AMSC- generate the decision date + 5 days after Submit Part II Conclusion is completed/expired.	1	Modernisation- Workflow simplification topic
22	Implementing the highlight changes for removal	1	Modernisation- Workflow simplification topic
23	Possibility toc change the trial category in an SM	1	Current system
24	Withdrawal of an SM application that contains Part I to apply to all MSCs	1	Current system
25	Simplification of Part II assessment tasks	1	Modernisation- Workflow simplification topic
26	Complete "Re-express willingness" Task	1	Modernisation- Workflow simplification topic
27	Rollback scenarios	7	Modernisation- Workflow simplification topic
28	Facilitate application of a Corrective measure if the sponso opinion is provided faster than 7 days	1	Current system
29	Different issues when users work simultaneously in the same application.	1	Modernisation- Reduce lockers simplification topic
30	Edit/ Delete subtask	1	Modernisation- Workflow simplification topic
31	Publication of Non Substantial Modification	1	Current system
Total		**46**	

Note: The improvements strikethrough are already implemented

CTIS Change Management

Change Enabler Team

Awareness & promotion raising:
-Newsletter/Newsflash
-CTIS Release Communications

Answer basic questions

Monitor the adoption

Engagement

Frequent & transparent communication

Info Sessions and workshops: CTIS Info Day

Q&A clinics: bitesize & walk-in sessions

End-users' empowerment (register)

Training

Comprehensive training materials

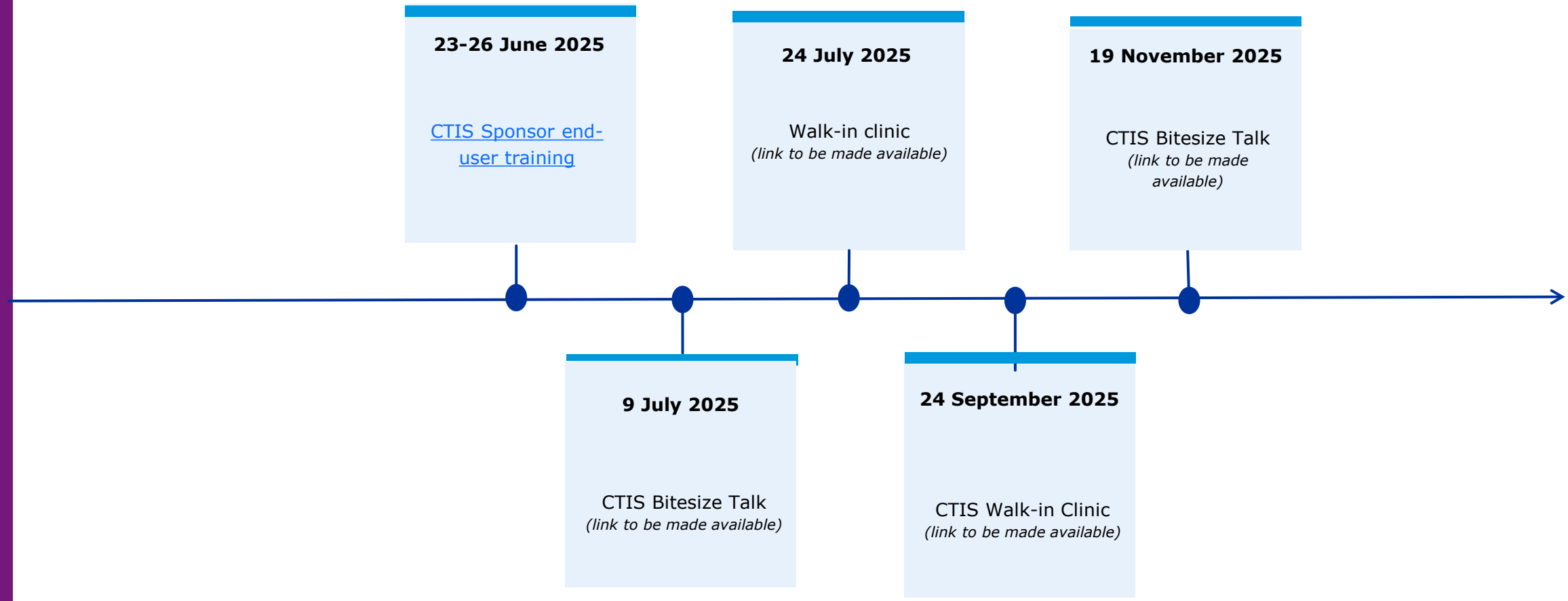
E-learning

Quick Reference Guides, Q&A

Instructor-led training for key users

Support to promote, engage, foster collaboration and empower stakeholders

Upcoming Meetings, Events, and Communications for sponsors of clinical trials – CTIS



WHO ICTR Contribution

- CTIS became a WHO **data provider** in May 2023
- A new CTIS WHO interface was created to align with the new public portal
- Request to become a WHO **primary registry** submitted in September 2024
- The WHO audit visit required to become a primary registry took place in January 2025
- **CTIS designated as WHO Primary Registry on 3 April 2025**
- EMA and WHO communicated this relevant achievement after this designation:
- EMA: in the News announcement and social media
- WHO: in their News

World Health Organization

EMA

Key Messages

- CTIS remained stable despite a high volume of transitional trials just before the end of the transitional period.
- Relevant guidance and training materials are available to help end users familiarise themselves with CTIS before creating a service ticket. (Links can be found on page 7.)
- Several improvements and bug fixes have been implemented across various sections, including during the knowledge transfer activities, contributing to CTIS stabilisation and enhancing user experience and performance.
- CTIS simplification has progressed successfully, with several topics already completed (e.g., Role Matrix, User Management, safety (ASR, saMS) etc.), whose outputs will drive the upcoming CTIS modernisation.
- Knowledge transfer has progressed according to plan, and the new vendor is now fully in charge of continuing CTIS maintenance and future modernisation.
- The CTIS Modernisation kicked off in March with the aim of delivering a roadmap by the end of June 2025.
- A welcomed trial map was launched in early March and is available on the new Public Portal.
- CTIS became a WHO Primary Registry in April 2025, ensuring comprehensive research information is accessible to healthcare decision-makers globally.

Thank you.

 mumtaz.Sultani@ema.Europa.eu

 ema.europa.eu

 linkedin.com/company/european-medicines-agency/

 bsky.app/profile/ema.europa.eu

Send a question via our website

Reference

CTIS Training Environment update

- The CTIS Training environment survey (Survey 4.0) is available:
- https://ec.europa.eu/eusurvey/runner/2abb5ba8-0ec4-9979-b692-0c63f4508b9b
- This survey collects expressions of interest in accessing the CTIS training environment, information and contact details of representative individuals, the organisations that they represent and the planning for use of CTIS of these organisations is available.
- All details will serve to proactively identify the needs and intention of use of CTIS and grant access accordingly.