EMA
EUROPEAN MEDICINES AGENCY

# Updates on CTIS programme

## CTIS Info Day

## 17 June 2026

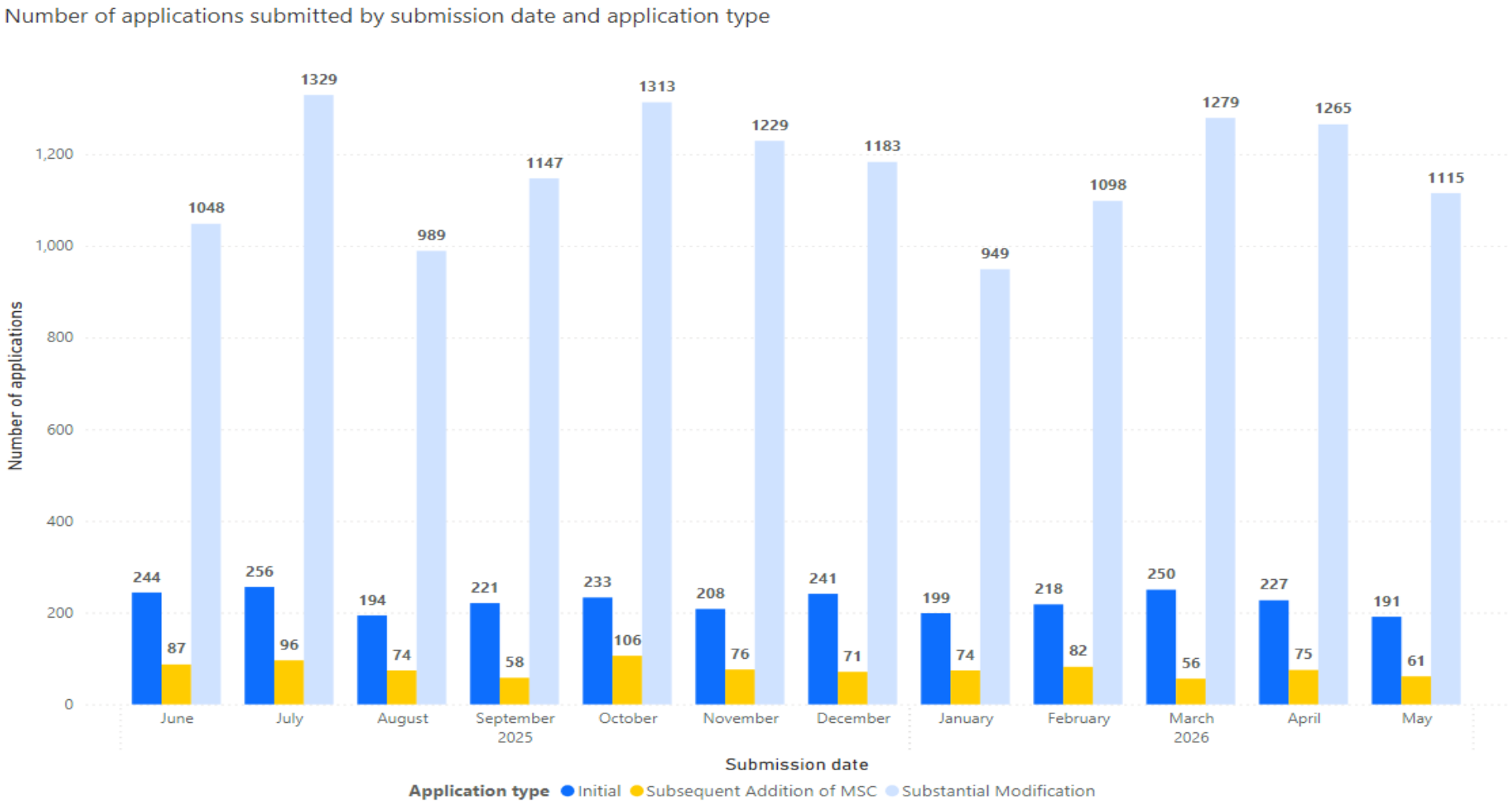
Presenter: Oskia Bueno

Data Analytics and Methods Task Force (TDA)

