

EUDRACT USER MANUAL (GET EUDRACT NUMBER)

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1 ABOUT THIS DOCUMENT

This document describes the first part of the EudraCT system from a user perspective. It describes how the system can be used to obtain a EudraCT number but does not attempt to describe the business processes required by the Sponsor or Requestor to manage the request for, or use of the EudraCT number.

2 SYSTEM OVERVIEW

2.1 General

The system is divided into two parts. The first part is aimed at providing a security code reference as a means of validating the EudraCT Number request. The second part identifies some simple information about the requestor and the Sponsor's Protocol Code Number of the trial for which the EudraCT number is required. There are two simple forms to collect the information required and the security code and EudraCT number will be returned by e-mail.

2.1.1 Entering Data

The system is based on web enabled request forms. These collect the information required for the request of a security code and EudraCT Number and provide the results as e-mail messages. The data entry fields have pre-determined lengths and it is not possible to enter data in excess of these.

2.1.2 Saving and Printing

The data entered on the web pages can be saved by saving the web page. The information returned as e-mails can be saved and printed from within the e-mail system.

3 GETTING STARTED

3.1 System Requirements

3.1.1 E-mail requirement

To operate the EudraCT system you will need to have a current e-mail account and have software on your PC that enables you to receive e-mails.

3.1.2 Browser requirement

The system operates most effectively using Microsoft Internet Explorer v5 and above.

3.1.3 PC specification

There is no special set-up required. Your PC should ideally be set to use Internet Explorer v5 or higher and the screens are best viewed at a screen resolution of 1024x768. All pages that are larger than the screen view will scroll so that all the information on a page can be viewed at any screen resolution.

4 ACCESSING THE SYSTEM

4.1 Access to the EudraCT System

The EudraCT system is accessed using a link from the EMEA public home page that has the address:

www.emea.eu.int

4.2 Navigating the system

There are certain navigation principles applied to the system. In particular:

- The standard browser navigation buttons (Forward and back) should **NOT** be used
- Only the navigation buttons on the EudraCT screens should be used

The following Navigation keys are used in the system:

Cancel

This link will clear any data that you may have entered on a form and will return you to the EudraCT Welcome Page.

Get Security Code and Get EudraCT Number

These links will submit the appropriate form for processing to obtain the security code or EudraCT number respectively.

Continue or OK

These links are used on information and error message screens and will take you back to the EudraCT Welcome page

4.3 The EudraCT Welcome page

This is main index to the EudraCT system and has two links under the following headings.

Apply for Security Code.

If you require a security code please press this link

Apply for EudraCT Number

Once you have the security code and wish to obtain a EudraCT Number please press this link

Eudra home page

Click here to return to Eudra home page

In addition to these system links there are also links for:

FAQ

This is provides a list of frequently asked questions.

Help

This link provides on-line access to this user manual.

Contact

This link provides the facility to send an e-mail to the system support group at.

