EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Roles and permissions matrix summary

Sponsors Workspace

CTIS Training Programme – Module 7

Version 2.29 – October 2022

CT Role-Permission Matrix

This document gives an overview of the permissions linked to the Sponsor workspace roles, covering not only the sponsor roles but also the marketing authorisation holder ones.

a) Definitions

- **Role:** business job function with a collection of permissions
    - Administrator roles (MS Admin, Sponsor Admin, CT Admin etc.)
    - Business roles (preparer, submitter etc.)

- **Permission:** an approval to do something on data or other system resources. There are business permissions (e.g. create considerations, create AR, create responses to RFI) and access permissions (view, prepare and submit). Permissions are 'positive'.

b) Types of permissions

Viewer role

- **View permission**: allows user to view structured data, documents, and includes download of documents.

Preparer role

- **Create permission**: it allows the user to edit, upload documents, save and update saved drafts. It also allows users to copy from an existing CTA to create a new one.
- **Delete permission:** delete refers to eliminate/cancel draft items.

Submitter role

- **Share permission:** it allows the user to share the respective data/documents within their workspace per the use cases (this is only applicable to MS roles).
- **Submit permission:** it allows the user to submit data/documents from their respective workspace to the EUPD.
- **Update permission**: it allows updating submitted information.

Other

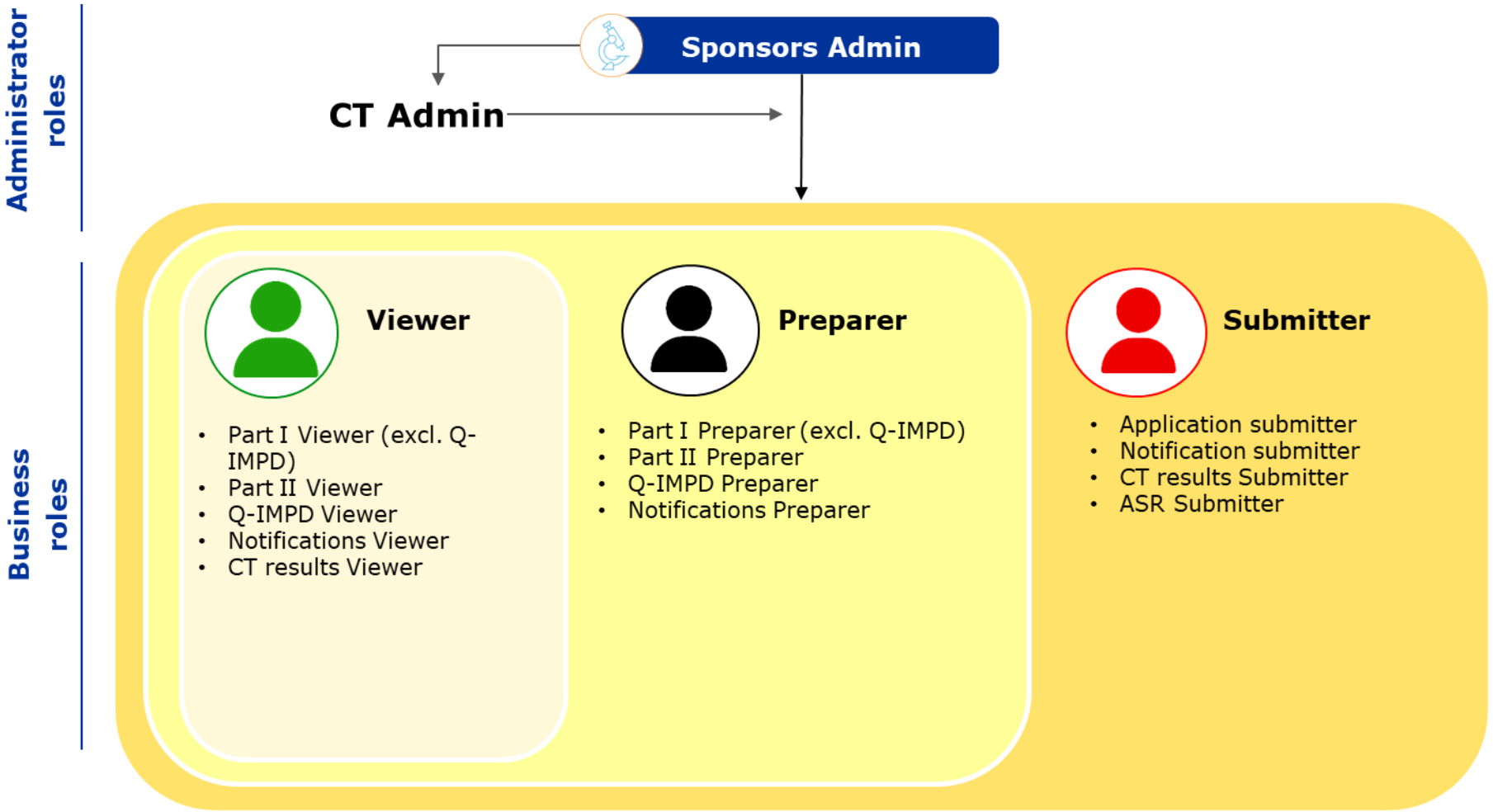
- Permission related to user management (assign roles etc.) and management of tasks (assign tasks etc.).

