



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guide on CTIS Common features

Overview of CTIS workspaces and common
system functionalities

CTIS Training Programme – Module 02

Version 2.1 – June 2024



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Record of updated versions

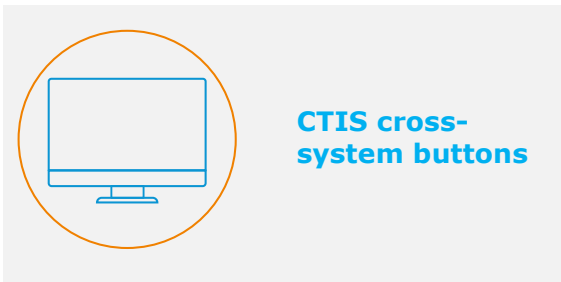
The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
2.1	Minor changes: Additional information on CTIS cross-system button (Add).	June 2024
2	New section: How to remove personal information from properties of documents	January 2023
1.4	Minor changes: Additional information in some CTIS cross-system buttons (Update and Add).	August 2022
1.3	Updated section: CTIS cross-system buttons (new format and minor changes) New section: Access and Practicalities	May 2022
1.2	Training material version published at CTIS go-live.	January 2022

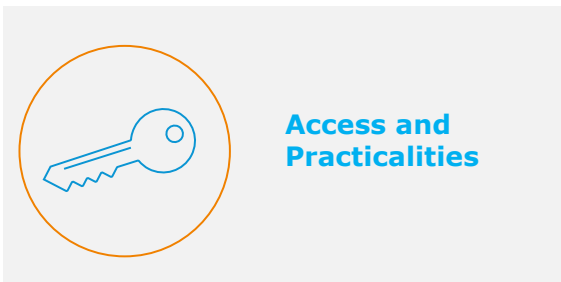
Guide on CTIS common features

This document outlines the main CTIS common features available across the various tabs in both Authority and Sponsor workspaces. These features enable users to perform actions supporting their day-today 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 access and navigation in CTIS. Some of the buttons described in this document are in document placeholders and help users to manage the CTA documents. In the last section, users can find some indicative guidelines on how to remove personal information from the properties of documents that are uploaded to their trials in CTIS. The aim of this document is that users can quickly be familiarised with CTIS.

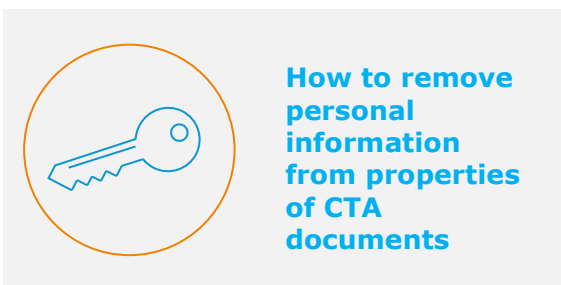
The document is divided in three sections:



This section outlines the characteristics of cross-system buttons (dependences, users' permissions, similarities, and locations) and the description of the most common buttons.



This section outlines the CTIS access links and some guidelines for a proper use of CTIS.



This section outlines how users can remove personal information from properties of CTA documents that they upload to their trials in CTIS.

1. CTIS cross-system buttons

A group of buttons can be found across CTIS to support users' main activities. These cross-system buttons share a set of characteristics that will help users to understand their behaviour. Additionally, a list of these cross-system buttons is detailed in section 1.2, where users can find for each one its name, icon, and the feature it supports.

1.1. Characteristics of CTIS cross-system buttons

This section details the characteristics of the most common buttons available in CTIS. For a good understanding of the buttons, it is important to note the following aspects:

Dependencies

During the users' workflow, not all action buttons in the system are always available. Users need to perform certain actions in order for the buttons to appear or become activated. For example, in some workflow steps users need first to press 'Share' in order to be able to 'Submit', i.e. 'Submit' is dependent on 'Share'.

Sometimes these dependencies can be identified by the colour of the buttons. Some buttons change colour once they 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).

