Sponsors Business Processes and Roles

Use of Sponsors Preparedness

CTIS Training Programme – Module 7

Version 1.43 – January 2022
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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

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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
Objectives of the document

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

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

- Sponsors
- Member States
- European Commission
- EMA

Overview of Sponsor CT processes

Summary of Sponsor permissions/tasks by role and process
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
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 submit data/documents from their respective workspace to the EU CT database and withdraw or update the submitted information.

- **Other permissions**
  - Permission related to user management (assign roles etc.) e.g. Sponsor Administrator

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 Sponsors 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.

### Business roles

- **Viewer**
  - Part I Viewer (excl. Q-IMPD)
  - Part II Viewer
  - Q-IMPD Viewer
  - Notifications Viewer
  - CT results Viewer

- **Preparer**
  - Part I Preparer (excl. Q-IMPD)
  - Part II Preparer
  - Q-IMPD Preparer
  - Notifications Preparer

- **Submitter**
  - Application submitter
  - Notification submitter
  - CT results Submitter
  - ASR Submitter

### Administrator roles

- **Sponsors Admin**
- **CT Admin**
- **EMA Admin**
- **MAH Admin**
- **Viewer / Submitter**
  - CSR Viewer
  - CSR Submitter
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
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:

<table>
<thead>
<tr>
<th>CT processes (level 0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Create initial application</td>
</tr>
<tr>
<td>2. Evaluate application</td>
</tr>
<tr>
<td>3. Change Clinical Trial</td>
</tr>
<tr>
<td>4. Issue notifications</td>
</tr>
<tr>
<td>5. Supervise Clinical Trial</td>
</tr>
<tr>
<td>6. Submit results</td>
</tr>
<tr>
<td>7. Manage publishing</td>
</tr>
<tr>
<td>8. Manage access</td>
</tr>
<tr>
<td>9. Manage reports</td>
</tr>
<tr>
<td>10. Manage user profiles</td>
</tr>
<tr>
<td>11. Configure business rules</td>
</tr>
<tr>
<td>12. Configure reports</td>
</tr>
<tr>
<td>13. Configure user roles &amp; capabilities</td>
</tr>
<tr>
<td>14. Submit ASR</td>
</tr>
<tr>
<td>15. Evaluate ASR</td>
</tr>
</tbody>
</table>

Stakeholders:
- Sponsors
- Member States
- EMA
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
Overview of CT business processes in the Sponsor workspace

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 models identifies which is the sub-process of each group from level 0

**Level 2**
Level 2 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:

<table>
<thead>
<tr>
<th>Previous input of the ongoing process</th>
<th>Role permissions according to the CTA sections to be populated/submitted/withdrawn</th>
<th>Current phase of the process</th>
<th>Role with the permissions to perform all steps of the process</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Legend of the roles involved in the process:
- **Preparer roles permissions**
- **Submitter roles permissions**

Next output of the ongoing process:
Within the Sponsor’s workspace, there are four main processes.

**Overview of CT processes in the Sponsor workspace**

1. Create initial application
2. Evaluate application
3. Change Clinical Trial
4. Issue notifications
5. Supervise Clinical Trial
6. Submit results
7. Manage publishing
8. Manage access
9. Manage reports
10. Manage user profiles
11. Configure business rules
12. Configure reports
13. Configure user roles & capabilities
14. Submit ASR
15. Evaluate ASR

**Stakeholders:**
- Sponsors
- Member States
- EMA

CT life cycle

Support & management
Overview of CT processes in the Sponsor workspace: Initial CTA

CT processes (level 0)

1. Create initial application

Training materials on how to create, submit and withdraw an initial application can be found in Module 10.

2. Evaluate application

3. Change Clinical Trial

4. Issue notifications

5. Supervise Clinical Trial

6. Submit results

7. Manage publishing

8. Manage access

9. Manage reports

10. Manage user profiles

11. Configure business rules

12. Configure reports

13. Configure user roles & capabilities

14. Submit ASR

15. Evaluate ASR

Stakeholders:
- Sponsors
- Member States
- EMA
The first step in the creation of an initial application is the generation of the EU number.