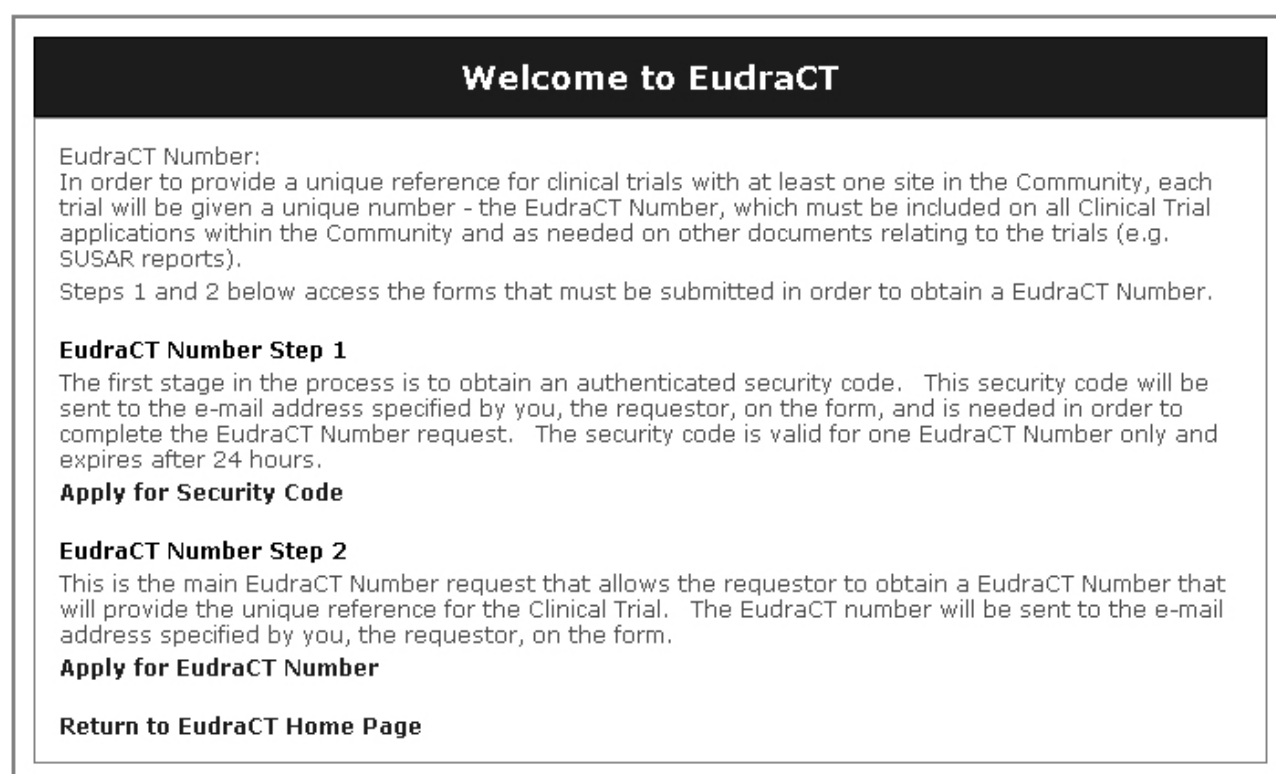


Fig 1. EudraCT Welcome Screen

5 REQUESTING A EUDRACT SECURITY CODE

5.1 Introduction

A EudraCT Security code is needed in order to make a successful request for a EudraCT Number. The security code will be valid for only 24 hours from the time is received and can be used for only request for a EudraCT Number.

It is therefore not good practice to obtain security codes too far in advance of the EudraCT number request that they are required for.

5.2 The Process for Obtaining a Security Code

To obtain a security code use the following sequence:

1. From the EudraCT Welcome Screen take the link:
'If you require a security code please press this link.'

The following screen will appear



Get Security Code

Fields marked with '*' must be completed.
When you have completed the form, press the 'Get Security Code' button and an e-mail with a Security Code will be sent to the e-mail address entered.
If you wish to cancel this application for a security code then press the 'Cancel' button which will return you to the main menu.

Requestor Name(*):

Requestor e-mail(*):

Get Security Code **Cancel**

Fig 2. Get Security Code Screen

2. Complete both fields which are mandatory.
The e-mail should be accurate so that the e-mail with the security code is sent to the correct recipient.
3. When the fields have been correctly completed press the "Get Security Code" link and a confirmation screen will appear. The e-mail will arrive shortly afterwards (depending on network traffic etc.).



Get Security Code Success

An e-mail has been sent to martin.gregory@emea.eu.int with the details.

Continue

Fig 3. Get Security Code Success Screen

4. Check the e-mail address printed on this confirmation screen to be sure that it does not contain any typing errors. If the e-mail address is incorrect then the e-mail cannot be delivered. (See section 5.3.2 Entering an invalid e-mail format)
5. At this point press 'Continue' to return to the EudraCT Welcome Screen.
The e-mail that contains the security code will be sent to the e-mail address used in the request form.
6. Open this e-mail account to find the e-mail. This will be from user:
EudraCT@eudra.org
and with the subject:
Application for Security Code
7. Open the message to obtain the Security code.



Fig. 4 Security Code e-mail

8. Make a note of the security code for use in your request for a Eudract number. The security code can be also be selected and copied from the e-mail for pasting into the EudraCT Number request form.

5.3 Problems that may be encountered

5.3.1 Not entering mandatory data

The two fields on the 'Get Security Code Screen' are mandatory. If an entry is omitted then an appropriate error message will be displayed at the top of the form when the link 'Get Security Code' is pressed. Either or both of the warning messages shown on the following will be seen if the relevant fields are not completed.

Get Security Code

Fields marked with '*' must be completed.
When you have completed the form, press the 'Get Security Code' button and an e-mail with a Security Code will be sent to the e-mail address entered.
If you wish to cancel this application for a security code then press the 'Cancel' button which will return you to the main menu.

- The Requestor Name is required
- The Requestor e-mail is required

Requestor Name(*):

Requestor e-mail(*):

Get Security Code Cancel

Fig 5. Get Security Code warning messages

To correct the error either:

1. Enter valid information in the fields identified in the error message(s) and press the 'Get Security Code' link to obtain a security code
2. Take the 'Cancel' link to return to the 'EudraCT Welcome Screen' and if a security code is required take the appropriate link back to the 'Get Security Code' screen

5.3.2 Entering an invalid e-mail format

The EudraCT system will check to ensure that the e-mail address entered complies with the standard format. If an e-mail address with an incorrect format is entered, the following error message will appear on the screen when the 'Get Security Code' link is pressed.

- **You have entered an invalid Requestor's e-mail address**

Fig 6. Invalid e-mail address format warning

To correct the error either:

1. Enter an e-mail address with a valid format and press the 'Get Security Code' link to obtain a security code
2. Take the 'Cancel' link to return to the 'EudraCT Welcome Screen' and if a security code is required take the appropriate link back to the 'Get Security Code' screen.

