



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Step-by-step guide

## Union Controls in CTIS

CTIS Training Programme – Module 21  
Version 1.1 – December 2021

### Learning Objectives

- Understand how to create and submit a Union Control report.
- Understand how to view, download, update and withdraw a Union Control report.

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# Union Controls in CTIS

CTIS allows European Commission users to **conduct Union Controls** in order to verify that the EU/EEA Member States correctly supervise compliance with the Clinical Trial Regulation (EU) No 536/2014 (CT 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 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.

This guide explains how to create and share Plans / Programmes for Union Controls, and how to create, submit, view, download, update and withdraw Union Control reports.



## Create and share Plans / Programmes

This section outlines the steps to create and share Plans / Programmes for Union Controls.



## Create and submit reports

This section outlines the steps to create and submit Union Control reports.



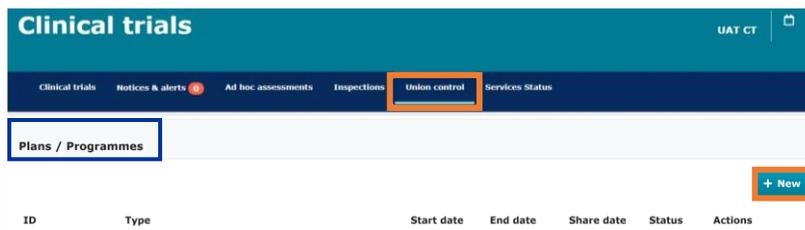
## View, download, update and withdraw

This section outlines the steps to view and download Union Controls in both the Authority workspace and the CTIS Public Website, and to update and withdraw an already submitted Union Control report.

# Create and share Plans / Programmes

## Create and share Plans / Programmes for Union Controls

1. On the CTIS 'Union Control' tab, the **Plans and Programmes** are listed in the first section. Users can click on the '+ New' button to fill in a new Plan / Programme form.



2. Users can **populate the form and complete all mandatory fields** marked with an asterisk. Once the form is completed, users can click on the '**Share**' button, and then on the confirmation button, to share it with the rest of the **authority users** (i.e. Member States and EMA).

The screenshot shows the 'Plan/Programme for union controls' form. The form includes fields for 'Start date \*' (08/08/2021) and 'End date \*' (12/04/2024). The 'Type \*' section has two options: 'Plan for union controls in Member States' (checked) and 'Programme for union controls in third countries' (unchecked). There is an 'Add document' button. A callout bubble points to the 'Add document' button, stating: 'Users can upload at least one document with the Plan / Programme, which will not be publicly accessible'. Below the form, there is a 'Supporting Documents' section with another 'Add document' button. A callout bubble points to the 'Save' and 'Share' buttons, stating: 'Users can save a draft to work on it at a later stage.' To the right, a 'Share' dialog box is shown with the question: 'Are you sure you want to share this Plan/Programme for Union Controls with the Member States?' and 'Cancel' and 'Share' buttons.

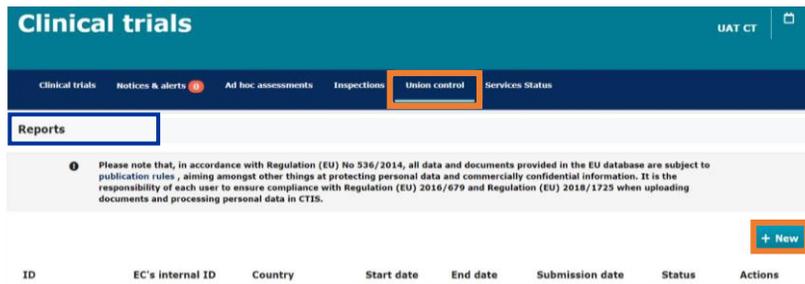
3. After sharing it, the Plan / Programme is listed with the status of '**Shared**'.

ID	Type	Start date	End date	Share date	Status	Actions
UCP-2021-0040	Plan for Union Controls in Member States	08/08/2021	12/04/2024	09/11/2021	Shared	