1. DEFAULT ROLE

This role is given by default to any registered user as birth right permission.

Role	Birth rights permissions
Default Role	Create CTA
	View Document
	Delete Document
	Upload Document
	View my roles
	Update personal profile
	Request role
	View organisation/location
	Create organisation/location
	Update organisation/location

2. SPONSOR ROLES



Permission label:

	Permission not allowed to a particular role
	Permission allowed to a particular role

2.1. ADMINISTRATORS' ROLES AND PERMISSIONS

Role (Use Case)	Detailed Permissions	Sponsor Administrator	CT Administrator[1]
Administrator (1014)	Manage role assignment		
	Allocate trials to users		
	View user roles and request		

1. These roles have also mapped the permissions of all the related business roles (please refer to business roles in the next pages).

2.2 SPONSOR VIEWER ROLES*

*Viewer roles do not get notices and alerts related to the mentioned business tasks, unlike other user roles.

Permissions	Part I Viewer (excl. Q-IMPD)	Q-IMPD Viewer	Part II Viewer	Notifications Viewer	CT results Viewer
Form: cover letter, proof of payment, Compliance Reg. 2016/679 and deferral					
MSC					
Part I dossier: Q-IMPD/ scientific advice restricted document					
Part I dossier: excl. Q-IMPD					
Part II dossier					
RMS selection (from the evaluation tab)					
RMS selected (from the summary tab)					
Validation information: RFI/RFI response - Q-IMPD					
Validation information: RFI/RFI response – excl. Q-IMPD					
Validation information: validation conclusion					
Assessment Part I information: assessment Part I information – quality-related information					
Assessment Part I information: assessment Part I information - excluding quality-related information					
Assessment Part I information: part I conclusion					
Assessment Part I information: part I disagreement					

Permissions	Part I Viewer (excl. Q-IMPD)	Q-IMPD Viewer	Part II Viewer	Notifications Viewer	CT results Viewer
Assessment Part II information (RFIs, responses to RFIs, final Part II AR and Part II conclusion)					
MSC Decision (including Revert decision)					
Timetable					
CT list and summary tab					
Full trial information tab					
Notifications tab					
CT Results tab (Result summary)					
Corrective measures tab (including request for opinion, view of the opinion)					
Assessment additional information tab (RFI and RFI response)					
Users tab					
Tasks and messages (notices and alerts)					
Inspection					
Union Control					
Download CT (only information that users have access to according to role permissions**)					

** Each role can download according to the view permissions mapped in the role (e.g. a Part II role can download information related to Part II role etc.).

2.3 SPONSOR CTA PREPARER AND SUBMITTER ROLES

(**Black** text refers to soft tasks, and **red** text refers to hard tasks)

Phase	Permissions/Tasks	CT Admin	Part I preparer (excl. Q-IMPD)	Part II Preparer	Q-IMPD Preparer	Application Submitter
Create CTAs	Create a new trial (initiate)					
	Create a CTA copy or resubmit a CTA[1]					
	Create subsequent applications (SM, AMS, non-SM)					
Create initial application	**Form:** create cover letter/Compliance Reg. 2016/679/ Deferral/ (CT Transition)[2]					
	Form: proof of payment					
	MSC: add MSCs involved					
	Part I: Populate information Part I (Q-IMPD)					
	Part I: Populate information Part I (excl. Q-IMPD)					
	Part II: Populate information for Part II					
	Timetable: Modify Winter clock stop					
	Cancel/ **submit/ withdraw** a CTA					
Create substantial modification	Initiate creation SM					
	Form: cover letter/SM description					
	Form: proof of payment					
	MSC: Modify the expected number of subjects					
	Part I: Modify Part I (Q-IMPD)					
	Part I: Modify Part I (excl. Q-IMPD)					
	Part II: Modify Part II					
	Timetable: Modify Winter clock stop					
	Cancel/ **submit/withdraw** SM					

1. Only CT Admin (scope **All roles**) can copy or resubmit a trial, not CT Admin with scope **Specific trial(s)**.
2. This section is only applicable for transitional trials.

