

EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# FAQs

## Union Controls in CTIS

### CTIS Training Programme – Module 21

Version 1.1 – December 2021

#### What you will find

- Answers to general questions regarding Union Controls.
- Answers to questions regarding the plans/programmes for Union Controls.
- Answers to questions regarding the Union Control reports.

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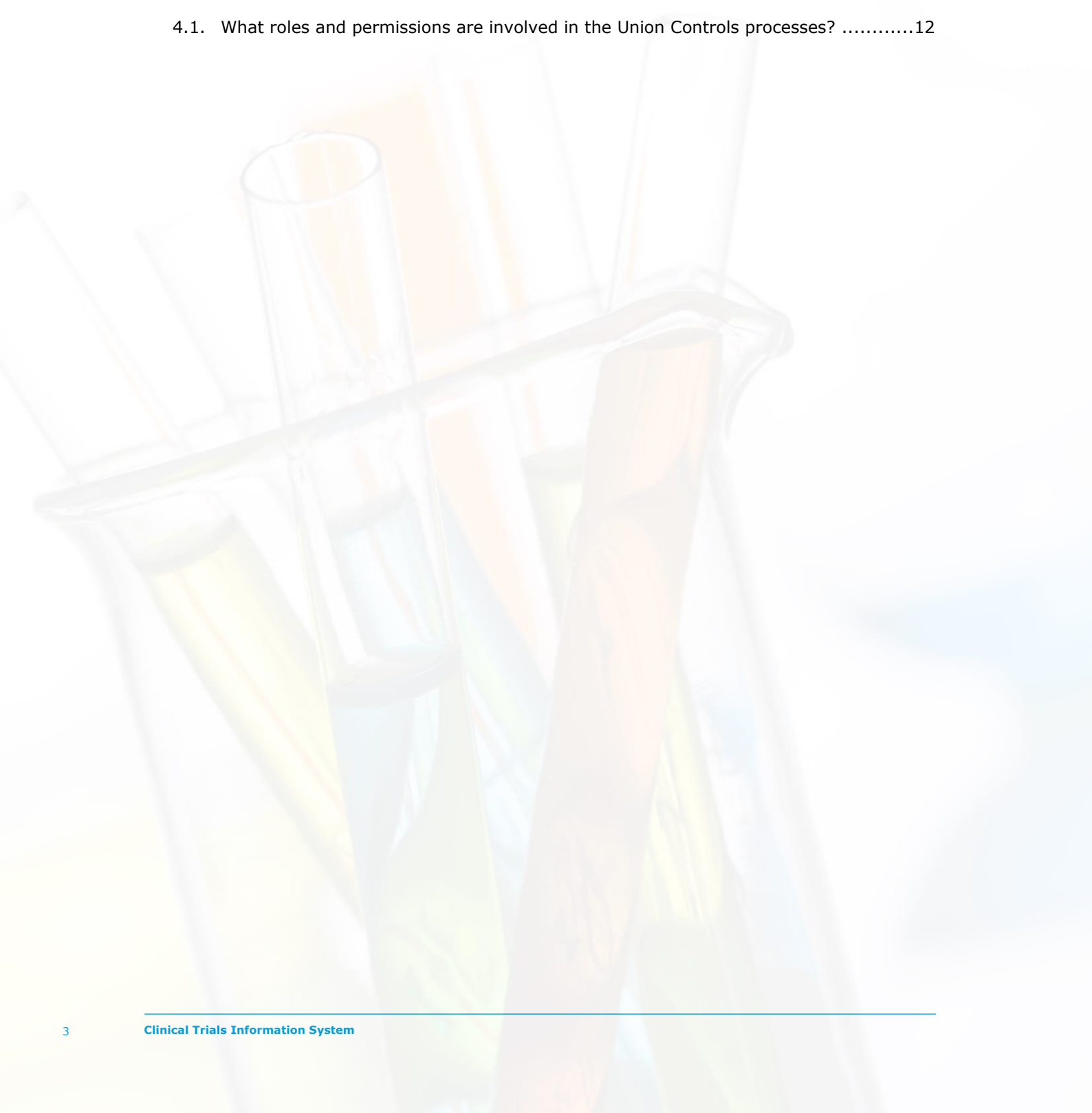
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# FAQs



