



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Roles and permissions matrix summary

Authority Workspace

CTIS Training Programme – Module 7

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CT Role-Permission Matrix

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.).
- Note:** *The job profile of a user can be built by combining roles.*
- **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:** it allows the user to view structured data, documents, and includes download of

Preparer role*

- **Create permission:** it allows the user to edit, upload documents, save and update saved drafts.
- **Delete permission:** delete refers to eliminate/cancel draft items.

Submitter role*

- **Share permission:** it 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 permission:** it allows the user to submit data/documents from their respective workspace to the EUPD.
- **Update permission:** it allows updating submitted information.

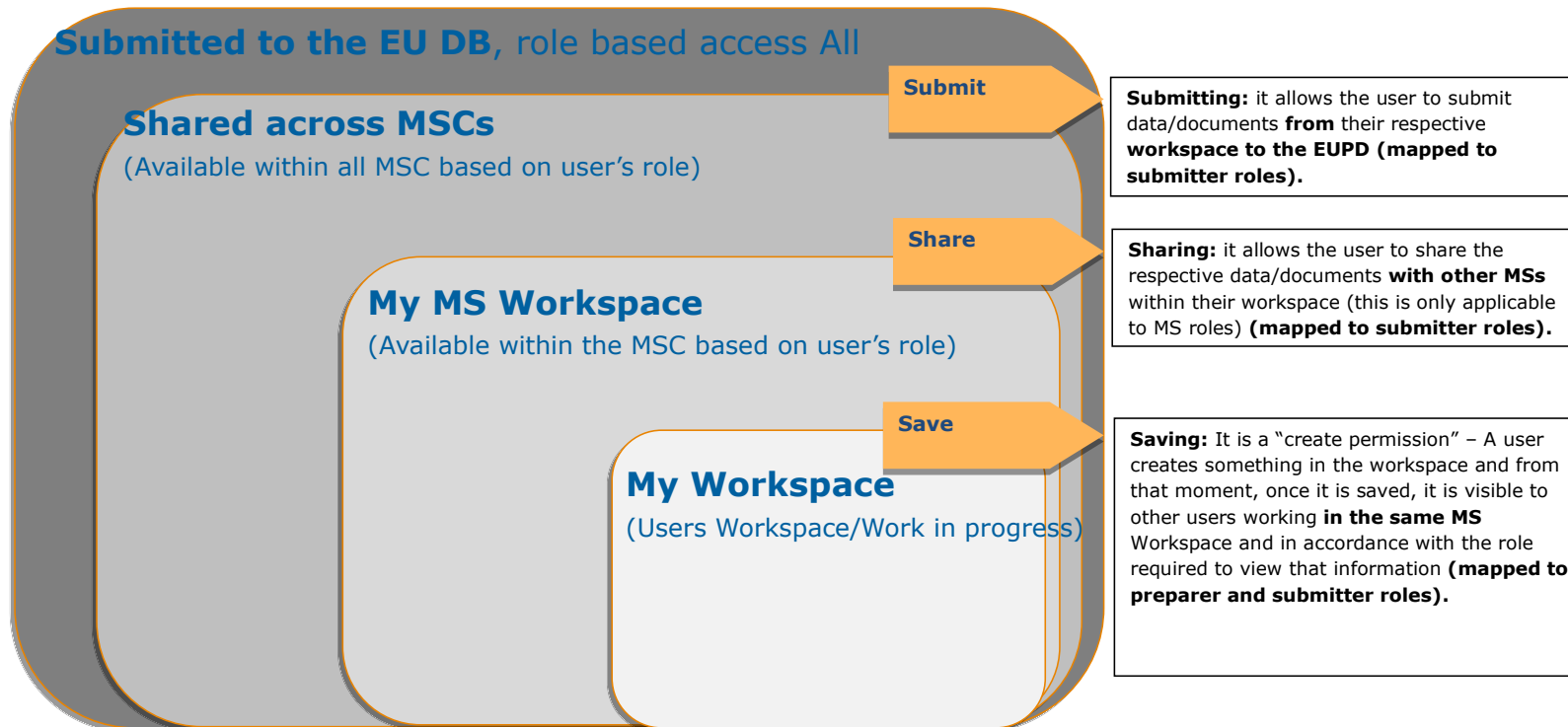
Other

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

* It should be noted that "Preparer" and "Submitter" roles have mapped the "View" permissions of the viewer roles and they will only be able to execute their preparer and submitter permissions according to what they can view (e.g. a role with restricted view of the Q-IMPD should not be able to create Q-considerations).

