

EudraCT protocol: package creation and other functionalities

The present part of the user manual provides instructions to the following EudraCT processes:

- [Package creation](#) (this can be done after the [Clinical Trial Application/third country file has been filled in](#))
- [Switch an XML between Third Country and EEA](#) (if needed)
- [Compare Clinical Trial Application](#) (if needed)

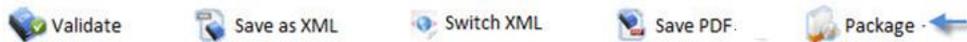
Click on the relevant link to go to the relevant instructions. **The package creation is essential when submitting a Clinical Trial Application to the relevant EU/EEA National Competent Authority(ies), while it is not mandatory when finalising a third country file.** The following two processes are also optional: switching an XML file from a CTA format to the third country file one and vice-versa, comparing two Clinical Trial Applications.

Full overview of EudraCT processes is provided in the [EudraCT step-by-step guide](#). In case support is needed, see [here](#).

Package creation

The following steps are required for preparing a submission package which should be sent to the concerned NCA in the case of an EEA clinical trial application or to an Independent Ethics Committee for their opinion. In the case of a third country file, a submission package is not submitted to an EEA NCA or Independent Ethics Committee. However, a package can be created for your records for further use outside EudraCT. A package can be created after the clinical trial application or third country file is complete and validated.

1. To create a package, the CTA/third country file needs to be loaded on EudraCT.
2. Click on the option Package at the top right corner of the clinical trial application menu



3. Click on 'Create submission package for National Competent Authority' or 'Create submission package for Independent Ethics Committee', as applicable, and click on Save to save the file locally. In case of third country file, click on 'Create Submission Package'



4. The package is created automatically, with the following name convention: [EudraCT number] [Country of CT] [YYYYMMDD] CTA Package.zip.

Sponsors of EU/EEA trials can now send the package to the relevant contact according to their business processes. A list of Member States contacts is available [here](#). Third country data provider can keep the third country file package stored locally, for recording purposes.

Switch an XML between Third Country and EEA

To switch an XML from the Third Country to EEA format, or vice-versa, the file needs to be loaded into the system (see [relevant instructions](#)), after having been saved locally during or after its completion. Any user can load and switch a CTA/Third Country using the application: a user does not need to log in the system in order to load an XML file.

1. The Clinical Trial Application Menu the Task Bar at the top of the screen includes the option 'Switch XML':



2. Click on 'Switch XML' and the XML you currently have loaded is converted to the other flavour of XML (in this example an EEA CTA is loaded, so a Third Country CTI is created):
3. You can 'Save File' or 'Open with' an XML reader (if you have one installed).

The switched XML may now be used as needed.

Compare Clinical Trial Application

This functionality is only available for Clinical Trial Applications, not for third country files.

This feature enables users to compare Clinical Trial Application forms on the system (and stored locally) in a way that indicates differences between the two CTAs. It can be performed with EEA CTAs in all the areas of the database, including those which are being viewed.

To compare two CTAs, one CTA XML file needs to be loaded into the system (see [relevant instructions](#)), while the other needs to be saved locally during or after its completion. Any user can use this option for a CTA in the application: a user does not need to log in the system in order to load an XML file.

1. Once a CTA is loaded, the Clinical Trial Application Menu appears
2. The Clinical Trial Application Menu the Task Bar at the top of the screen includes the option 'Compare':



3. Click on 'Compare' to compare the currently loaded CTA with another CTA. The 'Find XML to Compare to' page appears
4. Click 'Local File System' to find the XML file you wish to compare with the currently loaded CTA and load an XML file from Local File System
5. When the comparison is complete, the 'Comparison Results' page appears:

Comparison Results			
Expand All Collapse All Return to XML File Source Menu			
Sections	Inserted	Updated	Deleted
▶ D. IMP Identification	0	0	197
▶ D.9. Site(s) where the qualified person certifies batch release	0	1	8
▶ E. General Information on the Trial	1	12	25

6. Click on 'Expand All' to see the differences between the two CTAs or click on the arrow beside each section:

Sections	Inserted	Updated	Deleted
▼ D. IMP Identification	0	0	197
▶ D.1 IMP - Name: supranin copy/dream1-dream1/sx-551/Concentrate and solvent for concentrate for solution for infusion <u>null</u>			

Characteristics:

- Details of all insertions, updates and deletions.
 - Ability to expand and collapse the entire report to the lowest level of granularity.
 - Click a section to expand and display child elements.
 - Click 'Return to XML File Source Menu' to return to the Clinical Trial Application Menu with the loaded Clinical Trial Application.
7. To view the details of the changes between the two compared files, click on the Section you wish to view in more detail (in this example 'D. IMP Identification').
8. To view the details as tracked changes, scroll down the page.
- The marked up text (replaced) is that which is in the 'compare' file
 - the underlined text (inserted) is that which is in the loaded file (the CTA currently loaded/being worked on).

Note: it is recommended to use Google Chrome as browser to ensure the formatting of the report displays correctly.

Support needed?

For questions, refer to our [Frequently Asked Questions](#). If the answer to your question is not there, [Contact us](#).