EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

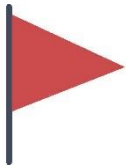
Member States Business Processes and Roles

Use of Member States Preparedness

CTIS Training Programme – Module 7

Version 1.68 – March 2022

Content



Objectives of the document

Description of roles within the CTIS MS Workspace

High-level overview of CT business processes in CTIS

Overview of CT business processes in the MS Workspace

Summary of tasks by role and process

Content

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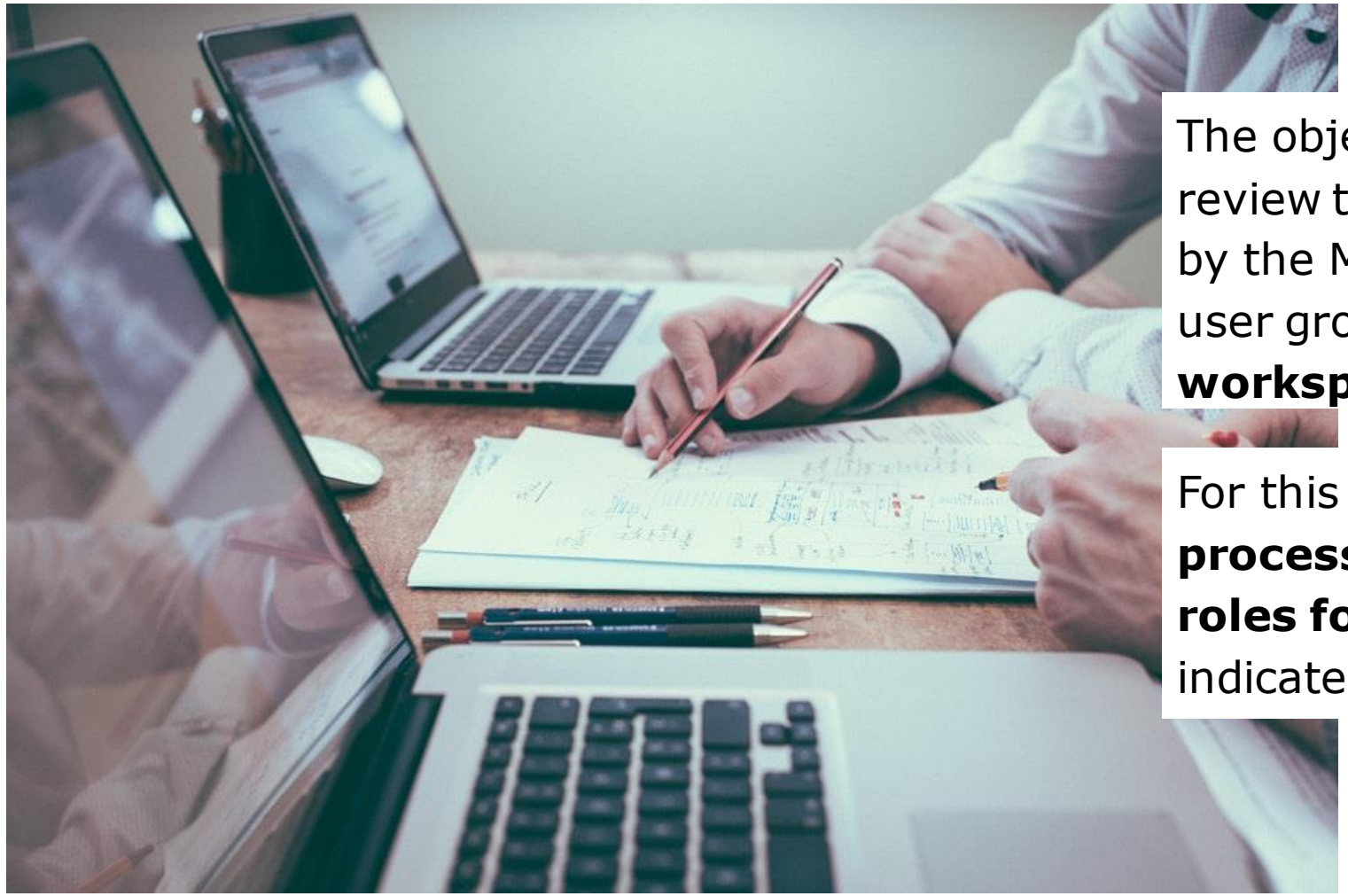


The objective of this document is to review the **roles** and **tasks** performed by the MS and European Commission user groups within the **CTIS MS workspace.**

For this purpose, all the **business processes** have been defined and the **roles for each task** have been indicated.

Objectives of the document

The document will provide detailed information on the business processes to be considered by the Member States when using CTIS: stakeholders involved, roles, steps of the processes and permissions/tasks.

Find below the main topics of the document:

Description of the stakeholders and roles within CTIS

Overview of MS Workspace CT processes

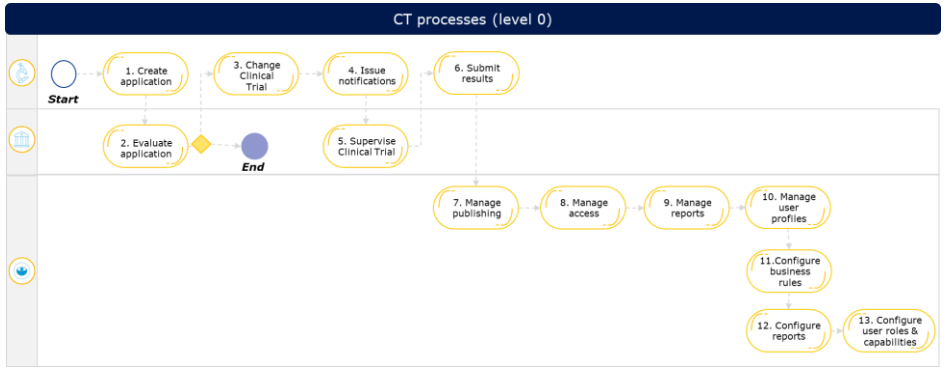
Summary of MS WS permissions/ tasks by role and process

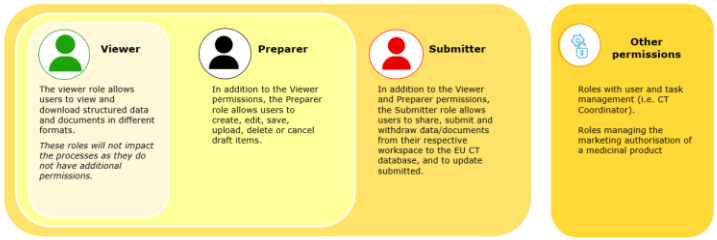
Sponsors

Member States

European Commission

EMA





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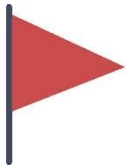

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Description of the roles within the CTIS MS workspace

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CTIS is a **role-based system** that enables users to perform different actions depending on the permissions attached to the roles assigned to them by the administrator roles. There are multiple roles in CTIS, which allow users to execute different actions in the system, in accordance with their respective responsibilities regarding a Clinical Trial.

These roles can be grouped according to the following **4 types of access permissions**:

Viewer

The viewer role allows users to view and download structured data and documents in different formats.

These roles will not impact the processes as they do not have additional permissions.

Preparer

In addition to the Viewer permissions, the Preparer role allows users to create, edit, save, upload, delete or cancel draft items.

Submitter

In addition to the Viewer and Preparer permissions, the Submitter role allows users to share and submit data/documents from their respective workspace to the EU database, and to withdraw or update submitted data.

Other permissions

Roles with user and task management (i.e. CT Coordinator, MS Admin etc.).

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.

Description of the roles within the CTIS MS Workspace-MS group of users

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The authority workspace comprises **25 roles available for the Member States group of users**, including 23 business roles and 2 administrator roles:

Administrator roles

Member State Admin

NOA(s)*

Coordinator

Business roles

Viewer

- Viewer Part I full rights
- Viewer Part I restricted rights
- Viewer Part II
- BI Report viewer

Preparer

- Validator preparer full rights (Part I & II)
- Validator Preparer rest. rights (Part I exc. Q-IMPD & II)
- Validator preparer Part II
- Assessor Part I preparer full rights
- Assessor Part I Preparer restricted rights
- Assessor Part II preparer
- Supervisor preparer
- Inspector preparer
- BI Report preparer
- ASR assessor

Submitter

- Validator submitter full rights (Part I and II)
- Validator Part II submitter
- Assessor Part I submitter full rights
- Assessor part II submitter
- Decision-maker submitter
- Supervisor submitter
- Inspector submitter
- ASR Decision Maker-Submitter

Other permissions

- CT Coordinator

***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).

Description of the roles within CTIS MS Workspace - EU Commission group of users

The authority workspace comprises 6 roles for **the European Commission group of users**, 5 business roles and 1 high-level administrator role:

Administrator roles

European Commission Admin

Business roles

Viewer

- Union Controller Viewer
- BI Report viewer

Preparer

- Union Controller Preparer
- BI Report preparer

Submitter

- Union Controller Submitter

Content

High-level overview of CT business processes in the CTIS MS Workspace

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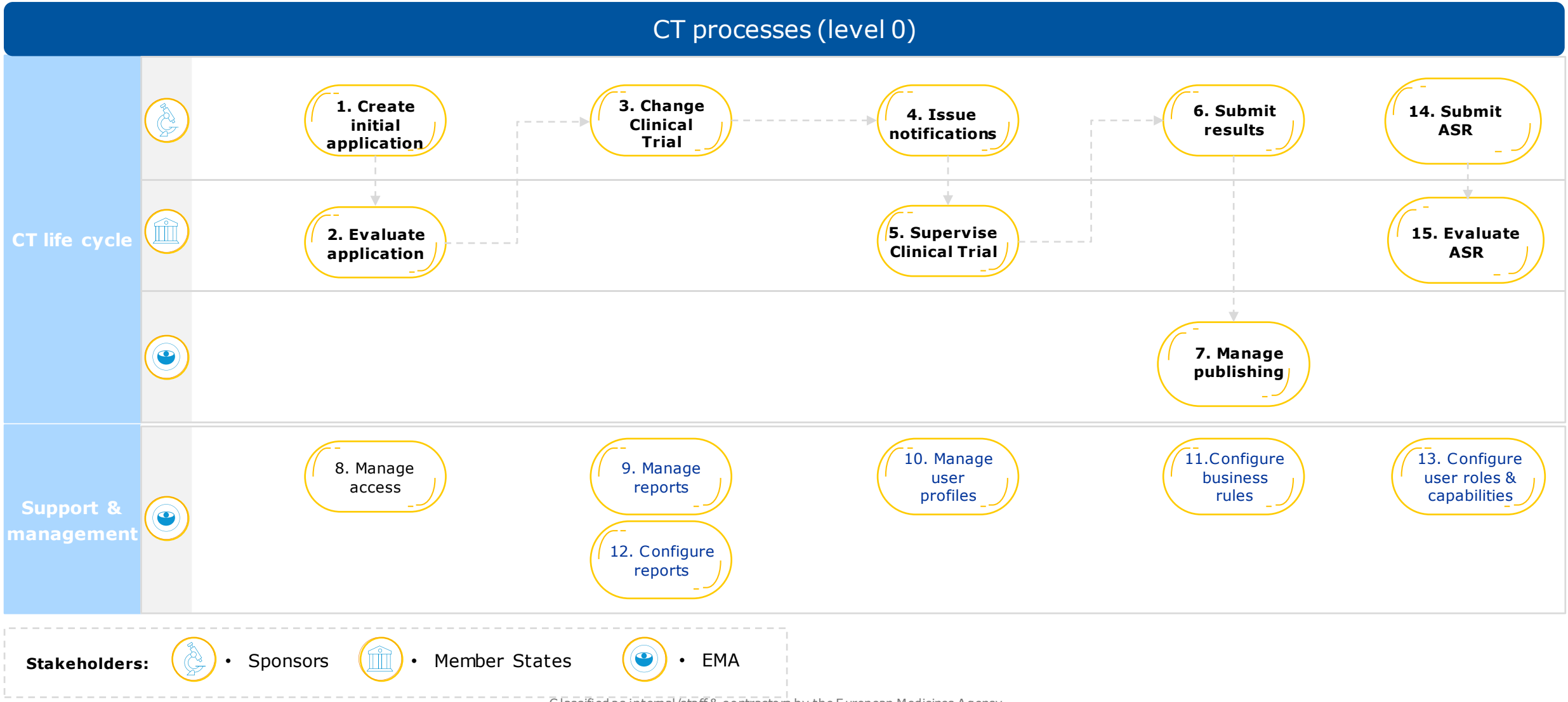
The level 0 for all the business processes and each CTIS stakeholder can be found below. The business process is divided in two main blocks (CT life cycle and Support & management) and further split by stakeholder:



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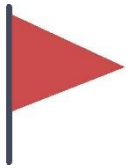

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Overview of CT business processes in the MS Workspace

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To gain a detailed understanding of the processes carried out by the Member States, we have followed a process modelling methodology previously used in the EMA:

Level 0
Level 0 model identifies a high level view of the CT process

Level 1
Level 1 model identifies which is the sub-process of each group from level 0

Level 2
Level 2 model outlines the specific tasks performed by each role

Overview of CT business processes in the MS Workspace (example)

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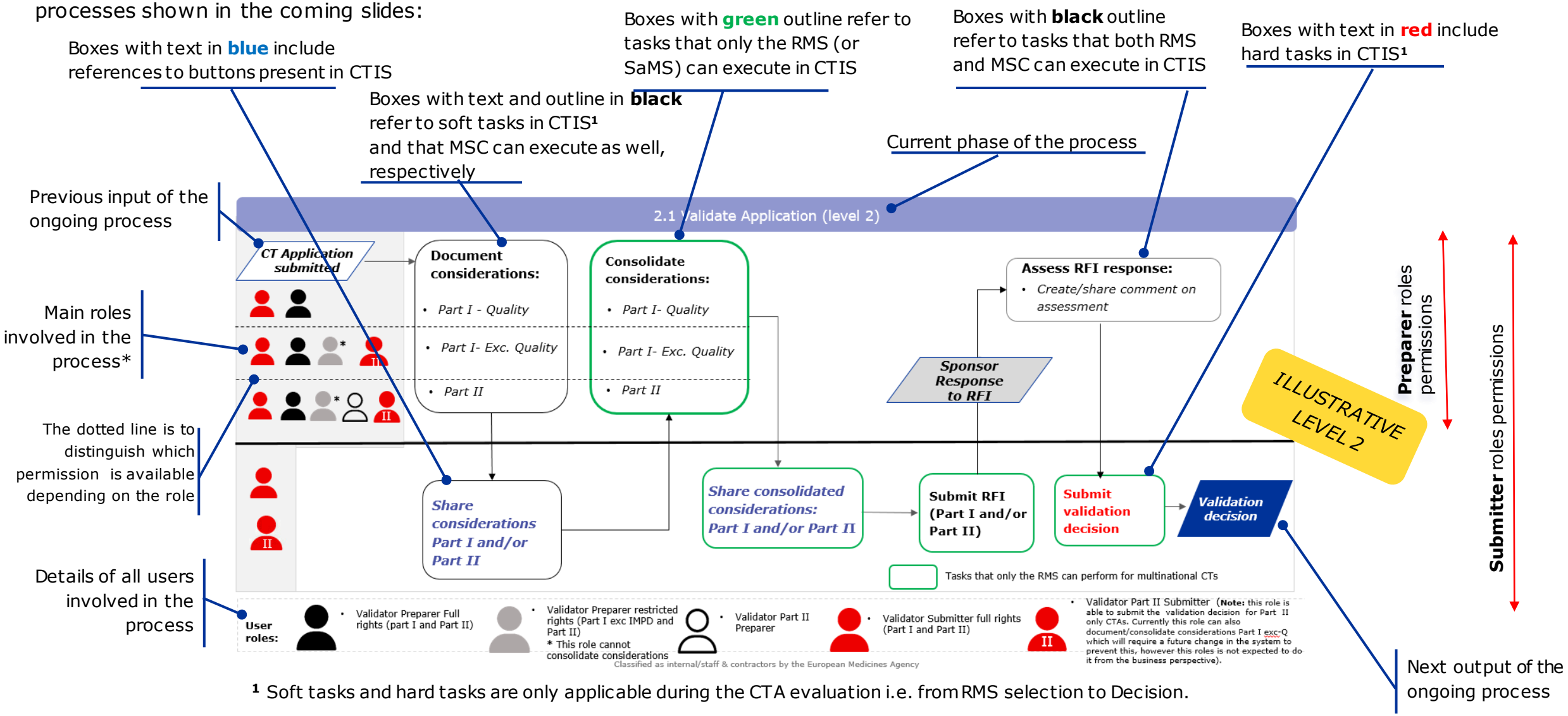
In order to provide a clear picture of each role's tasks, all the phases of the process will be thoroughly detailed. Find below the structure of the processes shown in the coming slides:



[1] Soft tasks and hard tasks are only applicable during the CTA evaluation i.e. from RMS selection to Decision.

Note: The processes will not include those roles that do not participate in the core activities of the process (i.e. BI report viewer is not a role required to perform business processes).