In this document, we list common questions regarding *Module 21: Union Controls in CTIS*. They are categorised into general questions regarding the processes of creating and sharing the Plans / Programmes for Union Controls, and creating and submitting Union Controls reports. The specific learning objectives of this module are:

1. Remember what a Union Control is and when a European Commission user can create one.
2. Understand how to create and submit a Union Control report.
3. Understand how to view, download, update and withdraw a Union Control report.
4. Understand the roles and permissions involved in the Union Controls process.

We encourage you to read these questions and answers carefully. If you have any questions that are not covered in this document, please contact us at [CT.Training@ema.europa.eu](mailto:CT.Training@ema.europa.eu) so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

# 1. General questions

## 1.1. What is a Union Control?

According to Article 79 of the Clinical Trial Regulation,<sup>1</sup> Union Controls are performed by the European Commission in order to verify that the EU/EEA Member States correctly supervise compliance with the Regulation, and to verify that the regulatory system applicable to clinical trials conducted outside the Union ensures that point 8 of the Introduction and general principles contained in Annex I to Directive 2001/83/EC<sup>2</sup> is complied with; or that the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of the Regulation is complied with.

## 1.2. What are Plans / Programmes for Union Controls?

The Plans and Programmes are the internal planning regarding the Union Controls that the European Commission arranges to conduct in both the EU/EEA Member States and third countries, respectively. Both are created outside CTIS, and once ready, they need to be uploaded and shared in the system. These Plans / Programmes are not published on the CTIS Public Website, and each Union Control report will need to be associated with a corresponding Union control plan or programme.

## 1.3. What is the difference between Plans and Programmes?

The Plans are related to the Union Controls created to supervise the compliance with the Clinical Trial Regulation in the EU/EEA Member States, and the Programmes are related to the Union Controls to verify the regulatory system applicable to clinical trials conducted outside the EU countries.

## 1.4. What is a Union Control report?

The Union Control report is the outcome document of the control performed by the European Commission. The report is prepared and created outside CTIS, and when ready is uploaded and submitted in CTIS. Each Union control report is associated with a corresponding shared

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<sup>1</sup> European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: [https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)

<sup>2</sup> European Commission, *Directive (EU) No 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, EU Official Journal L311. 28 of November of 2001. Available at: [https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/dir\\_2001\\_83\\_consol\\_2012/dir\\_2001\\_83\\_cons\\_2012\\_en.pdf](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf)

Plan / Programme. The Union Control report is published on the CTIS Public Website as soon as it is submitted.

### 1.5. Where can users access Union Controls information?

In the 'Union Control' tab of the Authority workspace of CTIS, users have access to all shared and removed Plans / Programmes; and submitted and withdrawn Union Control reports. The draft versions of both Plans / Programmes and reports are only visible in the CTIS Authority workspace to the users working on them, or users of the same organisation with the same role.

### 1.6. Which actors are involved in Union Controls processes?

European Commission users are the actors involved in the creation of Union Controls. Member States users have visibility of both Plans / Programmes and reports being conducted by the European Commission. However, public users have visibility only of the submitted Union Control reports via the CTIS Public Website.

### 1.7. What is published on the CTIS Public Website about Union Controls?

Public users have access to the Union Controls submitted by the European Commission on the 'Union Controls' tab of the CTIS public Website. Users can select one report using the radio button and click on the 'View' button; this way, users can see all the related information regarding the Union Control report via a pop-up window.

Only Union Control reports are published on the CTIS Public Website, once they are submitted by the European Commission. No draft versions of Union Control report forms or Plans / Programmes are made public on the CTIS Public Website, regardless of their status.

### 1.8. What is the difference between 'sharing' a Plan / Programme and 'submitting' a report?

Once users complete a Plan / Programme for Union Controls form, they can click on the 'Share' button. This action will share the Plan / Programme with the rest of the authority users. Plans / Programmes are only available on the Authority workspace.