5.3.3 Not receiving the e-mail

There may be several reasons why the e-mail does not arrive. The most commonly occurring are:

1. Failure of the e-mail system or communication links.
The e-mail may have been sent to a correct e-mail recipient, but the mail servers are slow or the communications links may have failed.
The EudraCT system cannot help in this instance. You may decide to wait to be sure that the e-mail has not (will not) arrive and then make a new request for a security code.
2. Wrongly typed e-mail address
You may have included an e-mail address in the correct format, but mistyped the name. In this instance the e-mail from the EudraCT system will be returned to EudraCT as 'undeliverable'. The EudraCT system cannot do any more in this instance and your e-mail will not arrive. You must make another request for a security code.
3. E-mail address of another recipient.

If you use another person's e-mail and not your own then you will not receive the e-mail in your mail account. Either contact the other person to check that they have received the e-mail with the security code or request a new security code to be sent your own e-mail address.

5.3.4 Using incorrect navigation keys

The standard internet browser keys should not be used to find forms that have been already been submitted. If a page that has been submitted once is submitted a second time then the following error message will appear.

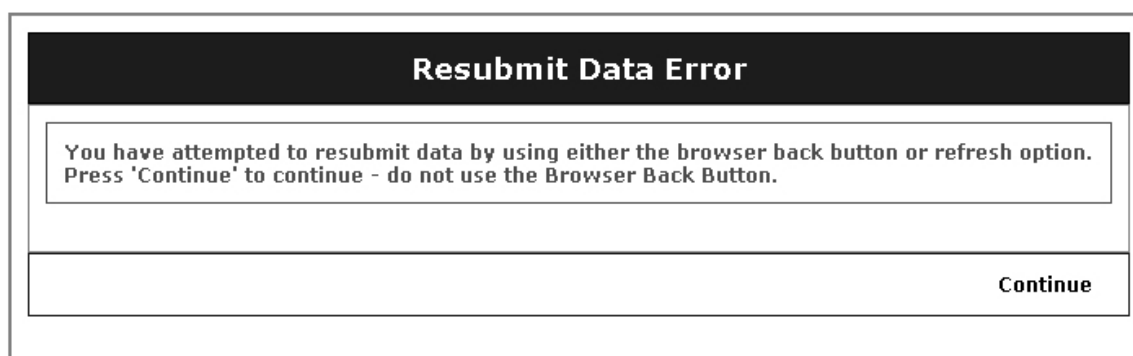


Fig 7. Resubmit Data Error Screen

This error is corrected by taking the 'Continue' link which returns to the 'EudraCT Welcome' screen. From here the appropriate link can be used to obtain a security code.

5.3.5 Unexplained processing errors

There are situations that may cause the application to fail that are out of the control of the application environment. When such a situation occurs the 'error' screen will be displayed. Press the 'OK' link to return to the EudraCT Welcome screen. To prevent further errors it advisable to exit your internet browser, restart it and re-enter the EudraCT system from the main link on the Eudra home page. (See section 4.1 Access to the EudraCT System)

Such errors should be reported to the system administrators by e-mail, using the 'contact' link on the EudraCT Welcome screen

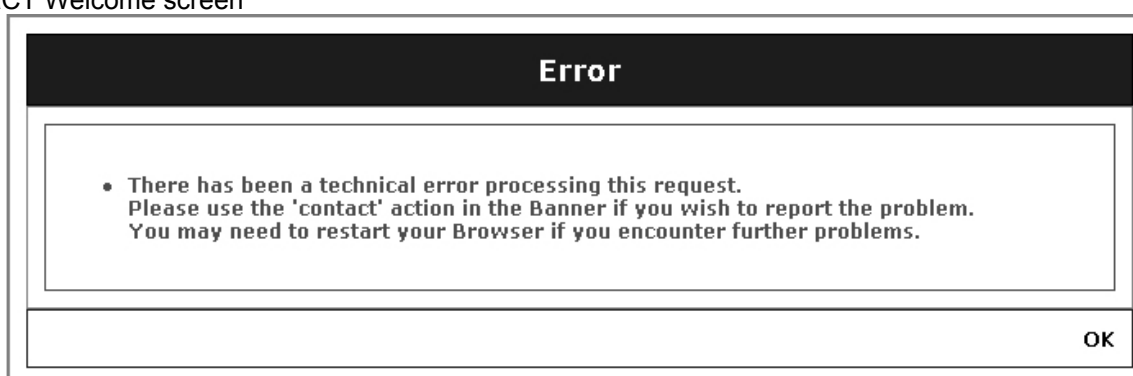


Fig 8. EudraCT Technical Error Processing screen

6 REQUESTING A EUDRACT NUMBER

6.1 Introduction

This part of the system is used to obtain a EudraCT number for the Clinical Trial. A EudraCT Number is needed in order to make a successful Clinical Trial Application with Europe. Once a EudraCT number has been issued it is to be used as the unique reference for the clinical trial throughout Europe and the use of more than one EudraCT number to describe the same Clinical Trial is prohibited.

6.2 The Process for Obtaining a EudraCT Number

To obtain a EudraCT Number use the following sequence.