Overview of the CT business processes in the MS Workspace

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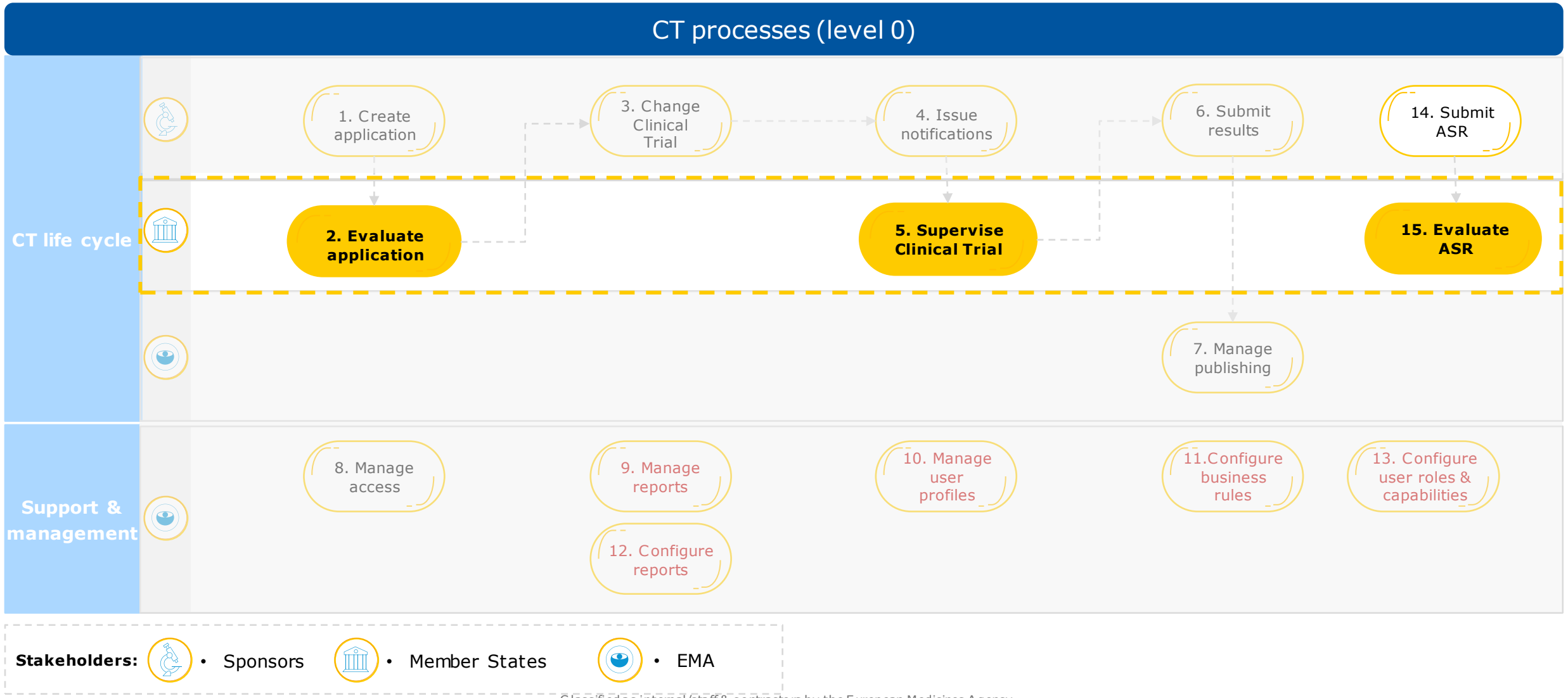
Within the Authority's workspace, there are two main business processes. The aim is to have a complete overview of the workflow by going into detail of each of these processes:



Overview of the CT business processes in the MS Workspace: Evaluate CTA

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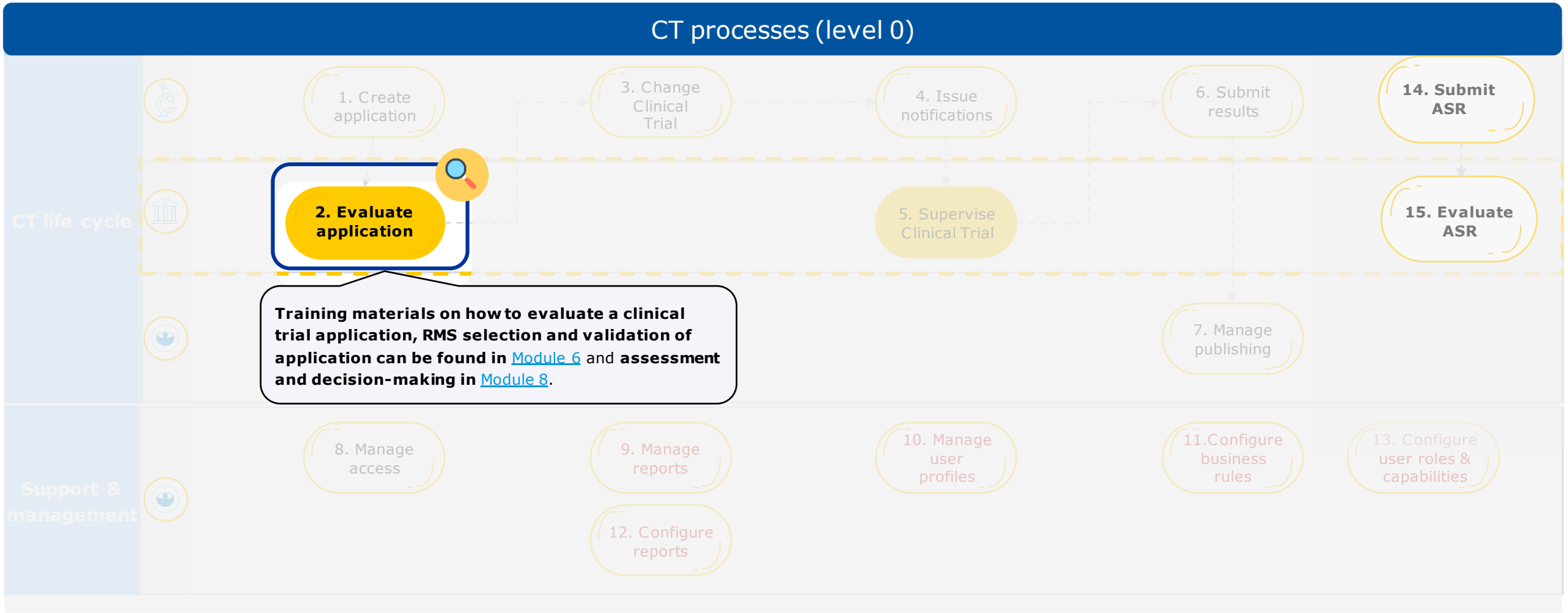
Evaluate application process:



Overview of CT processes – MS processes, Evaluate Application

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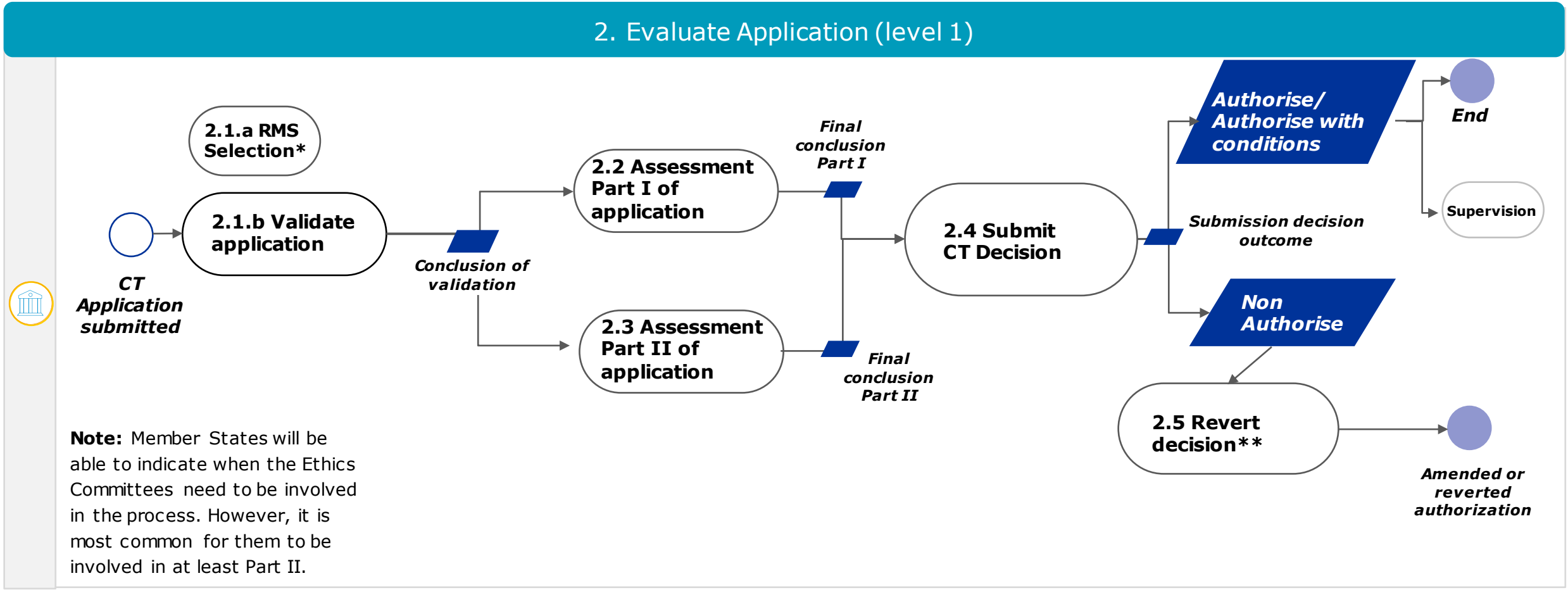
Member States use CTIS to assess CTAs, authorise the CT and supervise the conduct of the CT. Each of the phases to be followed by the Member States in CTIS are shown below:

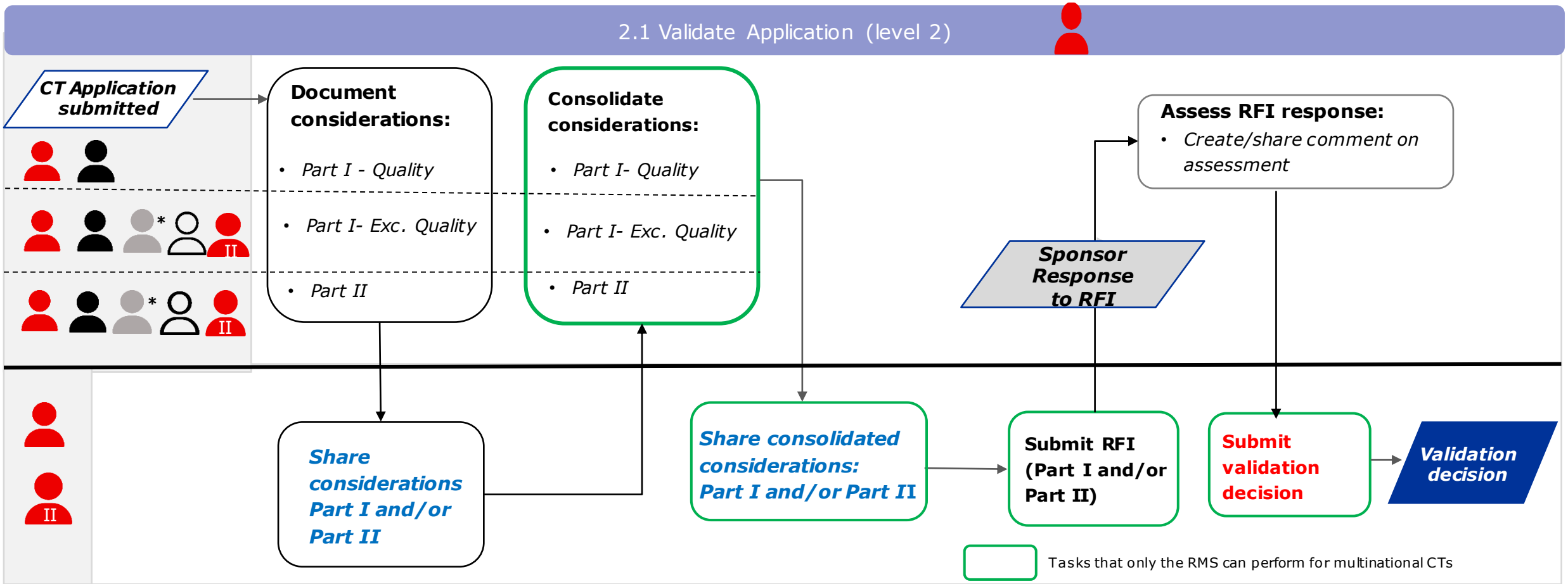


Roles: • Member States

* Only for multinational trials.
** This action will only be performed in case of a favourable appeal process for the sponsor.

Evaluate Application: Validation

A **Validator submitter** can perform all the business processes below, while the **Validator preparer** can perform almost all, except those related to sharing and submitting permissions.



User roles:

- Validator Preparer Full rights (part I and Part II)
- Validator Preparer restricted rights (Part I exc IMPD and Part II) * This role cannot consolidate considerations.
- Validator Part II Preparer (Note **b)** listed for Validator Part II submitter also apply for this role, except for sharing)
- Validator Submitter full rights (Part I and Part II)
- Validator Part II Submitter (**Note: a)** this role is able to submit the validation decision for Part II only CTAs. **b)** Currently this role can also document and share considerations and consolidate considerations Part I exc-Q, although from the business perspective it is not expected to do it. A future change in the system will be required to prevent this).

Evaluate Application: Assessment Part I

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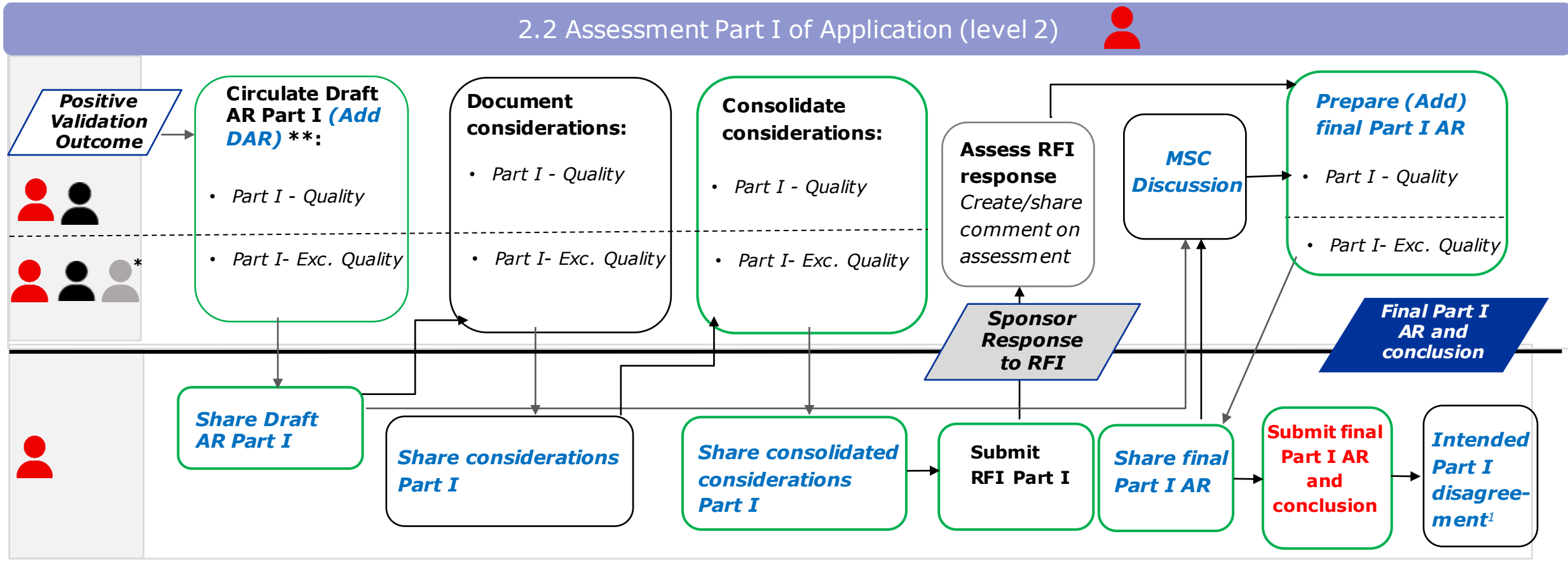
Assessor Part I submitter full rights can perform all the business processes below related to Part I assessment, while the **assessor preparer** can perform almost all, except those related to sharing and submitting permissions.



1. To express disagreement with Part I, when Part II is missing and pending to arrive (it can be staggered 2 years).

User roles:

- Assessor Part I Preparer full rights
- Assessor Part I Preparer restricted rights (excluding quality)
- Assessor Part I submitter full rights

* This role cannot consolidate considerations

Tasks that only the RMS can perform for multinational CTs

** This task allows the users with the required role to prepare the draft AR (i.e. upload the different parts- clinical, quality) but only the submitter can share it with other MSC.

Evaluate Application: Assessment Part II

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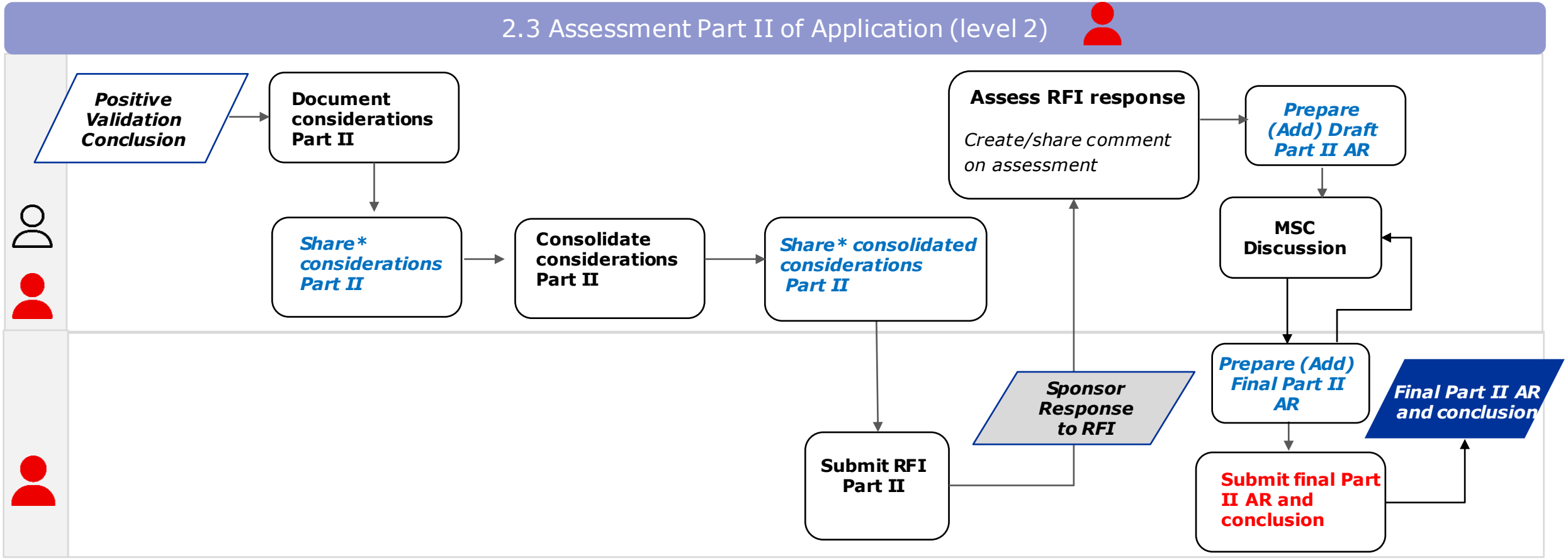
Assessor Part II submitter can perform all the business processes below related to Part II assessment, while the **assessor Part II preparer** can perform almost all, except those related to sharing and submitting permissions.



User roles:

- Assessor Part II Preparer
- Assessor Part II Submitter

* 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 MSC.