Users' permissions

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

Similarities

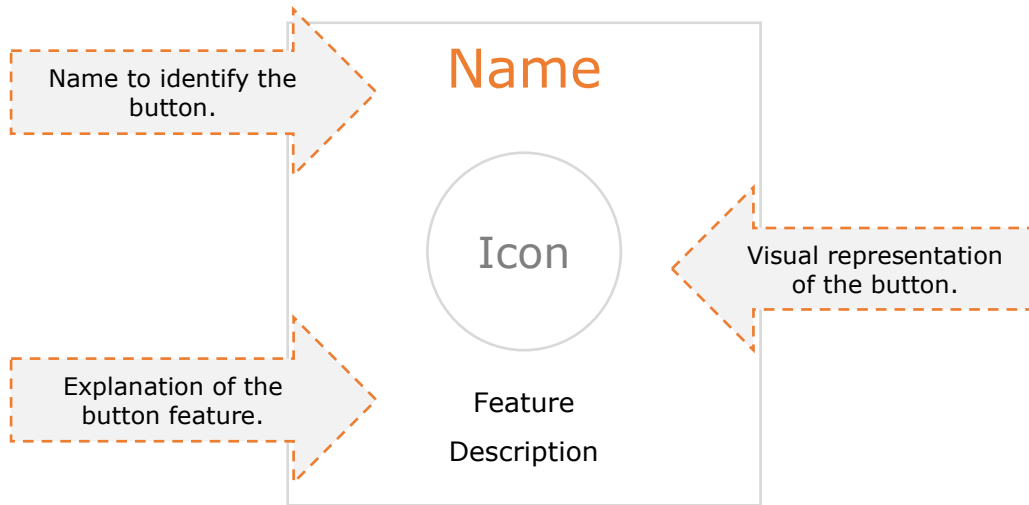
Some buttons, such as 'Cancel' and 'Withdraw', are illustrated with the same 'cross' icon but behave differently.







Locations








Depending on the process and section, 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. However, when submitting a Request for Information (RFI), 'Submit' appears in the lower side of the page.

1.2. Summary of main CTIS cross-system buttons

This section outlines the main CTIS cross-system buttons. Below an illustrative example of the information to be detailed is shown:



<p>Search</p>  <p>Allows users to search and retrieve clinical trials, clinical trial applications, notices and alerts, tasks and other information across the system.</p>	<p>Padlock</p>  <p>Allows users to lock a field in CTIS and work on it. This prevents other users from accessing a field/subsection in which other user is working.</p>	<p>Save</p>  <p>Allows users to save their work and makes it visible to others who have been assigned the necessary permissions in the same workspace.</p>
<p>Check</p>  <p>Also 'Accept'</p> <p>Allows users to check whether all mandatory fields have been completed.</p>	<p>Cross</p>  <p>'Cancel' or 'Withdraw'</p> <p>Cancel an action and prevent the changes from being saved in the system before the submission, or withdraw information that was already submitted to the system.</p>	<p>Upload</p>  <p>Also 'Add' or 'Submit'</p> <p>The same icon is used to allow users to add documents into the system and to progress with submission.</p>

<p style="text-align: center;">Download</p> <p style="text-align: center;"></p> <p>Allows users to download data and documents that they have permission to view.</p>	<p style="text-align: center;">Pencil</p> <p style="text-align: center;"></p> <p>Allows users to edit the documents and data before submission.</p>	<p style="text-align: center;">Update</p> <p style="text-align: center;"></p> <p>Allows users to upload new versions of a document once the application and the documents are submitted. It is not allowed to update a new document to replace the original one when the CTA is still in draft. To update a document in a draft CTA, users need first to remove it and then add a new document.</p>
<p style="text-align: center;">Trashcan</p> <p style="text-align: center;"></p> <p>This enables the user to remove previously uploaded information.</p>	<p style="text-align: center;">Add¹</p> <p style="text-align: center;"></p> <p>This button is a cross system functionality that appears after uploading the first version of the document intended for publication. It is only available in CTIS sections where the documents to be uploaded are published. The 'add' button allows users to submit a document version 'not for publication'.</p>	<p style="text-align: center;">Versioning</p> <p style="text-align: center;"></p> <p>Allows users to see the version of documents, applications, or records submitted.</p>
<p style="text-align: center;">Share</p> <p style="text-align: center;"></p> <p>Allows users to share data and documents with other Member States within the workspace.</p>		

¹ With the implementation of the revised transparency rules, the plus icon button will be visible only to documents subject to publication.