Initiate an application (level 2)

Sponsor wishes to create a new trial

Log in to the system

Populate general trial information*

Creation of a new trial (EU number generation)

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

Notes:

- To initiate an application via the organization centric approach the CT Admin has to have the role assigned with scope “all trials”.
- CTIS has also “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 previous note, in order to copy a trial via organization centric approach the CT Admin has to have the role assigned with scope “all trials”.

User roles:

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

### Populate an application (level 2)

1. **Creation of a new trial**
   - **Form:**
     - Cover letter/Compliance Regulation 2016/679/Deferral / (CT Transition*)
   - Proof of payment
   - MSC: add MSCs involved

2. **Create Part I:**
   - Q-IMPD/Q- SA**
   - Exc. Q-IMPD/Q- SA

3. **Create Part II:**
   - Timetable: modify winter clock stop

4. **Cancel or Submit a Clinical Trial Application**
   - Submitted application
   - Withdraw Clinical Trial Application

### User roles:
- Part I Preparer (exc Q-IMPD)
- Q-IMPD Preparer
- Part II Preparer
- Application submitter
- CT Admin

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*This section is only applicable for transition trials

**Create the CTA allows for saving and checking (system validation) of the CTA

**Quality Scientific Advice

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*Classified as internal/staff & contractors by the European Medicines Agency
Overview of CT processes in the Sponsor workspace: Change CTA

CT processes (level 0)

1. Create initial application
2. Evaluate application
3. Change Clinical Trial

Training materials on how to create, submit and withdraw Substantial modification/ Non-substantial modification/ Additional MSC, can be found in Module 10.

4. Issue notifications
5. Supervise Clinical Trial
6. Submit results
7. Manage publishing
8. Manage access
9. Manage reports
10. Manage user profiles
11. Configure business rules
12. Configure reports
13. Configure user roles & capabilities
14. Submit ASR
15. Evaluate ASR

Support & management

CT life cycle

Stakeholders: • Sponsors • Member States • EMA
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 application.

**Stakeholders:**
- Sponsors

**Change Application (level 1)**

1. **Authorised Clinical Trial**
   - 3.1 Create substantial modification
   - 3.2 Evaluate application
   - 3.3 Create non-substantial modification
   - 3.4 Add additional Member State concerned
   - 3.5 Assess additional MSC application

**EU-ended Clinical Trial**
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.

**Form:**
- Cover letter/SM description/ Compliance Reg 2016/679
- Proof of payment

**MSC:** Modify the expected number of subjects

**Modify** Part I:
- Q-IMPD/Q- SA
- Exc. Q-IMPD /Q- SA

**Modify Part II**

**Timetable:** modify winter clock stop

**Cancel or Submit SM**

**Evaluate application**

**Withdraw SM**

**User roles:**
- Part I Preparer (exc Q-IMPD)
- Q-IMPD Preparer
- Part II Preparer
- Application submitter
- CT Admin
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 Trials by the MSCs.

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**Change CTA: Non-Substantial Modification (NSM)**

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 Trials by the MSCs.

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**Create and populate non-substantial modification (NSM) (level 2)**

- **Authorised CT**
  - Initiate creation NSM
  - **Form:**
    - NSM description
    - Proof of payment

- **Modify**
  - **Part I:**
    - Q-SA
    - Exc. Q-SA
  - **Part II:**

- **Cancel or Submit NSM**

---

**User roles:**
- Part I Preparer (exc Q-IMPD)
- Q-IMPD Preparer
- Part II Preparer
- Application submitter
- CT Admin

---

* Modify the CTA allows for saving and checking (system validation) of the CTA

** Quality Scientific Advice
This process allows the Sponsors to add additional Member States.

Create and populate Additional Member State Concerned (AMS) (level 2)