Evaluate application: RMS selection, Decision (incl. revert)

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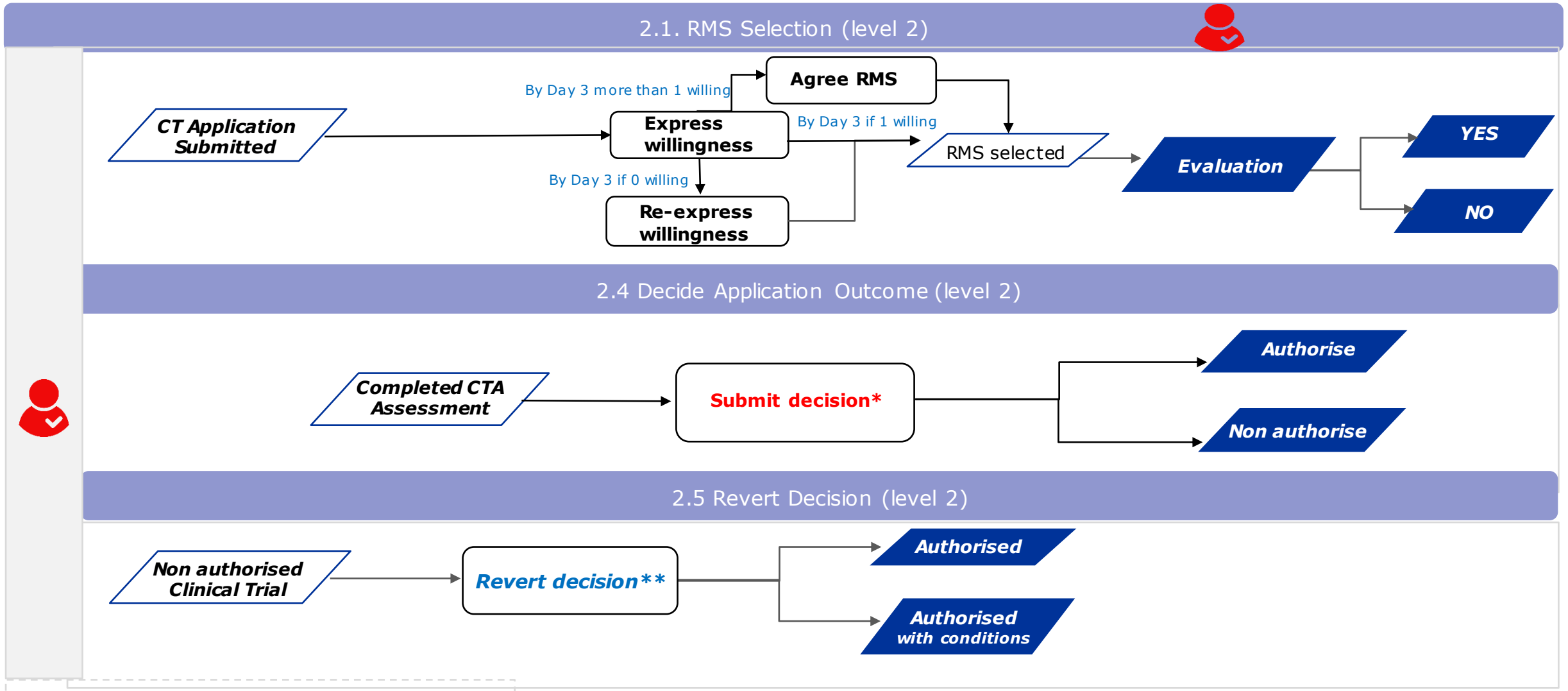
The **Decision-maker submitter** role is responsible for all the business processes described below.



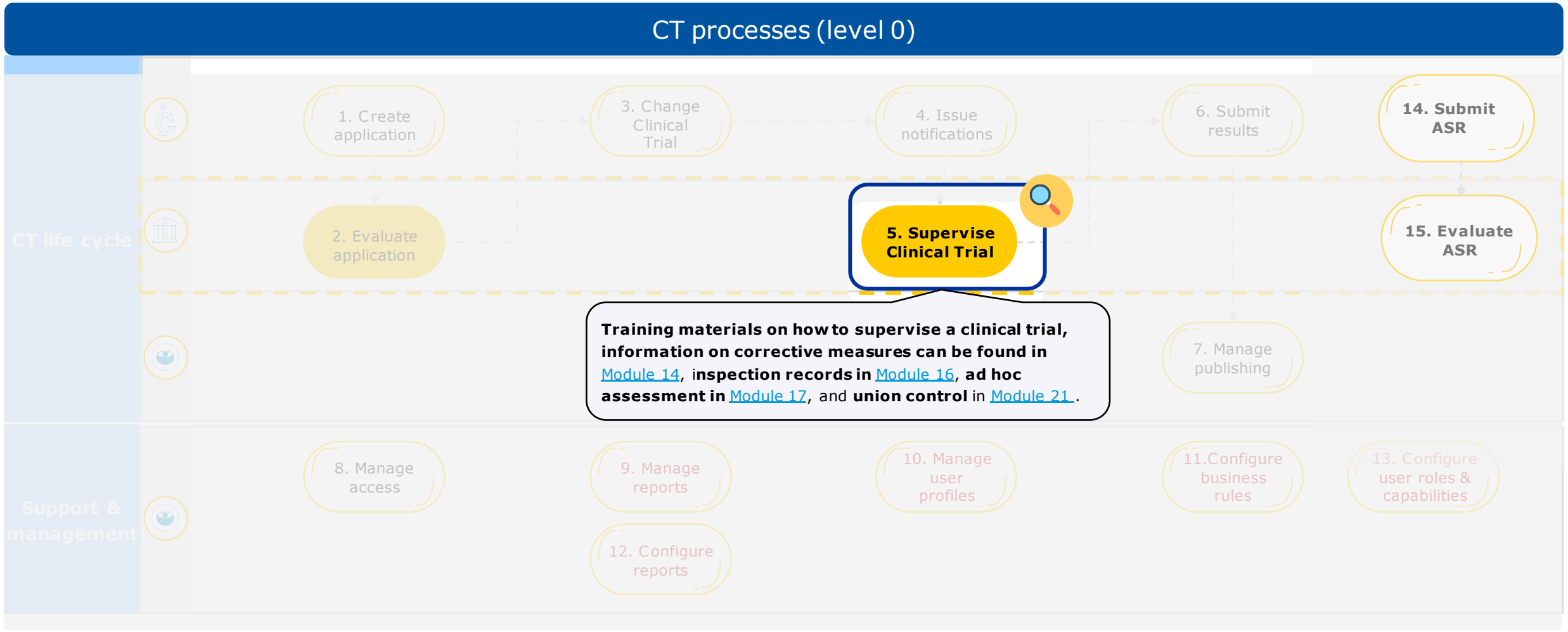
User roles:

- Decision Maker-Submitter

* Under Evaluation/Decision area an MSC, as applicable, can issue a disagreement on Part I.
** This action will only be performed in case of a favourable appeal process for the sponsor.

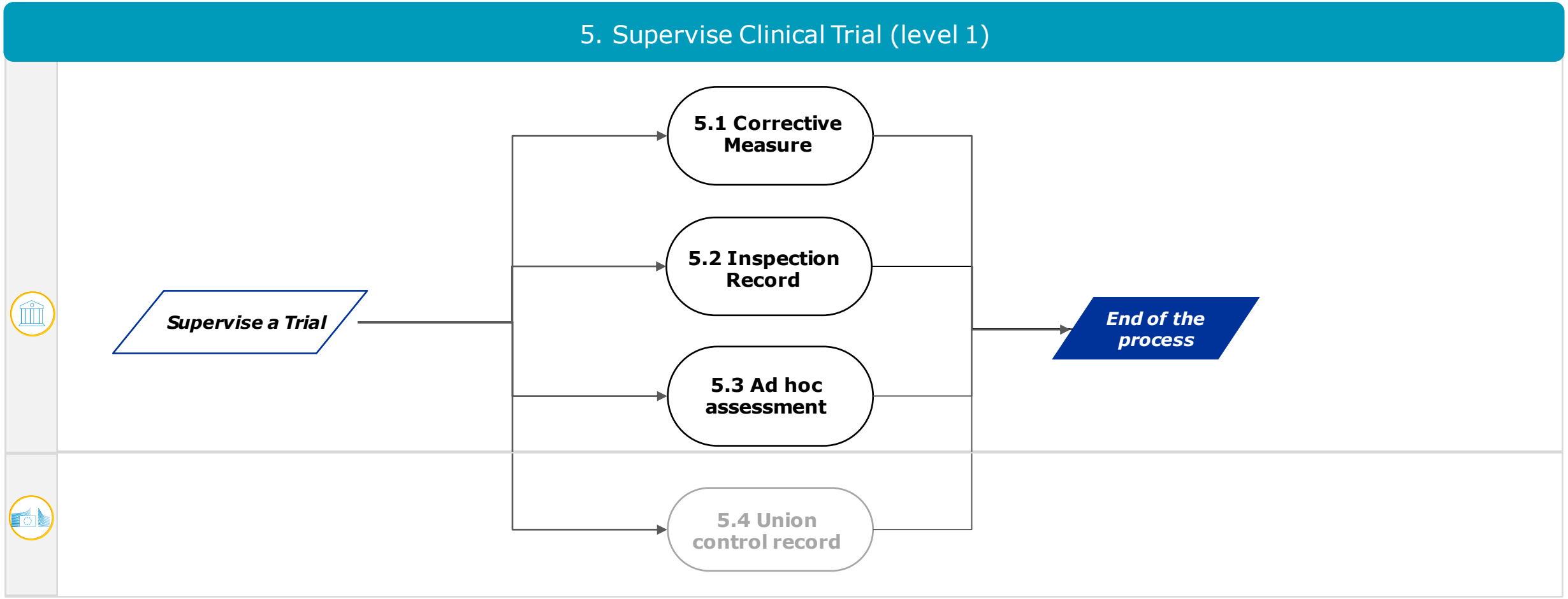
Overview of CT processes – MS processes in the MS Workspace: CT Supervision