European Medicines Agency

# CTs in numbers – evolution of CTIS applications

Status: 31 May 2026



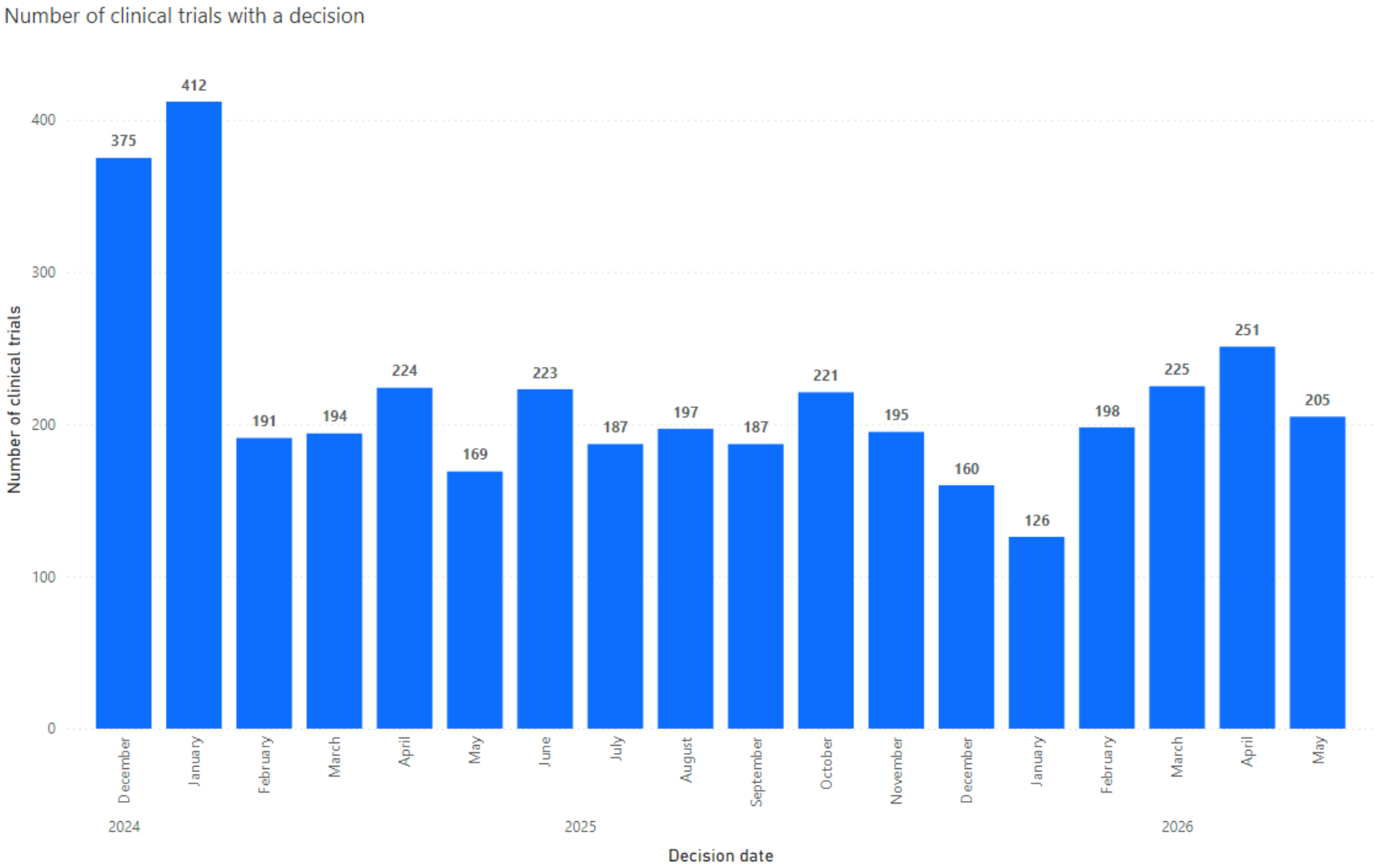

| Total initials |
| --- |
| 14,184 |

| Total substantial modifications |
| --- |
| 30,387 |

| Total additional MSC |
| --- |
| 2,630 |

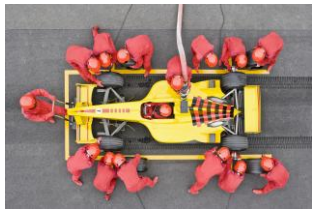
# CTIS update

## CTAs with a Decision
### Initials (including Transitional)




Status: 31 May 2026

# CTIS Key Milestones 2025-2026 Roadmap



## CTIS Maintenance

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

## CTIS Enhancements

- New improvements/features

## CTIS Modernisation

- New Safety Module (2026, in progress)
- Email alerts (2026)
- Document management Module (2026, in progress)
- Analysis and Design (Biotech Act)