**Authorised CT**

- Initiate creation AMS

**Form:**
- Cover letter/ Compliance Reg 2016/679
- Proof of payment

**MSC:** Add the expected number of subjects

- Add translations **Part I**
  - Part I Q-IMPD/Q- SA**
  - Part I exc. Q-IMPD/Q- SA
- Create: **Part II**

**Timetable:** modify winter clock stop

- Cancel or Submit AMS

Evaluate application

Withdraw AMS

**User roles:**
- Part I Preparer (exc Q-IMPD)
- Q-IMPD Preparer
- Part II Preparer
- Application submitter
- CT Admin

**Notes:**
- **Quality Scientific Advice**

**Classification:** Classified as internal/staff & contractors by the European Medicines Agency
Sponsors need to reply to RFIs raised by MSC from the evaluation of a CTA (initial, SM or AMS).

1. RFI is submitted from the Member States Workspace.
2. This creation includes update the previously submitted CTA. The users can create/update response according to the CT information they have access to i.e. Part I exc. Q and/or Part II etc. (refer to business processes for initial, SM and AMS above, which describe what access each role has).

Training materials on how to reply to an RFI can be found in Module 11.
Overview of CT processes in the Sponsor workspace

CT processes (level 0)

CT life cycle

1. Create initial application
2. Evaluate application
3. Change Clinical Trial
4. Issue notifications
5. Supervise Clinical Trial
6. Submit results

Support & management

7. Manage publishing
8. Manage access
9. Manage reports
10. Manage user profiles
11. Configure business rules
12. Configure reports
13. Configure user roles & capabilities
14. Submit ASR
15. Evaluate ASR

Stakeholders:
- Sponsors
- Member States
- EMA

Training materials on how to submit notifications can be found in Module 5.
This process allows Sponsors to notify MSC about a relevant events occurred during the conduct of a CT once the CT is authorised.

Stakeholders: Sponsors
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).

4.1 Submit notification (level 2)

- Authorised Clinical Trial

1. Create trial and recruitment periods notifications
2. Create other notifications

Submit/Update/Withdraw notification

1. Start of trial, end of trial (early termination and MS, EEA and global end), restart of trial, temporary halt, start of recruitment, end of recruitment, restart recruitment.
2. Unexpected event; Serious breach; Urgent safety measure; 3rd Country Inspectorate Inspection.

User roles:
- CT Admin
- Notification Preparer
- Notification Submitter
Overview of CT processes in the Sponsor workspace: CT Results

<table>
<thead>
<tr>
<th>CT life cycle</th>
<th>Support &amp; management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Create initial application</td>
<td>8. Manage access</td>
</tr>
<tr>
<td>2. Evaluate application</td>
<td>9. Manage reports</td>
</tr>
<tr>
<td>3. Change Clinical Trial</td>
<td>10. Manage user profiles</td>
</tr>
<tr>
<td>5. Supervise Clinical Trial</td>
<td>12. Configure reports</td>
</tr>
<tr>
<td>6. Submit results</td>
<td></td>
</tr>
<tr>
<td>Training materials on how to submit Clinical Trial Results summary can be found in Module 5.</td>
<td></td>
</tr>
<tr>
<td>Training materials on how to submit Clinical Study Report can be found in Module 13.</td>
<td></td>
</tr>
</tbody>
</table>

Stakeholders: • Sponsors • Member States • EMA

Classified as internal/staff & contractors by the European Medicines Agency
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 MAA is granted, rejected or withdrawn.

Submit result (level 1)

1. including intermediate analysis data results, as applicable
The sponsor is responsible for the submission of the summary of results (including lay summary) within one year from the end of the CT.

1. including intermediate analysis data results, as applicable
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.
Overview of the CT business processes in the MS Workspace

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:

CT processes (level 0)

1. Create application
2. Evaluate application
3. Change Clinical Trial
4. Issue notifications
5. Supervise Clinical Trial
6. Submit results
7. Manage publishing
8. Manage access
9. Manage reports
10. Manage user profiles
11. Configure business rules
12. Configure reports
13. Configure user roles & capabilities
14. Submit ASR
15. Evaluate ASR

Stakeholders:
- Sponsors
- Member States
- EMA

Training materials on how to create and submit an ASR and respond to related RFI can be found in Module 18.
CT Results: Submit an Annual Safety Report (ASR)

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.