Once users complete a report form, they can click on the 'Submit' button to share it with the rest of the authority users. The difference regarding the shared Plans / Programmes is that

the submitted Union Control reports will also be automatically published on the CTIS Public Website as soon as they are submitted.

## 2. Plans / Programmes for Union Controls

### 2.1. How can users create a Plan / Programme for Union Controls form?

Users can access the 'Union Controls' tab in CTIS in order to view the Plans / Programmes for the Union Controls conducted. Then users with the appropriate roles (i.e. Union Controller Preparer, and Union Controller Submitter) can create a Plan / Programme for Union Controls form by clicking on the '+ New' button on the top right corner of the 'Union Controls' tab in CTIS and start populating the form.

### 2.2. What information do users have to populate on the Plan / Programme for Union Controls form?

The Plan / Programme for Union Controls form is articulated into a single section where the user can include information regarding the dates of the Plan / Programme, the type, and the necessary documents (i.e. the Plan or Programme and supporting documentation, if needed).

### 2.3. Can users save a draft of a Plan / Programme for Union Controls form?

Users can click on 'Save' button to create a draft and keep working on it at a later stage in case they have not finished it. This is only an option and not a mandatory step in the process. Before sharing it, users are expected to complete all mandatory fields marked with an asterisk on the form.

### 2.4. Who can view a draft of a Plan / Programme for Union Controls form?

The draft versions of the Plans / Programmes for Union Controls forms are only visible in the CTIS Authority workspace to the users working on them, or users of the same organisation with the same role.

## 2.5. How can users share Plans / Programmes for Union Controls?

Once users complete the Plans / Programmes for Union Controls form, they can click on the 'Share' button to share it with the rest of the authority users. After clicking on the 'Share' button, the Plan / Programme for Union Controls will be listed below as a shared Plan / Programme with the corresponding Union Control Plan / Programme ID, share date and the status.

## 2.6. How can users update Plans / Programmes for Union Controls?

Users can update a shared Plan / Programme for Union Controls in order to change any details by clicking on the pencil icon. The Plan / Programme form will open, and users will be able to update all details of it, except the ID number. Once the necessary updates are done, users can click on the 'Update' button. Back in the 'Union Controls' tab in CTIS, the Plan / Programme will be listed as a new version of it. A new versioning button will be enabled, listing all the versions of that shared Plan / Programme.

## 2.7. How can users remove shared Plans / Programmes for Union Controls?

Users can remove Plans / Programmes that have been previously shared. They can start this process by clicking on the pencil icon of a Plan / Programme on the CTIS 'Union Controls' tab. This action will open the Plan / Programme form, and users will be able to remove it by clicking on the 'Remove' button; after clicking on the 'Confirmation' button, the previously shared Plan / Programme will be listed below with the status of 'Removed', and no other actions can be taken.

## 2.8. What are the possible statuses of a Plan / Programme for Union Controls?

The Plan / Programme for Union Controls can have three possible statuses:

- **Draft:** The Plan / Programme for Union Controls form has not yet been submitted, and a user is currently working on it.
- **Shared:** The Plan / Programme for Union Controls form has been shared. The status remains as 'Shared' when users update the Plan / Programme for Union Controls. The Union Control is visible to the other users having access to the CTIS Authority workspace.



- **Removed:** The Plan / Programme for Union Controls has been removed.

## 2.9. What happens to a Plan / Programme when linked Union Control reports are withdrawn?

The status of the Plans / Programmes will not be affected when its corresponding Union Control reports are withdrawn.

## 2.10. How are users notified about shared, updated, and removed Plans / Programmes for Union Controls?

All Member States and the EMA users in CTIS receive a notice when the European Commission users share a Plan / Programme for Union Controls. In addition, all Member States and the EMA users will receive a notice when the European Commission users update or remove a Plan / Programme for Union Controls.

# 3. Union Control reports

## 3.1. How can users create a Union Control report form?

Users can access the 'Union Controls' tab in CTIS in order to view the Union Control reports section, below the Plans / Programmes for Union Controls. Then users with the appropriate roles (i.e. Union Controller Preparer and Union Controller Submitter) can create a Union Control report form by clicking on the '+ New' button on the right of the 'Reports' section of the 'Union Controls' tab in CTIS and start populating the form.