2. Access and Practicalities

This section aims to provide users with access routes to the system and some good practice recommendations.

2.1. Access

Clinical trials website



Clinical trials

<https://euclinicaltrials.eu/home>

Workspaces and Public website



Sponsor Workspace

<https://euclinicaltrials.eu/ct-sponsor-services/login>



Authority Workspace

<https://euclinicaltrials.eu/ct-authority-services/login>



Public website

<https://euclinicaltrials.eu/search-clinical-trials-reports>

2.2. Practicalities

Navigation

- **Compatible browsers and internet connection:** Users can use modern browsers such as Chrome 88, Edge, Firefox to navigate through CTIS, however, Chrome is the most recommended. For acceptable user experience, the Internet connection should support at least 3MBps download and 1MBps upload transfer rates. Higher network transfer rates are recommended for optimal user experience.
- **Navigation:** If the users navigate between the public portal and the workspace, they will have to log in to access the account again.
- **Session timeout:** If users stay more than 45 minutes idle, they will be logged out automatically.

Users

- **Blank users:** Blank users need to log in first using small letters for the username (e.g. hu-training instead of HU-Training).
- **Search roles:** Users can click on their username button at the top-right corner of the CTIS interface and then click on 'My roles', then they have to press 'Search' in order to view the roles as the system does not display them by default.

Documents and structured data

- **Edition:** Users can complete and/or update any section by clicking on the 'Padlock' button. Once they have finished editing the section, they need to click on the 'Padlock' button again to save the changes and make them visible to other users. If a user locks a section, this section cannot be accessed by others, however, in case the user stays more than 45 minutes idle, it will be logged out automatically.
- **Mandatory fields:** users can find an asterisk every time a field/section is mandatory. *For more information, please refer to the [Checklist of required field per application type](#) document of Module 10.*
- **Fields update:** Users can refresh the CTIS page to view the latest updates in the process.
- **Numeric fields:** Users can complete numeric fields (e.g. dose) with a maximum of two decimal and separated by a dot (.).
- **Documents upload:** Users can upload documents using any external/internal/cloud storage location and using an appropriate dialog box or the drag-and-drop upload functionality.
- **Documents size:** Documents to be uploaded to the system must have a maximum size of 50 MB. However, documents related to ASR process have a maximum of 10 MB.
- **Document name length:** The name of the documents can be a maximum of 100 characters. No special characters (/,.;|) allowed.
- **CTIS storage:** The system allows for storage of clinical trial data with a maximum size of 220 GB.
- **Sponsors data fields:** The [CTIS Structured data form Instructions](#) document provides guidance on the data fields sponsors will fill in CTIS when creating an initial application (IN), an additional MSC application, a Substantial Modification (SM) and a non-substantial modification (non-SM).