Submit Annual Safety Report (ASR) (level 2)

Create & Submit ASR report → Evaluation of ASR: Submit RFI → Create & Submit ASR RFI Response

End

User roles: • ASR Submitter
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 for the Sponsor user group

**Summary of permissions/tasks by role and process**
Summary of permissions/tasks by role and process

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

<table>
<thead>
<tr>
<th>Phases</th>
<th>Permissions/Tasks</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create initial application</td>
<td></td>
<td>CT Adevi</td>
</tr>
<tr>
<td></td>
<td>Creation of a new trial</td>
<td>Part I Preparer (exc. Q-HMPD)</td>
</tr>
<tr>
<td></td>
<td>Forms: create cover letter/deferral</td>
<td>Part II Preparer</td>
</tr>
<tr>
<td></td>
<td>Forms: proof of payment</td>
<td>Q-HMPD Preparer</td>
</tr>
<tr>
<td></td>
<td>MSC: add MSCs involved</td>
<td>Application submitter</td>
</tr>
<tr>
<td></td>
<td>Part I: Populate information Part I (Q-HMPD)</td>
<td></td>
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<tr>
<td></td>
<td>Part I: Populate information Part I (exc. Q-HMPD)</td>
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<tr>
<td></td>
<td>Part II: Populate information for Part II</td>
<td></td>
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<tr>
<td></td>
<td>Timetable: Modify Winter clock stop</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cancel/submit/withdraw 2 CTA</td>
<td></td>
</tr>
<tr>
<td>Create substantial modification</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forms: cover letter/SM description</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forms: proof of payment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MSC: Modify the expected number of subjects</td>
<td></td>
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<tr>
<td></td>
<td>Part I: Modify Part I (Q-HMPD)</td>
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<tr>
<td></td>
<td>Part I: Modify Part I (exc. Q-HMPD)</td>
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<td>Part II: Modify Part II</td>
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<td></td>
<td>Timetable: Modify Winter clock stop</td>
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<td></td>
<td>Cancel/submit/withdraw 2 CTA</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Permission label</th>
<th>Permission not allowed to a particular role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permission allowed to a particular role</td>
<td>Permission not allowed to a particular role</td>
</tr>
</tbody>
</table>

Users with permissions
Permissions/tasks in which each role is involved
List of phases of the process
List of permissions/tasks by phases
## Summary of permissions/tasks by role and process – Create initial and SM

<table>
<thead>
<tr>
<th>Phases</th>
<th>Permissions/Tasks</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CT Admin</td>
</tr>
<tr>
<td>Create CTAs</td>
<td>Create a new trial (initiate)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Create a CTA copy or resubmit a CTA</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Create subsequent applications (SM, AMS, non-SM)</td>
<td>X</td>
</tr>
<tr>
<td>Create initial application</td>
<td><strong>Form:</strong> Cover letter/Compliance Reg 2016/679/Deferral /(CT Transition)¹</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td><strong>Form:</strong> proof of payment</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td><strong>MSC:</strong> add MSCs involved</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td><strong>Part I:</strong> Populate information Part I (Q-IMPD)</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>Part I:</strong> Populate information Part I (excl. Q-IMPD)</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>Part II:</strong> Populate information for Part II</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>Timetable:</strong> Modify Winter clock stop</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>Cancel/submit/withdraw a CTA</strong></td>
<td>X</td>
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<tr>
<td>Create substantial modification</td>
<td><strong>Initiate creation SM</strong></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td><strong>Form:</strong> cover letter/SM description/Compliance Reg 2016/679</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td><strong>Form:</strong> proof of payment</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>MSC:</strong> Modify the expected number of subjects</td>
<td>X</td>
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<tr>
<td></td>
<td><strong>Part I:</strong> Modify Part I (Q-IMPD)</td>
<td>X</td>
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<td><strong>Part I:</strong> Modify Part I (excl. Q-IMPD)</td>
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<td><strong>Part II:</strong> Modify Part II</td>
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<td></td>
<td><strong>Timetable:</strong> Modify Winter clock stop</td>
<td>X</td>
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<td></td>
<td><strong>Cancel/submit/withdraw SM</strong></td>
<td>X</td>
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</tbody>
</table>
### Summary of permissions/tasks by role and process – Create NSM and Add MSC