Supervise Clinical Trial:



Overview of CT processes – MS processes, Supervise CT

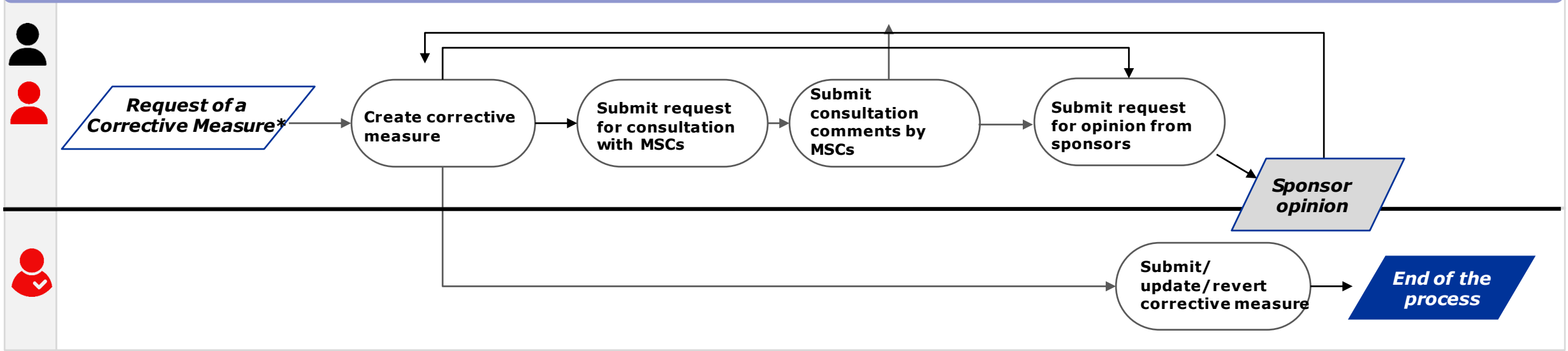
The Supervise Clinical Trial process allows Member States Concerned (for MS where the trial has been authorised, including with conditions) to apply **corrective measures**, submit **inspection record**, and **assess additional information** (such as notifications).



Supervise CT: Corrective measure

Users with a supervisor role (preparer and submitter) **ensure that the CT is conducted in the appropriate** manner and will apply, if applicable, any required corrective measure to an ongoing CT. These corrective measures will be notified directly to the sponsor conducting the CT. Both **Supervisor roles** (preparer and submitter) can prepare them but only the **decision maker-submitter** can submit it, i.e. apply the corrective measure.

5.1 Corrective measure (level 2)



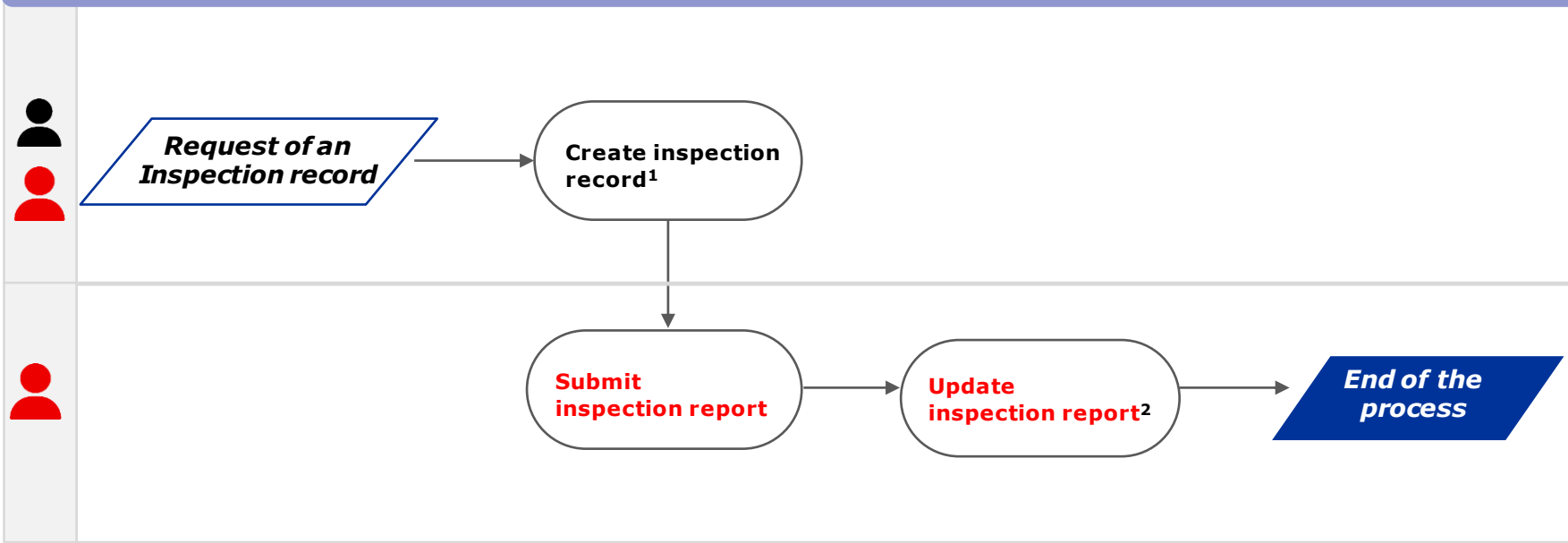
* According to Art. 77 of CTR, the following measures can be applied by the MSs: revoke the authorization, suspend the CT or request to modify any aspect of the trial.

User roles: • Supervisor preparer • Supervisor submitter • Decision Maker-Submitter

Supervise CT: Inspection record

Inspector roles ensure that the trials meet the **standards of Good Clinical Practice (safety and integrity of trial subjects as well as the reliability of the data**). Inspector roles are responsible for sharing inspection plans and submit Inspection reports. The **Inspector submitte**r can perform all the business processes below while the **Inspector preparer** can perform almost all, except those related to sharing and submitting permissions.

5.2 Inspection record (level 2)



1. Populate general information, inspection details (planning information, inspection outcomes, sponsor notification related to the trial inspection), and overall inspection outcome.

2. Update is not possible when the inspection record has the status "completed".

User roles: Inspector preparer · Inspector submitter

Supervise CT: Ad hoc Assessment

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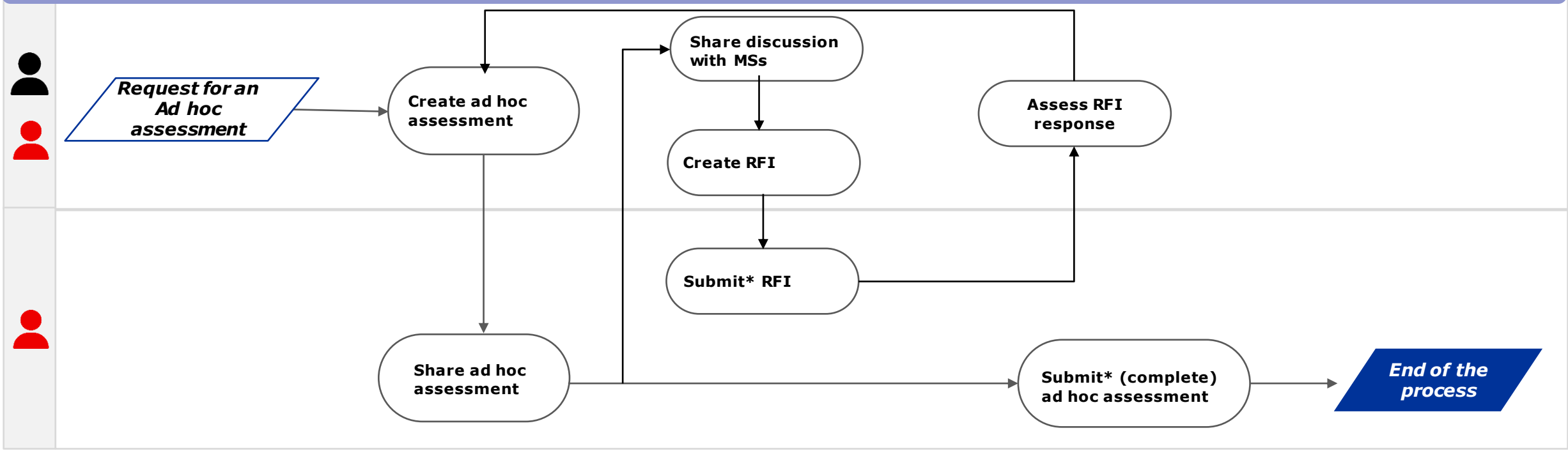
Supervisor submitter can perform all the business processes below related to Part II assessment, while the **Supervisor preparer** can perform almost all, except those related to sharing and submitting permissions.

5.3 Ad hoc Assessment (level 2)



User roles: • Supervisor preparer • Supervisor submitter

* The ad hoc reports are kept in the Authority workspace but are not submitted to the EU database and, therefore, they are not subject to publication. This is the reason why the word "submit" does not appear in red, being equivalent to the concept of sharing, which also happens within the workspace.