Saving, sharing and submitting concepts

Authority
Workspace 

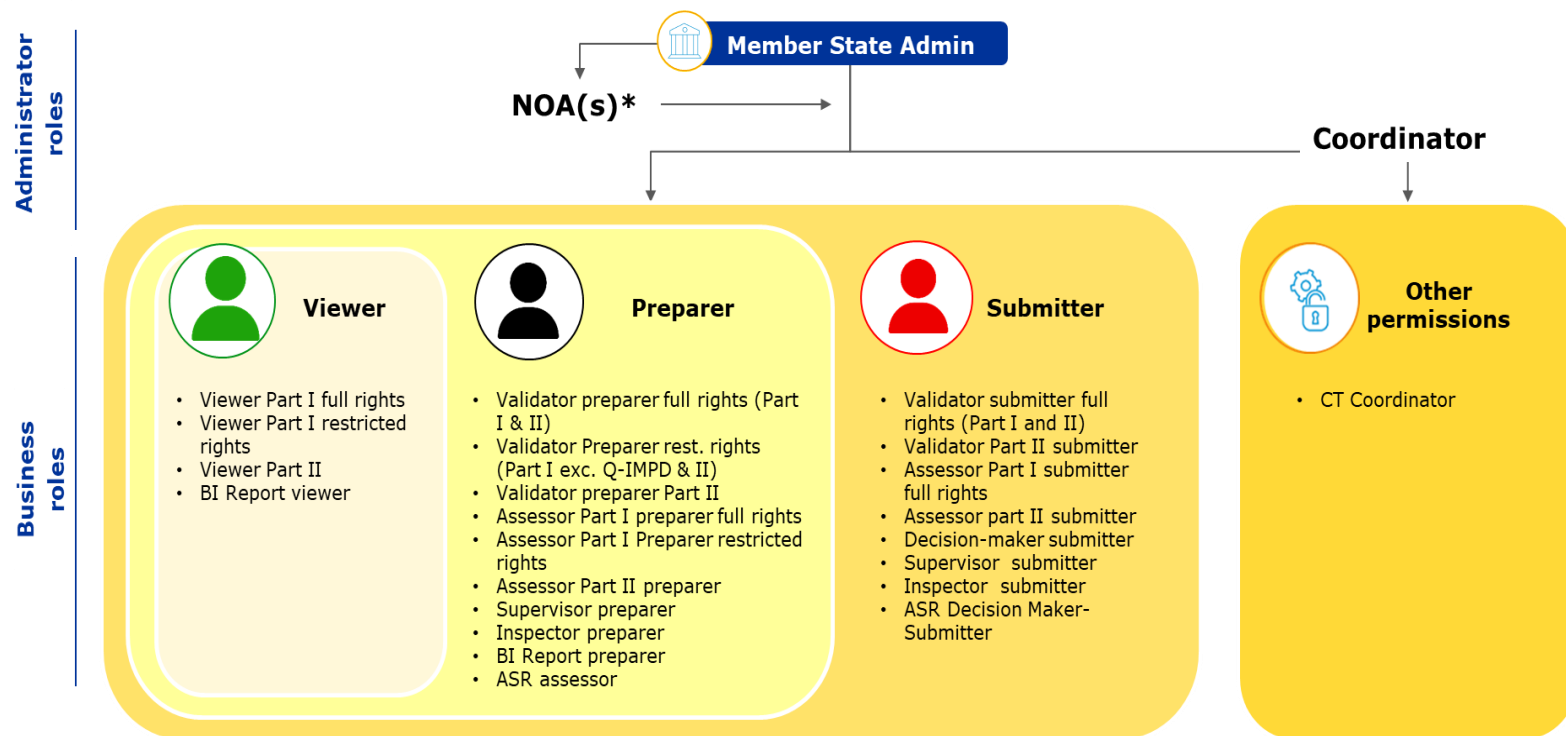


1. DEFAULT ROLE

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

Role (Use Case)	Birth rights permissions
Default Role (1001, 1006, 1014, 1017)	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. MEMBER STATES ROLES



Bear in mind that the roles are embedded in each other, i.e. the 'Preparers' have also the 'Viewers' permissions and the 'Submitters' have both the Viewers' and Preparers' permissions.

***National Organisation Administrators (NOA):** medium-level administrator for the Member States user group. It operates as the administrator of a Member State organisation that is expected to be different from the one of the MS Admin (such as Ethics Committees).

