EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

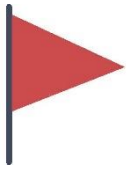
Sponsors Business Processes and Roles

Use of Sponsors Preparedness

CTIS Training Programme – Module 7

Version 1.45 – March 2022

Content



Objectives of the document

Description of roles within the CTIS Sponsor workspace

High-level overview of CT business processes in CTIS

Overview of CT business processes in the Sponsor workspace

Summary of permissions/tasks by role and process

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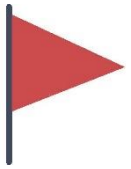

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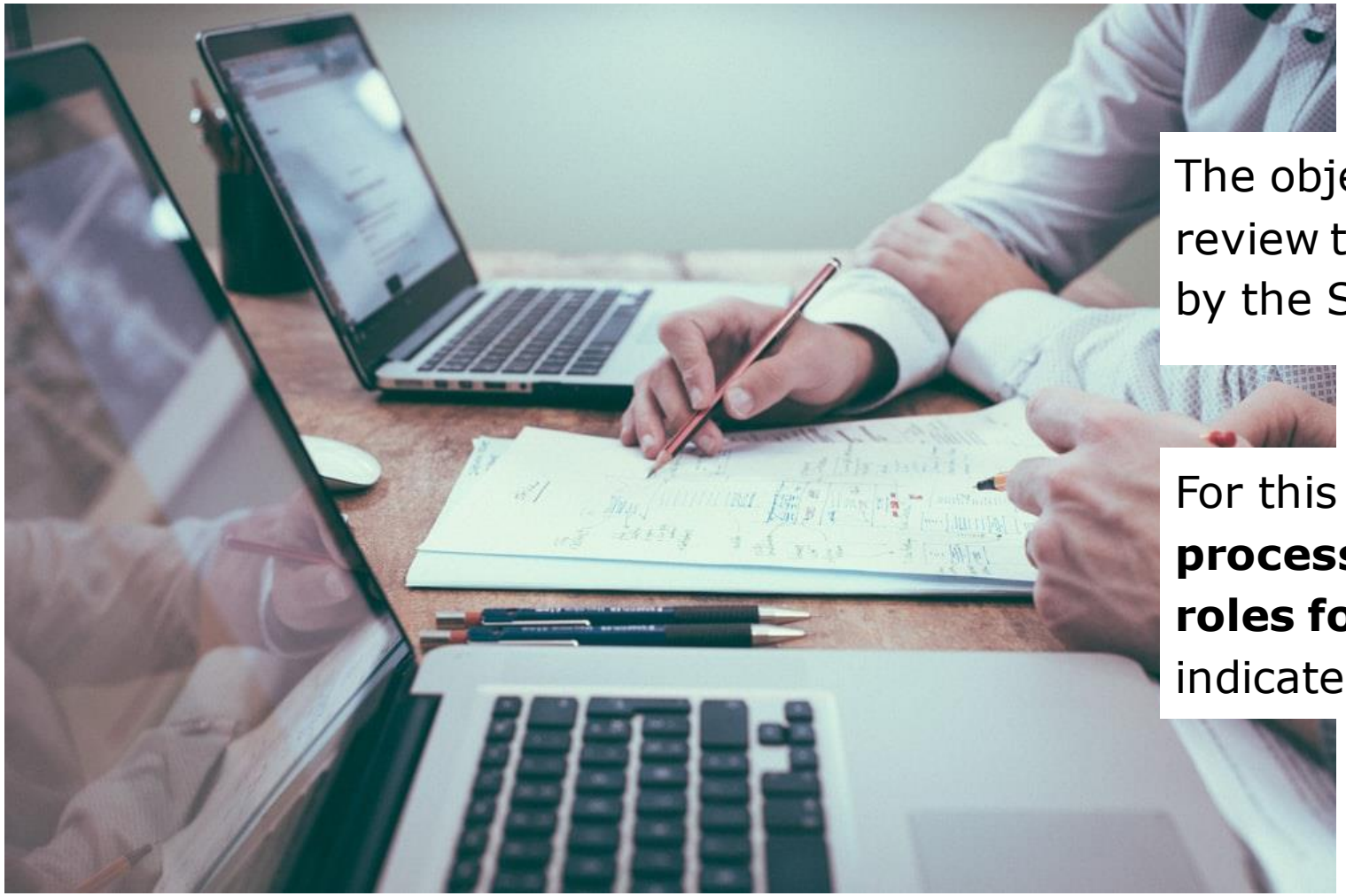

The objective of this document is to review the **roles** and **tasks** performed by the Sponsors within CTIS.

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

Objectives of the document

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

Find below the main topics of the document:

Description of the stakeholder and roles within CTIS

Overview of Sponsor CT processes

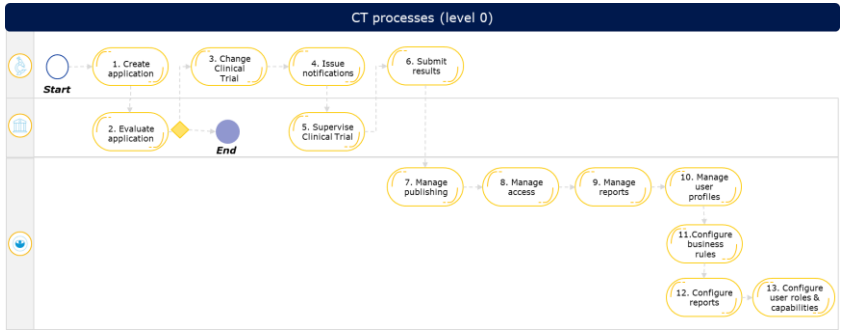
Summary of Sponsor permissions/tasks by role and process

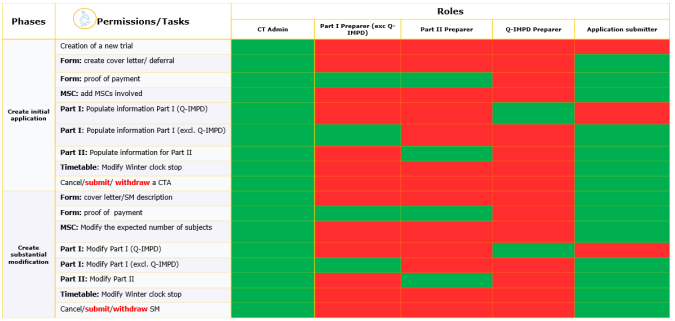
Sponsors

Member States

European Commission

EMA





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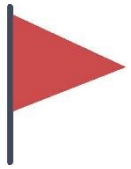

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Description of the roles within the CTIS Sponsor workspace

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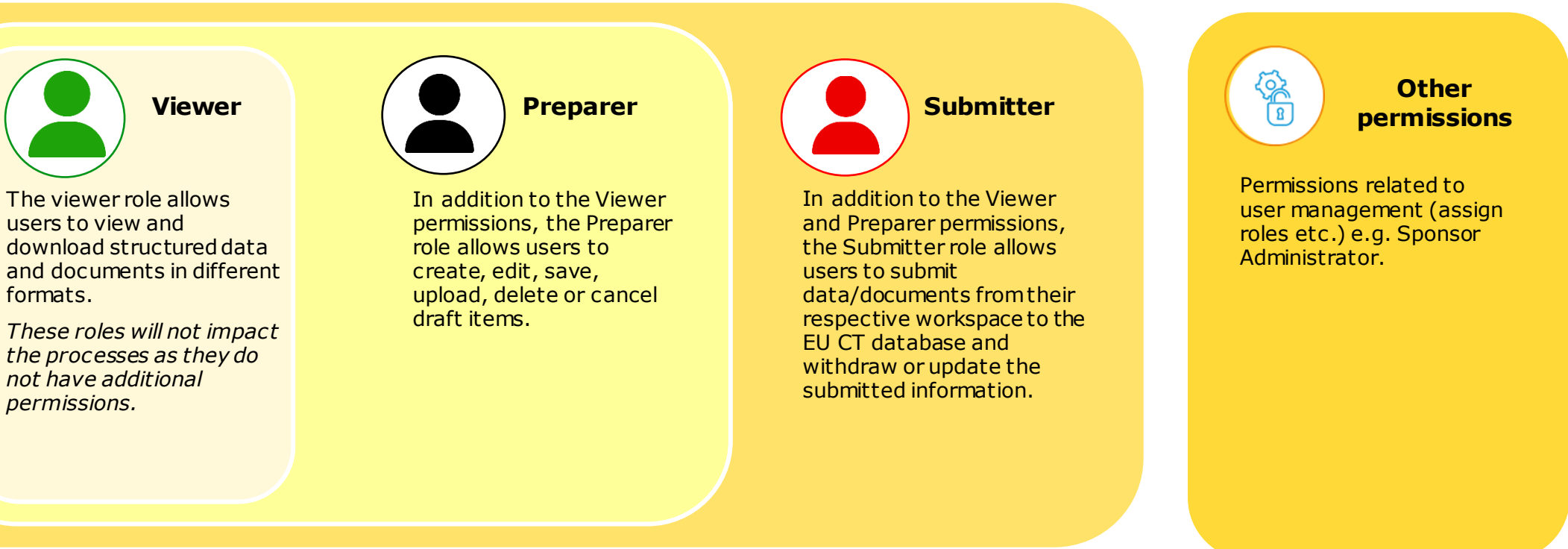
CTIS is a **role-based system** that enables users to perform different actions depending on the permissions attached to the roles assigned to them by the administrator roles. There are multiple roles in CTIS, which allow users to execute different actions in the system, in accordance with their respective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

