EMA
EUROPEAN MEDICINES AGENCY

Simplification Taskforce activities

CTIS Info Day

22nd May 2025

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Data Analytics and Methods Task Force (TDA)

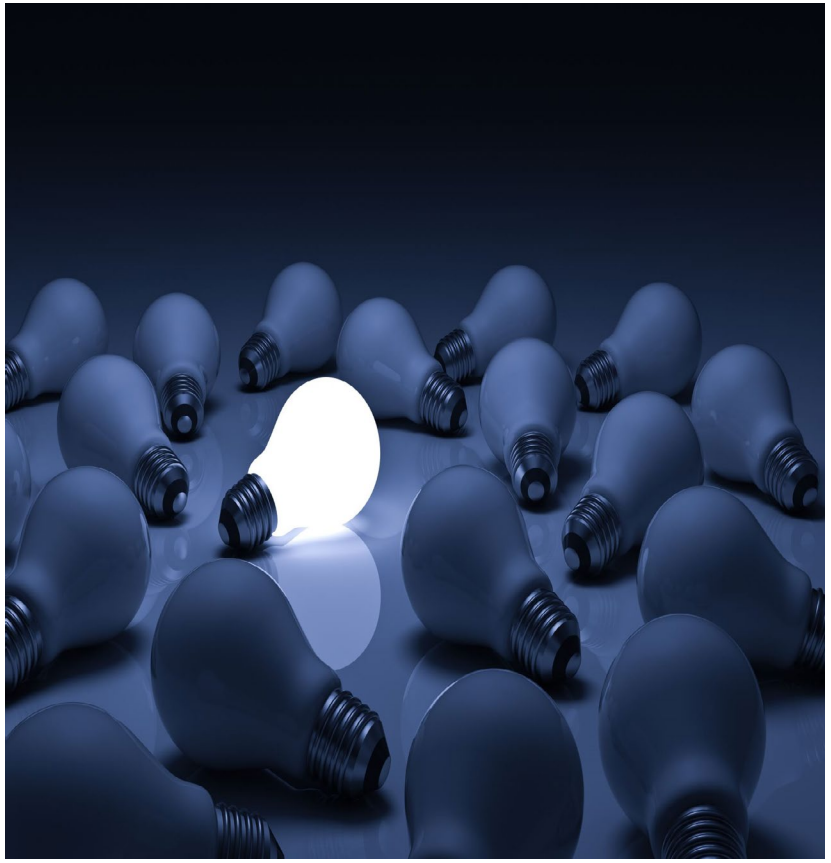
European Medicines Agency

Simplification Task Force

- The CTIS simplification task force was set up in March 2024 to streamline CTIS functionalities and **establish CTIS simplification principles to prepare for CTIS modernisation** in 2025 and beyond.

- The **goals** of the CTIS simplification task force are:
  - Simplify the CTIS business rules to enable enhanced user experience
  - Increase operational system stability
  - Facilitate optimisation of training and change management
  - Reduce operational costs

- **Membership**: EMA, HMA and the European Commission, CTIS Product Owners and CTIS SMEs from the Member States, commercial and non-commercial sponsors.



Prioritisation criteria

- Improve **user experience**
- **Security**
- Functionalities related to existing **backlog** or related to problems with high priority
- **Complexity** of functionalities
- **Dependency** with other functionalities
- **Benefit for the user** – areas identified after receiving **user feedback** via CTIS service desk tickets, from surveys, stakeholder fora, governance meetings, etc.,
- Reduced system **maintenance effort**
- Items requiring **legal input**
- **Complexity** of root cause analysis

Simplification task force

- Good progress has been made, with the analysis of six topics already completed.