<table>
<thead>
<tr>
<th>Phases</th>
<th>Permissions/Tasks</th>
<th>Roles</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CT Admin</td>
</tr>
<tr>
<td>Create non-substantial modification</td>
<td>Initiate creation NSM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Form: NSM description</td>
<td></td>
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<tr>
<td></td>
<td>Form: proof of payment</td>
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<tr>
<td></td>
<td>Part I: Modify Part I documents (Q-SA)</td>
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<tr>
<td></td>
<td>Part I: Modify Part I documents (excl. Q-SA)</td>
<td></td>
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<tr>
<td></td>
<td>Part II: Modify Part II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cancel or <strong>submit</strong> NSM</td>
<td></td>
</tr>
<tr>
<td>Additional Member State Concerned</td>
<td>Initiate creation AMS</td>
<td></td>
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<tr>
<td></td>
<td>Form: cover letter/ Compliance Reg 2016/679</td>
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<tr>
<td></td>
<td>Form: proof of payment</td>
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<tr>
<td></td>
<td>MSC: Add the expected number of <strong>subjects</strong> 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Part I: Add Translations to Part I (Q-IMPD)</td>
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<td></td>
<td>Part I: Add Translations to Part I (excl. Q- IMPD)</td>
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<td></td>
<td>Part II: Create Part II</td>
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<tr>
<td></td>
<td><strong>Timetable</strong>: Modify Winter clock stop</td>
<td></td>
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<tr>
<td></td>
<td>Cancel or <strong>submit</strong> additional MS application</td>
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</tr>
</tbody>
</table>

1. This section is only applicable for transition 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

<table>
<thead>
<tr>
<th>Phases</th>
<th>Permissions/Tasks</th>
<th>CT Admin</th>
<th>Part I Preparer (exc Q-IMPD)</th>
<th>Part II Preparer</th>
<th>Q-IMPD Preparer</th>
<th>Application submitter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RFI Response</strong></td>
<td>Add supporting documentation – General</td>
<td></td>
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<td></td>
<td>Add supporting documentation - Quality</td>
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<tr>
<td></td>
<td>Change CTA Part I excl. Q-IMPD/add CTA changes</td>
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<tr>
<td></td>
<td>Change CTA Part I Q-IMPD/add CTA changes</td>
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</tr>
<tr>
<td></td>
<td>Change CTA Part II/add CTA changes</td>
<td></td>
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<tr>
<td></td>
<td>Reply to Part I excl. Q-IMPD considerations/add document</td>
<td></td>
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<tr>
<td></td>
<td>Reply to Part I Q-IMPD considerations/add document</td>
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<tr>
<td></td>
<td>Reply to Part II considerations/add document</td>
<td></td>
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<tr>
<td></td>
<td>Discard CTA changes/Submit RFI response</td>
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</tr>
</tbody>
</table>
## Summary of tasks by role and process – Sponsor, Notification and CSR

<table>
<thead>
<tr>
<th>Phase</th>
<th>Permissions/Tasks</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Submit notification</strong></td>
<td>Create trial and recruitment periods notifications</td>
<td>CT Admin, Notification preparer, Notification submitter</td>
</tr>
<tr>
<td></td>
<td>Create other notifications</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Submit/update/withdraw notification</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Study Report result summary</strong></td>
<td>Create summary of results*</td>
<td>CT Admin, CT Results submitter</td>
</tr>
<tr>
<td></td>
<td>Create lay person summary of results</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Submit/update/withdraw summary of results</strong></td>
<td></td>
</tr>
</tbody>
</table>