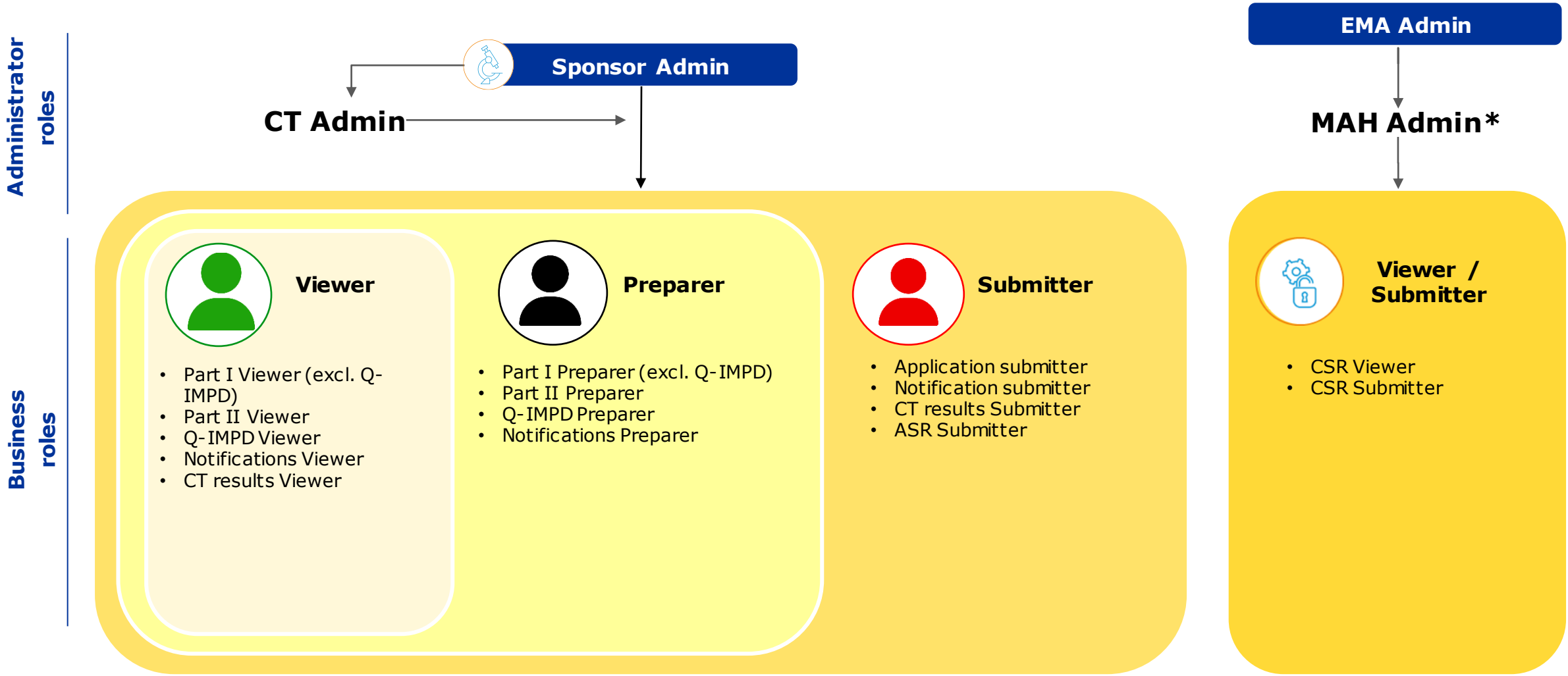
These roles can be grouped according to the following **4 types of access permissions:**



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 Sponsor workspace

The Sponsor workspace comprises **15 business roles and 3 administrator roles** (including Sponsor Admin, CT Admin and MAH Admin):



***Marketing Authorisation Holder (MAH):** user group within the Sponsor workspace that is responsible for managing CSRs.

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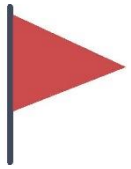

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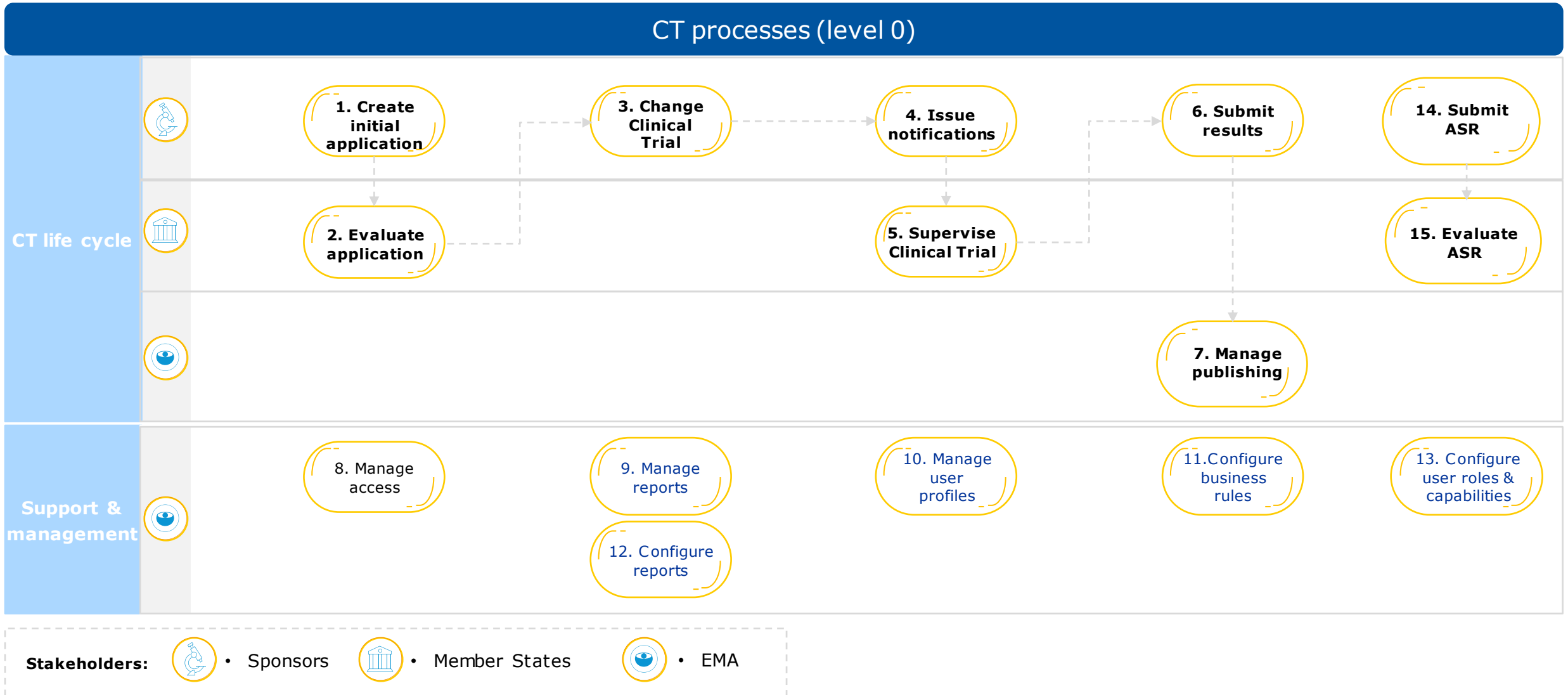
High-level overview of CT business processes in the CTIS

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



Content

Overview of CT business processes in the Sponsor workspace

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

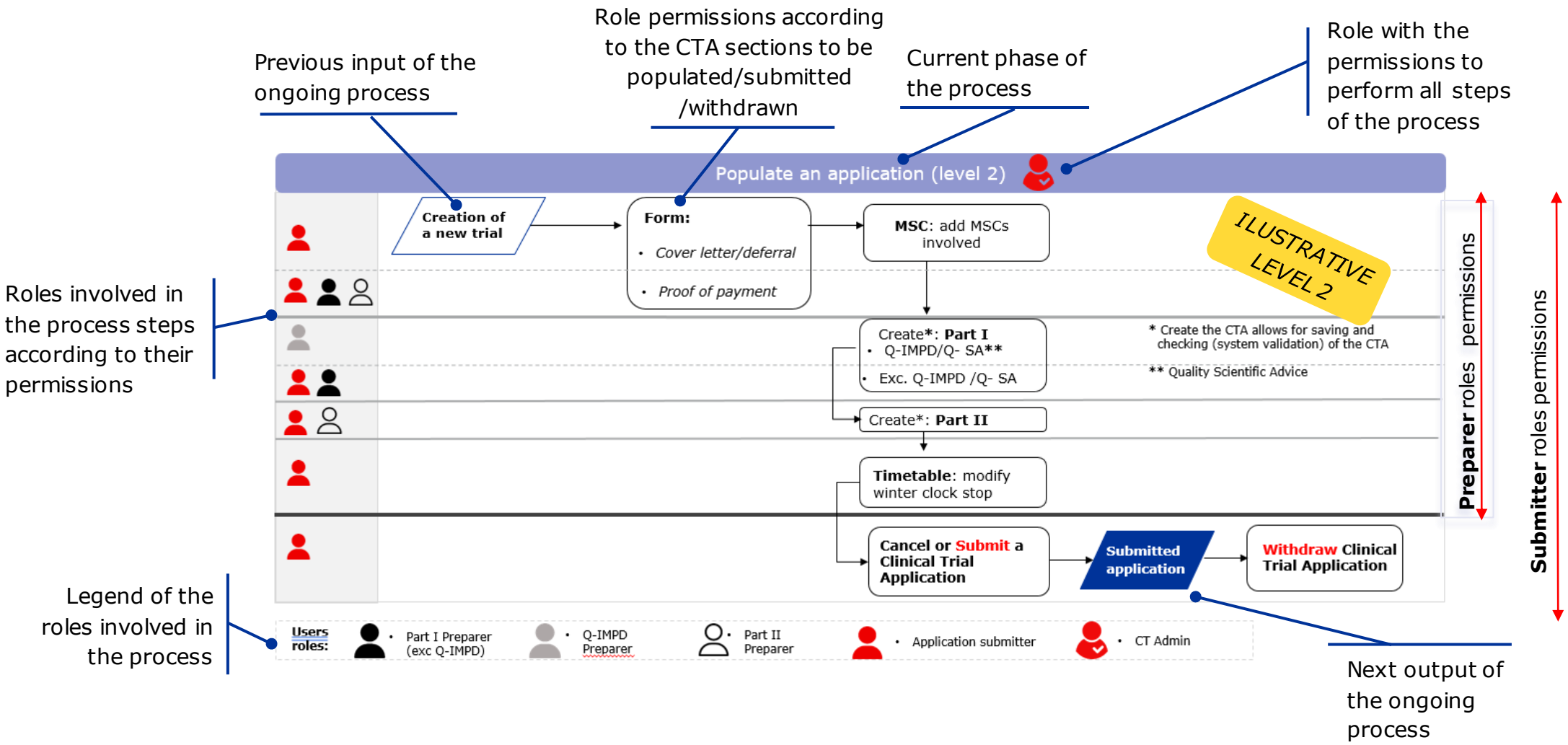
Level 0
Level 0 model identifies a high level view of the CT process