1. From the EudraCT Welcome Screen take the link:
'Once you have the security code and wish to obtain a EudraCT Number please press this link'
The following screen will appear

Get EudraCT Number

All fields marked with '*' must be completed in all requests.

If you are requesting the EudraCT number as an individual, then you may leave the 'Requestor's organisation name' empty. In this case the system will copy your 'Requestor's name' into the 'Requestor's organisation name' box. You must include your contact details in the 'Requestor's organisation town/city' and 'Requestor's organisation country' boxes.

When you have completed the form, press the 'Get EudraCT Number' button and an e-mail with a EudraCT Number will be sent to the e-mail address entered. If you want to cancel this application for a EudraCT number, press the 'Cancel' button which will take you back to the main menu.

Requestor's organisation name:

Requestor's organisation town/city(*):

Requestor's organisation country(*):

Sponsor's protocol code number(*):

Requestor name(*):

E-mail to which the EudraCT number will be sent(*):

Enter the security code sent earlier(*):

Please select the Member States where it is anticipated that the trial will be run:

AUSTRIA: ☐

CZECH REPUBLIC: ☐

FINLAND: ☐

GREECE: ☐

IRELAND: ☐

LIECHTENSTEIN: ☐

MALTA: ☐

POLAND: ☐

SLOVENIA: ☐

UNITED KINGDOM: ☐

BELGIUM: ☐

DENMARK: ☐

FRANCE: ☐

HUNGARY: ☐

ITALY: ☐

LITHUANIA: ☐

NETHERLANDS: ☐

PORTUGAL: ☐

SPAIN: ☐

CYPRUS: ☐

ESTONIA: ☐

GERMANY: ☐

ICELAND: ☐

LATVIA: ☐

LUXEMBOURG: ☐

NORWAY: ☐

SLOVAKIA: ☐

SWEDEN: ☐

Get EudraCT Number

Cancel

Fig 9. Get EudraCT Number Screen

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2. The requestor will complete all the mandatory fields which are marked with (*)
 - “Requestor’s Organisation Name”. Include in here the name of the organisation that the requestor works for.
If the requestor is not making the request on behalf of an organisation, but on their own behalf, then the “Requestor’s Organisation Name” should be left blank, but you should use the fields “Requestor’s Organisation Town / City” and “Requestor’s Organisation Country” to enter your own Town or City and Country respectively.
 - “Requestor’s Organisation Town / City”. This is a mandatory field.
 - “Requestors organisation Country”. This is a mandatory field. Select the appropriate country from the drop-down list of all the countries of the world.
 - “Sponsor’s Protocol Code Number”. This is the Protocol Code Number for the clinical trial that will be linked to the EudraCT number obtained from this request. It can be entered in the normal format used by the requestor’s organisation.
 - “Requestor name”. Enter your name.
 - “E-mail to which the EudraCT Number will be sent”. Enter the e-mail address to which the EudraCT Number should be sent. Any valid e-mail address is acceptable and need not be the requestor’s e-mail.
 - “Enter the security code sent earlier”. Enter here the EudraCT security code obtained by using the ‘Get Security Code’ link. This security must not have been used on another application and it must be less than 24 hours since it was issued.
 - “Please select the Member States where it is anticipated that the trial will be run”. This is not mandatory information, but completion will provide some advanced indication of likely Clinical Trial applications in each Member State. The Member States selected will represent the best available information and may change. However, should this information change there is no requirement to notify any Member States of the changes.
3. When the fields have been correctly completed you should press the “Get EudraCT Number” link and a confirmation screen will appear. The e-mail will arrive shortly afterwards (depending on the speed of your local e-mail servers).

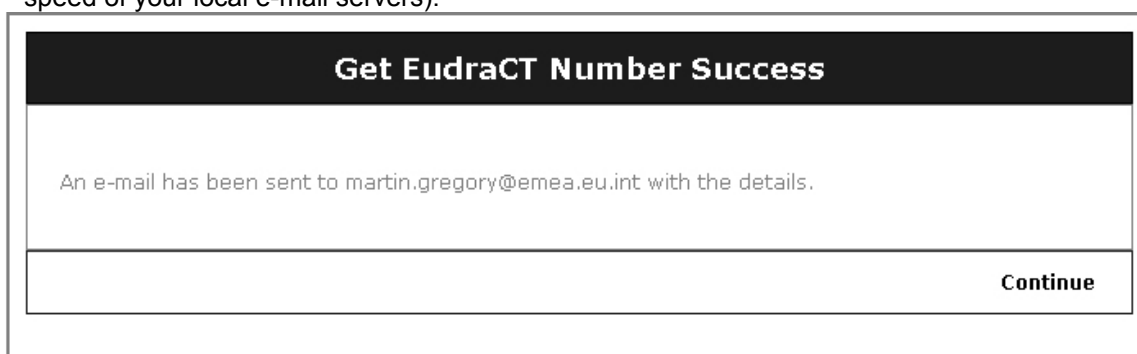


Fig. 10. Get EudraCT Number Success Screen

4. Check the e-mail address printed on this confirmation screen to be sure that it does not contain any typing errors. If the e-mail address is incorrect then the e-mail cannot be delivered. (See section 5.3.2 Entering an invalid e-mail format)
5. At this point press “Continue” to return to the EudraCT Welcome Screen.
The e-mail that contains the EudraCT Number will be sent to the e-mail address used in the request form.
6. Open this e-mail account to find the e-mail. This will be from user:
EudraCT@eudra.org
and with the subject:
Application for EudraCT Number
7. Open the message to obtain the EudraCT Number.