Simplification topic	Status of analysis	Status remarks
1. Safety (saMS and ASR)	Open In progress Completed	• Report for saMS selection adopted in November 2024, revised ASR adopted in **December 2024** • Task force recommended creation of a new safety module
2. Timetable visualisation	Open In progress Completed	Taskforce endorsed final recommendation to keep this feature in the system in **November 2024**
3a. Role matrix	Open In progress Completed	Revised role matrix proposal, after further consultation with stakeholders, was adopted in **December 2024**
3b. User Management	Open In progress Completed	Key improvements that will provide immediate benefits to administrators have been recommended in **March 2025**, with the aim to make the user administration more efficient and user friendly
4. CTA Submission and Assessment Workflow	Open In progress Completed	Scope involves several sub-topics: • increasing flexibility on the application submission rules • reducing number of Notices and Alerts • reducing number of Tasks • workflow automatic triggers • RFIs and considerations • Cloning functionality

Simplification Taskforce

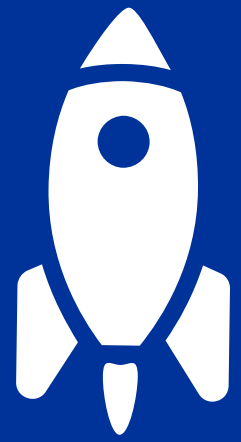
Simplification topic	Status of analysis	Status remarks
5. MS API	Open In progress Completed	To discuss initial proposal with EMA business
6. IMPD-Q Only Application	Open In progress Completed	In **January 2025**, taskforce recommended to keep the current process while closely monitoring whether there is a need to implement an alternative solution in the future
7. Ad-hoc assessment	Open In progress Completed	In **March 2025**, taskforce recommended to keep the current process with potential implementation of some improvements based on priorities.
8. Lock mechanism	Open In progress Completed	Topic accepted for analysis under the STF but not started yet
9. Download management	Open In progress Completed	Topic accepted for analysis under the STF but not started yet

Legend:

- **Open:** topic accepted to be analysed under the STF but not started yet
- **In progress**: topic ongoing, already started
- **Completed:** topic tasks finalised under the scope of the STF (the final report/artefact is done)

Safety (ASR and saMS selection)

- **New safety module**, with the aim to simplify the overall business rules for the Annual Safety Report (ASR) while enabling the selection of the safety assessing Member State (saMS) in CTIS.
- Proposal has been drafted in close collaboration with ACT EU Clinical Trials Safety Working Group and in consultation with sponsors and wider regulatory stakeholders.
- Adopted in December 2024
- **Technical safety module prototype** to be developed in Q2/2025 (proof of concept)



If successful prototype, ***new safety module*** *is foreseen to be implemented in* ***early 2026****.*

Safety (ASR and saMS selection)

- Features involved:
  - Add the possibility to use **substance centric approach**
  - **Allow sponsors to create a drafts**
  - **Reduce the number of notices and alerts** (from 14 to 6)
  - **Enable email notification**
    - Improve communication and reduce the number of notices
  - **Clean up old notices**
    - 30 days after the finalisation of the ASR
  - **Display saMS to sponsors**
  - **Provide flexibility**
    - Add co-sponsor reduces the number of ASR submission -> the number of assessment
    - Update structure data, sponsor info, link more trials etc. during the RFI

Roles Matrix

- The Task force has recommended reducing the number of user roles and simplifying granularity of permissions.
- Feeback from sponsors and Member States obtained from surveys launched in Aug 2024 and Sep 2024, respectively.
- The following **guiding principles** applied for simplification:

- Maintaining the **organisation-centric** and the **CT-centric** approaches.
- Preserving roles with a scope for **all trials** or for a **specific trial**.
- Upholding the distinction between **full rights** and **restricted rights**.
- Retaining all **seven administrator roles**.
- Maintaining the ‘Q-IMPD Preparer’, ‘ASR Submitter’, ‘MS API user’ roles unchanged.
- Maintaining a separate ‘**Inspector**’ role to secure the independence of the inspection function.
- **Merging** current viewer, preparer and submitter roles into one role in most cases.
- **Merging** separated Member State/Sponsor business activities into one role.
- Maintaining a Sponsor and an Authority **viewer** roles to ensure better segregation of responsibilities.

Roles Matrix

- Number of roles simplified from **50 roles to 18 roles**
- List of roles of the **revised roles matrix** (adopted in December 2024):

Sponsor roles	Authority roles
Sponsor Admin	**MS Admin**
CT Admin restricted rights	**NOA Admin**
CT Submitter restricted rights	MS Evaluator Supervisor full rights
CT Part I Preparer restricted rights	MS Evaluator Supervisor restricted rights
CT Submitter Part II	MS Inspector
IMPD-Q Preparer	**MS API**
ASR Submitter	**EMA Admin**
Viewer restricted rights	**EC Admin**
MAH Admin	MS Viewer full rights

Details on the current roles matrix can be found in Module 7 of the CTIS training materials

User Management

- The Task Force has recommended to implement **7 key improvements**, with the aim to make the user administration **more efficient and user friendly**.