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 permissions linked to each role

Overview of CT business processes in the Sponsor workspace

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:



Overview of CT processes in the Sponsor workspace

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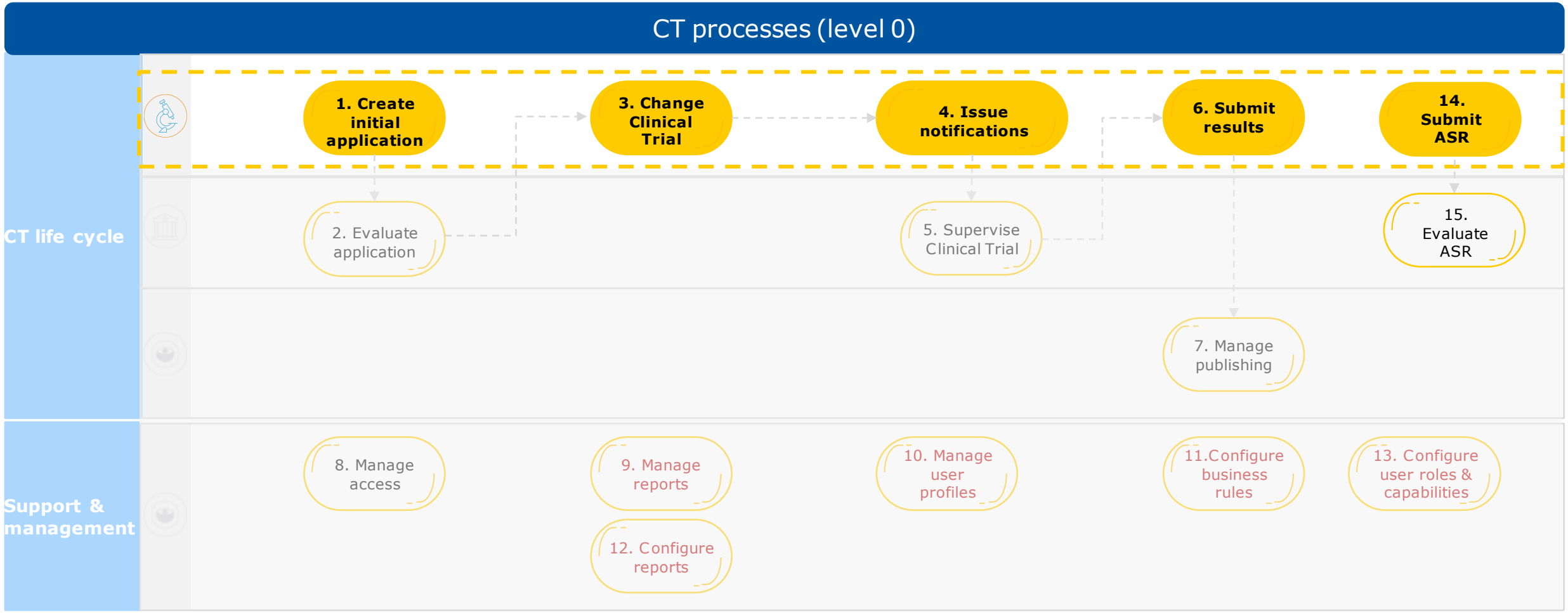
Within the Sponsor workspace, there are four main processes.



Overview of CT processes in the Sponsor workspace: Initial CTA

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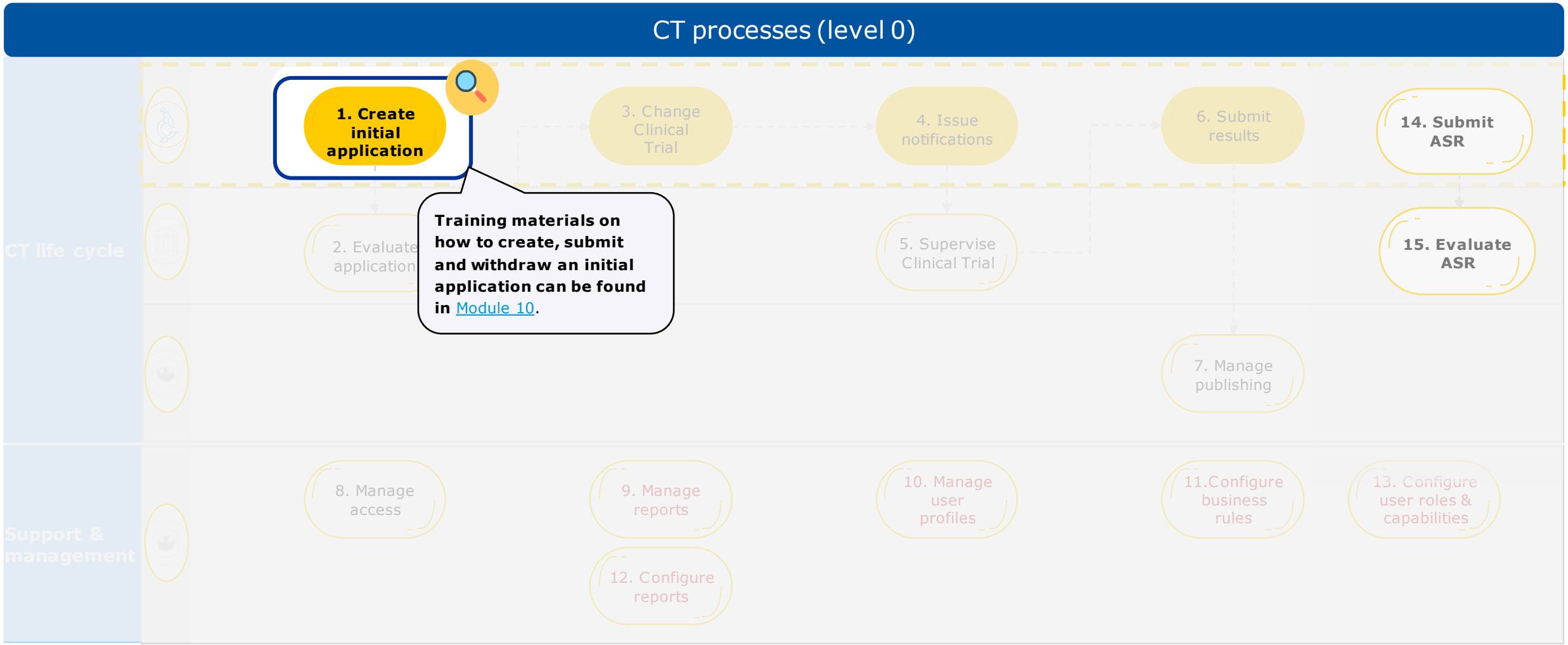
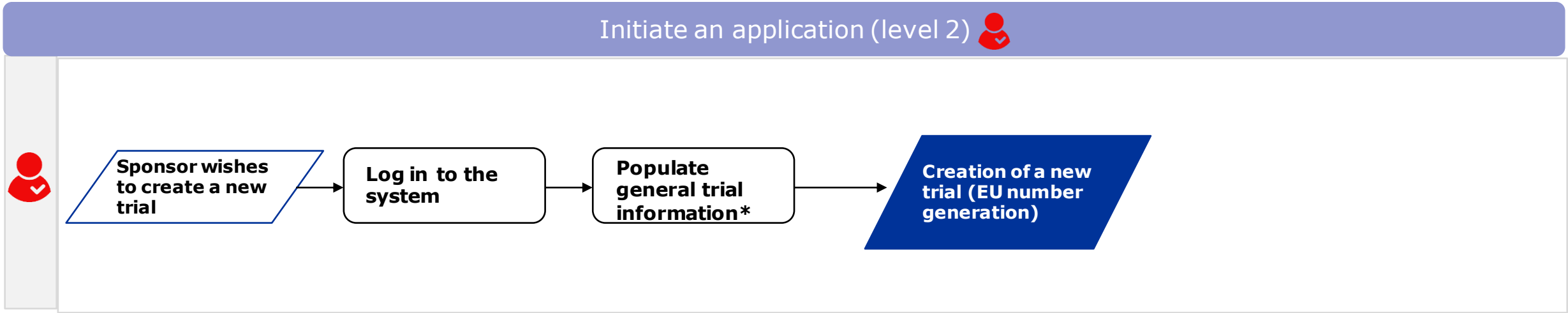


Stakeholders: • Sponsors • Member States • EMA

Initial CTA: Initiate an application

The first step in the creation of an initial application is the generation of the EU number.



* You need to populate the CT title and the Sponsor organisation to create a new CT. In addition, in the case of a transitional trial you will also need to tick the box "Transition Trial".