## CTIS Taskforce

- Repurposed of the Simplification Taskforce to identify changes needed to support the Biotech Act

## Change Management

- Training
- Engagement
- Communication

# 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:
    - **CTIS Sponsor Handbook** – ***new 9 July 2025***
    - **CTIS Sponsor FAQ** - ***new 26 March 2026***
    - **CTIS training material**
    - **List of known issues and proposed workarounds**
    - **Clinical Trials Highlights**
    - **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:

- ✓ The **update of the content labelling** document through a substantial modification creates now a new version of that document instead to be displayed as a separate one.
- ✓ The **submission date of cloned documents** is no longer updated when creating a new application. Only newly uploaded or modified documents update versioning and metadata, preserving document history.
- ✓ Sponsor users can now submit the **outstanding Part II** of an Initial Application even when a withdrawn MSC is included. The submit button correctly appears for the active MSC.
- ✓ An MSC remains visible in the participating MSC list after an **“End of Trial” withdrawal** in subsequent applications. The authorization workflow now is generated correctly, preventing the MSC from remaining in “Under Evaluation” status.
- ✓ Sponsor users can now submit a new multinational **Substantial Modification** without being blocked by an incorrect “SM under evaluation” message caused by a **lapsed or withdrawn RMS/MSC from a previous SM**.
- ✓ Sponsor users can now **change the primary sponsor** via an SM Part I even when one or more **MSCs have “Ended” or “Revoked” status**. The new sponsor is correctly displayed, and previous sponsor access and roles are revoked.

# CTIS Maintenance: Problem Resolution (2/3)

## ACCESS AND USER MANAGEMENT:

- ✓ Sponsor users with **Part II–only roles (Viewer or Preparer)** can now access the Part II dossier from the Clinical Trial Summary page when a Part I RFI is pending.

- ✓ Authority users with a **large number of trial-specific roles** can now view CT-related tasks in the “Tasks” tab without delays or timeouts.

## NOTIFICATIONS:

- ✓ Sponsor users are now able to submit a **Start/End of Trial or Start/End of Recruitment** notification, even in the case the date to be selected falls between the trial’s initial authorisation date and the submission date of a subsequent Non-Substantial Modification (NSM).

- ✓ Sponsor users are now able to **create or update** Serious Breach, Unexpected Event, Urgent Safety Measure, or Third Country Inspectorate Inspections **notifications when a clinical trial is halted**.

## RFI REQUEST/RESPONSE ISSUES:

- ✓ Sponsor users with the appropriate roles are now able to **load the expected RFIs in the RFI tab.**

# CTIS Maintenance: Problem Resolution (3/3)

## NOTICES & ALERTS:

- Alerts for the submission of the **layperson's summary and summary of results are now timely issued** (three months, one month, and five days prior to the submission deadline based on the sponsor's anticipated summary of results date).

## TIMETABLE:

✓ The **Part I conclusion** in the "**Timetable**" is now correctly aligned with the expected due date (following the removal of an extension caused by the RFI phase being counted twice), ensuring consistency with the timeline shown in the "Tasks" tab.

## WORKFLOW AND TASKS:

✓ In cases where validation expires and a **tacit validation** is triggered, the tasks "Submit Part I conclusion" and "Submit Part II conclusion" now expire on their due date, as expected, instead of an earlier date.