Overview of the CT business processes in the MS Workspace: Evaluate ASR

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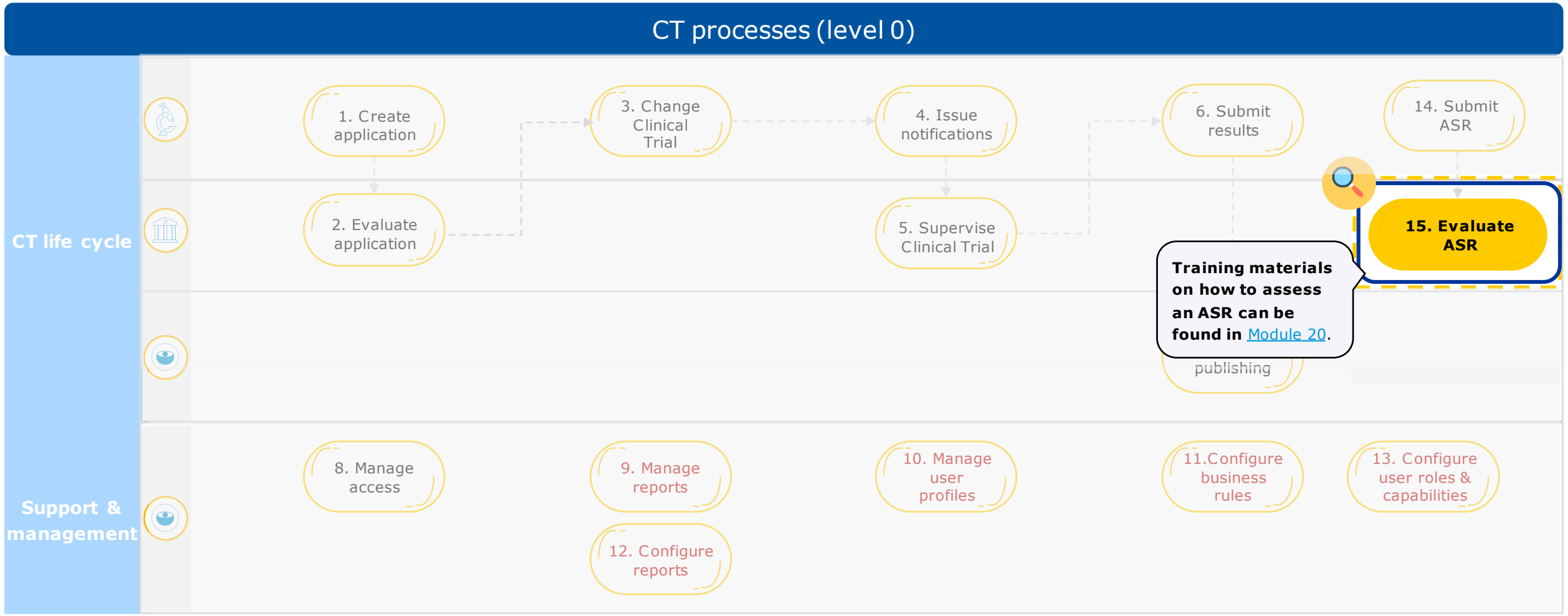
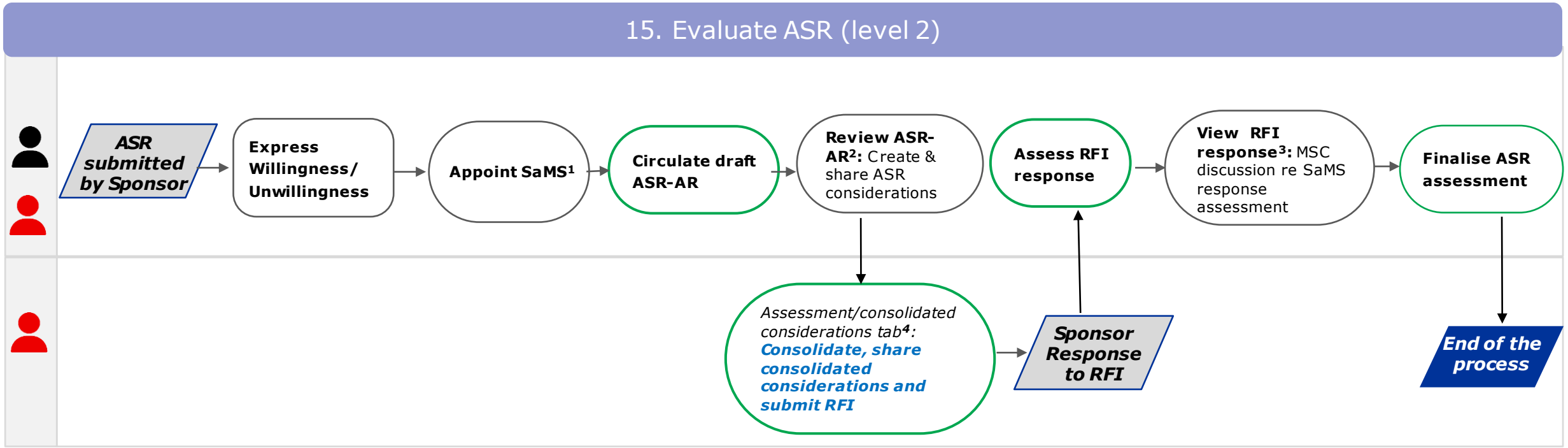
Within the Authority workspace, there are two main business processes. The aim is to have a complete overview of the workflow by going into detail of each of these processes:



Overview of CT processes – MS processes, Evaluate ASR

ARS Decision Maker-Submitter and ASR Assessor can execute the business processes related to the assessment of the Annual Safety Report submitted by the sponsor as outlined below.



1. Task displayed to the candidate SaMS when more than one willing or none willing.
2. This task is displayed to the MSC (no task for SaMS) for them to create and share considerations in relation to the circulated ASR-AR. SaMS can also document considerations by navigating to the ASR tab assessment/considerations.
3. This task is displayed to the MSC (no task for SaMS) for them to discuss the SaMS assessment to the sponsor RFI response. SaMS can also provide comments to the discussion in the ASR tab assessment/RFI. There is not a specific task to consolidate and submit RFI by SaMS, so these business steps can be done by navigating to the ASR tab assessment/considerations.

User roles: • ASR Assessor • ASR Decision Maker-Submitter

Overview of CT processes – EU Commission processes, Union Control

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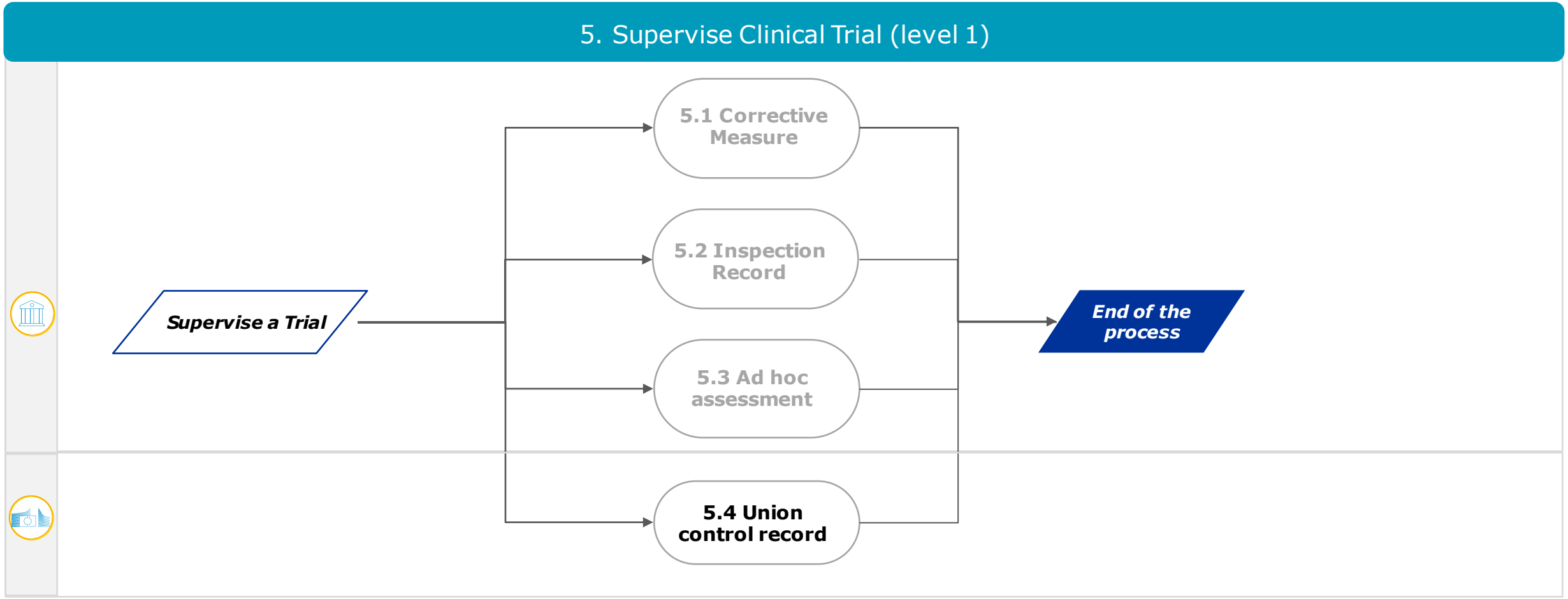
The EU Commission may conduct Union Controls to supervise compliance with the Regulation by MS and third countries.