Permission label:



Permission not allowed to a particular role

Permission allowed to a particular role

ADMINISTRATORS ROLES AND PERMISSIONS

Role (Use Case)	Detailed Permissions	MS Administrator ¹	National Organisation Administrator
Administrator (1014)	Manage role assignment		
	Allocate Trials to Users		
	View user roles and requests		

1. This role has also the viewer role part I full rights & part II (Please refer to MS viewer roles).

COORDINATOR ROLE AND PERMISSIONS

High level permission (Use case)	Detailed Permissions	Coordinator
Manage trials and applications (1016)	View application (full trial information)	
	View trial (list and summary)	
	View users	
Manage Tasks (1040/1032)	View tasks	
	Assign task	
	Release task	
	View subtask	
	View notice/alert	
Timetable (1070)	View timeline	

MS BUSINESS VIEWER ROLES

Permissions	MS VIEWER ROLES		
	Part I rights		Part II
	Full	Restricted	
Form: Cover letter, proof of payment and deferral			
MSC			
Part I dossier: Full Part I			
Part I dossier: Full Part I excl. Q-IMPD/Scientific advice restricted document			
Part I dossier: Protocol and IB			
Part II dossier			
RMS selection			
Validation information: All validation information			
Validation information: All validation information excl. Q-IMPD			
Assessment Part I information: Full assessment Part I			
Assessment Part I information: Full assessment Part I excl. Q-IMPD			
Assessment Part I information: Part I conclusion			
Assessment Part II information: Full assessment Part II			
Assessment Part II information: Part II conclusion			
MSC decision (including revert decision and Part I disagreement)			
Timetable			
CT list and summary tab			
Full trial information tab			
Notifications tab			
Trial results tab (result summary and clinical study report)			
Corrective measure tab (including request for opinion, view of the opinion and MSC consultation)			

There is no viewer role in relation to ASR. The ASR assessor and decision maker have mapped view permissions required to perform their business activities.

MS BUSINESS VIEWER ROLES (Cont.)

Permissions	MS VIEWER ROLES		
	Part I rights		Part II
	Full	Restricted	
Assessment additional information tab (request for additional information and responses to requests for additional information)	Green	Green	Green
User's tab	Green	Green	Green
Tasks¹ and messages (notices and alerts)	Green	Green	Green
Predefined BI Reports²	Red	Red	Red
Inspection	Green	Green	Green
Union Control	Green	Green	Green
Download CT (only information that users have access to according to role)	Green	Green	Green

1. A user with only a viewer role cannot view tasks, as this user cannot execute tasks in the system. However, it is left in green because the permission to view tasks is mapped to preparer and submitter roles and therefore these roles can view the tasks from the Tasks tab.
2. The OBI viewer role needs to be assigned to the user in order to have access to the pre-defined OBI reports.

BUSINESS VALIDATOR PREPARER AND SUBMITTER ROLES

(**Black** text refers to Workflow (WF) soft tasks, **red** text to WF hard tasks and **blue** text refers to enabled buttons in CTIS).

Phase	Permission/Tasks	Validator				
		Preparer			Submitter	
		Full rights (Part I and Part II)	Restricted rights (Part I excl. Q-IMPD and Part II) ¹	Part II ²	Full rights (Part I and Part II)	Part II Submitter ¹
Validate Application	Document considerations: Part I (Q-IMPD)	Green	Red	Red	Green	Red
	Document considerations: Part I (excl. Q-IMPD)	Green	Green	Green	Green	Green
	Document considerations: Part II	Green	Green	Green	Green	Green
	Share considerations Part I and/or Part II	Red	Red	Red	Green	Green
	Consolidate considerations: Part I (Q- IMPD)	Green	Red	Red	Green	Green
	Consolidate considerations: Part I (excl. Q- IMPD)	Green	Red	Green	Green	Green
	Consolidate considerations: Part II	Green	Red	Green	Green	Green
	Share consolidated considerations Part I and/or Part II	Red	Red	Red	Green	Green
	Submit RFI (Part I and/or Part II)	Red	Red	Red	Green	Part II only CTAs
	Assess RFI: Create/share comment on assessment	Green	Green	Green	Green	Green
Submit validation decision	Red	Red	Red	Green	Part II only CTAs	

1. This role can document considerations but not consolidate considerations.

2. Currently, these roles can document and consolidate considerations Part I excl.-Q (validator Part II submitter can also share), although from the business perspective they are not expected to do it. A future change in the system will be required to prevent this.