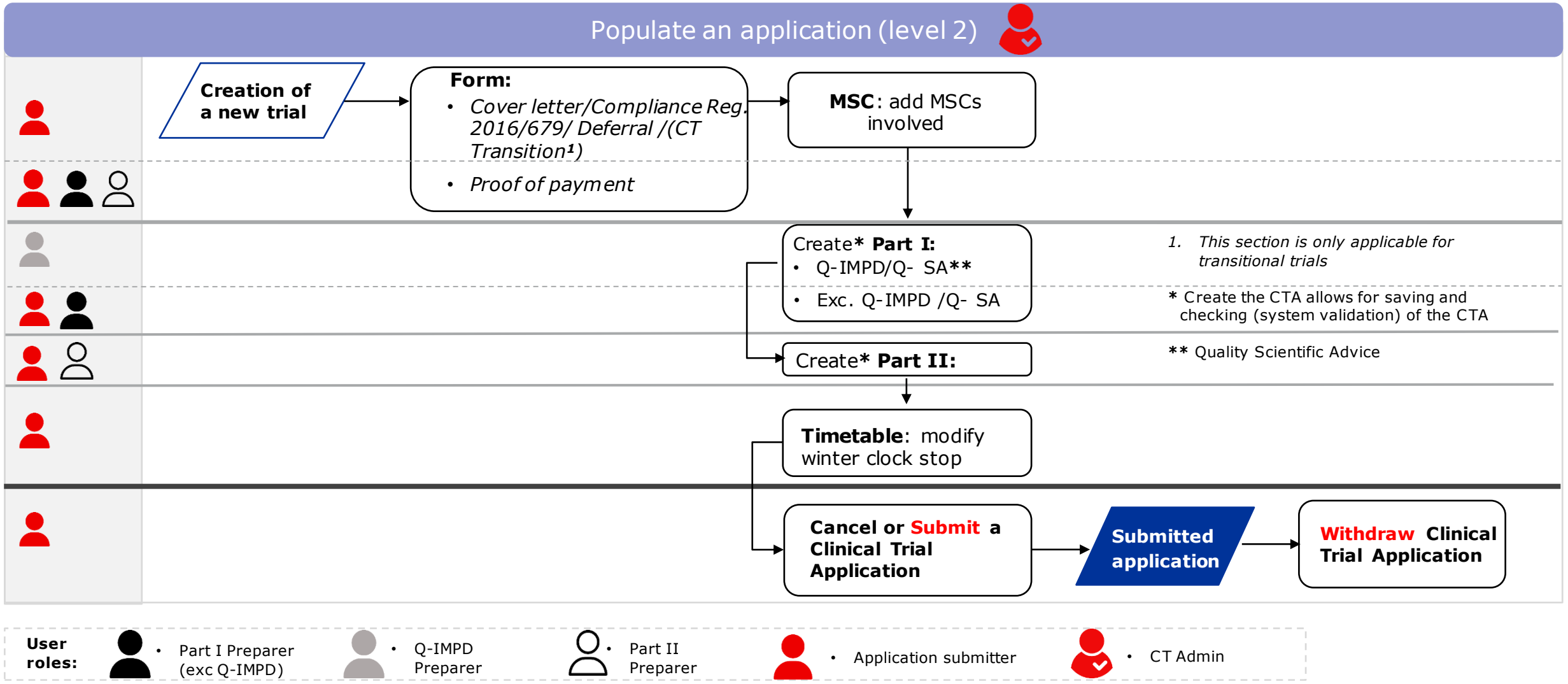
Notes:

- To initiate an application via the organisation centric approach, the CT Admin has to have the role assigned with scope "all trials".
- CTIS has also the "copy CTA" functionality for initial, SM and AMS applications and the CT Admin is the only role with the permission to use this functionality. The same as indicated in the previous note, in order to copy a trial via organisation centric approach, the CT Admin has to have the role assigned with scope "all trials".

User roles: • CT Admin

Initial CTA: Populate an application

Once the initial CTA has been created linked to an EU number, sponsor roles can start populating the different parts of the CTA according to the permissions mapped to the roles.



Overview of CT processes in the Sponsor workspace: Change CTA

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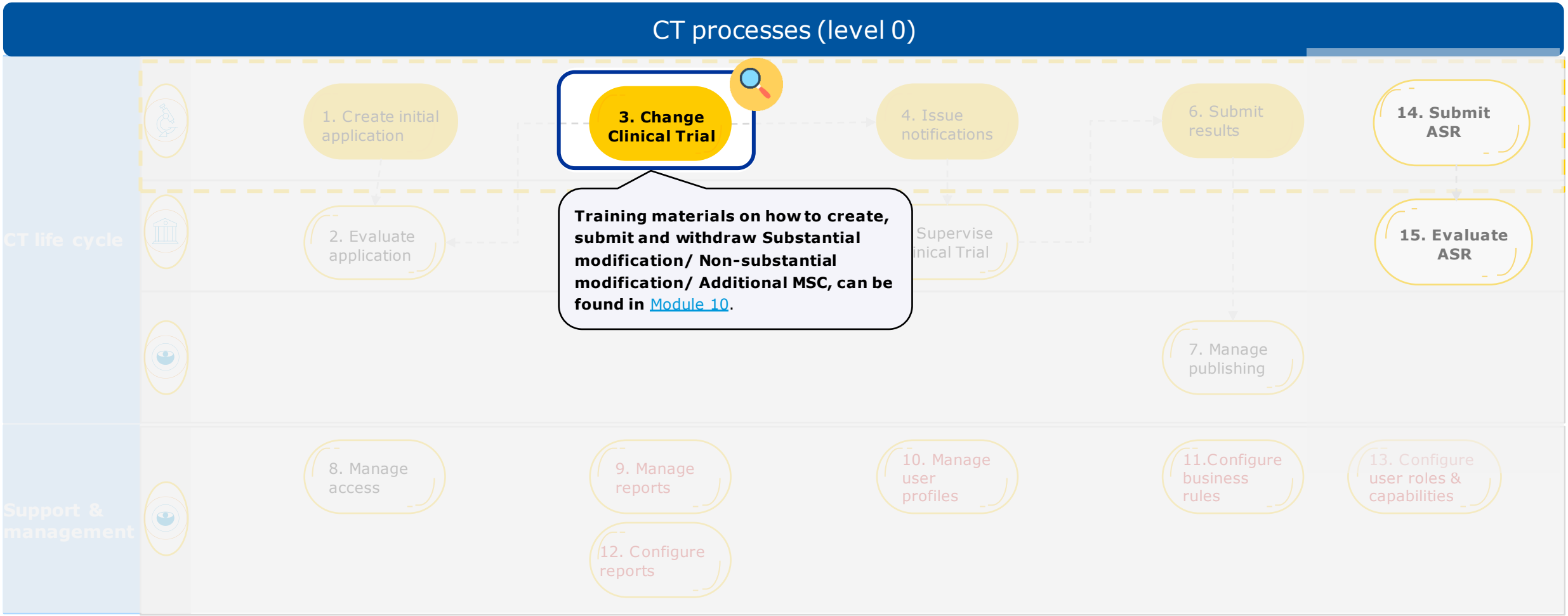

Stakeholders: • Sponsors • Member States • EMA

Overview of CT processes in the Sponsor workspace: Change CTA

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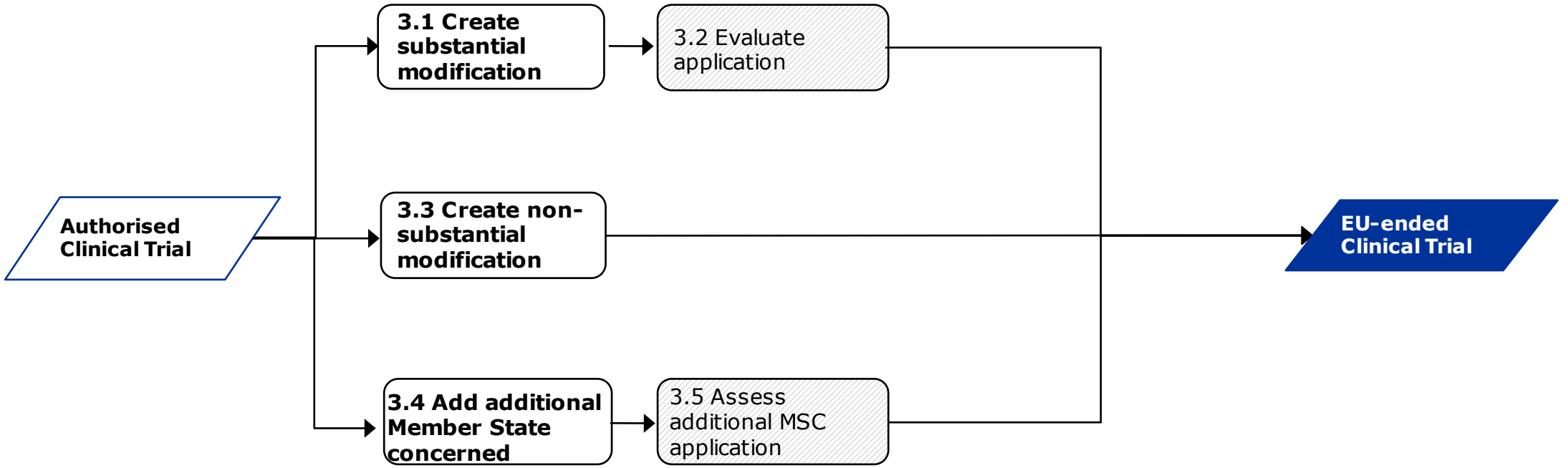
Once a clinical trial has been authorised (with or without conditions), the 'Change clinical trial' process allows the sponsor to submit substantial modifications, non-substantial modifications and additional MSC applications.