* including intermediate analysis data results, as applicable.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Permissions/Tasks</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Study Report</strong></td>
<td>Create CSR</td>
<td>MAH Admin, CSR submitter</td>
</tr>
<tr>
<td></td>
<td><strong>Submit/update/withdraw CSR</strong></td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>Permissions/Tasks</td>
<td>Roles</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Annual Safety Report</td>
<td>Create ASR</td>
<td>ASR submitter</td>
</tr>
<tr>
<td></td>
<td>Submit ASR</td>
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</tr>
</tbody>
</table>
## Summary of tasks by role and process – Sponsor Viewer Roles

<table>
<thead>
<tr>
<th>Permissions/Tasks</th>
<th>Part I Viewer (excl. Q-IMPD)</th>
<th>Q-IMPD Viewer</th>
<th>Part II Viewer</th>
<th>Notifications Viewer</th>
<th>CT results Viewer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viewer Roles</strong></td>
<td><em>Viewer roles do not get notices and alerts related to the mentioned business tasks, unlike other user roles.</em></td>
<td></td>
<td></td>
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<tr>
<td><strong>Form:</strong> cover letter, proof of payment, Compliance Reg 2016/679 and deferral</td>
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<tr>
<td><strong>MSC</strong></td>
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<tr>
<td><strong>Part I dossier:</strong> Q-IMPD/ scientific advice restricted doc</td>
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<tr>
<td><strong>Part I dossier:</strong> excl. Q-IMPD</td>
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<tr>
<td><strong>Part II dossier</strong></td>
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<tr>
<td><strong>RMS selection</strong> (from the evaluation tab)</td>
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<tr>
<td><strong>RMS selected</strong> (from the summary tab)</td>
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<tr>
<td><strong>Validation information:</strong> RFI/RFI response - Q-IMPD</td>
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</tr>
<tr>
<td><strong>Validation information:</strong> RFI/RFI response – excl. Q-IMPD</td>
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<tr>
<td><strong>Validation information:</strong> validation conclusion</td>
<td></td>
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</tr>
<tr>
<td><strong>Assessment Part I information:</strong> assessment Part I information - quality related information</td>
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</tr>
<tr>
<td><strong>Assessment Part I information:</strong> assessment Part I information - excluding quality related information</td>
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<tr>
<td><strong>Assessment Part I information:</strong> part I conclusion</td>
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<tr>
<td><strong>Assessment Part I information:</strong> part I disagreement</td>
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</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Permissions/Tasks</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment Part II information (RFIs, responses to RFIs, final Part II AR and Part II conclusion)</td>
<td>Part I Viewer (excl. Q-IMPD)</td>
</tr>
<tr>
<td>MSC Decision (including Revert decision)</td>
<td></td>
</tr>
<tr>
<td>Timetable</td>
<td></td>
</tr>
<tr>
<td>CT list and summary tab</td>
<td></td>
</tr>
<tr>
<td>Full trial information tab</td>
<td></td>
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<tr>
<td>Notifications tab</td>
<td></td>
</tr>
<tr>
<td>CT results tab (result summary)</td>
<td></td>
</tr>
<tr>
<td>Correctives measure tab (including request for opinion, view of opinion)</td>
<td></td>
</tr>
<tr>
<td>Assessment additional information tab (RFI and RFI response)</td>
<td></td>
</tr>
<tr>
<td>Users tab</td>
<td></td>
</tr>
<tr>
<td>Tasks and messages (notices and alerts)</td>
<td></td>
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<tr>
<td>Inspection</td>
<td></td>
</tr>
<tr>
<td>Union Control</td>
<td></td>
</tr>
<tr>
<td>Download CT (only information that users have access according to role permissions**)</td>
<td></td>
</tr>
</tbody>
</table>

** 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.)