BUSINESS ASSESSOR PREPARER AND SUBMITTER ROLES – Part I

(**Black** text refers to WF soft tasks, **red** text to WF hard tasks and **blue** text refers to enabled buttons in CTIS).

Phase	Permissions/Tasks	Assessor Part I		
		Assessor Part I Preparer full rights	Assessor Part I Preparer restricted rights (Excl. Q-IMPD) ¹	Assessor Part I Submitter full rights
Assessment Part I of Application	Circulate Draft Assessment Report (DAR): Add Part I (Q-IMPD) DAR			
	Circulate Draft Assessment Report (DAR): Add Part I (exc. Q-IMPD) DAR			
	Share Draft Assessment Report (AR) Part I			
	MSC Discussion			
	Document considerations: Part I (Q-IMPD)			
	Document considerations: Part I (exc. Q-IMPD)			
	Share considerations Part I			
	Consolidate considerations: Part I (Q-IMPD)			
	Consolidate considerations: Part I (exc. Q-IMPD)			
	Share consolidated considerations Part I			
	Submit RFI Part I			
	Assess RFI response: Create/ share comment on assessment			
	Prepare (add) Final Part I Assessment Report (AR): Part I (Q-IMPD)			
	Prepare (add) Final Part I Assessment Report (AR): Part I (exc. Q-IMPD)			
	Share Final Part I Assessment Report (AR)			
Submit final Part I AR and conclusion				
Intended Part I disagreement				

1. This role can document considerations but not consolidate considerations.

BUSINESS ASSESSOR PREPARER AND SUBMITTER ROLES – Part II

(**Black** text refers to WF soft tasks, **red** text to WF hard tasks and **blue** text refers to enabled buttons in CTIS).

Phase	Permissions/Tasks	Assessor Part II	
		Assessor Part II Preparer	Assessor Part II Submitter
Assessment Part II of Application	Document considerations Part II		
	<i>Share considerations Part II</i>		
	Consolidate considerations Part II		
	<i>Share* consolidated considerations Part II</i>		
	Submit RFI Part II		
	Assess RFI response: Create/ share comment on assessment		
	<i>Prepare (add) draft Part II AR</i>		
	MSC Discussion		
	<i>Prepare (add) Final Part II AR</i>		
	Submit final Part II AR and conclusion		

* In the context of Part II, sharing is equivalent to save, which explains why the preparer roles can also execute this permission. The Part I functionality is re-used for Part II, but the considerations are not shared with other MSCs.

BUSINESS DECISION MAKER/ SUPERVISOR PREPARER AND SUBMITTER ROLES

(**Black** text refers to WF soft tasks, **red** text to WF hard tasks and **blue** text refers to enabled buttons in CTIS. N/A for table re CM and ad hoc assessment)

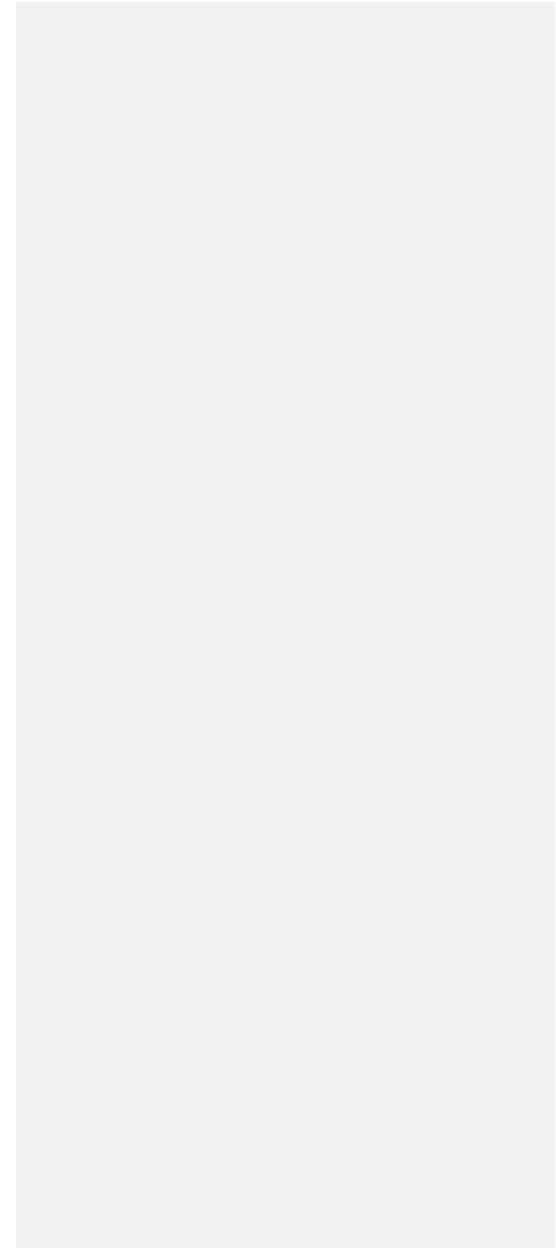
Phase	Permissions/Tasks	Decision Maker-Submitter
RMS Selection	Agree RMS	
	Express willingness	
	Re-express willingness	
Decision	<i>Issue disagreement for Part I</i>	
	Authorise	
	<i>Revert decision</i>	