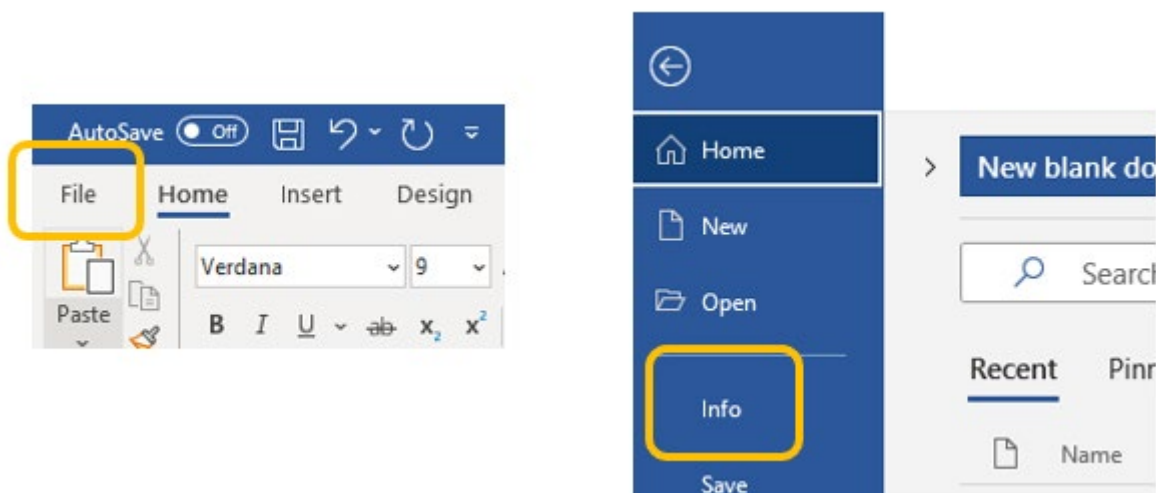
3. CTIS How to remove personal information from properties of CTA documents

Users need to upload many documents, WORD files or PDF files, in their trials submitted via CTIS. After preparing the documents in their computers and **before uploading** them to their trials in CTIS, users need to make sure that they have removed any personal information from the **properties** of their documents. Users can follow some simple steps to remove the data from the properties of their documents. Be aware that the steps, described below are **indicative** and might differ from user to user, **depending on the application they use**.

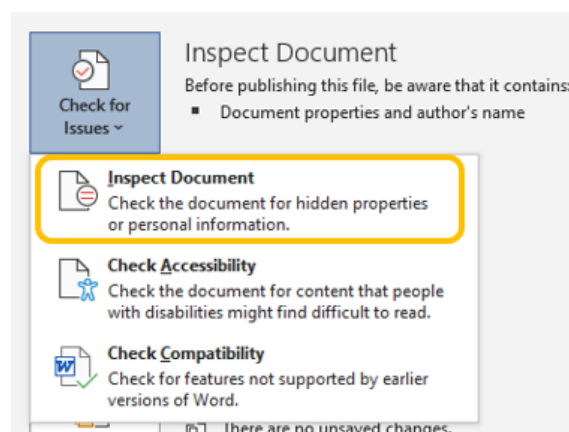
3.1. Removing personal information from properties of word files

Personal information might be saved in the **properties of a word document**. Users can remove it **before uploading** the file to their trials in CTIS, by following the steps below:

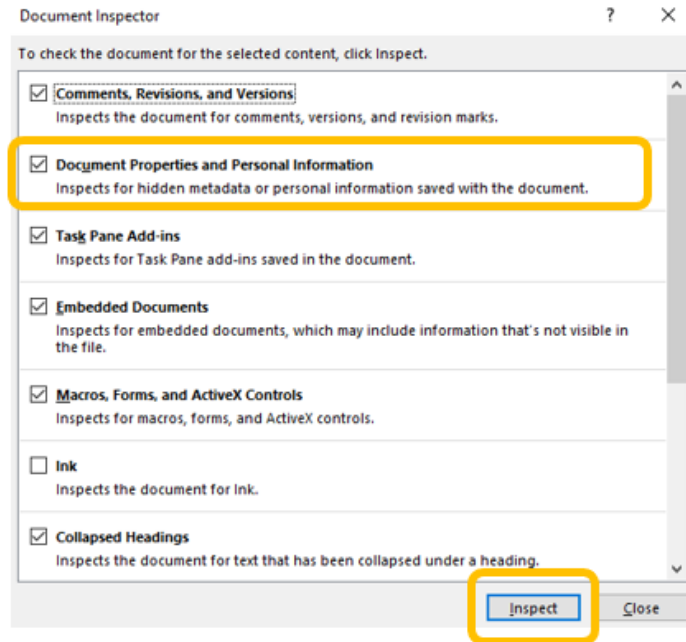
1. Click on the '**File**' tab of the word document and then on the '**INFO**'.