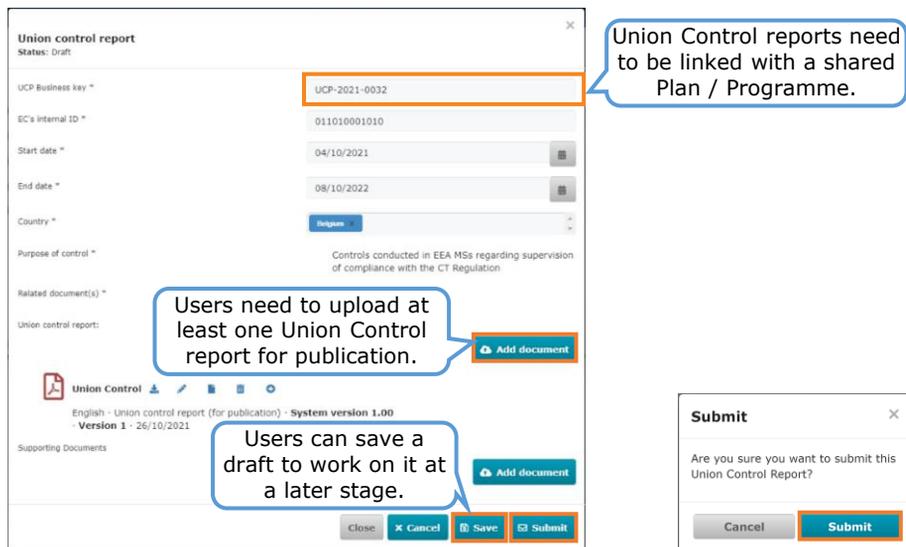
# Create and submit reports

## Create and submit Union Control reports

1. On the CTIS 'Union Control' tab, below the Plans / Programmes section, the **Union Control reports** are listed. Users can click on the '+ New' button to fill in a new Union Control report form.



2. Users can **populate the form and complete all mandatory fields** marked with an asterisk. Once the form is completed, users can click on the '**Submit**' button, and then on the confirmation button, to share it with the rest of the **authority users** (i.e. Member States and EMA), and on the **CTIS Public Website**.



3. After the submission, the Union Control report is listed with the status of '**Submitted**'.

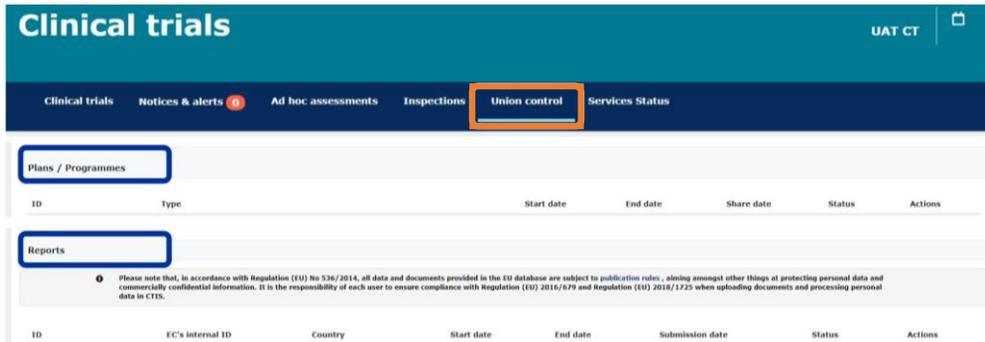
ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions
UCR-2021-0024	1234567	Austria	25/10/2021	26/10/2021	27/10/2021	Submitted	 

4. All Member States and the EMA users in CTIS **receive a notice** in the 'Notices & alerts' tab when the **European Commission users submit a Union Control report**.

Notice	Ref number	Source type	Evaluation process	Received	IMP	Sponsor
<b>Union control submitted</b> The European Commission have submitted a union control report.		Union control		27/10/2021		

View and download Union Controls in the Authority workspace.

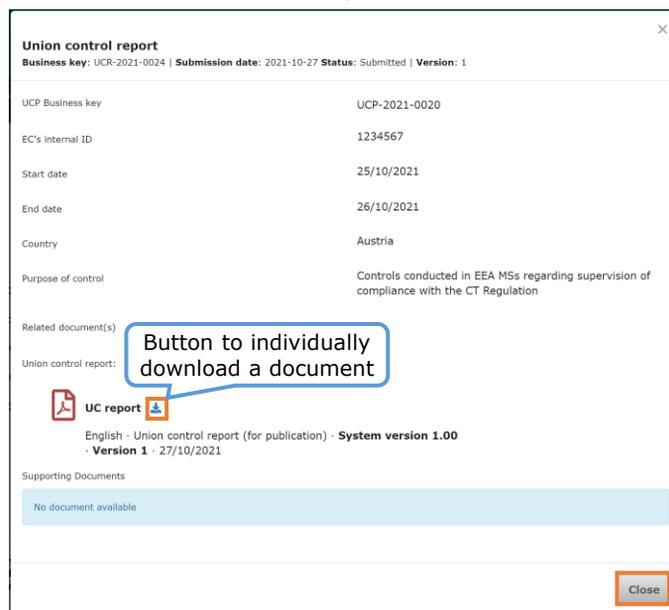
1. On the CTIS 'Union Control' tab, users have access to the list of all shared and removed **Plans / Programmes for Union Controls**, and the submitted and withdrawn **Union Control reports**.