Phase	Permissions/Tasks	Decision Maker-Submitter	Supervisor	
			Supervisor Preparer	Supervisor Submitter
Corrective Measure	Create corrective measure			
	Submit request for consultation with MSCs			
	Submit consultation comments by MSCs			
	Submit request for opinion from sponsors			
	Submit/ update/ revert corrective measure			

Phase	Permissions/Tasks	Supervisor Preparer	Supervisor Submitter
Ad hoc Assessment	Create ad hoc assessment		
	Share ad hoc assessment		
	Submit (complete) ad hoc assessment		
	Share discussion with MSs		
	Create RFI		
	Submit RFI		

BUSINESS INSPECTOR PREPARER AND SUBMITTER ROLES

Phase	Permissions/Tasks	Inspector Preparer	Inspector Submitter
Inspection Record	Create Inspection record	[Green]	[Green]
	Submit inspection record	[Red]	[Green]
	Update inspection record	[Red]	[Green]

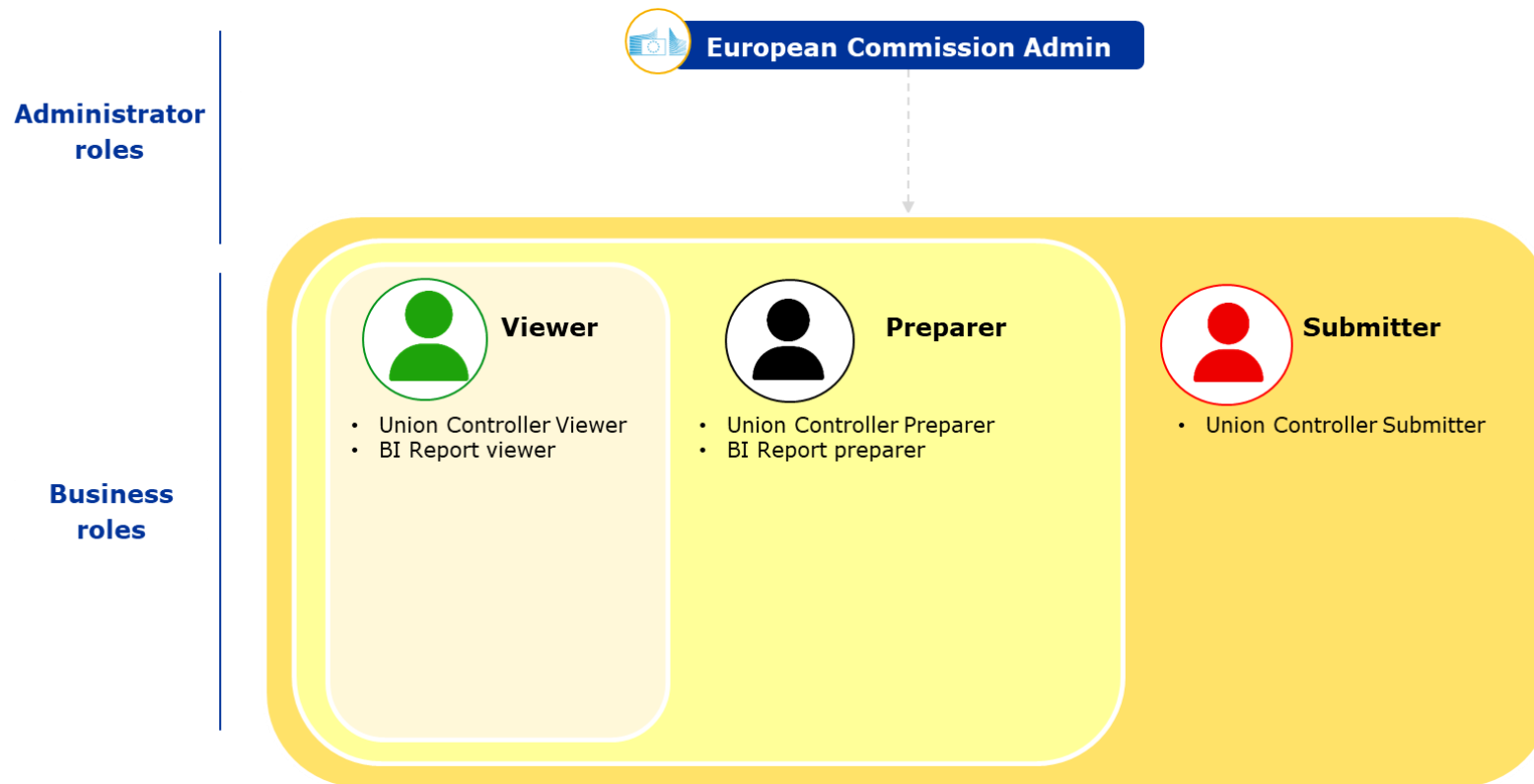


BUSINESS ASR ASSESSOR AND ASR DECISION MAKER-SUBMITTER ROLES

(**Black** text refers to ASR assessment WF tasks and **Blue** text refers to enabled buttons in CTIS)

Phase	Permissions/Tasks	ASR	
		ASR Assessor	ASR Decision Maker-Submitter
Evaluate ASR	Express willingness/unwillingness		
	Appoint SaMS		
	Circulate draft ASR-AR		
	Create ASR considerations		
	Share ASR considerations		
	<i>Consolidate considerations</i>		
	<i>Share consolidated considerations</i>		
	<i>Submit RFI</i>		
	Assess RFI response		
	View RFI response		
	Finalise ASR		

2. EUROPEAN COMISSION ROLE



ADMINISTRATORS ROLES AND PERMISSIONS

Role (Use Case)	Detailed Permissions	EC Administrator ¹
Administrator (1014)	Manage role assignment	
	Allocate Trials to Users	
	View user roles and requests	

1. This role has also mapped the permissions of the Union Control viewer, preparer and submitter roles.

EC BUSINESS VIEWER ROLES

Permissions/Tasks	Details	Union Controller Viewer
Form: Cover letter and deferral (no proof of payment)		
MSC		
Part I dossier: Full Part I		
Part I dossier: Full Part I excl. Q-IMPD/Scientific advice restricted document		
