Clinical Trials Information System (CTIS) common features

Guide to the user on common functions and user interface in CTIS

CTIS Training Programme – Module 2

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Document Overview

This document lists a set of CTIS common features available across the various tabs in both restricted workspaces. They enable authorities and sponsors users to perform actions supporting their day-to-day business throughout the life cycle of a clinical trial.

Users will find a general description of the characteristics of the buttons that support these features and some guidance for some inconsistencies in the appearance and behaviour of CTIS. Below, a list of icons of buttons in CTIS is provided, along with its title, the feature they support, a description and some examples.

Characteristics and locations of icons and buttons

1. Dependent buttons enabling workflow to continue

Not all action buttons in the system are always available and certain actions need to be performed in order for the buttons to appear or to become activated, and to enable the workflow to continue. For example, in some workflow steps a user needs first press "share" in order to be able to "submit", i.e. "submit" is dependent on "share".

The colour of buttons in CTIS can also indicate whether the button is inactivated, and thus unavailable to use. A previous action activates the button, and the button changes colour once it become activated. For example, the colours grey and light blue indicate an inactivated button and an action is needed to activate it.

Once activated, the button will change colour to blue (if previously grey) or dark blue (if previously light blue). If the user lacks the correct permissions to perform the action that the button represents, the button will remain deactivated even if the user attempts to activate it using the correct steps.

2. Buttons relating to user permissions

Some action buttons are available only to users with specific permissions. If a button is missing in your workspace, it could be because the user lacks permission to perform that action and the button is hidden. An example is the action to raise an RFI in the authority workspace, which is available only for a 'submitter' role.

3. Similarity of certain buttons

Some icons, such as "cancel" and "withdraw", appear the same but behave differently. Further examples can be seen in the table below.

4. Different locations of buttons

Some buttons in CTIS can appear in different areas. For example, when creating a Clinical Trial Application (CTA), "check", "save", "cancel" and "submit"' are always found in the upper side of the page. When submitting a Request for Information (RFI), "submit"' appears in the lower side of the page.

Icon	Functionality	Description	Examples
"Plus" ➕	Add new	Allows users to create a new element	Add New – create new notification Create new Clinical trial
"Share"	Share	Allows users to share data and documents with other Member States within the workspace	Share a Draft Assessment Report for part I
"Save"	Save	Allows users to save their work and makes it visible to others who have been assigned the necessary permissions in the same workspace	Save a Clinical Trial application (CTA)
"Upload"	Add	The same icon is used to allow users to add documents into the system and to progress with submission.	Upload; Attach; Add; – add document into the system
	Submit		Submit - Submit data and documents from your workspace to the EU CT Database

Icon	Functionality	Description	Examples
"Download"	Download	Allows users to download data and documents that they have permissions to view	Download CTA data and documents in different formats such as XML and PDF
"Search"	Search	Allows users to search and retrieve clinical trials, clinical trial applications, notices and alerts, tasks and other information across the system.	
"Padlock"	Lock button	Allows users to lock a field in CTIS and work on it. This avoid overlap of multiple users working on the same part of the application at the same time.	CTA completion, assessment reports, inspection records
"Pencil"	Edit	Allows users to edit the documents and data before submission	Edit a CTA or a notification before it is submitted
"Asterisk"	Mandatory fields	Marks mandatory fields	All CTA fields and documents that should be provided prior to submission
"Tick"	Check	Allows users to check whether all mandatory fields have been completed	Verify CTA completion prior to submission
	Accept		
"Versioning"	Versioning	Allows users to see the version of document, applications, or records submitted	
"Trashcan"	Delete	This enables the user to remove previously uploaded information.	
	Remove		
"Cross"	Cancel	Before submission: Cancel an action and prevent the changes from being saved in the system	Cancel a draft CTA prior to submission
	Withdraw	After submission: Withdraw information that was already submitted to the system.	Withdraw a CTA after submission but before the

Icon	Functionality	Description	Examples
			decision on the application is issued.