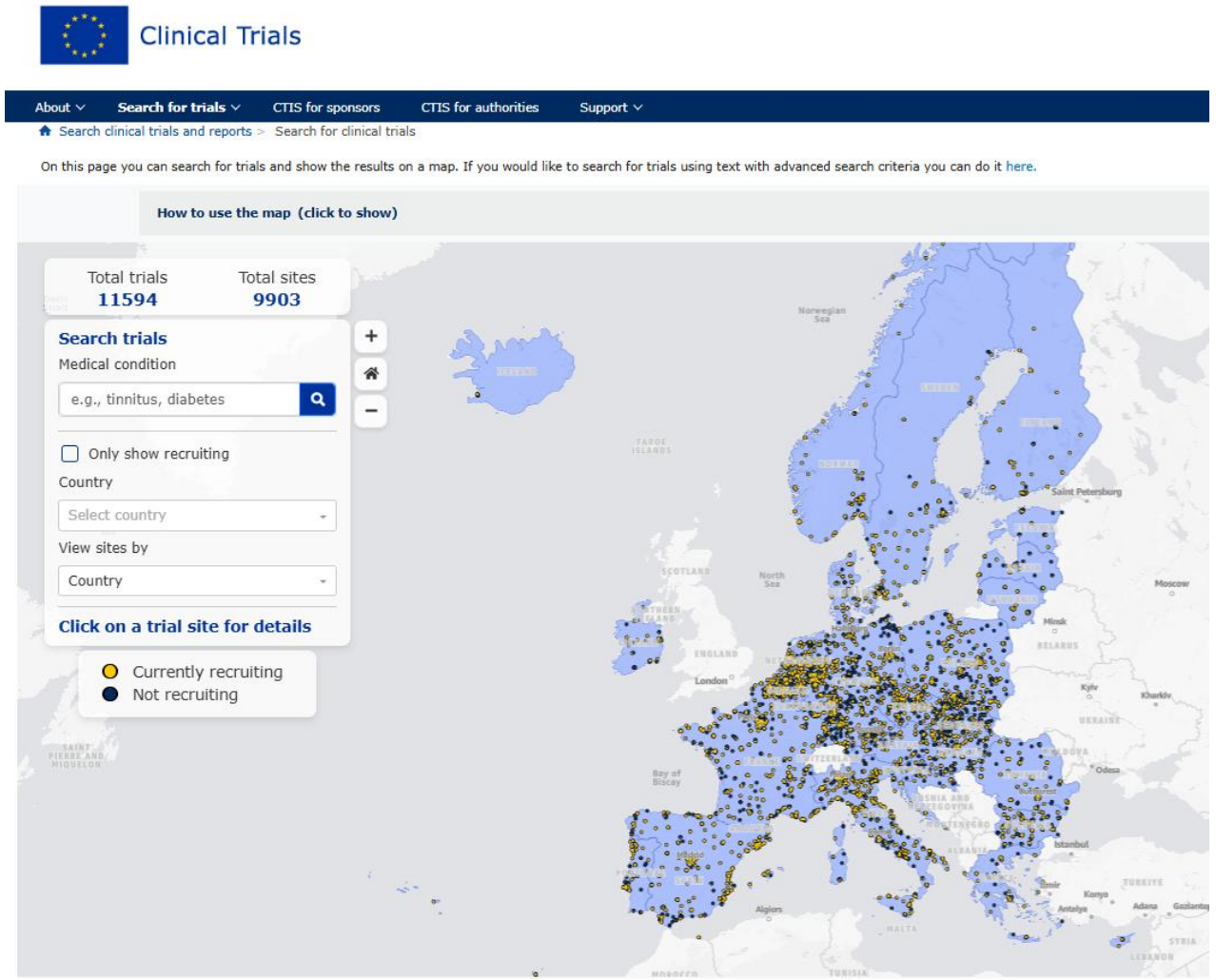
✓ In multinational clinical trials, following a **tacit authorisation** for a Part II-only or Part I-only SMs, the application status in the back end is now correctly updated (instead of remaining "under evaluation"), ensuring that subsequent submissions can proceed as expected with no error message referring to an application under evaluation.