Change Application (level 1)



Stakeholders: • Sponsors

Refer to Member States workspace

Change CTA: Substantial Modification (SM)

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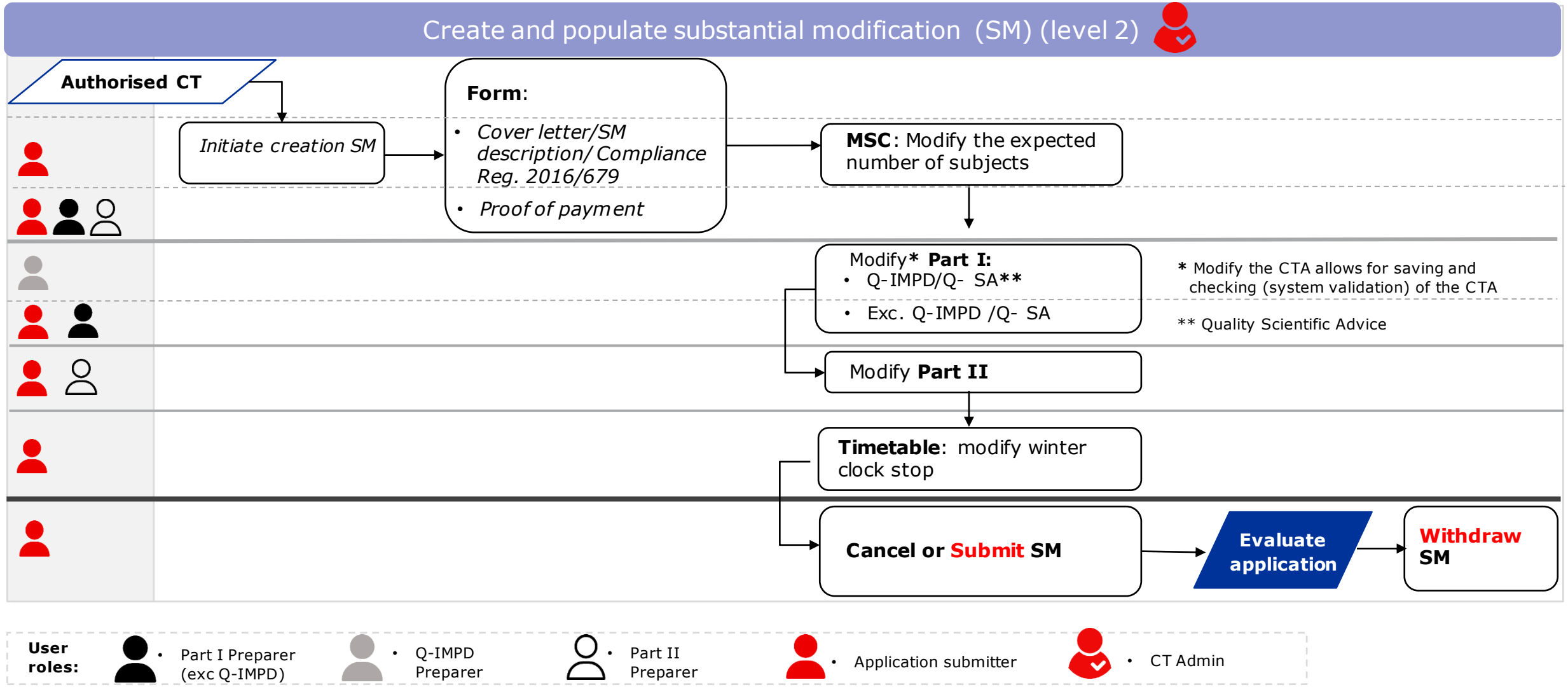
This process allows the Sponsors to modify substantial aspects in the different sections of a CTA that might have an impact on the subjects' safety, rights or the robustness and reliability of the data generated in the CT.



Change CTA: Non-Substantial Modification (NSM)

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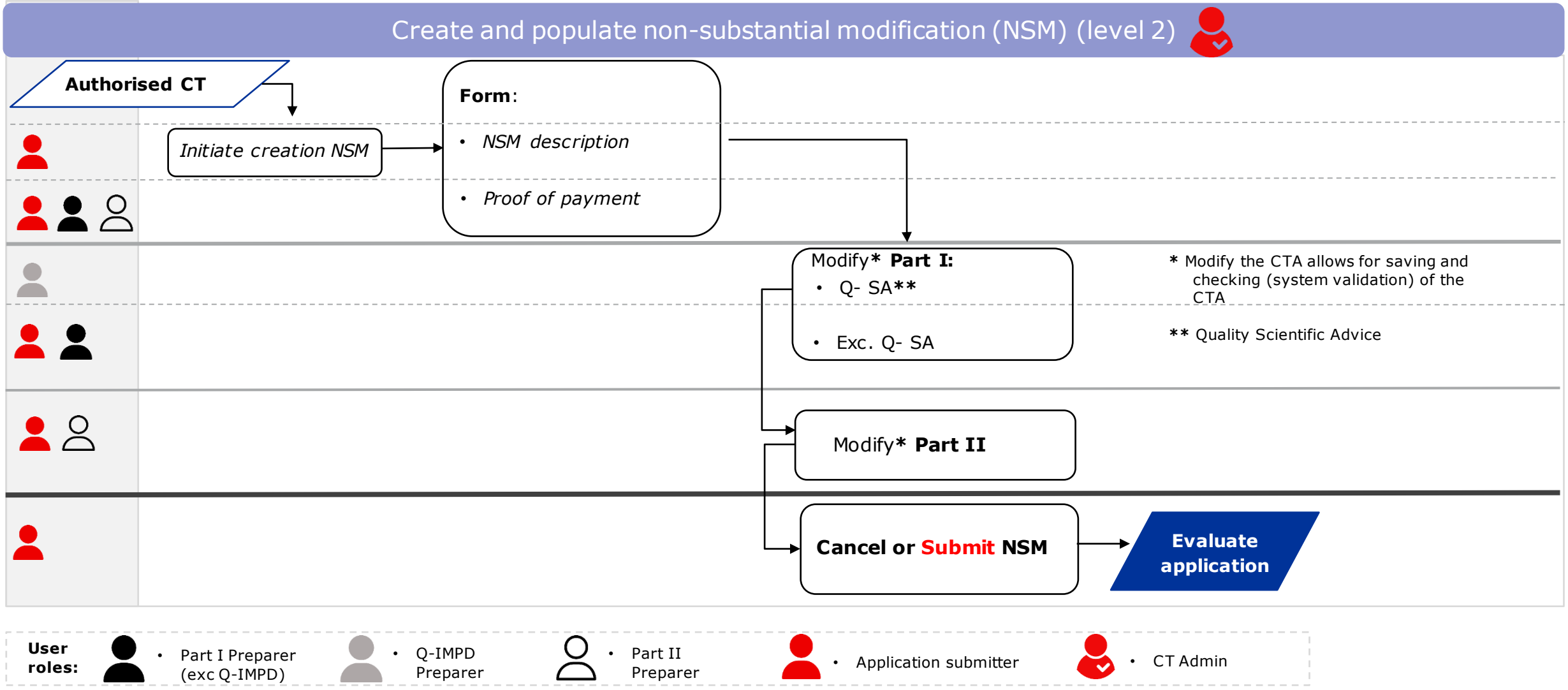
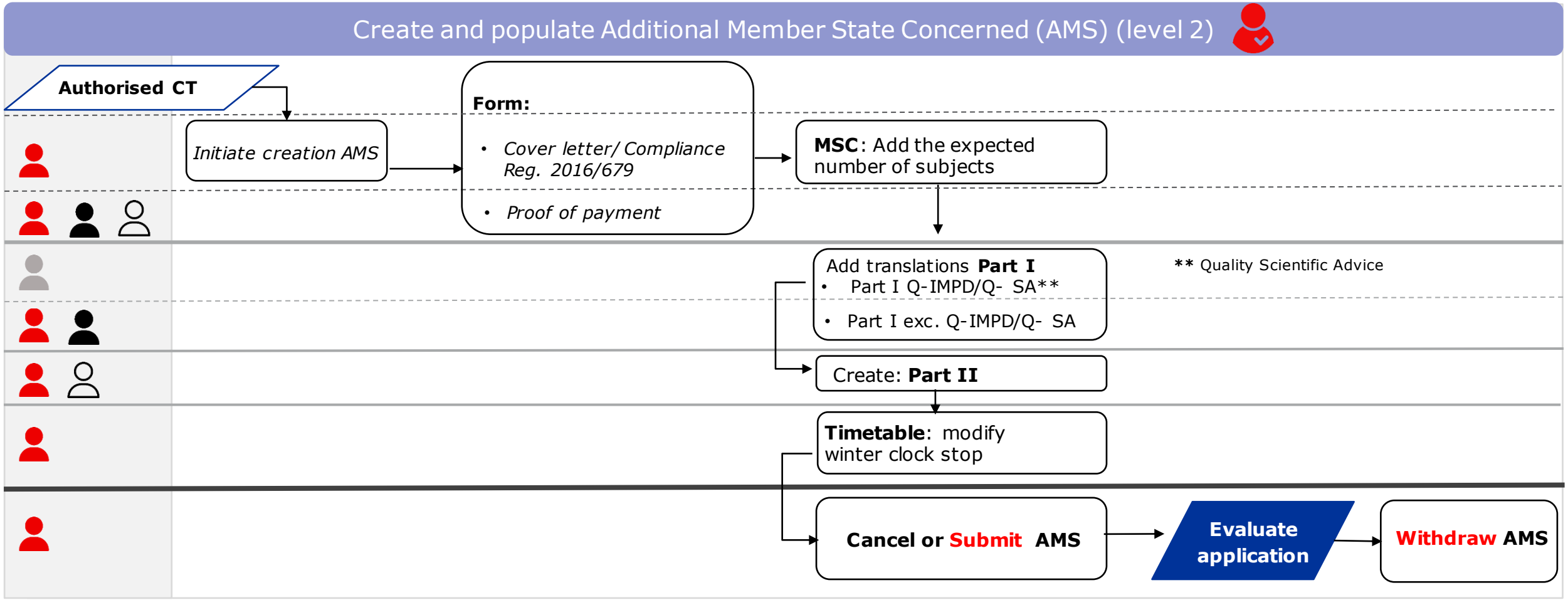
The Sponsors may need to submit a modification with information on any changes to a Clinical Trial, which are not substantial but are, nevertheless, relevant for the supervision of the Clinical Trial by the MSCs.



Change CTA: Additional Member State (AMS)

This process allows the Sponsors to add additional Member States.



