



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sponsor roles and permissions in CTIS

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EMA Clinical trial sponsor training for SME and academia

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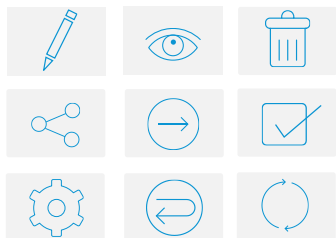
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A flexible system that can be adapted in the near future

Permissions

example



Roles

example

Mix and match

Business Roles
(validator, assessor, supervisor etc.)

Administrators



Coordinator
(only for MS WS)



Viewer



Preparer



Submitter



Assign roles to people

Registered user profile



Each user can be assigned **one or more roles** to allow him/her to execute relevant actions in the system

Roles will be created by grouping respective permissions



Create



View



Delete



Share



Submit



Assign/release task



Assign roles/trials














Withdrawal



Update



There are **three types of permissions**. Roles in CTIS come with a specific set of permissions attached to them.

Types of permissions		Match with roles
User management permissions	Administrator Roles	High and Medium- level administrator roles (User management permissions) <div>  View  Assign role </div>
Task management permissions	Business Roles	Coordinator role (Task management permissions – <i>only for Member States</i>) <div>  View  Assign task </div>
Access level permissions		Other business roles (Access level permissions) <div> <div>  Share  Submit  Withdraw  Update Submitter role </div> <div>  Create  Delete Preparer role </div> <div>  View Viewer role </div> </div>



Roles are predefined group of actions that users are able to perform in CTIS regarding a CTA or data and documents submitted during the CT life-cycle, **in accordance with their responsibilities established in the CT Regulation.**



Administrator roles



High-level administrators

- Assigned in the **EMA Account Management System***
- Need to be validated by the EMA
- They can:
 - **Approve back ups** in EMA Account Management System
 - **Assign, amend or revoke** roles in CTIS.

Medium-level administrators

- Assigned by high-level administrators in **CTIS** (Sponsor Admin)
- They can: **Manage roles, but limited to their specific organisation & their same user profile** (CT Admin)



Business roles




CT Coordinator (only for MS)

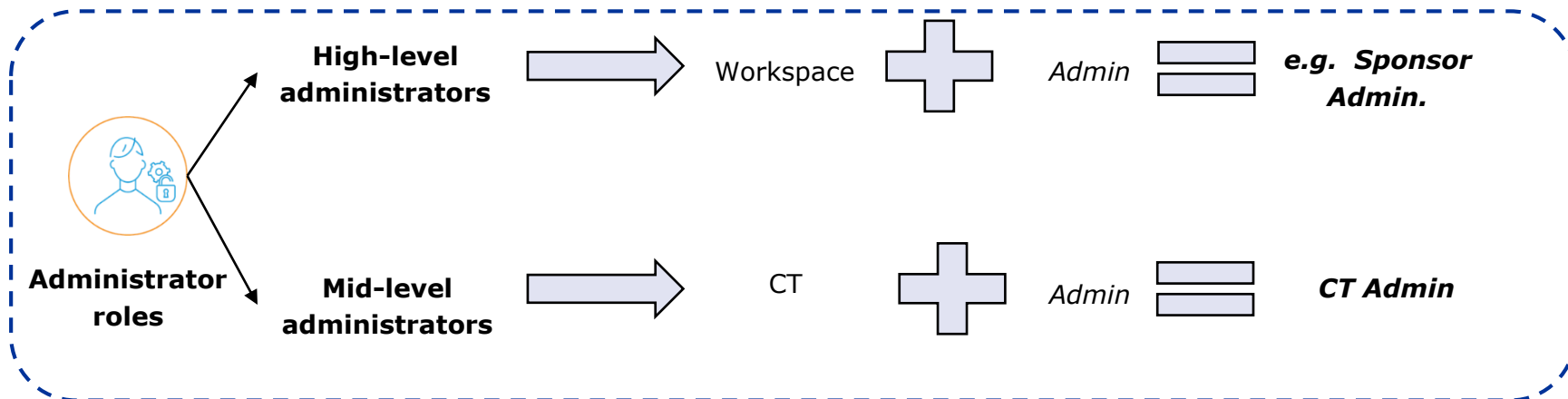
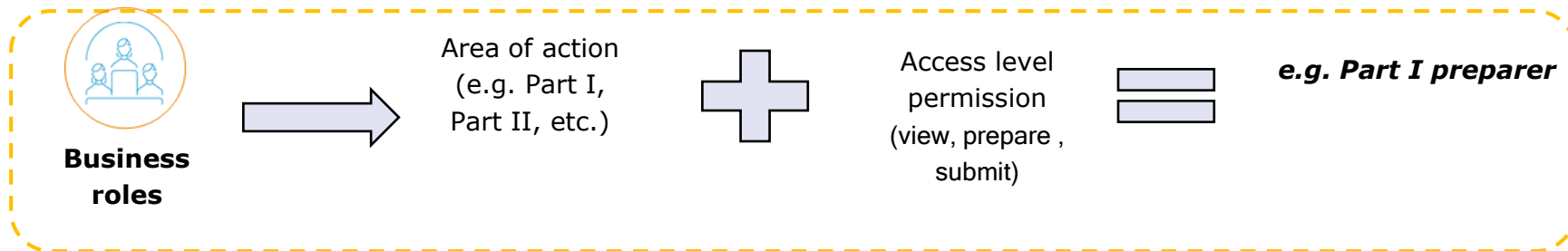
- Need to be assigned by an administrator user.
- They can: **Assign tasks to other business roles to support workload management.**