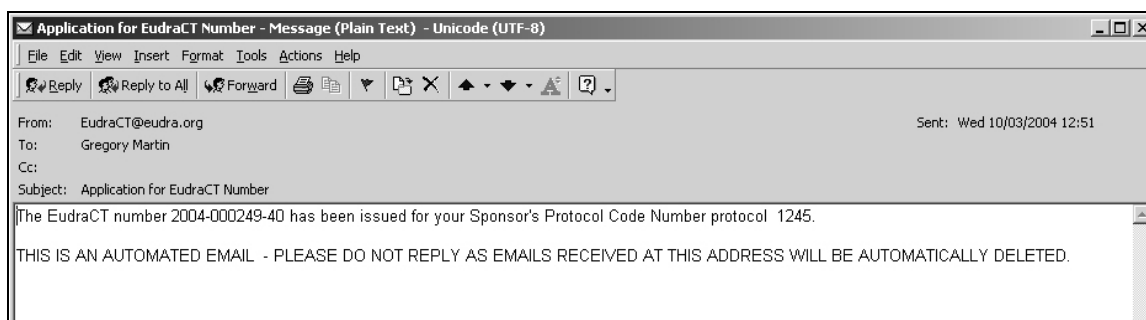


Fig 11. EudraCT Number e-mail

This e-mail also includes the Sponsor Protocol Code Number for this request.

8. Save this e-mail. It is the receipt of confirmation of EudraCT number required as one of the documents to be included in the request for the Clinical Trial.

6.3 Problems that may be encountered

6.3.1 Not entering mandatory data.

Most of the fields on the "Get EudraCT Number" screen are mandatory. If an entry is omitted then an appropriate error message will be displayed at the top of the form when the link 'Get EudraCT Number' is pressed. Any combination of the following warning messages may appear depending on which fields have not been correctly completed.

The screenshot shows the 'Get EudraCT Number' form. At the top, a black header bar contains the title 'Get EudraCT Number' in white. Below the header, the form contains instructional text and a list of error messages. The instructional text states: 'All fields marked with '*' must be completed in all requests.' It also provides guidance for individuals requesting the number and explains the process of receiving the number via email. The error messages are listed in a bulleted format: 'The Requestor's organisation town/city is required', 'The Requestor's organisation country is required', 'The Sponsor's protocol code number is required', 'The Requestor name is required', 'The E-mail to which the EudraCT number will be sent is required', and 'The Security Code is required'. Below the error messages, the form fields are visible: 'Requestor's organisation name:', 'Requestor's organisation town/city(*):', 'Requestor's organisation country(*):', 'Sponsor's protocol code number(*):', 'Requestor name(*):', 'E-mail to which the EudraCT number will be sent(*):', and 'Enter the security code sent earlier(*):'.

Get EudraCT Number

All fields marked with '*' must be completed in all requests.

If you are requesting the EudraCT number as an individual, then you may leave the 'Requestor's organisation name' empty. In this case the system will copy your 'Requestor's name' into the 'Requestor's organisation name' box. You must include your contact details in the 'Requestor's organisation town/city' and 'Requestor's organisation country' boxes.

When you have completed the form, press the 'Get EudraCT Number' button and an e-mail with a EudraCT Number will be sent to the e-mail address entered. If you want to cancel this application for a EudraCT number, press the 'Cancel' button which will take you back to the main menu.

- The Requestor's organisation town/city is required
- The Requestor's organisation country is required
- The Sponsor's protocol code number is required
- The Requestor name is required
- The E-mail to which the EudraCT number will be sent is required
- The Security Code is required

Requestor's organisation name:

Requestor's organisation town/city(*):

Requestor's organisation country(*):

Sponsor's protocol code number(*):

Requestor name(*):

E-mail to which the EudraCT number will be sent(*):

Enter the security code sent earlier(*):

Fig. 12. Get EudraCT number field warnings

To correct the error either:

1. Enter valid information in the fields identified in the error message(s) and press the 'Get Security Code' link to obtain a security code
2. Take the 'Cancel' link to return to the 'EudraCT Welcome Screen' and if a EudraCT Number is required take the appropriate link back to the 'Get EudraCT Number' screen

6.3.2 Entering an invalid e-mail address format

The EudraCT system will check to ensure that the e-mail address entered complies with the standard format. If an e-mail address with an incorrect format is entered, the following error message will appear on the screen when the 'Get Security Code' link is pressed.