Role assignment: Assign multiple roles to a user at once.

Trial assignment: Assign multiple specific trials to a user at once.

Bulk user assignment: Assign roles and trials to multiple users at once, within the same organisation, or across multiple sponsor organisations.

Bulk management: Introduce a 'Select all' option in search results to revoke, approve, reject, or amend roles in bulk.

Export: Allow export of user search results in XLS format for better oversight.

Copy profile: Enable administrators to copy a user's profile (roles/scope) and assign it to one or more new users.

Self-service revocation: Allow users to revoke their own roles when no longer needed, reducing administrative workload.

Improvements of the user administration feature are required before the implementation of the revised roles matrix.

Timetable

- Timetable is a dynamic tool that projects and adjusts the **evaluation timelines** in a graph. Analysis showed accuracy of the projected due dates and identified training issues from end users on this feature.

- The Task force has recommended:

  - **Keep the timetable** functionality in CTIS (other alternative solutions were proved to still require maintenance, or not accurate albeit simpler)

  - **Increase awareness** on the behaviour of this functionality (i.e: calculation of due dates), as the majority (60%) of incidents in Service Desk are training related (understanding on how to calculate the timelines)

    - Relevant article was published on NewsFlash issue of 17/12/2024
    - Review training materials (ongoing)
    - Other actions to consider: offer dedicated training events (i.e: BiteSize Talk) if needed.

  - Plan the **fix** of the few timetable related issues (following backlog prioritization process).

IMPD-Q

- CTIS integrates the submission of quality IMPD into the clinical trial application, where sponsors are concerned about potentially exposing CCI to CTIS administrators.
- Analysis of the usage of the current process showed few trials are affected (3%), mostly non-commercial (1.8 %).
- The Task force has recommended:
    - **Keep the current process at this stage,** while closely monitoring whether there is a need to implement an alternative solution in the future
    - **Promote existing cross-referencing,** where possible (Part I > Trial information> Associated clinical trials)
    - Share **best practices** to **improve the training** material about the workaround

Ad-hoc assessment

- Process that allows Member States to launch an assessment regarding a submitted notification, an investigational medicinal product, or any other information relevant to the supervision of a trial.
- Current Ad-hoc Assessment functionality works properly.
- Recommendation has been drafted in consultation with ACT EU Clinical Trials Safety Working Group, sponsors SMEs and wider regulatory stakeholders.
- The Task force has recommended:
    - **Maintain Ad-hoc Assessment AS-IS**
    - **Implement low-risk fixes/improvements** to the current feature (following backlog prioritization process), such as complete ad-hoc or send outcome to sponsor.
    - **Modernise Ad-hoc** feature to better support the assessment of safety and non-safety notifications, Serious Breaches, Quality issues as part of modernisation effort.

CTA Submission and Assessment Workflow

- The scope of this topic is to analyse the workflow holistically, considering the 6 sub-topics:

Application submission rules

Notices and Alerts

Tasks

Workflow automatic triggers

RFIs and considerations

Cloning functionality

Application submission rules

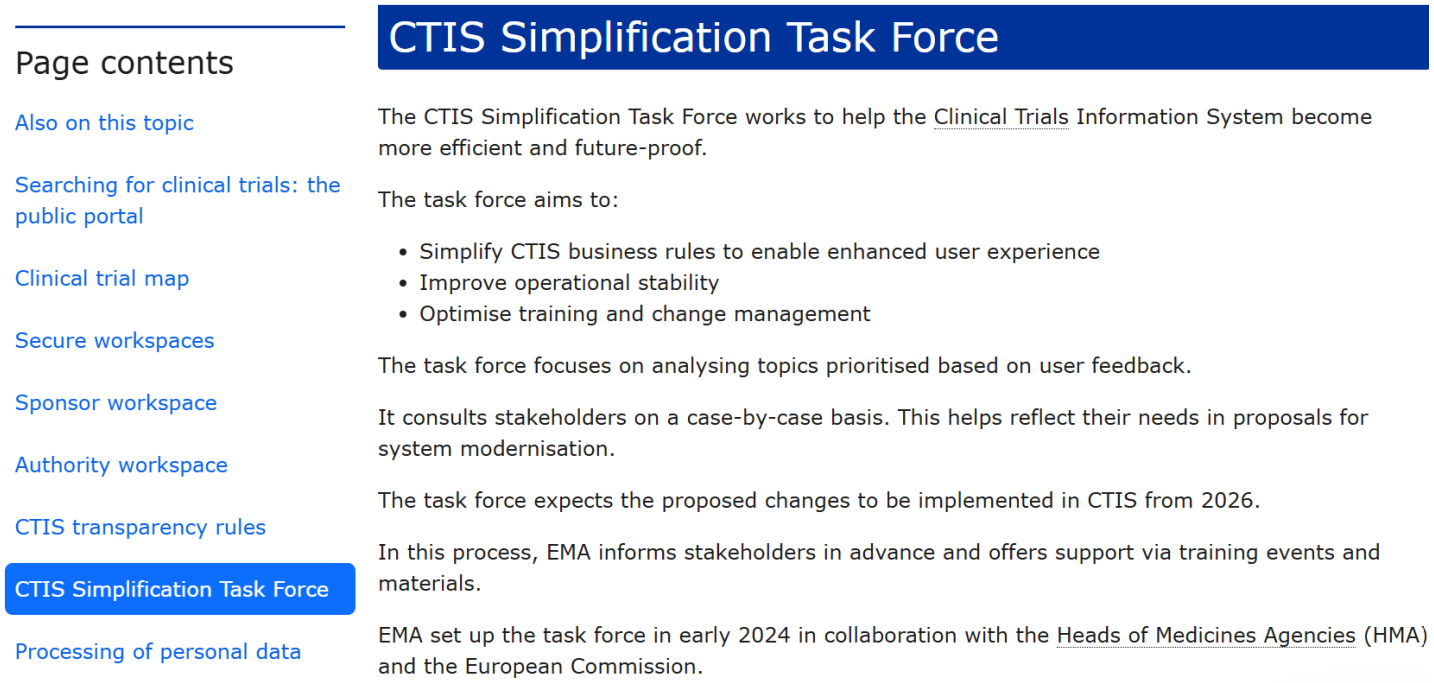
- Analysis ongoing, with the aim to introduce **more flexibility** in the submission of clinical trial applications.

- **Needs** that have been discussed:

  - Submission of **NSM Part II** if SM Part II is ongoing in other MSC.
  - Increase flexibility for the submission of **SM Part II** in multinational trials (i.e: to allow submission as soon as that MSC has authorised the trial, without waiting decision of all MSC).
  - Increase flexibility for the submission of **AMSC** applications (i.e: to allow submission as soon as one MSC has authorised the trial, without waiting decision of all MSC).
  - Facilitate submission of **SM Part I** to a MSC that received a **partial initial application (art 11)**.
  - **Other possibilities**: mutually exclusive SMs (i.e: submission of SM Part I when a SM Part II is ongoing), parallel SMs (i.e: parallel SMs Part II in the same MSC). This requires more investigation on the feasibility.

Topics updates

- Updates on topics are published on the new section dedicated to the Simplification task force on the EMA website.



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Clinical trial map

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Sponsor workspace

Authority workspace

CTIS transparency rules

CTIS Simplification Task Force

Processing of personal data

CTIS Simplification Task Force

The CTIS Simplification Task Force works to help the Clinical Trials Information System become more efficient and future-proof.

The task force aims to:

- Simplify CTIS business rules to enable enhanced user experience
- Improve operational stability
- Optimise training and change management

The task force focuses on analysing topics prioritised based on user feedback.

It consults stakeholders on a case-by-case basis. This helps reflect their needs in proposals for system modernisation.

The task force expects the proposed changes to be implemented in CTIS from 2026.

In this process, EMA informs stakeholders in advance and offers support via training events and materials.

EMA set up the task force in early 2024 in collaboration with the Heads of Medicines Agencies (HMA) and the European Commission.

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Thank you

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