Survey on simplification of CTIS sponsor roles

Fields marked with * are mandatory.

Introduction

This survey presents the proposed simplified Roles matrix for the Sponsor workspace of the Clinical Trials Information System (CTIS). The aim is to gather feedback from system users on the best approach to balance user needs, system security and efficiency in the proposed roles.

This is preparatory work with no change expected until 2025. The feedback from stakeholders will be instrumental in completing the analysis and design, ensuring the specifications are finalised ahead of the implementation by the second half of 2025. The CTIS user community will be informed of any changes ahead of time. EMA is committed to facilitating the process for sponsors and ensuring a better user experience.

The new roles aim to reduce complexity and improve functionality for users, in line with regulatory requirements.

Rationale for change

The current system contains complex business rules, added during the system design phase, that are not required by the Clinical Trials Regulation (EU) No 536/2014, hereinafter CTR. Over the past 2,5 years since the launch of CTIS, this complexity has led to a challenging technical implementation and continuous development efforts focused on stabilisation and bug fixing.

Simplifying the CTIS business rules will reduce complexity to improve user experience and pave the way to modernisation, while ensuring alignment with CTR requirements.

EMA's CTIS Simplification Task Force identified several topics as candidates for simplification. Among these topics, the Task Force prioritised the simplification of the Roles matrix as an area of high potential

benefit for users.

CTIS supports a diverse group of stakeholders, including Sponsors, Clinical research organisations (CROs), Marketing authorisation holders (MAHs), Member States (MS), Ethics Committees, the European Commission and European Medicines Agency. From a technical perspective, the system should ideally have a limited number of access roles, i.e. around 10, to optimise system operation and user experience. However, as each stakeholder group has different access needs, the current system design allows for a combination of 48 roles.

Taking into account this complexity, as well as the necessity to accommodate varied organisational models and security requirements, a streamlined set of roles is proposed. The objective is to simplify the system for users while respecting the different organisational models and the level of granularity required for Sponsors and Member States user roles, in accordance with the principle of least-privilege.

Guiding principles

The CTIS Simplification Task Force reviewed the organisational models of Sponsors and analysed system usage over the past few years. The data showed that most users consistently use specific role combinations, indicating that some roles can be grouped. Based on this analysis, the general principles guiding the proposal for simplification of the CTIS Roles matrix are as follows:

- Maintaining the organisation-centric and the CT-centric approaches.
- Preserving the ability to assign roles with a scope for all trials or for a specific trial.
- Upholding the distinction between full rights and restricted rights to prevent commercially confidential information (CCI) breaches of quality information.
- Retaining all three administrator roles except ‘CT Admin’, which is now ‘CT Admin restricted rights’ requiring the ‘Q-IMPD preparer’ role for full rights. Admin roles will continue to be assigned in IAM, except for the roles of ‘CT Admin’ and ‘MAH Admin’ which will only be managed through CTIS.
- Maintaining the ‘Q-IMPD Preparer’ and ‘ASR Submitter’ roles unchanged.
- Merging current viewer, preparer and submitter roles into one role in most cases.
- Merging separate Sponsor business activities into one role (e.g., Sponsor application, notifications and results submitter roles combined into one 'CT Submitter restricted rights' role).

Additional enhancement in role management

In addition to the rationalisation of the roles, the **user administration** feature will be enhanced, to enable multi-role assignment and selection of multiple EU CT numbers (multiple trials) when the scope is trial-specific.

This aims to address user concerns and facilitate a smoother experience with the proposed roles.

Sponsor workspace roles

A simplified set of roles that users can assign in the system to perform business activities is proposed, reducing the roles from 18 to 8:

- 7 roles for Sponsors
- 1 role for MAH

The table below lists the 8 proposed roles for the Sponsor workspace, along with their permissions:

CURRENT ROLES FOR SPONSORS	PROPOSED ROLES	PERMISSIONS	TRIAL SCOPE
Sponsor Admin	**Sponsor Admin**	• User Management (role/trial assignment, manage user roles/requests)	All
CT Admin **(without Q-IMPD permissions)** Notifications Submitter CT Results Submitter	**CT Admin restricted rights**	• User Management (role **(excluding Q-IMPD and ASR roles)**/trial assignment, manage user roles/requests) • Create/Resubmit/Copy/Submit/Withdraw CTAs (IN, SM, NSM and AMS) • Populate (IN, SM, NSM and AMS) CTA sections (Form, MS, Part I ~~quality/~~exc quality and Part II) • Respond to Part I ~~quality/~~exc quality and/or Part II RFIs • Create, submit, update and withdraw notifications/Respond to ad hoc assessment RFIs • Create, submit, update and withdraw Summary of Results • ~~Create and submit ASR /Respond to ASR RFIs~~ • View permissions – refer to permission of the role "Viewer restricted rights" ***Notes on the 'CT Admin restricted rights' role:*** - *This is the only administrator role that includes business permissions in addition to user management.* - *Users with this role may have additional roles, including 'Q-IMPD Preparer' and 'ASR Submitter', which they can also assign to other users.* - *Users with the combined roles 'CT Admin restricted rights' and 'Q-IMPD Preparer' have permissions equivalent to the current CT Admin role.* - *When creating a CT-centric trial, the system will assign the user a combination of 'CT Admin restricted rights' and 'Q-IMPD preparer' roles.*	Specific trial / All
Application Submitter Notifications Submitter CT Results Submitter	**CT Submitter restricted rights**	• ~~User Management (role/trial assignment, manage user roles/requests)~~ • ~~Create/Resubmit/Copy/~~Submit/Withdraw Part I and/or Part II CTAs (IN, SM, NSM and AMS) • Populate (IN, SM, NSM and AMS) CTA sections (Form, MS, Part I ~~quality/~~exc quality and Part II) • Respond to Part I ~~quality/~~exc quality and/or Part II RFIs • Create, submit, update and withdraw notifications/Respond to ad hoc assessment RFIs • Create, submit, update and withdraw Summary of Results • ~~Create and submit ASR /Respond to ASR RFIs~~ • View permissions– refer to permissions of the role "Viewer restricted rights"	Specific trial / All
Part II Preparer Notifications Preparer	**CT Preparer Part II only**	• ~~User Management (role/trial assignment, manage user roles/requests)~~ • ~~Create/Resubmit/Copy/Submit/Withdraw CTAs (IN, SM, NSM and AMS)~~ • Populate (IN, SM, NSM and AMS) CTA sections (Form, MS, ~~Part I quality/exc quality and~~ Part II) • Respond ~~to Part I quality/exc quality and/or~~ Part II RFIs • Create, ~~submit, update and withdraw~~ notifications/Respond to ad hoc assessment RFIs • ~~Create, submit, update and withdraw Summary of Results~~ • ~~Create and submit ASR /Respond to ASR RFIs~~ • View permissions Part II	Specific trial / All
Q-IMPD Preparer	**Q-IMPD Preparer**	• Populate (IN, SM, NSM and AMS) CTA sections (~~Form, MS,~~ Part I quality/~~exc quality and Part II~~) • Respond to Part I quality/~~exc quality and/or Part II RFIs~~ • View drafted/submitted quality related information	Specific trial / All
ASR Submitter	**ASR Submitter**	• View, create and submit ASR • Respond to ASR RFIs	Specific trial / All
Part I Viewer (exc Q-IMPD) Part II Viewer Notifications Viewer CT Results Viewer	**Viewer restricted rights**	• View ~~draft/~~submitted Part I ~~quality/~~ exc quality and/or Part II (IN, SM, NSM and AMS) • View draft/submitted RFI • View ~~draft/~~submitted Response to Part I ~~quality/~~exc quality and/or Part II RFIs • View draft/submitted RMS selected • View draft/submitted Validation information ~~quality/~~exc quality • View draft/submitted Part I ~~quality/~~exc quality Assessment information (conclusion, ARs and Part I disagreement) • View draft/submitted Part II Assessment information (conclusion and ARs) • View draft/submitted MSC decision/reverted decision • View CT list (~~draft/~~submitted CTs) • View Summary tab (including ~~draft/~~submitted CTAs) • View Full trial information tab • View Notifications tab (~~draft/~~submitted notifications) • View CT Results tab (~~draft/~~submitted summary of results/lay person summary) • View Corrective measures tab (draft/submitted request for opinion/final opinion and ~~draft/~~submitted opinion response) • View ad hoc assessment tab (draft/submitted RFI and ~~draft/~~submitted RFI response) • View Notices and Alerts tab • View users tab • Download CT (only information that users have access to according to role permissions)	Specific trial / All
MAH Admin	**MAH Admin**	• User Management (role/trial assignment, manage user roles) • View, create, submit, update and withdraw Clinical Study Report	Specific trial

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[Table_with_proposed_changes_to_CTIS_sponsor_roles.pdf]

The completion of the survey is expected to take 30 minutes.

Deadline: 15 September 2024 (midnight CET).

Thank you for your contribution.

Organisation details

* **Please identify the type of sponsor you represent**
  - ( ) Commercial sponsor (large industry)
  - ( ) Commercial sponsor (small and medium-sized enterprises - SMEs)
  - ( ) Non-commercial sponsor (i.e., investigators teams, research institutions, major medical centers)
  - (•) Other

* If other, please specify

industry trade association

* **Name of the institution/company you represent:**

ACRO (Association of Clinical Research Organizations)

If you also represent an association, please provide the association name:

ACRO (Association of Clinical Research Organizations)

Survey

Note: In this survey, 'current' refers to existing roles, while 'proposed' refers to the new roles.

Key Notes:

a. The user administration feature will be improved to facilitate role assignment (refer to section 'Additional enhancements in role management').
b. Users with the 'CT Admin restricted rights' role, when assigned additional roles (e.g., 'CT Admin' combined with 'Q-IMPD Preparer' or 'ASR Submitter') will be able to assign these extra roles to others.
c. The ability to assign roles with either trial-specific scope or for all trials is preserved.