- **You have entered an invalid Requestor's e-mail address**

Fig 13. Invalid e-mail address format warning

To correct the error either:

1. Enter an e-mail address with a valid format and press the 'Get Security Code' link to obtain a security code
2. Take the 'Cancel' link to return to the 'EudraCT Welcome Screen' and if a security code is required take the appropriate link back to the 'Get Security Code' screen.

6.3.3 Not receiving the e-mail

There may be several reasons why the e-mail does not arrive. The most commonly occurring are:

1. Failure of the e-mail system or communication links.
The e-mail may have been sent to a correct e-mail recipient, but the mail servers are slow or the communications links may have failed.
The EudraCT system cannot help in this instance. You may decide to wait to be sure that the e-mail has not (will not) arrive and then make a new request for a security code.
2. Wrongly typed e-mail address
You may have included an e-mail address in the correct format, but mistyped the name. In this instance the e-mail from the EudraCT system will be returned to EudraCT as 'undeliverable'. The EudraCT system cannot do any more in this instance and your e-mail will not arrive. You must make another request for a security code.
3. E-mail address of another recipient.
If you use another person's e-mail and not your own then you will not receive the e-mail in your mail account. Either contact the other person to check that they have received the e-mail with the security code or request a new security code to be sent your own e-mail address.

6.3.4 Duplicate Sponsor's Protocol Code Number

The EudraCT system will check that the Sponsor's Protocol Code Number submitted on the form is unique within the EudraCT database. It is very unlikely that different sponsors will use the same Protocol Code Numbers for their trials. However, it may be that the Sponsor's protocol Code Number submitted already exists and then a warning message is displayed when the 'Get EudraCT Number' link is taken

- A EudraCT Number has already been issued for Protocol Code Number Prot-123-2004. Are you sure that you wish to proceed to generate another EudraCT number? It is likely that a EudraCT number for this Protocol Code Number has already been issued to another individual within your organisation or another collaborator on this trial. Please check whether you have duplicated this EudraCT number request for your clinical trial. If you are absolutely sure that you wish to continue, then click the "Get EudraCT Number" button below otherwise click the "Cancel" button.

Fig 14. Duplicate Sponsor's Protocol Code Message

It is very unlikely that different sponsors will use the same Protocol Code Numbers for their trials. However this may happen and within the Community it is the EudraCT Number that will provide the truly unique reference to the sponsor's trial. If the system detects a duplicate sponsor protocol code number, the system will warn the requestor and in this case the most likely explanation is that a EudraCT number has already been requested by someone from the same organisation or another collaborator in the trial. The option is given to exit the system without creating a new EudraCT number so that checks within the organisation or trial collaborators can be completed.

To deal with this warning either:

1. Press the 'cancel' button which will return to the 'Welcome to Eudract' screen. The appropriate link can then be used to request a EudraCT Number.
2. Press the 'Get EudraCT Number' button. In this instance the system will issue a EudraCT Number but the warning that you have used duplicate Sponsor's Protocol Code Number will be included in the e-mail sent to the e-mail address on the EudraCT Number request form.

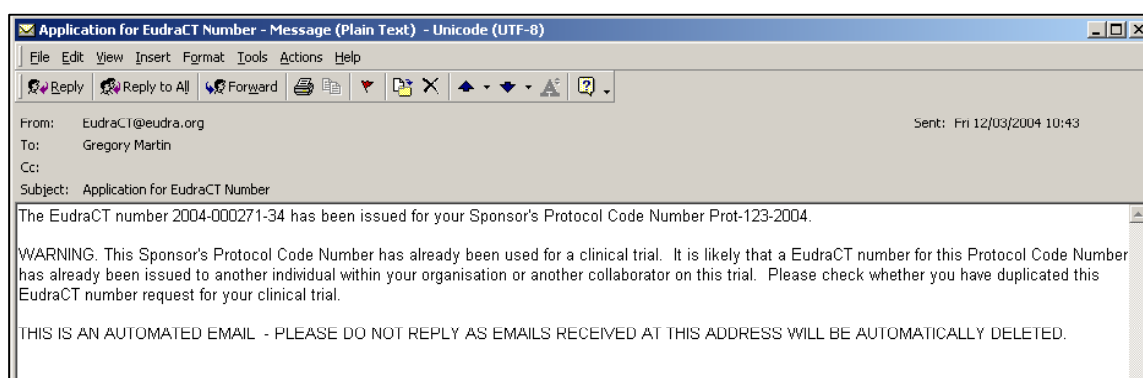


Fig 15. Duplicate Sponsor's Protocol Code

6.3.5 Using an invalid security code

If an invalid or expired security code is entered then the following messages will appear when the 'Get EudraCT Number' link is taken, depending on the particular situation.

- **The Security Code entered must be 8 digits**
- **Unable to find security code**

Fig 15. Security Code Error Messages

To correcting the error depends on the reason for the failure.

1. If the security code had been incorrectly typed then enter the correct code and take the 'Get EudraCT Number' link.
2. If the security code is incorrect then press the 'Cancel' link to return to the EudraCT Welcome page and apply for a new security code.