## 3.2. What information do users have to populate on the Union Control report form?

Users can include in the Union Control report form information regarding the corresponding Union Control Plan / Programme (UCP) ID, the European Commission internal identification code for the Union Control report, the dates of the Union Control, the countries, the purpose of the control, and the necessary documents (i.e. the Union Control report and supporting documentation, if needed).

### 3.3. Can Union Control reports be linked to more than one Plan / Programme?

No. Users are required to link each Union Control report to a single existing shared Plan / Programme. This can be done by typing the Union Control Plan / Programme (UCP) ID in the appropriate field in the Union Control report form.

### 3.4. Can users save a draft of a Union Control report form?

Users can click on 'Save' button to create a draft and keep working on it at a later stage in case they have not finished it. This is only an option and not a mandatory step in the process. Users are expected to complete all mandatory fields marked with an asterisk on the form and upload a Union Control report for publication before submitting the report.

### 3.5. Who can view a draft of a Union Control report form?

The draft versions of the Union Control reports forms are only visible in the secure domain to the users working on them, or users of the same organisation with the same role.

### 3.6. How can users submit Union Control reports?

Once users complete the Union Control report form, they can click on the 'Submit' button to make it accessible to the rest of the authority users. At this point, it will be automatically available to the CTIS Public Website. After clicking on the 'Submit' button, it will be listed below as a submitted Union Control report with the corresponding submission date and status.

### 3.7. How can users update Union Control reports?

Users can update a submitted Union Control report in order to change any details by clicking on the pencil icon of a report on the list of Union Control reports on the CTIS 'Union Controls' tab. The Union Control report form will open, and users will be able to update all details of it (e.g. users can upload newer versions of documents in the form). Once the necessary updates are made, users can click on the 'Update' button to update the Union Control report, and they will go back to the 'Union Controls' tab in CTIS, where the Union Control reports will be listed as a new version of it. A new action button will be enabled, listing all the versions of that updated Union Control report.

### 3.8. How can users withdraw Union Control reports?

Users can withdraw Union Control reports that have been submitted. They can start this process by clicking on the pencil icon of a report on the list of Union Control reports on the CTIS 'Union Controls' tab. This action will open the Union Control report form, and users will be able to withdraw it by clicking on the 'Withdraw' button; after clicking on the confirmation button, the previously submitted Union Control report will be listed below with the status of 'Withdrawn', and no other actions can be taken.

### 3.9. What happens to a Union Control report when its corresponding Plan / Programme is removed?

The status of the Union Control report will not be affected by its corresponding Plans / Programmes being removed.

### 3.10. What are the possible statuses of a Union Control report?

The Union Control reports can have three possible statuses:

- **Draft:** The Union Control report form has not yet been submitted, and a user is currently working on it.
- **Submitted:** The Union Control report form has been submitted. The status remains as 'Submitted' when users update a Union Control report.
- **Withdrawn:** The Union Control report has been withdrawn.

### 3.11. How are users notified about submitted, updated, and withdrawn Union Control reports?

All Member States and the EMA users in CTIS receive a notice when the European Commission users submit a Union Control report. In addition, all Member States and the EMA users will receive a notice when the European Commission users updates or withdraws a Union Control report.

## 4. Roles and permissions

### 4.1. What roles and permissions are involved in the Union Controls processes?

There are four main roles involved in the Union Controls process: three business roles and one European Commission Administrator. The business roles are linked to permissions structured in a cascade approach, so that each level includes the permissions of the lower levels. Below we list the different permissions for the three Union Controller roles:

- **Manage role assignment; View users roles and requests:** EC Admin
- **Update/Withdraw/Submit Union Control reports:** Union Controller Submitter.
- **Create Union Control reports / Plans; Delete draft Union Control reports; Delete Plans / Programmes for Union Controls; Share Plans / Programmes for Union Controls:** Union Controller Preparer.
- **View Union Control reports; View Union Control Plans / Programmes for Union Controls:** Union Controller Viewer.

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