

**EUROPEAN UNION TELEMATICS CONTROLLED
TERMS FREQUENTLY ASKED QUESTIONS (FAQ)
EUTCT**

1. WHAT IS EUTCT?..... 2
2. WHICH EU TELEMATICS SYSTEMS DOES EUTCT SUPPORT? 2
3. WHO HAS ACCESS TO THE CONTROLLED TERMS LIST?..... 2
4. WHAT ARE THE DIFFERENT USER PROFILE TYPES?..... 2
5. HOW CAN I BECOME A REGISTERED USER OF EUTCT?..... 3
6. HOW CAN I MODIFY THE CONTROLLED TERM LISTS?..... 3
7. HOW OFTEN DO YOU UPDATE THE CONTROLLED TERMS? 3
8. WHEN WILL THE NEW CONTROLLED TERM LISTS BE INCLUDED IN EUTCT? 3
9. HOW CAN I GET FURTHER ASSISTANCE WITH EUTCT?..... 3
10. WILL THE CONTROLLED TERMS BE AVAILABLE IN OTHER EUROPEAN LANGUAGES?.. 3
11. HOW CAN I CONVERT A DOWNLOADED .XML/.CSV LIST INTO AN EXCEL (.XLS) LIST?
3

1. What is EUTCT?

The European Union Telematics Controlled Terms (EUTCT) system is a European Community (EC) repository and provider of Controlled Terms in multiple languages for the ongoing exchange of data between information systems and applications throughout the European Medicines Regulatory Network (EMRN).

2. Which EU Telematics systems does EUTCT support?

EUTCT currently holds lists that are required for EMA systems such as SIAMED and CorpGxP, Eudra systems such as EudraPharm, EudraCT, EudraVigilance, EudraGMP, eAF and PIM, NCA systems and other systems like CTS and ENCEPP.

3. Who has access to the Controlled Terms List?

Different user profiles have different levels of access to EUTCT. See [What are the different user profile types?](#) question below.

4. What are the different user profile types?

These are the user profile types available within EUTCT. Registered users may have more than one user name and role. These roles and their activities are listed in the table below.

User Profile Type	Activities
Secretariat	Secretariats are responsible for managing all changes to the Controlled Terms in the EUTCT system. This profile type is issued to members of EMA's EUTCT secretariat.
Licensed	Licensed users may perform the following activities: <ul style="list-style-type: none">• Browse and search for Controlled Terms in all of the Controlled Term Lists in EUTCT.• Download full or parts of a Controlled Term Lists in XML (using the published schema) and CSV format (if practical) from the EUTCT system.
Change Requestor	Change Requestors may perform the following activities: <ul style="list-style-type: none">• Browse and search for Controlled Terms in all of the Controlled Term Lists in EUTCT.• Raise Change Requests using the EUTCT system.• Consume information concerning any submitted Change Request.
Translator	Translators may perform the following activities: <ul style="list-style-type: none">• View the Controlled Terms and their approved and unapproved translations.• Browse and search for Controlled Terms in all of the Controlled Term Lists in EUTCT (but not download the lists).• Translate Controlled Terms in the language of their designated translator role on a Term by Term basis.• Save translation changes for immediate viewing by all users. <p>The Translator user role is specifically issued to individuals appointed to translate Controlled Terms in EUTCT.</p>
Guest	Guest users have read-only access to the EUTCT Controlled Term Lists.

Guest users access EUTCT via a link at the bottom-left of the welcome page.

5. How can I become a registered user of EUTCT?

If you are a NCA staff member, you don't have a EUTCT user role and you feel that you have a justification for one, please contact your [NCA Co-ordinator](#).

For members of the general public, this version of EUTCT allows read-only access to the EUTCT Controlled Term Lists.

6. How can I modify the Controlled Term Lists?

If you are a registered Change Requestor user, you can request a change to a Controlled Terms List using the EUTCT Change Request process.

Members of the general public, who have read-only access to EUTCT, should send an email with the request to the EUTCT secretariat at eutct-secretariat@ema.europa.eu.

7. How often do you update the Controlled Terms?

There is no fixed publication cycle. Published Controlled Term Lists get updated whenever a Change Request (for a new, updated or make non-current Controlled Term) has been approved.

8. When will the new Controlled Term Lists be included in EUTCT?

EUTCT is an ongoing project and the inclusion of new Controlled Term Lists is foreseen until 2013. New Controlled Term Lists will be published as part of new releases of the EUTCT system.

9. How can I get further assistance with EUTCT?

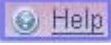
If you need further assistance with using EUTCT, or want to request an enhancement to EUTCT, please send your questions and comments to eutct@ema.europa.eu for consideration.

10. Will the Controlled Terms be available in other European languages?

The Controlled Terms will become available in other languages as they are provided by the National Competent Authorities (NCAs) through our Translation process. If you are an NCA staff member, contact your [NCA Co-ordinator](#) if you feel you're well placed to contribute translations for Controlled Terms as a Translator.

11. How can I convert a downloaded .xml/.csv list into an Excel (.xls) list?

Licensed and Secretariat users only: You can open and convert .csv and .xml files using Microsoft Excel 2003 onwards. For more detailed information:

1. Click  in the page that displays a single Controlled Term List. This opens the EUTCT Help for that page.
2. Choose **Downloading Controlled Term Lists** from the Table of Contents.

Other Users: The functionality of downloading XML or CSV files of the Controlled Term Lists in EUTCT is not available to the following user roles: Guest, Change Requestor and Translator.