6.3.6 Using an expired security

If an expired security code is entered then the following messages will appear when the 'Get EudraCT Number' link is taken.

- **The security code has expired. An e-mail has been sent to <e-mail address> with this information.**

Fig 16. Expired security code error message

An e-mail will be sent to the e-mail address on the EudraCT Number request form so that there is a positive record that a EudraCT number has not been issued for the request.

To correct the error:

1. Press the 'Cancel' link to return to the EudraCT Welcome page, request a new security code and then start the request for the EudraCT Number again.

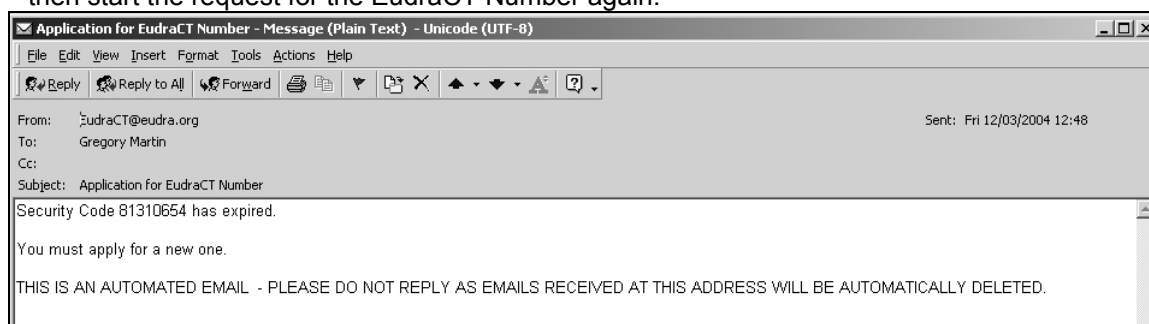


Fig 17. Expired security code e-mail

6.3.7 Using a security code more than once

Security codes are only valid for one EudraCT Number request. If the security code is used more than once then the following error will be received when the 'Get EudraCT Number' link is taken.

- **The security code has already been used in a request for a EudraCT number. Please check the security code, and if necessary, request a new one. An e-mail has been sent to <e-mail address> with this information.**

Fig 16. Duplicate security code error message

An e-mail will be sent to the e-mail address on the EudraCT Number request form so that there is a positive record that a EudraCT number has not been issued for the request.

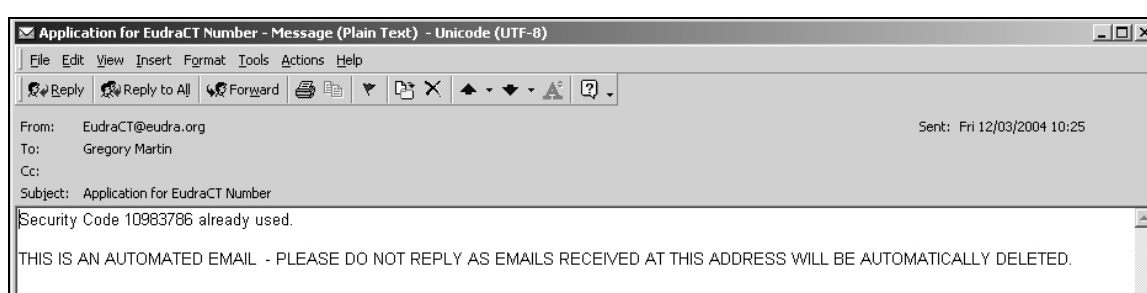


Fig 17. Duplicate security code e-mail

To correct this error:

1. Take the 'Cancel' link on the 'Get EudraCT Number' page to return to the 'EudraCT Welcome' screen and request a new security code to be used in a new EudraCT Number request.

6.3.8 Using incorrect navigation keys

The standard internet browser keys should not be used to find forms that have been already been submitted. If a page that has been submitted once is submitted a second time then the following error message will appear.

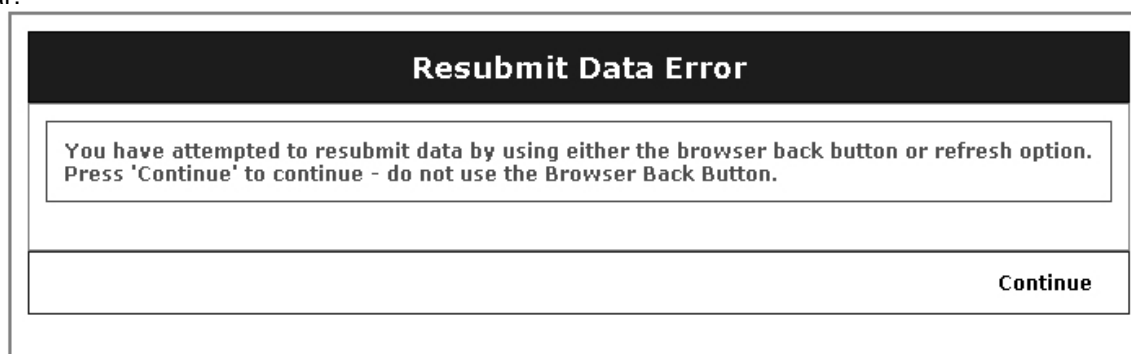


Fig 15. Resubmit Data Error Screen

This error is corrected by taking the 'Continue' link which returns to the 'EudraCT Welcome' screen. From here the appropriate link can be used to obtain a security code.