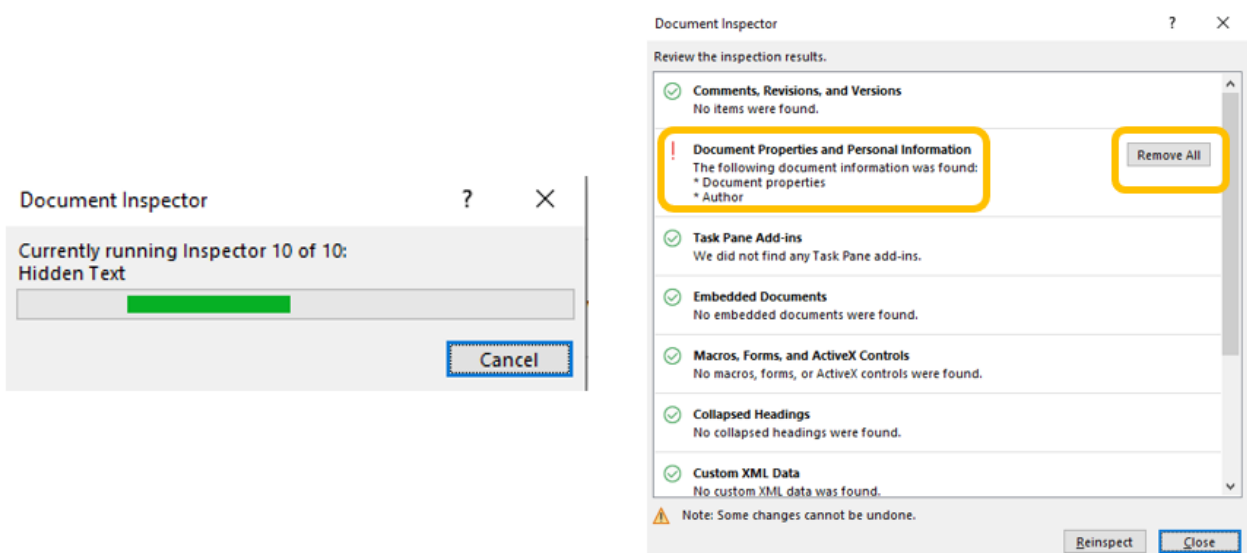
2. Click on the '**Check for Issues**' drop-down list, found on the '**Inspect Document**' section, and select '**Inspect Document**' option.



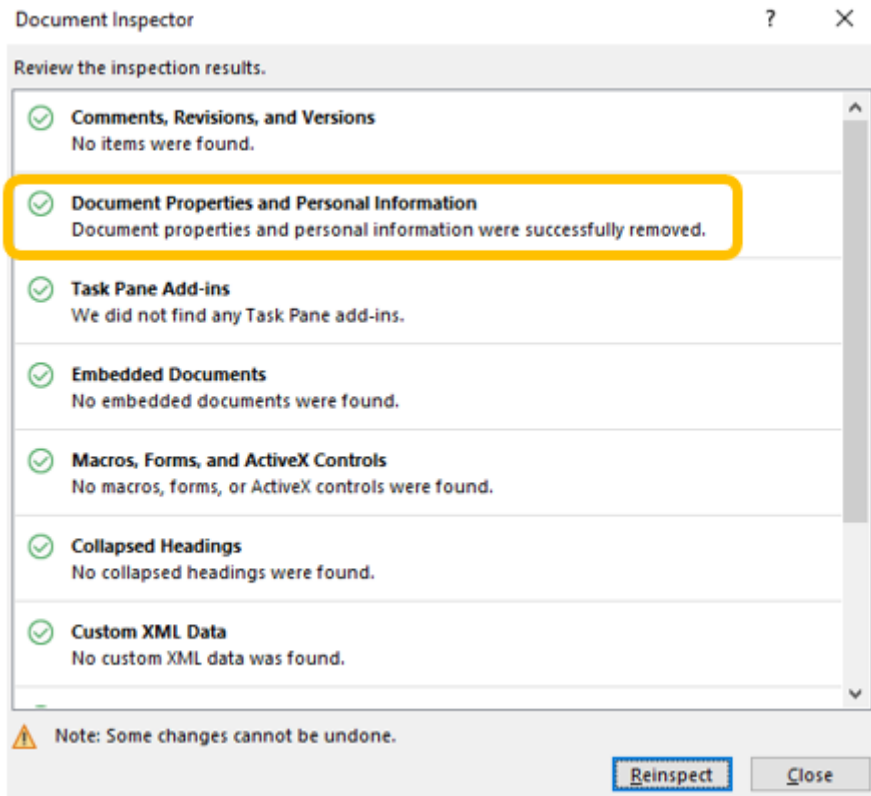
3. Make sure that '**Document Properties and Personal Information**' option is ticked in, and then click on the '**Inspect**' button.