Other business roles

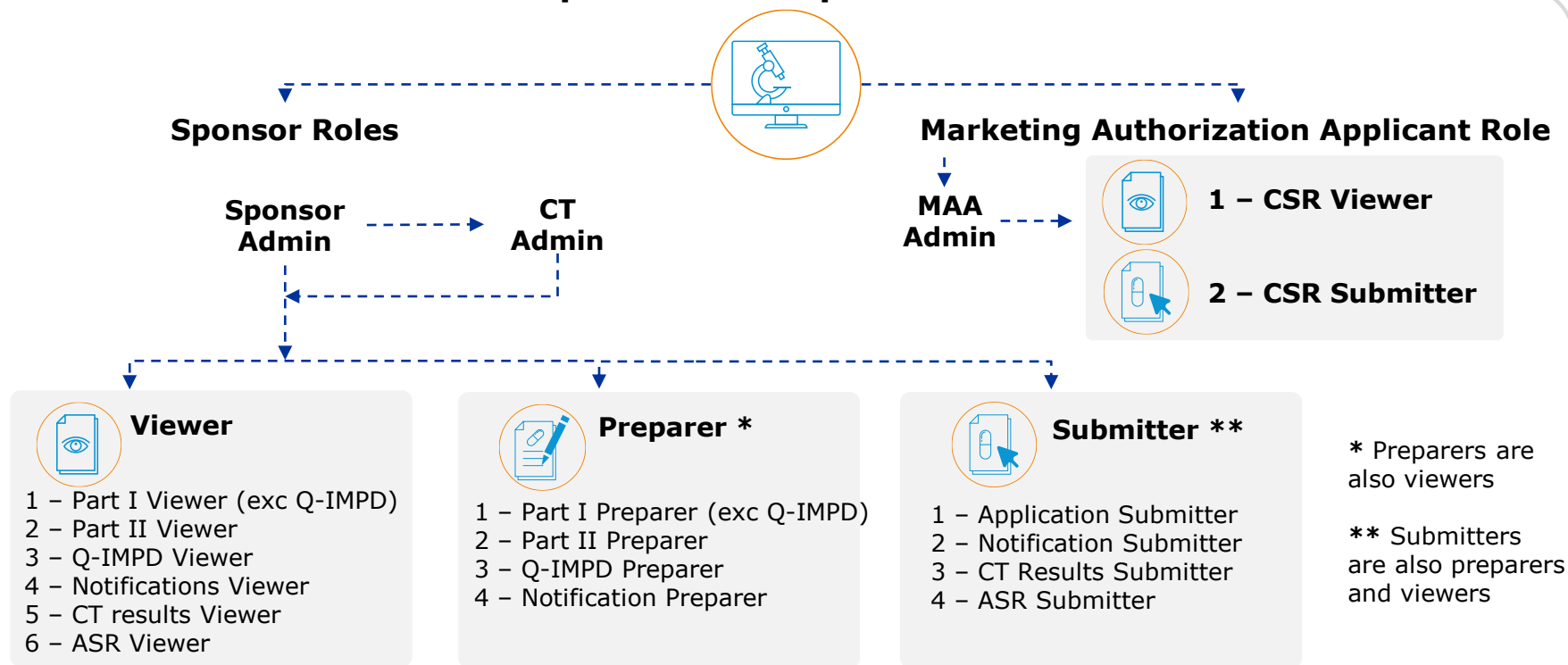
- Need to be assigned by an administrator user.
- They can **perform specific business activities in CTIS** according to the access level permissions linked to them (i.e. submitters, preparers, viewers).