Request for Information (RFI) Response

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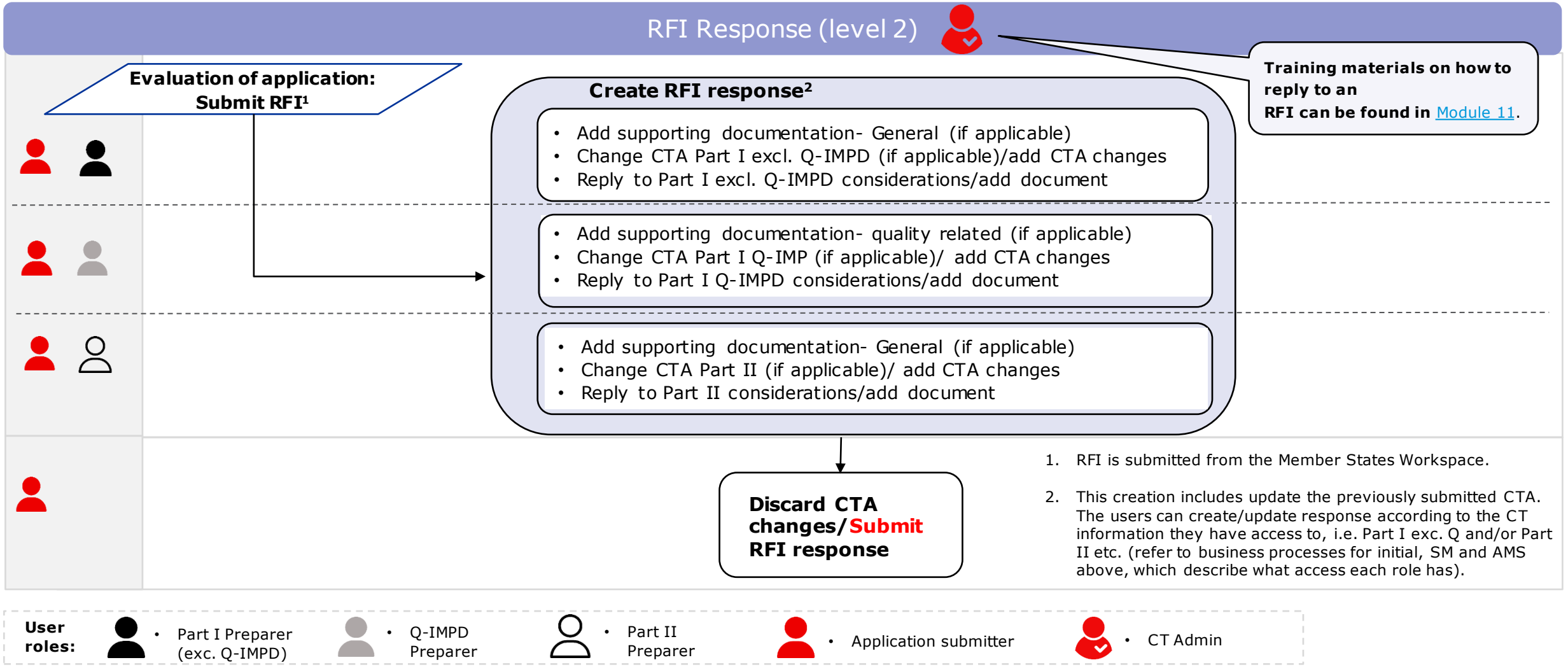
Sponsors need to reply to RFIs raised by MSC from the evaluation of a CTA (initial, SM or AMS).



Overview of CT processes in the Sponsor workspace

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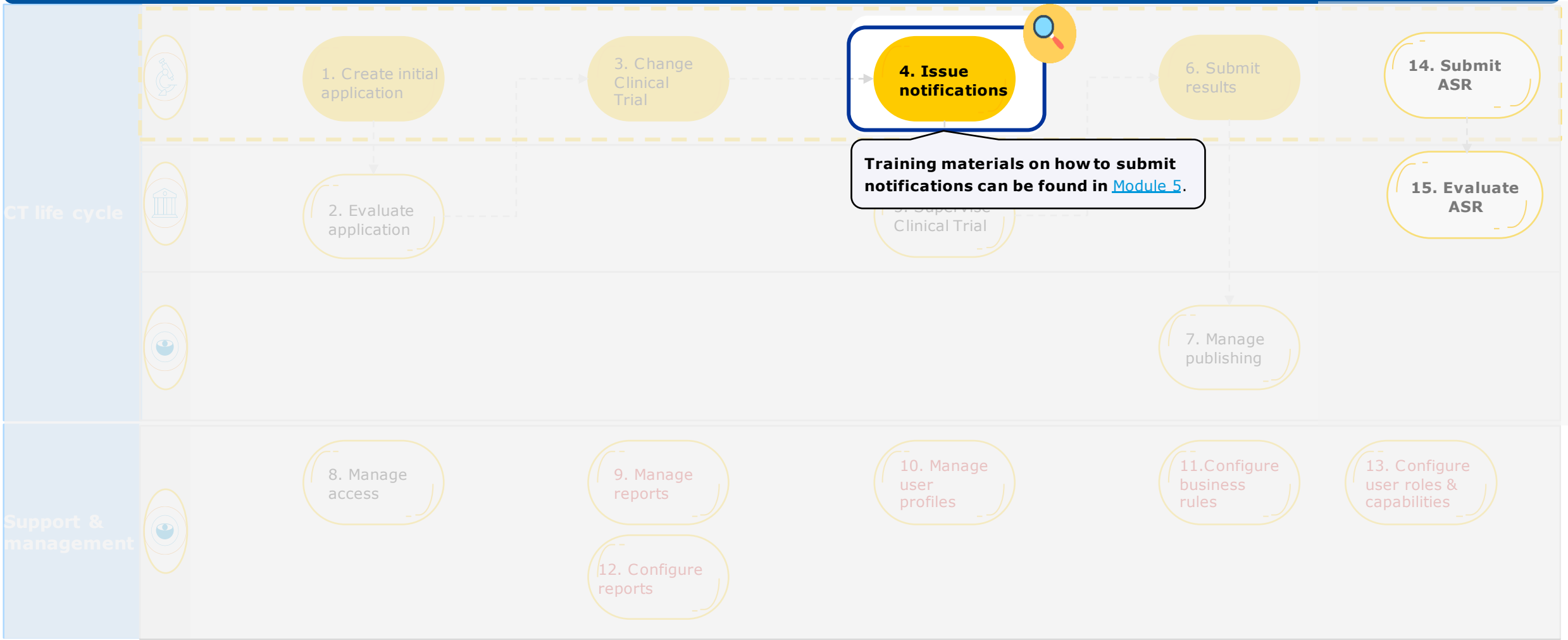
CT processes (level 0)



Stakeholders: • Sponsors • Member States • EMA

Overview of CT processes in the Sponsor workspace: Notifications

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This process allows Sponsors to notify the MSC about relevant events occurred during the conduct of a CT, once the CT is authorised.

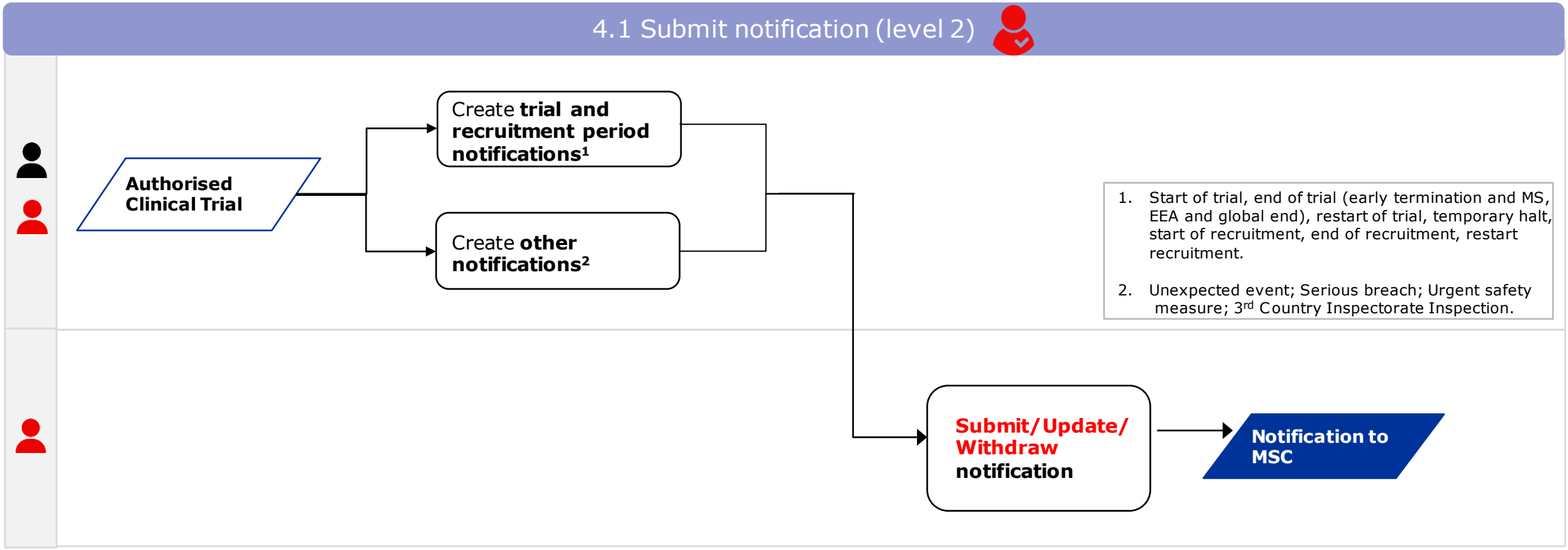
Issue notification (level 1)

Stakeholders:

- Sponsors

Notifications: Submit notifications

The notification can be classified in two main groups: trial and recruitment periods (they refer to the CT life cycle), and other type of notifications (only needed in certain circumstances).



Overview of CT processes in the Sponsor workspace: CT Results

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CT processes (level 0)

Training materials on how to submit Clinical Trial Results summary can be found in Module 5.

Training materials on how to submit Clinical Study Report can be found in Module 13.