4. Document inspector will run and if personal information is found on the properties of the document, an **exclamation mark** and a '**Remove all**' button will appear on the '**Document Properties and Personal Information**'.



5. Click on the '**Remove all**' button. A **green tick** sign will appear on the '**Document Properties and Personal Information**' section **indicates that personal information has been removed.**

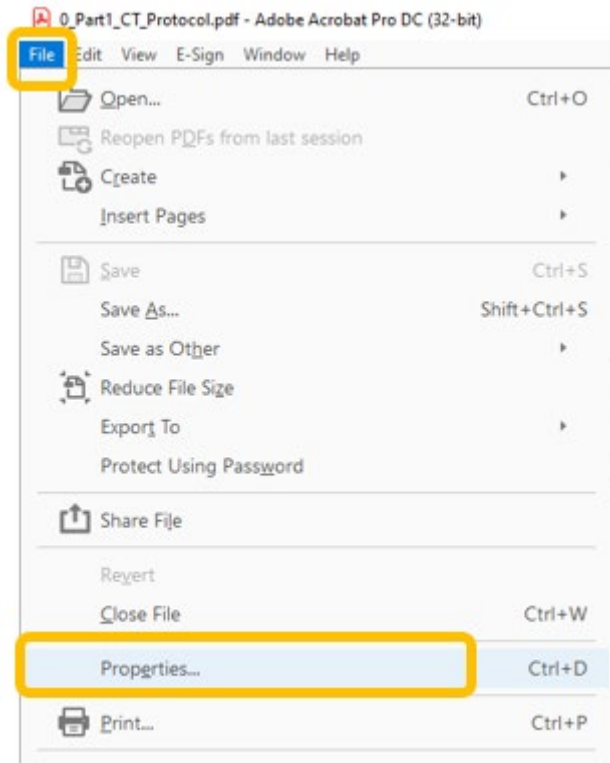


6. Save the document. Now you are **ready to upload** the document to your trial in CTIS.

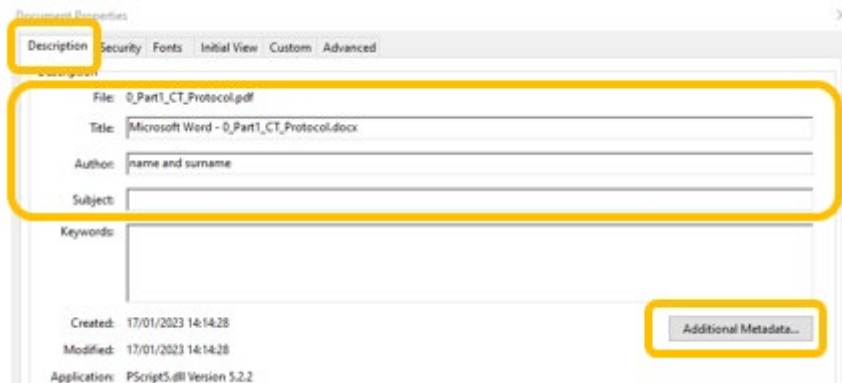
3.2. Removing personal information from properties of PDF files