Please keep in mind that the following roles remain unchanged: '**Sponsor Admin**', '**MAH Admin**', '**Q-IMPD Preparer**', '**ASR Submitter**' (refer to the table 'Sponsor workspace roles' section).

1. CT Admin restricted rights:
1a. This role can be assigned to users in isolation or combined with the '**Q-IMPD Preparer**' role, making it equivalent to the current '**CT Admin**' role. Does the flexibility to use this role in isolation or in combination with the '**Q-IMPD Preparer**' meet your organisational model needs, considering the key points a, b and c highlighted above?
  - (•) Yes

- ○ No
- ○ Not applicable

1b. The current '**CT Admin**' does not have ASR permissions unless the '**ASR Submitter**' role is assigned. The same applies to the proposed '**CT Admin restricted rights**', with the difference highlighted in the key point b above. Does the flexibility to use this role in isolation or in combination with the '**ASR Submitter**' role meet your organisational model needs, considering the key points a, b and c highlighted above?

- ◉ Yes
- ○ No
- ○ Not applicable

2. CT Submitter restricted rights:

This role is equivalent to the current '**Application Submitter**' Part I and Part II role combined with the '**Notifications Submitter**' and '**CT Results Submitter**'. Has your organisation already assigned this combination of roles with the mapped permissions (refer to table) to any user(s)? If not, could it fit your organisational model, considering the need for simplification?

- ○ Yes, this combination of roles is already assigned to one or more users
- ○ This combination of roles is not yet assigned to any users but could fit
- ◉ No, it does not fit
- ○ Not applicable

* If you answered No, it does not fit, please explain:

1000 character(s) maximum

While this combination of roles is not yet assigned to any users but could fit, the pooling of multiple submission permissions to a user while his role may only be limited to a subset of those (i.e. Part II, start of trial / recruitment and other country level notifications, results posting), may be a concern in the business model of certain pharma companies focused on the least privilege rule (effectively aiming to restrict access for CTIS users only to those areas they should edit) and affect negatively those business models, scope and extent of outsourcing. As such, ACRO would strongly favor a more granular approach to submission delegation, at least around study level versus country level activities (add a country submission profile in addition to the study level one)

3. CT Preparer Part II:

This role is equivalent to the current '**Part II Preparer**' combined with the '**Notifications Preparer**'. This accommodates users preparing CTA related information (Part II and notifications). Has your organisation already assigned this combination of roles with the mapped permissions (refer to table) to any user(s)? If not, could it fit your organisational model, considering the need for simplification?

- ○ Yes, this combination of roles is already assigned to one or more users
- ○ This combination of roles is not yet assigned to any users but could fit
- ◉ No, it does not fit
- ○ Not applicable

* If you answered No, it does not fit, please explain:

1000 character(s) maximum

While this combination of roles is not yet assigned to any users but could fit, the pooling of multiple preparation permissions to a user while his role may only be limited to a subset of those (i.e. Part II, start of

trial / recruitment and other country level notifications, results posting), may be a concern in the business model of certain pharma companies focused on the least privilege rule (effectively aiming to restrict access for CTIS users only to those areas they should edit) and affect negatively those business models, scope and extent of outsourcing. As such, ACRO would strongly favor a more granular approach to submission delegation, at least around study level versus country level activities (add a study level preparer profile in addition to the Part II level one, in order not to rely on the CT Submitter restricted rights role and its conflicts with the least privilege rule)

4. Viewer restricted rights:
This role is introduced for simplification (refer to table permissions). Which of the below roles are more often used in your organisation model?

- ○ Restricted rights
- ○ Full rights
- ○ Not applicable

5. Role suitability: How well do the proposed roles meet/could meet your organisational model needs considering the need for simplification?

- ○ Very well
- ○ Well
- ◉ Neutral
- ○ Poorly
- ○ Very poorly

6. Permission Adequacy: Do the permissions assigned to each proposed role adequately cover the required activities for this role?

- ○ Yes
- ◉ No
- ○ Not applicable

* If you answered No, please specify which role and/or additional permission(s) are needed or should be removed"

1000 character(s) maximum

The lack of granularity under the preparer and submitter roles are a limitation for current outsourcing models towards CROs and current delegation schemes used by certain sponsors, heavily relying on the least privilege principle when delegating user access in regulated systems. As such we would recommend to ensure that both preparer and submitter roles include both an extensive set of permissions (initial / modifications for part I and part II, all notifications, results) and a more restricted set of permissions focused on country-level routine activities (Part II for initial and modifications, study lifecycle notifications without urgent safety measures, serious breaches unexpected events), as also commented in questions 2 and 3

7. Role combinations: Should any roles be further combined considering the need for simplification?

- ○ Yes
- ◉ No
- ○ Not applicable

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