2. On the '**Reports**' section, the Union Control reports are listed with the corresponding information regarding IDs, countries supervised, dates, status, etc. Users can **click on the eye icon** to view the Union Control report.



3. Users can **view the Union Control report form**, which contains all the relevant information of the report. Users can also download the report.



## View Union Controls in the CTIS Public Website

1. Once **Union Control reports are submitted**, they are published on the **CTIS Public Website** on a dedicated tab.



2. Users can view the Union Control reports listed. They can **select one report** using the radio button and **click on the 'View' button**.

Union Control Reports

Union Control Report

Union Control Report

	Business Key	EC's Internal Id	Start Date	End Date	Submission Date	Status
<input checked="" type="radio"/>	UCR-2021-0024	1234567	25/10/2021	26/10/2021	27/10/2021	Submitted
<input type="radio"/>	UCR-2021-0021	011010001010	04/10/2021	08/10/2022	26/10/2021	Submitted
<input type="radio"/>	UCR-2021-0013	EC 20	15/10/2021	15/10/2021	15/10/2021	Submitted
<input type="radio"/>	UCR-2021-0008	EC ID	01/10/2021	01/10/2021	01/10/2021	Submitted
<input type="radio"/>	UCR-2021-0001	234235353	21/09/2021	24/09/2021	21/09/2021	Submitted

Only Union Control reports with 'Submitted' status are displayed on the CTIS Public Website.

3. Users can view all the related **information regarding the Union Control report** in a **pop-up window**. Users can **view the versions of the report** using a **drop-down list**.

**Union Control Report**  
Business Key: UCR-2021-0024 | Submission date: 27/10/2021

2 | 27/10/2021

Business Key: UCR-2021-0024

EC's internal identifier: 1234567

Start Date: 25/10/2021

End Date: 26/10/2021

Status: Submitted

Purpose of control: Controls conducted in EEA MSs regarding supervision of compliance with the CT Regulation

Country: Belgium, Austria, Spain

Attached documents

Title	File type	Document Type
UC report	PDF	Union control report (for publication)

Close

## Update Union Control reports

1. On the CTIS 'Union Controls' tab, in the Reports section, users can **update a submitted Union Control report** by clicking on the **pencil icon**.

**Reports**

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

[+ New](#)

ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions
UCR-2021-0024	1234567	Austria	25/10/2021	26/10/2021	27/10/2021	Submitted	

2. The Union Control report form opens, and users can make modifications in any field (e.g. change the ID of the corresponding Plan / Programme or update a new document version). Then, users can click on the **'Update'** button, and on the confirmation button.

**Union control report**

Business key: UCR-2021-0024 | Submission date: 2021-10-27 Status: Submitted | Version: 2

UCP Business key \*

EC's internal ID \*

Start date \*

End date \*

Country \* Austria Spain Belgium

Purpose of control \*

Related document(s) \*

Union control report:

 UC report   

English - Union control report (for publication) - System version 2.00  
Submission date 09/11/2021  
Version 2 - 27/10/2021

[Add document](#) [Previous versions 1](#)

 UC report 

Version 1 - 27/10/2021 - English - Union control report (for publication) - System version 1.00

Supporting Documents [Add document](#)

[Close](#) [Withdraw](#) [Update](#)

**Update**

Are you sure you want to update this Union Control Report?

[Cancel](#) [Update](#)

3. Then, the previously updated Union Control report is listed with same **'Submitted'** status. A new **action button** is enabled listing the **previous versions** of the Union Control report forms.

[+ New](#)

ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions
UCR-2021-0024	1234567	Spain, Austria, Belgium	25/10/2021	26/10/2021	27/10/2021	Submitted	  
UCR-2021-0025	0110100010100	Spain, Portugal, Belgium	04/10/2021	11/03/2023	27/10/2021	Withdrawn	 version 2   27/10/2021
UCR-2021-0021	011010001010		04/10/2021	08/10/2022	26/10/2021	Submitted	 version 1   27/10/2021