# CTIS Enhancements: improvements/features (1/2)

- **Non-Substantial Modifications (NSM):**
  - ✓ Sponsor users are able now to update a **broader set of fields and documents within non-substantial modification applications (NSM)**, aligning the system behavior with real-world trial amendments.
- **Resubmission:**
  - ✓ Sponsor users are able now to **resubmit** an Initial Application (IN) or Substantial Modification (SM) application previously submitted but **with status "Not Valid**".
- **Extension of "Start Recruitment" or "Restart trial":**
  - ✓ An improvement has been implemented to **prevent the expiration of Clinical Trials** in case the sponsor requests **an extension of "Start Recruitment" or "Restart trial" beyond the two-year** limit, by introducing mandatory date fields within the selected Substantial Modification (SM) reason for extension and requiring the completion of at least one relevant date (Recruitment Start Date and/or Restart Trial Date) for one or more Member States Concerned (MSCs).
- **Performance:**
  - ✓ Notices and Alerts in CTIS will now be deleted **90 calendar days** after receipt to improve performance. A **banner** has been added to inform users of this change.

# CTIS Enhancements: improvements/features (2/2)

- **Public portal**:
  - ✓ Public users are able to view now any changes made to a clinical trial application through a Non-Substantial Modification (NSM), including the publication of Part I documents submitted in **NSM of historical trials**.
  - ✓ The language of documents in the CTIS Public Portal is now clearly displayed (through a **new 'Language' column** in the Trial Documents and Trial Results screens), enabling users to identify document language. (planned to be deployed on 23 June 2026).




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

# CTIS Modernisation: 2026 roadmap

*New Feature* | *Modernised Feature* | *BTA Feature*

★ *Go-live* ★ *Training environment*

**Q1 2026** | **Q2 2026** | **Q3 2026** | **Q4 2026**

**Email Notices**

**Safety Module MVP**

**Role Management** – Including Highest Priority Functional Enhancements

**Role Mgmt** – Remaining Enhancements

**Document Management**

**CTIS Submission & Authorisation***

Analysis & Design of **Biotech Act (BTA) Changes**

* High level Analysis and Design in Q2 and Q3



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# CTIS Roadmap 2026: Key milestones

## CTIS Modernisation

### New Features

- **New Safety Module MVP**
  - Delivery of a training environment
  - Delivery of Safety Module MVP by end September 2026
- **Notices and alerts via email**
  - Implementation by June 2026

### BTA

- **Analysis and Design** (A&D) of BTA changes

### Modernised Features

- **Role Management**
  - Implementation of new safety roles
  - Update of the Use Interface for the *User Management /My roles* functionalities
  - Implementation of functional enhancements* (e.g. export list of roles)
- **Document Management**
  - Address existing problems
  - Implementation of functional enhancements* (refinement of "all documents table"; improve download functionality)
- **CTIS 'core'**
  - Enable submission & authorization of CTAs

# BTA: Analysis & Design progress

| Topic | Requires implementing or delegating act? | Status of analysis |
|---|---|---|
| **Assessment workflow**<br>• Reduced timelines, RMS Selection, Removal ATMP extension, Part I/Part II alignment | No | Analysis ongoing |
| **Submission rules (parallel SMs)** | No | Analysis ongoing |
| **Low/Minimum intervention trials** | No | Analysis ongoing |
| **Collaboration space** | No | Analysis ongoing |
| **Change of RMS** | No | Analysis ongoing |
| **MS-API**[1] | No | Not started |
| **Product core dossier** | Yes | Not started |
| **Combined trials** | Yes | Not started |
| **Public Health Emergencies** | Yes | Not started |
| **Use of AI** | No | Not started |
| **Environmental risk assessment (ERA)** [1] | No | Not started |
| **Structured data (M11 implementation)**[1] | No | Not started |
| **Sandbox** | No | Not started |

[1] not a BTA topic

# CTIS Taskforce

- Simplification Taskforce has been repurposed into the **CTIS Taskforce.**
- CTIS Task Force officially kicked off 13-May 2026.
- **Membership:** Representatives from NCAs, Ethics Committees, commercial and non-commercial sponsors, European Commission and EMA.
- **Role**: Act in an informal **advisory capacity** on the regulatory requirements for new or amended CTIS functionalities which need to be developed in line with the proposed Biotech Act (BTA) and the CTR.
- **Objectives**: Provide advice on desired regulatory outcomes to drive the development of **modern**, **sustainable**, **user-friendly** and **simple** CTIS solutions for the implementation of new legal requirements with a view to reducing administrative burden, accelerating clinical trial processes and promoting the EU as an attractive environment for the conduct of clinical trials.