Stakeholders: • Member States • European Comission

Overview of CT processes – EU Commission processes, Union Control

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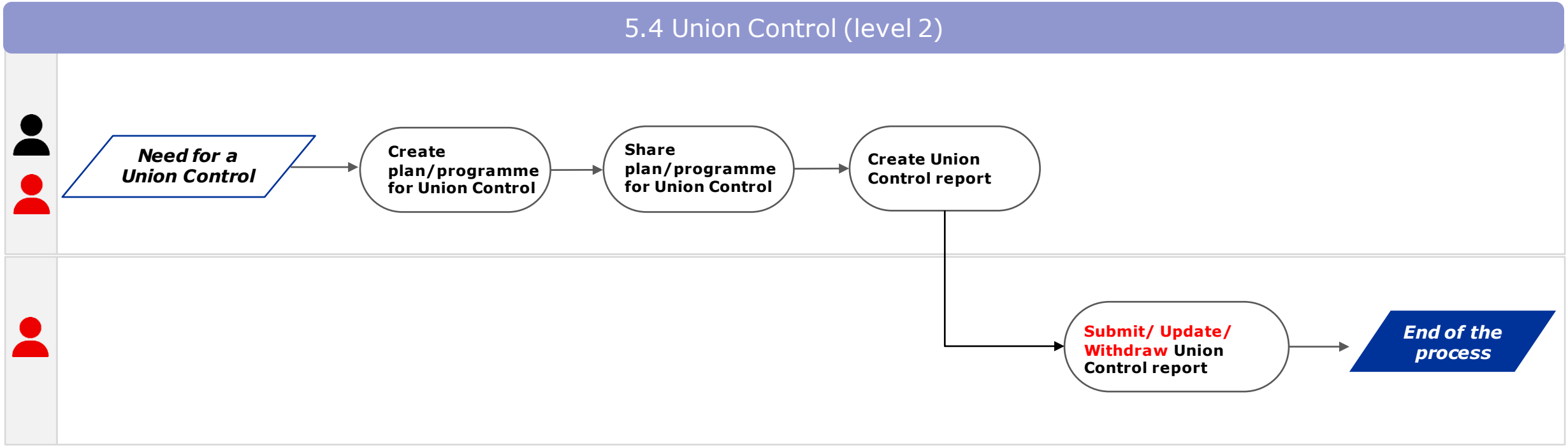
Union Control submitter can perform all the business processes below related to Part II assessment, while the **Union Control preparer** can perform almost all, except those related to sharing and submitting permissions.

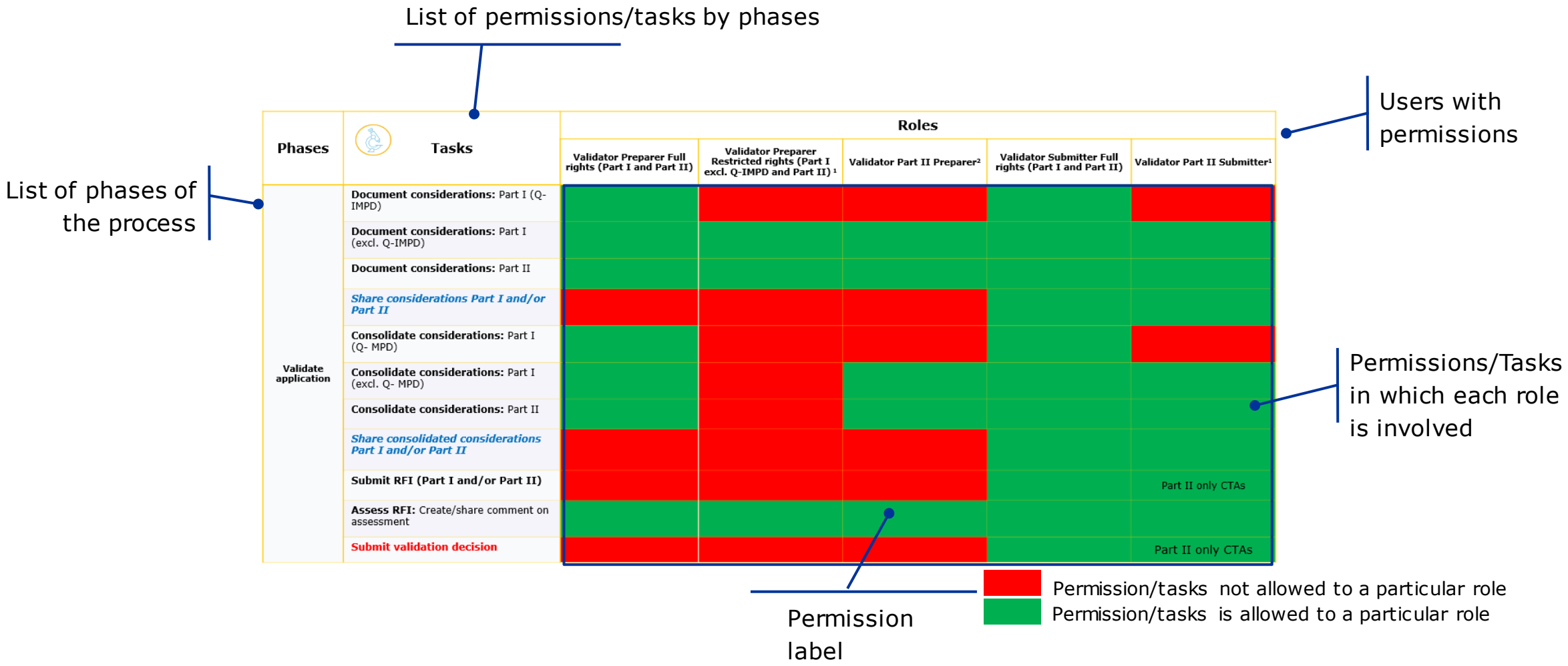


User roles: • Union Controller Preparer • Union Controller Submitter

Content

Summary of permission/tasks by role and process

In order to clearly define each role, we are going to summarise each user's permissions/tasks. Find bellow the structure of the coming slides:



Summary of permissions/tasks by MS role and process –Validation

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

1. This role can document considerations but not consolidate considerations.
2. Currently, these roles can also 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.

Summary of permissions/tasks by MS role and process – Assess Part I

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Phases	Permissions/Tasks	Roles		
		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.

Summary of permissions/tasks by MS role and process – Assess Part II

EUROPEAN MEDICINES AGENCY

Phases	Permissions/Tasks	Roles	
		Assessor Part II Preparer	Assessor Part II Submitter
Assessment Part II of Application	**Document considerations Part II**		
	Share considerations Part II		
	Consolidate considerations Part II		
	Share* consolidated considerations Part II		
	Submit RFI Part II		
	Assess RFI response: Create/ share comment on assessment		
	Prepare (add) draft Part II AR		
	MSC Discussion		
	Prepare (add) Final Part II AR		
	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.

Summary of permissions/tasks by MS role and process – RMS selection, Decision and Corrective Measures

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Phases	Permissions/Tasks	Roles
		Decision Maker-Submitter
RMS Selection	Agree RMS	
	Express willingness	
	Re-express willingness	
Decision	*Issue disagreement for Part I*	
	Authorise	
	Revert decision	

Phases	Permissions/Tasks	Roles		
		Supervisor Preparer	Supervisor Submitter	Decision Maker-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			

Summary of tasks by MS role and process –Inspection record and Ad hoc assessment

EUROPEAN MEDICINES AGENCY

Phases	Permissions/Tasks	Roles	
		Inspector Preparer	Inspector Submitter
Inspection Record	Create Inspection record		
	Submit inspection record		
	Update inspection record		

Phases	Permissions/Tasks	Roles	
		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		

Summary of tasks by MS role and process –Evaluate ASR

EUROPEAN MEDICINES AGENCY

Phases	Permissions/Tasks	Roles	
		ASR Assessor	ASR Decision Maker-Submitter
Evaluate ASR	Express willingness/unwilligness		
	Appoint SaMS		
	Circulate draft ASR-AR		
	Create ASR considerations		
	Share ASR considerations		
	Consolidate considerations		
	Share consolidated considerations		
	Submit RFI		
	Assess RFI response		
	View RFI response		
	Finalise ASR assessment		

Summary of tasks by MS role and process –Viewer Roles[1]

EUROPEAN MEDICINES AGENCY

	Permissions/Tasks	Roles		
		Viewer Part I full rights	Viewer Part I restricted rights	Viewer Part II
Viewer Roles	**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			

1. 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.

Summary of tasks by MS role and process –Viewer Roles

EUROPEAN MEDICINES AGENCY

	Permissions/Tasks	Roles		
		Viewer Part I full rights	Viewer Part I restricted rights	Viewer Part II
Viewer Roles	**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)			
	Assessment additional information tab (request for additional information and responses to requests for additional information)			
	Users tab			
	Tasks[1] and messages (notices and alerts)			
	Predefined BI Reports[2]			
	Inspection			
	Union Control			
	Download CT (only information that users have access 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.

Summary of tasks by EU Commission role and process – Union Control

EUROPEAN MEDICINES AGENCY

Phase	Permissions/Tasks	Roles	
		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		

Summary of tasks by EC role and process –Viewer Roles

EUROPEAN MEDICINES AGENCY

	Permissions/Tasks	Roles
		Union Control Viewer
Viewer Roles	**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: Final 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	

Summary of tasks by MS role and process –Viewer Roles

EUROPEAN MEDICINES AGENCY

	Permissions/Tasks	Roles
		Union Control Viewer
Viewer Roles	**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)	
	Assessment additional information tab (request for additional information and responses to requests for additional information)	
	Users tab	
	Tasks[1] and messages (notices and alerts)	
	Predefined BI Reports[2]	
	Inspection	
	Union Control	
	Download CT (only information that users have access 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.

Thank you for your attention

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