## Withdraw Union Control reports

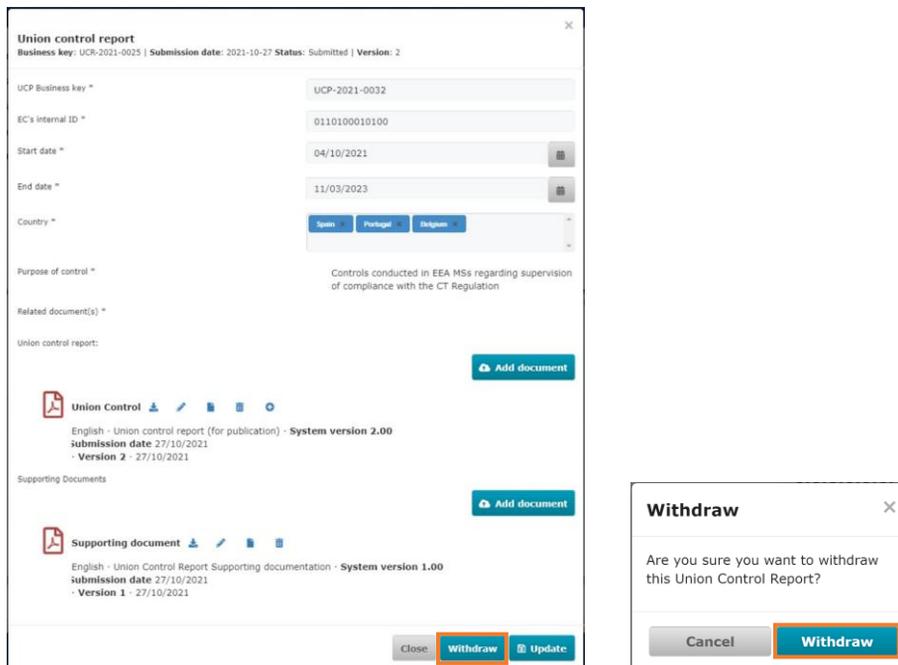
1. On the CTIS 'Union Controls' tab, in the Reports section, users can **withdraw a submitted Union Control report** by clicking on the **pencil icon**.



The screenshot shows the 'Reports' section of the CTIS interface. At the top, there is a 'Reports' tab and a '+ New' button. Below this is a table with the following columns: ID, EC's internal ID, Country, Start date, End date, Submission date, Status, and Actions. A single row is visible with the following data: ID: UCR-2021-0024, EC's internal ID: 1234567, Country: Austria, Start date: 25/10/2021, End date: 26/10/2021, Submission date: 27/10/2021, Status: Submitted. In the Actions column for this row, there is a pencil icon, which is highlighted with a red box.

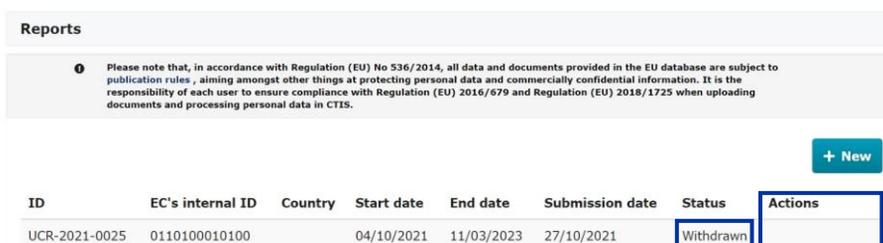
ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions
UCR-2021-0024	1234567	Austria	25/10/2021	26/10/2021	27/10/2021	Submitted	

2. The Union Control report form opens, and users are able to withdraw it by clicking on the **'Withdraw'** button, and then on the confirmation button.



The screenshot shows the 'Union control report' form and a 'Withdraw' confirmation dialog. The form contains fields for UCP Business key, EC's internal ID, start and end dates, country, purpose of control, and related documents. Below the form, there are two document entries: 'Union Control' and 'Supporting document'. The 'Withdraw' dialog is a small window with the text 'Are you sure you want to withdraw this Union Control Report?' and two buttons: 'Cancel' and 'Withdraw'.

3. Once withdrawn, Union Control reports appear in the Authority workspace listed with the status of **'Withdrawn'**, and no other actions can be taken.



The screenshot shows the 'Reports' section of the CTIS interface. At the top, there is a 'Reports' tab and a '+ New' button. Below this is a table with the following columns: ID, EC's internal ID, Country, Start date, End date, Submission date, Status, and Actions. A single row is visible with the following data: ID: UCR-2021-0025, EC's internal ID: 0110100010100, Country: Spain, Start date: 04/10/2021, End date: 11/03/2023, Submission date: 27/10/2021, Status: Withdrawn. The 'Status' and 'Actions' columns for this row are highlighted with a red box.

ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions
UCR-2021-0025	0110100010100	Spain	04/10/2021	11/03/2023	27/10/2021	Withdrawn	

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Clinical Trials Information System (CTIS)

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