*

 **Business roles name: the area of action within the CT dossier where the role is involved in and the access level permission.** Administrator roles are preceded by the user group the user belongs to.



Sponsor Workspace Roles



CTIS- Administrator roles: Type of permissions

Sponsor Administrator



CT Administrator



- Manage role assignment:
 - Assign role
 - Amend role
 - Revoke role
 - Approve users role requests
- Allocate scope/trials to users
- View users roles



	Users to be administered	Roles to be assigned in CTIS	Trial scope to be assigned	Act as Back-up	Business permissions
Sponsor Admin	All users affiliated to the sponsor organisation	All ¹	All or specific	All-Sponsor and CT Admins	No
CT Admin	All users or specific users, with a business role, depending on whether the CT Admin scope is "All" or "specific CT", .	All ¹	All or specific ²	CT Admin with the same scope	Yes ³

1. "All" means all roles except the sponsor administrator role , which is not assigned in CTIS but in IAM

2. If CT Admin s assigned with the scope specific trials then this role can only assign roles with the scope "specific trials"

3. CT Admin is also a business super user having mapped the business permissions of all business roles

Viewer



View

Allows user to view structured data, documents, and includes download of documents

Preparer (is also viewer)



Create

Allows the user to edit, upload documents, save, update saved drafts. It also allows users to copy from an existing CTA to create a new one



Delete

Delete refers to eliminate/cancel draft items

Submitter (is also preparer and viewer)



Share (only in MS WS)

Allows the user to share the respective data/documents with other MSs within the workspace (this is only applicable to MS roles).

Note: "Share" in the Part II section means "save" the information, making it available within that MS rather than to other MSs like for Part I.



Submit

Allows the user to submit data/documents from their respective workspace to the EUPD