Users are advised to remove the personal information from the properties of word files before converting them to PDF files. By doing so, users most probably won't find any personal information in the properties of the PDF files, unless the application they used for the conversion maintains any personal data in the resulting PDF file (i.e. a username that might be indicative of the user's full name). Therefore, users are advised to check the properties of their PDF files even after having removed any personal information from the properties of the sourcing word files, by following the steps below:

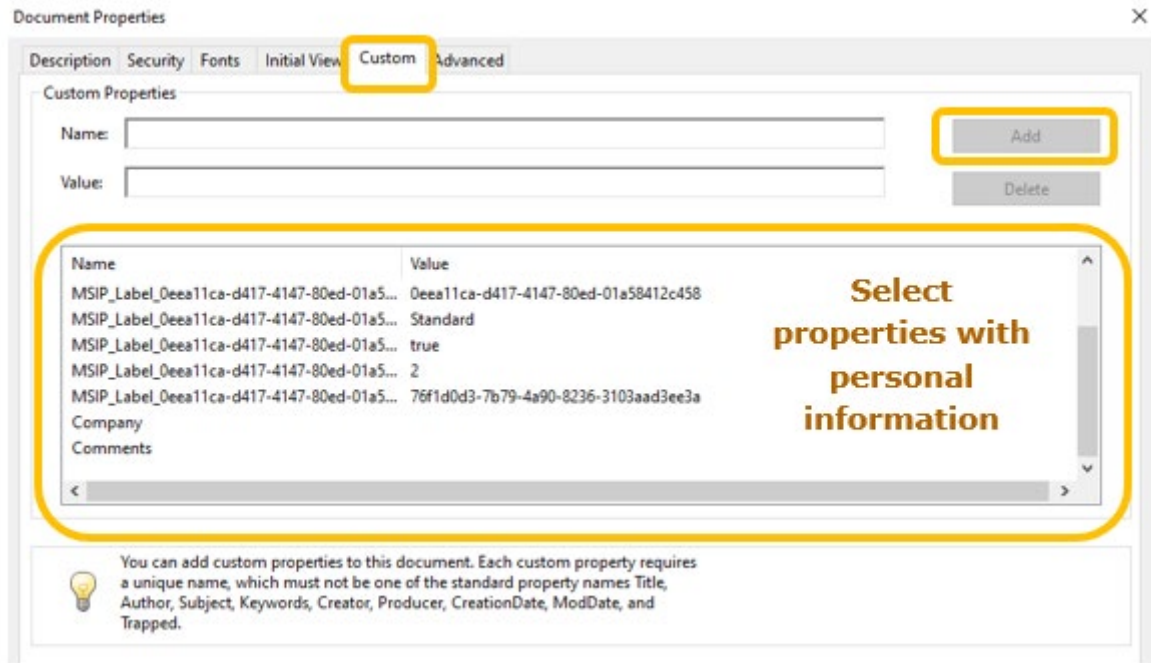
1. Open the PDF file, click on tab '**File**' and then on '**Properties**'.



2. The 'Document Properties' window will pop up. Click on the tabs '**Description**' to see if any personal information is included in the document properties. **Edit the fields** that have any personal information appropriately. Please be aware that additional fields can be seen if you click on the '**Additional Metadata**' button.



3. Click on the '**Custom**' tab, to see if any personal information can be found in the listed properties. If yes, **select one the properties** that contain personal information, to **activate the 'Delete'** button and click on it, to remove the selected property from the listed ones. You will need to repeat the step for any other property that might have personal information.



4. Save the PDF document. Now you are **ready to upload** the document to your trial in CTIS.

Note: You will need to open the PDF files with an application **that is not just reader**, to be able to edit the fields with personal information.

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Support document: Guide on CTIS common features.

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