Part I dossier: Protocol and IB		
Part II dossier		
RMS selection		
Validation information: All validation information		
Validation information: All validation information excl. Q-IMPD		
Assessment Part I information: Full assessment Part I		
Assessment Part I information: Full assessment Part I excl. Q-IMPD (no DAR)		
Assessment Part I information: Part I conclusion		
Assessment Part II information: Full assessment Part II		
Assessment Part II information: Part II conclusion		
MSC decision (including revert decision and Part I disagreement)		
Timetable		
CT list and summary tab		

EC BUSINESS VIEWER ROLES

Permissions	Details	Union Controller Viewer
Full trial information tab		
Notifications tab		
Trial results tab (result summary and clinical study report)		
Corrective measure tab (including request for opinion, view of the opinion and MSC consultation)		
Assessment additional information (request for additional information and responses to requests for additional information)		
Users tab		
Tasks¹ and messages (notices and alerts)		
Predefined BI Reports²		
Inspection		
Union Control		
Download CT (only information that users have access to according to role)		

1. A user with only a viewer role cannot view tasks, as this user cannot execute tasks in the system. However, it is left in green because the permission to view tasks is mapped to preparer and submitter roles and, therefore, these roles can view the tasks from the Tasks tab.
2. The OBI viewer role needs to be assigned to the user in order to have access to the pre-defined OBI reports.

BUSINESS UNION CONTROL PREPARER AND SUBMITTER ROLES

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

Phase	Permissions/Tasks	Union Controller	
		Union Controller Preparer	Union Controller Submitter
Union Control	Create plan/programme for Union Control		
	Share plan/programme for Union Control		
	Create Union Control Report		
	Submit/ Update/ Withdraw Union Control report		

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