Stakeholders: • Sponsors • Member States • EMA

Overview of CT processes in the Sponsor workspace: CT Results

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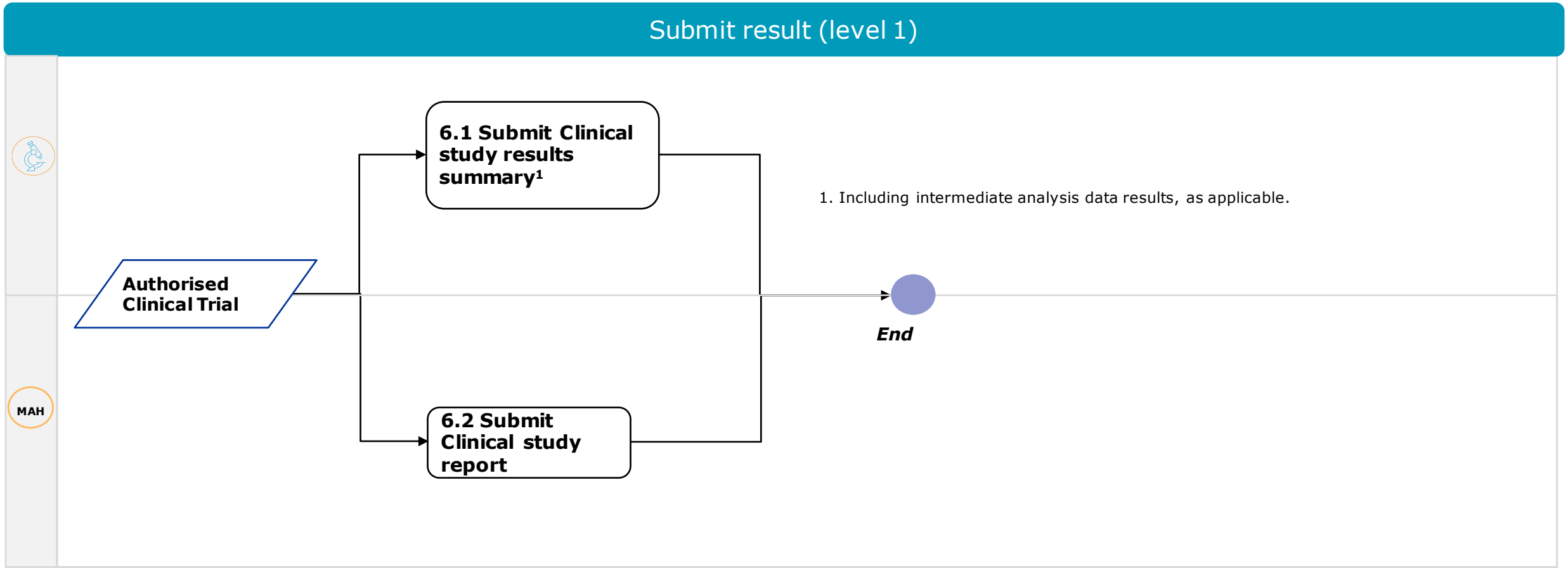
Once a clinical trial has been authorised and ended, the 'Submit results' process allows the submission of clinical study results. The sponsor is responsible for the submission of the summary of results (including lay summary) within one year from the end of the CT (6 months for paediatric CTs). The MAH has also the obligation to submit the clinical study report (CSR) in the context of a Marketing Authorization within 30 days regardless if the MAH is granted, rejected or withdrawn.

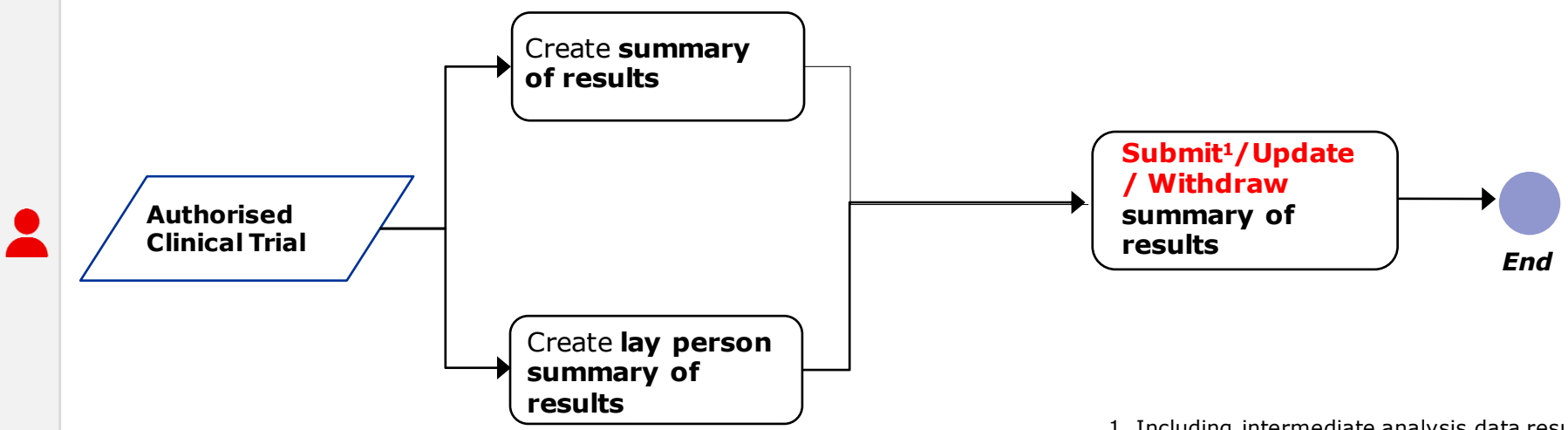


Stakeholders: • Sponsors • MAH

CT Results: Submit CT Results Summary

The sponsor is responsible for the submission of the summary of results (including lay summary) within one year from the end of the CT.

Submit Clinical study results summary (level 2)



1. Including intermediate analysis data results, as applicable.

User roles:

- CT Admin
- CT Results Submitter

CT Results: Submit Clinical Study Reports (CSR)

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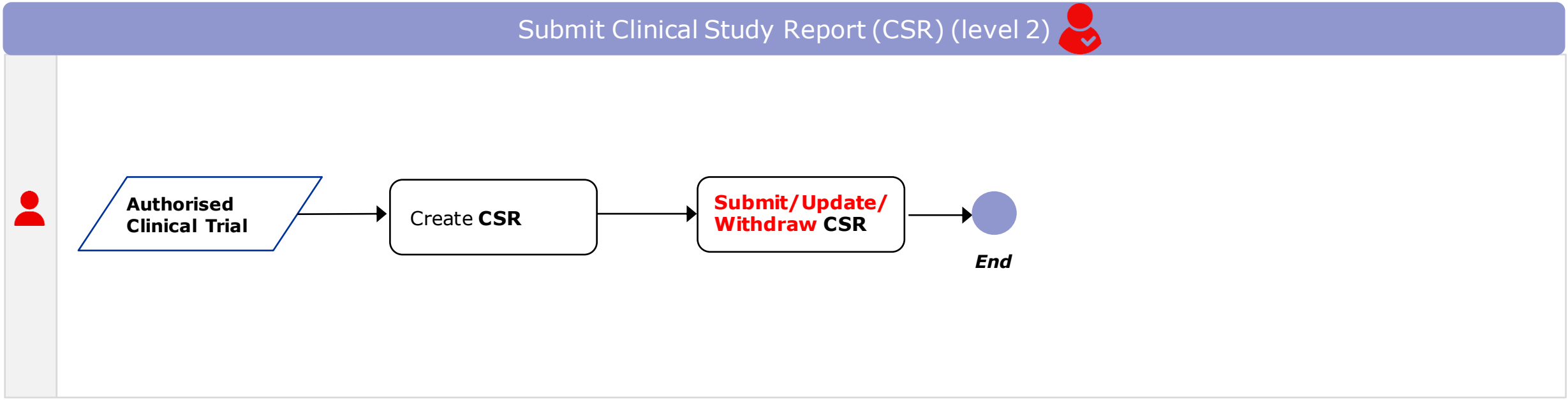
The MAH has the obligation to submit the clinical study report (CSR) in the context of a Marketing Authorization within 30 days form the date the MAH is granted, rejected or withdrawn.

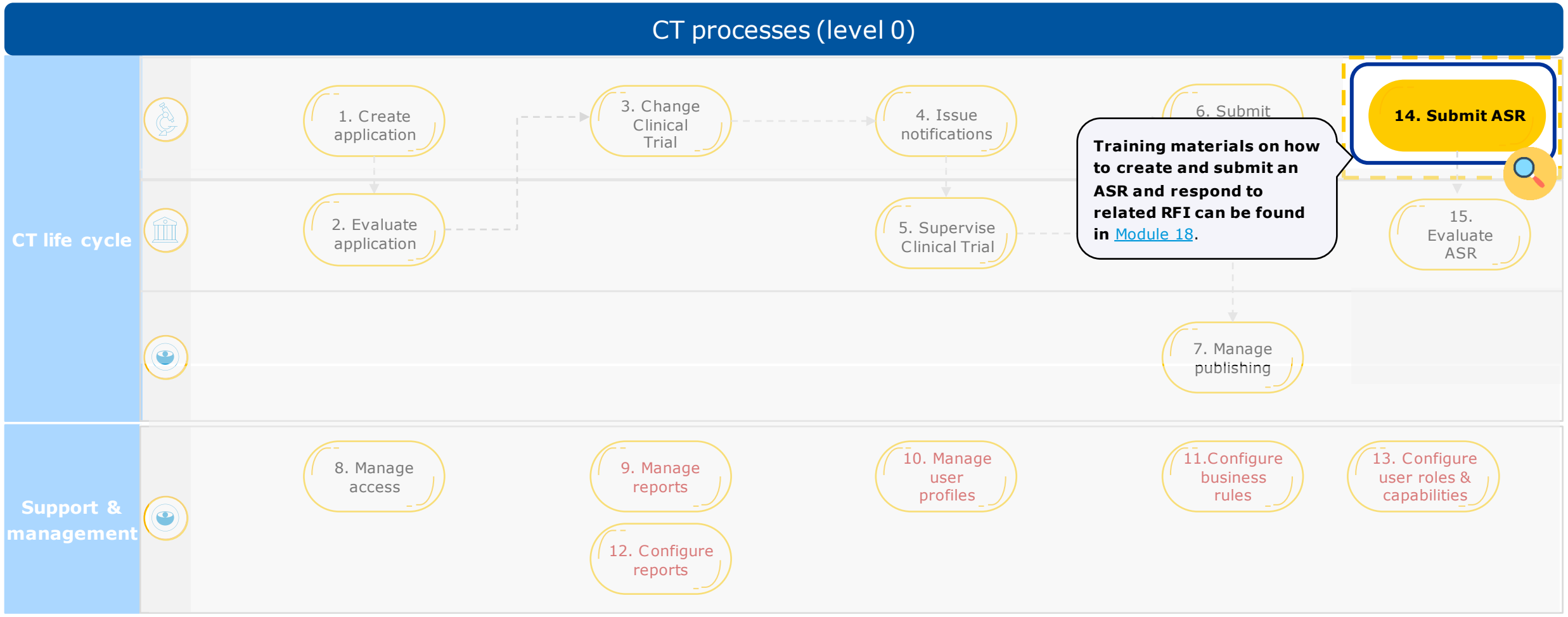


User roles:

- MAH Admin
- CSR Submitter

Overview of the CT business processes in the MS Workspace

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:



CT Results: Submit an Annual Safety Report (ASR)

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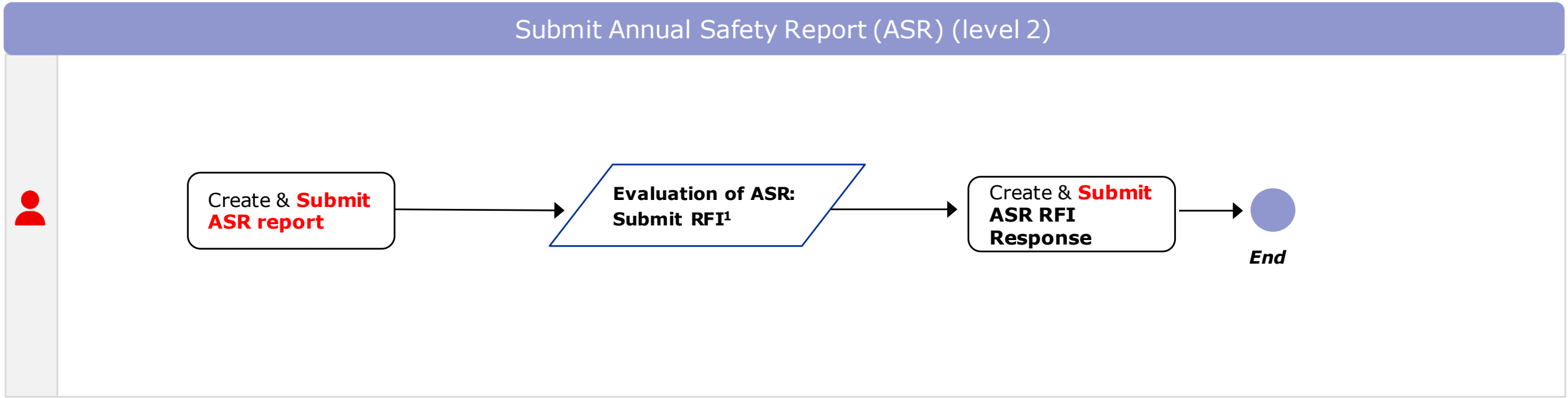
CTIS allows sponsors to submit an Annual Safety Report (ASR), a document provided to the authorities regarding the monitoring and evaluation of the evolving safety profile of the Investigational Medicinal Product (IMP) and the mitigation of potential risks.



User roles:

- ASR Submitter

Content

Summary of permissions/tasks by role and process

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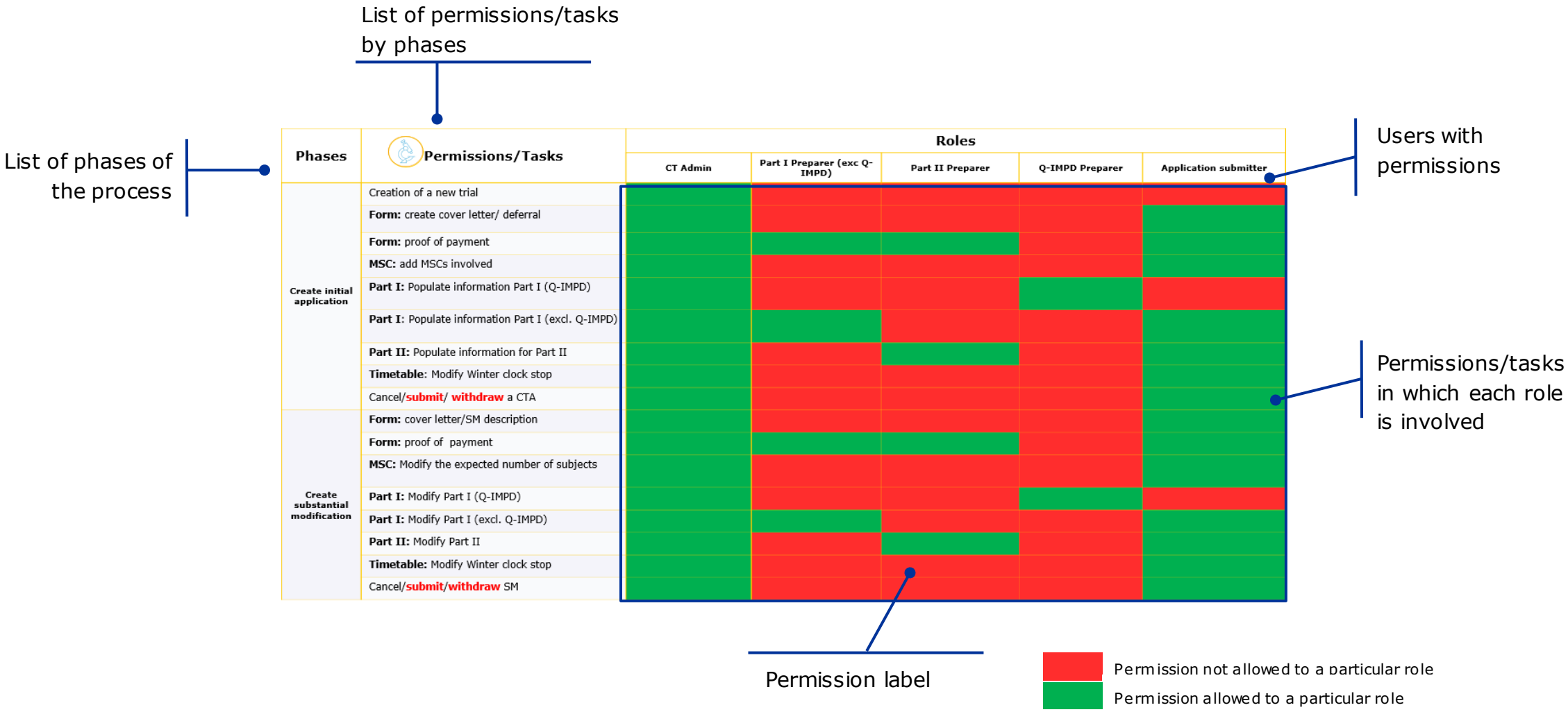
In order to clearly define each role, we are going to summarise each user's permissions/tasks. Find below the structure of the coming slides:



Phases	Permissions/Tasks	Roles: CT Admin	Part I Preparer (exc Q-IMPD)	Part II Preparer	Q-IMPD Preparer	Application submitter
Create initial application	Creation of a new trial					
	Form: create cover letter/ deferral					
	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	**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					

Summary of permissions/tasks by role and process – Create initial and SM

Phases	Permissions/Tasks	Roles				
		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					
	Create subsequent applications (SM, AMS, non-SM)					
Create initial application	**Form:** Cover letter/Compliance Reg. 2016/679/ Deferral /(CT Transition[1])					
	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/Compliance Reg 2016/679					
	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					

Summary of permissions/tasks by role and process – Create NSM and Add MSC

Phases	Permissions/Tasks	Roles				
		CT Admin	Part I Preparer (exc 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[2]					
	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					

1 This section is only applicable for transitional trials.

2 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.

Summary of permissions/tasks by role and process – Create RFI response

Phases	Permissions/Tasks	Roles				
		CT Admin	Part I Preparer (exc 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					

Summary of tasks by role and process – Sponsor, Notification and CSR

Phase	Permissions/Tasks	Roles		
		CT Admin	Notification preparer	Notification submitter
Submit notification	Create trial and recruitment period notifications			
	Create other notifications			
	Submit/**update**/**withdraw** notification			

Phase	Permissions/Tasks	Roles	
		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 data results, as applicable.

Phase	Permissions/Tasks	Roles	
		MAH Admin	CSR submitter
Clinical Study Report	Create CSR		
	Submit/**update**/**withdraw** CSR		

Summary of tasks by role and process – Sponsor, Submit ASR

Phase	Permissions/Tasks	Roles
		ASR submitter
Annual Safety Report	Create ASR	
	Submit ASR	

Summary of tasks by role and process – Sponsor Viewer Roles

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	Permissions/Tasks	Roles				
		Part I Viewer (excl. Q-IMPD)	Q-IMPD Viewer	Part II Viewer	Notifications Viewer	CT results Viewer
Viewer Roles*	**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					

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

Summary of tasks by role and process – Sponsor Viewer Roles

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	Permissions/Tasks	Roles				
		Part I Viewer (excl. Q-IMPD)	Q-IMPD Viewer	Part II Viewer	Notifications Viewer	CT results Viewer
Viewer Roles*	**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)					
	Correctives measure tab (including request for opinion, view of 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 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.)

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Clinical Trials Information System (CTIS).
Sponsors Business Processes and roles.