# CTIS Change Management

## Communications

Awareness & promotion raising:
-Newsletter
-CTIS Release Communications

Answer questions

Monitor the adoption

## Engagement

Frequent & transparent communication

Info Sessions and workshops: CTIS Info Day

Q&A clinics: bitesize & walk-in sessions

End-users' training

## Training

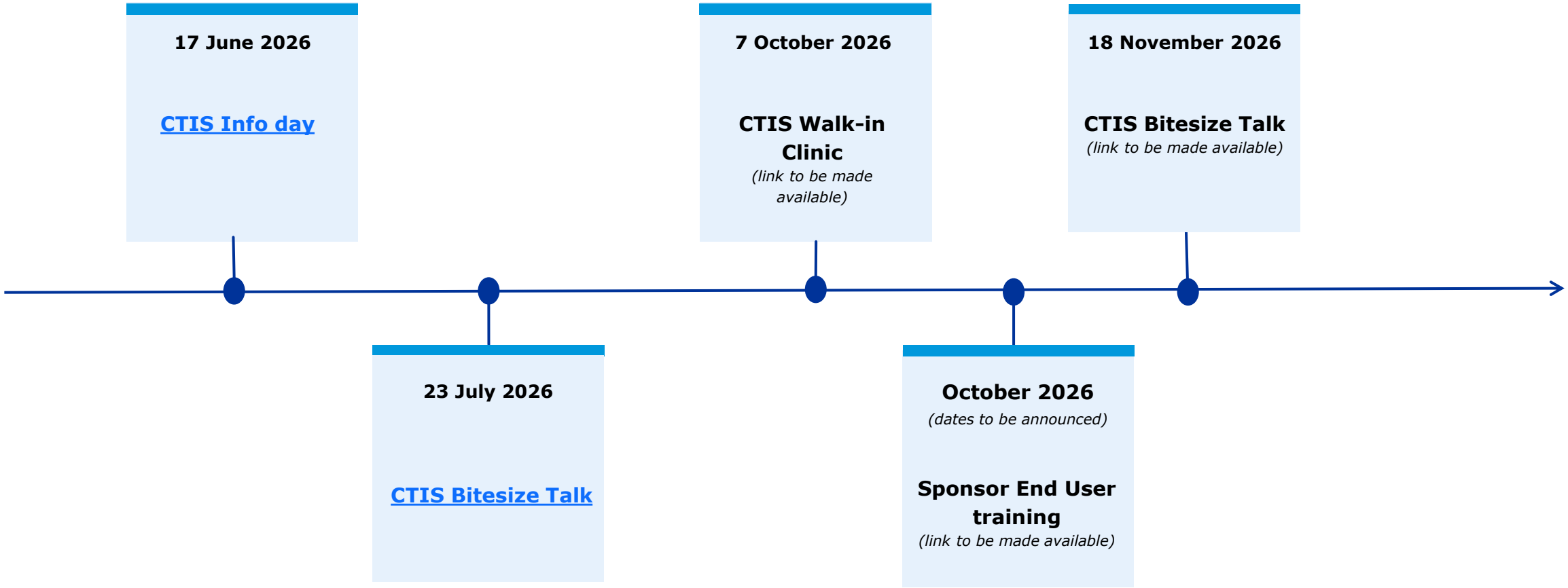
Comprehensive training materials

E-learning

Quick Reference Guides, Q&As

**Support to promote, engage, foster collaboration and empower stakeholders**

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



# Key messages

- CTIS remains stable, with over 200 new trials authorised per month.
- A completely new version of the Sponsor Handbook has been launched, integrating all training modules in one document, and a complementary FAQ was created where the most frequent questions from events and service desk were addressed.
- CTIS releases have contributed to CTIS stabilization and user experience improvement with the implementation of several enhancements and problem resolution across various sections.
- CTIS modernisation progressing with the new safety and document management modules planned for release in 2026.
- Proposal for Biotech Act (BTA) requires major new functionalities in CTIS. Analysis and Design has already started under the CTIS Taskforce.
- Repurpose of the CTIS Simplification Taskforce into a CTIS Task force focused on identifying CTIS changes required to support the Biotech Act proposal and deliver benefits for innovation and patients.

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# Thank you

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