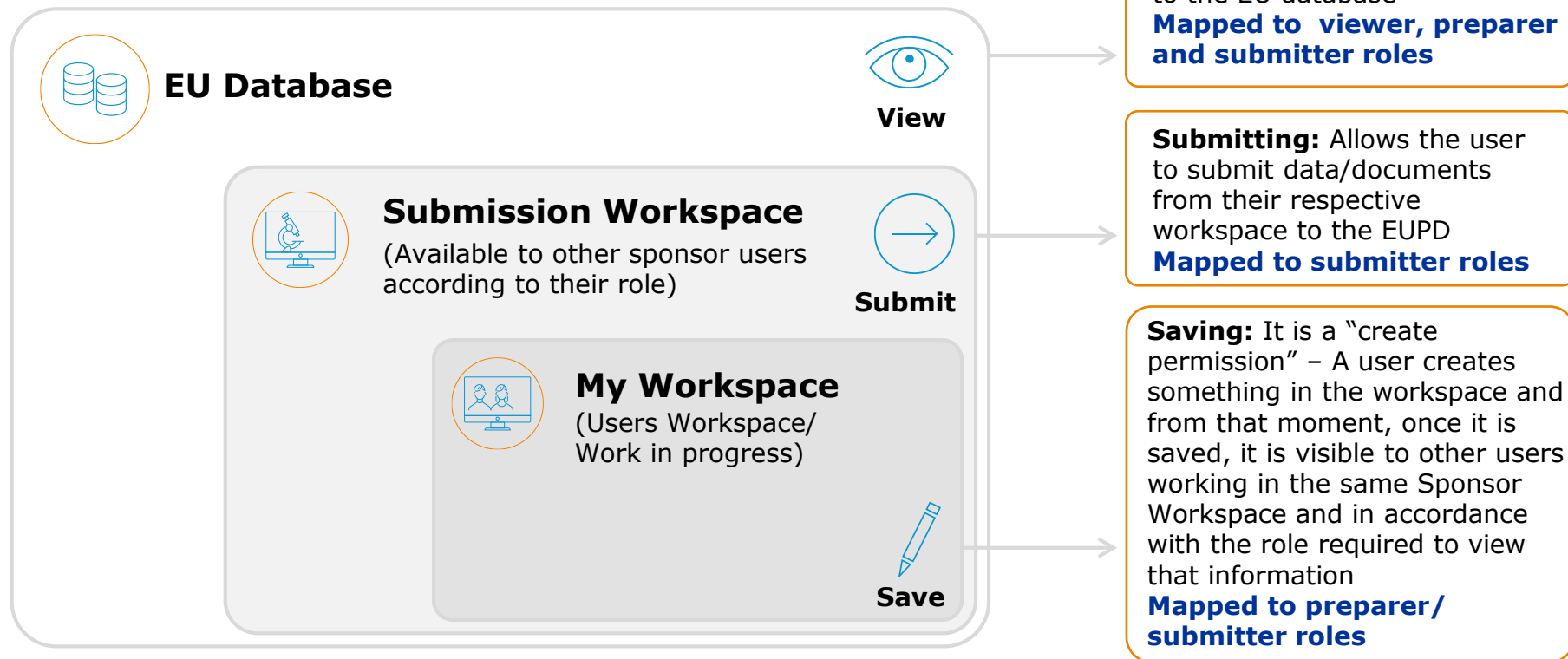
Update

Allows updating submitted information



Withdraw

Refers to the withdrawal of submitted items



SPONSOR BUSSINESS PREPARER AND SUBMITTER ROLES

High level permission	Detailed Permissions	PREPARER				SUBMITTER			CT Admin
		Part I (exc Q-IMP) ¹	Q-IMP ²	Part II ³	Notifications ⁴	Application ⁵	Notifications ⁴	CT results ⁶	
CTA application (1002, 1005,1008,1009,1010 1011, 1012, 1013, 1022, 1070)	Create initial application*								
	Create a CTA copy								
	Create subsequent applications (SM, AMS, non-SM)								
	Form: Create proof of payment								
	Form: Create deferral/cover letter								
	Create/Delete MSC								
	Create Part I except quality IMPD/Scientific Advice restricted document								
	Create Part I quality IMPD/Scientific Advice restricted document								
	Create Part II								
	Create request to change winter clock stop (Under Timetable)								
	Check CTA								
	Delete CTA (i.e. cancel the CTA)								
	Submit/Withdraw CTA								
Responses to RFI (1022)	Create RFI response including update CTA								
	Delete CTA changes in the RFI response/Submit RFI response								
Notifications (1091)	Create/Delete notification								
	Submit/Update/Withdraw notification								
Assess additional information (1064)	Create/submit responses to request for additional information								
Opinions regarding corrective measures (1039)	Create/Submit opinion								
Summary of results (1067)	Submit/Update/Withdraw summary of results								

EMA CTIS training programme Module 07 – Management of registered users and role matrix



Click [here](#) for online training materials related to this module.



Any questions?

Further information

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