2.3 SPONSOR CTA PREPARER AND SUBMITTER ROLES

(**Black** text refers to soft tasks, and **red** text refers to hard tasks)

Phase	Permissions/Tasks	CT Admin	Part I preparer (excl. Q-IMPD)	Part II Preparer	Q-IMPD Preparer	Application Submitter
Create non-substantial modification	Initiate creation NSM					
	Form: NSM description					
	Form: proof of payment					
	Part I: Modify Part I documents (Q-SA)					
	Part I: Modify Part I documents (excl. Q-SA)					
	Part II: Modify Part II					
	Cancel or **submit** NSM					
Additional Member State Concerned	Initiate creation AMS					
	Form: cover letter/ Compliance Reg. 2016/679					
	Form: proof of payment					
	MSC: Add the expected number of subjects[3]					
	Part I: Add Translations to Part I (Q-IMPD)					
	Part I: Add Translations to Part I (excl. Q-IMPD)					
	Part II: Create Part II					
	Timetable: Modify Winter clock stop					
	Cancel or **submit** additional MS application					

3. The AMS will be added when initiating the creation of the AMS CTA by the CT Admin or Application submitter. Therefore, only the expected number of subjects needs to be added in the MSC Form.

2.3 SPONSOR CTA PREPARER AND SUBMITTER ROLES

(**Red** text refers to hard tasks)

Phase	Permissions/Tasks	CT Admin	Part I preparer (excl. Q-IMPD)	Part II Preparer	Q-IMPD Preparer	Application Submitter
RFI Response	Add supporting documentation – General					
	Add supporting documentation - Quality					
	Change CTA Part I excl. Q-IMPD/add CTA changes					
	Change CTA Part I Q-IMPD/add CTA changes					
	Change CTA Part II/add CTA changes					
	Reply to Part I excl. Q-IMPD considerations/add document					
	Reply to Part I Q-IMPD considerations/add document					
	Reply to Part II considerations/add document					
	Discard CTA changes/Submit RFI response					

2.4 SPONSOR NOTIFICATIONS AND SUMMARY OF CT RESULTS PREPARER AND SUBMITTER ROLES

(**Red** text refers to hard tasks)

Phase	Permissions/Tasks	CT Admin	Notification Preparer	Notification Submitter
Submit notification	Create trial and recruitment period notifications			
	Create other notifications			
	Submit/update/withdraw notification			

Phase	Permissions/Tasks	CT Admin	CT Results Submitter
Clinical Study Report result summary	Create summary of results*		
	Create lay person summary of results		
	Submit/update/withdraw summary of results		

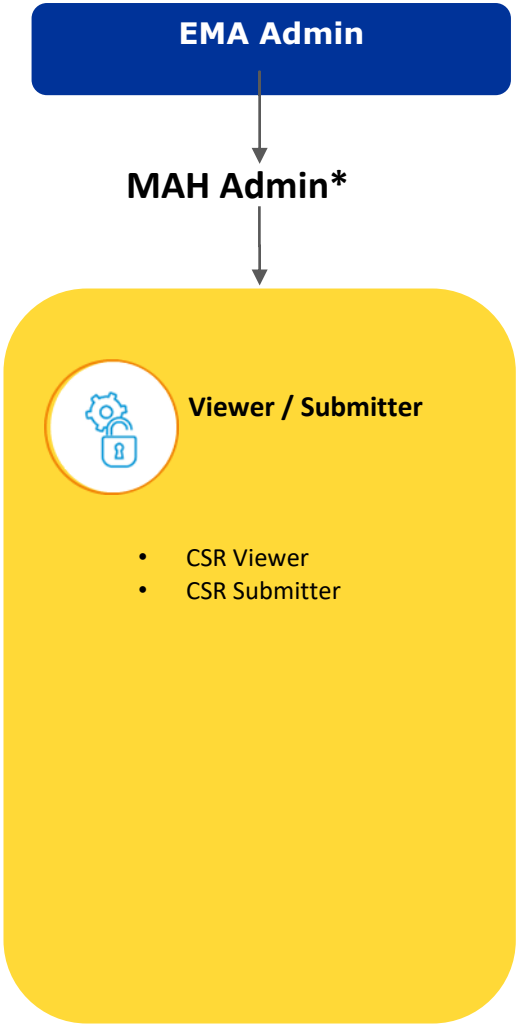
* Including intermediate analysis of data results, as applicable.

2.5 SPONSOR ANNUAL SAFETY REPORT SUBMITTER

The ASR role is responsible for the creation and submission of the Annual Safety Report.

Phase	Permissions/Tasks	ASR Submitter
Annual Safety Report	Create ASR	
	Submit ASR	

3. MARKETING AUTHORISATION HOLDER ROLES



Marketing Authorisation Holder (MAH):** user group within the sponsor workspace that is responsible for managing CSRs.(*detailed information can be found in **Module 13)

MAH ADMIN AND CSR VIEWER AND SUBMITTER ROLES

High Level permissions	Permissions	CSR Viewer
Manage Trial and applications	View trial (list and summary)	
Manage Tasks	View notice/alert	
CT Study reports	View	

Phase	Permissions/Tasks	MAH Admin	CSR Submitter
Clinical Study Report	Create CSR		
	Submit/update/withdraw CSR		

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Clinical Trials Information System (CTIS).

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