If the browser back key is used to find an earlier screen used to submit a request for a EudraCT, then on the resubmit of the screen there is likely to be additional revalidation of the submitted data which may result in duplicate Sponsor's Protocol Code Number warnings which should be dealt with in accordance with section 6.3.4 'Duplicate Sponsor's Protocol Code Number'

6.3.9 Unexplained processing errors

There are situations that may cause the application to fail that are out of the control of the application environment. When such a situation occurs the 'error' screen will be displayed. Press the 'OK' link to return to the EudraCT Welcome screen. To prevent further errors it advisable to exit your internet browser, restart it and re-enter the EudraCT system from the main link on the Eudra home page. (See section 4.1 Access to the EudraCT System)

Such errors should be reported to the system administrators by e-mail, using the 'contact' link on the EudraCT Welcome screen

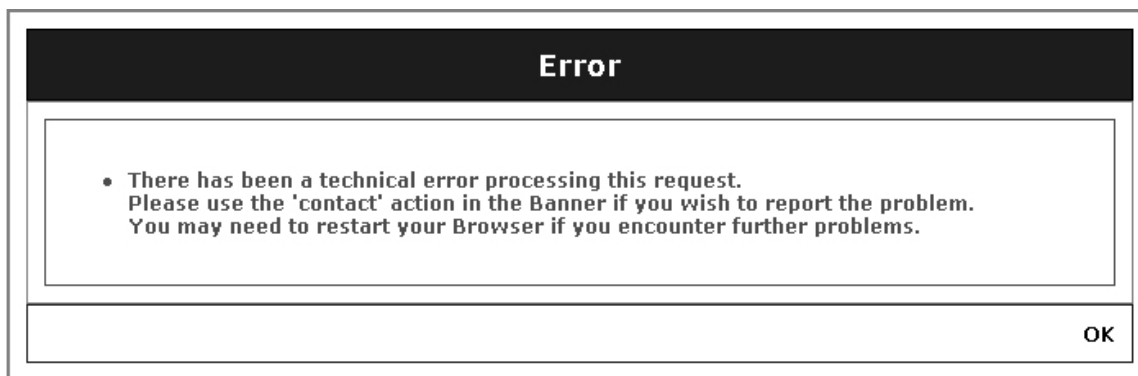


Fig 16. EudraCT Technical Error Processing screen

7 GLOSSARY OF TERMS

MSCA	Member State Competent Authority
MS	Member State
XML	The data format of the saved CT Application Form information
EC	Ethics Committee

8 SUMMARY OF SYSTEM ERROR MESSAGES

Message	Screen	Correction	Ref.
Requestor name is required	Get Security Code	Enter correct information or cancel	5.3.1
Requestor e-mail is required	Get Security Code	Enter correct information or cancel	5.3.1
You have entered an invalid Requestor's e-mail Address	Get Security Code and Get EudraCT Number	Enter correct information or cancel	5.3.2 6.3.2
You have attempted to resubmit data by using either the browser back button or refresh option	Get Security Code Get EudraCT Number	Press 'Continue' - do not use the Browser Back Button.	5.3.4 6.3.8
There has been a technical error processing this request.	Get security code and Get EudraCT Number	Press 'OK' and restart your Browser.	5.3.5 6.3.9
The Requestor's organisation town/city is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The Requestor's organisation country is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The Sponsor's Protocol Code Number is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The Requestor name is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The E-mail to which the EudraCT number will be sent is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The Security Code is required	Get EudraCT number	Enter the required mandatory information	6.3.1
The Security Code entered must be 8 digits	Get EudraCT number	An incorrect security code has been used. Check the security code provided from the e-mail and request a new code if required.	6.3.5
Unable to find security code	Get EudraCT number	An incorrect security code has been used. Check the security code provided from the e-mail and request a new code if required.	6.3.5

Message	Screen	Correction	Ref.
Eudract Number has already been issued for Protocol Code Number <Protocol Code Number>. Are you sure that you wish to proceed to generate another EudraCT Number? It is likely that a EudraCT Number has already been issued to another individual within your organisation or another collaborator on this trial. Please Check whether you have duplicated this EudraCT number request for your clinical trial. If you are absolutely sure that you wish to continue, then click the “Get EudraCT Number” button below otherwise click the “Cancel” button.	Get EudraCT number	Follow the screen instructions.	6.3.4
The security code has already been used in a request for a EudraCT number. Please check the security code, and if necessary, request a new one. An e-mail has been sent to <e-mail address> with this information.	Get EudraCT number	Follow the screen instructions	6.3.7
The security code has expired. An e-mail has been sent to <e-mail address> with this information.	Get EudraCT number	Obtain a new security code and make a new request for a EudraCT number	6.3.6