EUDRACT V7.0 USER MANUAL (PUBLIC WEBSITE)

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CONTENTS

1 About this document

This document describes the public website used to make an application for a Clinical Trial. It describes how the system can be used to obtain a EudraCT number and complete the Clinical Trial (CT) application form. This document does not describe the underlying business processes required by the Sponsor or Requestor to manage the request for the EudraCT number nor does it attempt to explain the CT process itself.

2 System Overview

2.1 General

The system is divided into two basic parts.

The first part provides the facilities for obtaining a EudraCT number for a Clinical Trial Application. This is a two-step process that first requires that a security code reference be obtained as a means of validating the EudraCT number request. The second step 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. The EudraCT number is used as the unique reference to a clinical trial on the CT application form.

The second, major part of the EudraCT system is based on a set of web pages that collect the information required to complete the CT application, save the data to disc, print paper copies for the National Competent Authorities (NCA) and Ethics Committees (EC) and then make an electronic copy for despatch to the NCA. There are also facilities to download forms for "The Request for Authorisation of a Substantial Amendment to a Clinical Trial" and for the "Declaration of the End of a Clinical Trial".

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, EudraCT number and the data required for a CT Application Form.

The system has been designed to be as flexible as possible in order to meet the varying requirements of each Member State. For this reason there are very few mandatory data items, so it is necessary for all users to carefully check the printed CT Application Form for data consistency.

2.1.2 Saving and Printing

For obtaining a security code or EudraCT number, 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.

The CT Application form is saved locally as an XML file and can be printed as the application to the NCA or as the application to the Ethics Committee.

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. The system has been tested to be compatible with Netscape and Mozilla (including Firefox) browsers. Mac users cannot use Internet Explorer, and it is recommended that they use Apple's own Safari web browser.

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.

3.1.4   For printing the application forms

The application forms require that Adobe Acrobat reader be installed on the PC. This is freely available from Adobe and can be downloaded from their site www.adobe.com or through a link on the EudraCT documentation page.

3.2 Data Entry Formats

Also refer to section 7.2 Data Conventions when Completing the CT Application Form.

3.2.1   General Concepts

The forms use only a small range of data entry types. These are:
Simple text box
Scrolling text box
Radio Buttons (Y/N)
Check Boxes
Drop-down lists
Dates

3.2.2   Data Validation

- **Simple text box**
   The length of the data entered is verified on the web screen as the information is entered and it is not possible to add more than the specified amount.
   If the text box is set to collect numeric information then this will be verified when the '**Continue**' button is selected and a warning given if non-numeric information is included.
   If the text box is for an e-mail address, then in most cases the entry will be checked for the inclusion of the '@' sign and when the '**Continue**' button is selected, a warning given if it is not present.
- **Scrolling text box**
   Text boxes that will allow large amounts of text (say greater than 100 Characters) are implemented as scrolling text boxes.
   If more information is entered than is specified for the text box then this will be verified when the '**Continue**' button is selected and a warning given.

Note: If long continuous lines of characters are entered that are wider than a normal page without spaces or hyphens then the system will not 'wrap' this text within the margins of the printed PDF documents and the information will run off the printed page. Include spaces or hyphens to prevent this happening.

- **Radio buttons (Y/N)**

  These are set as a pair of 'buttons' which can be set as either 'Yes' or 'No'. When a new form is entered the pair of buttons will have neither option selected. If either button is selected, then it **will not be possible to return to this original state,** but since the buttons can only be either 'Yes' or 'No', if a button is selected incorrectly, then answer the question in the most appropriate way.

- **Check boxes**

  This is a single box which is initially set to 'false' (unchecked) and which can be set to 'true' when it is checked.

- **Drop-down lists**

  Drop-down lists with pre-determined items from which to select are used where the there is a limited number of correct responses to the questions.

  In one situation (routes of administration) a multiple selection list is used.

- **Dates**

  All dates are entered in the format 'yyyy-mm-dd'. If this format is not used or if an incorrect date is entered then this will be verified when the '**Continue**' button is selected and a warning given.

  There are no other checks to cover whether a date should logically be in the past or the future. That is left to the user.

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:

www.emea.europa.eu

On this page, click the link "EudraCT Website" to link to the EudraCT Home Page (highlighted below):

4.2 The EudraCT Home Page

Fig. 1 – EudraCT Home Page

The EudraCT Home page has the following links.

Access to EudraCT Application
This is the link to the EudraCT system. Click here for the EudraCT Welcome Page.

Access to EudraCT supporting documentation
Click here for links to the CT Directive 2001/20/EC and subsidiary guidance documentation

Frequently Asked Questions
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
eudract@emea.europa.eu

4.3 The EudraCT Welcome Page

The main index to the EudraCT system:

Welcome to EudraCT

For further assistance on use of the system and completion of the form, refer to 'Help' and 'FAQ' in the Banner above.

EudraCT Number:
You need a EudraCT number in order to provide a unique reference for clinical trials in one, or more, of the following circumstances. It is emphasized that one individual clinical trial should be identified by one unique EudraCT number:
- There is at least one investigator site in the Community.
  - The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) (it may involve sites in the Community, in third country(ies) or both).
  - The clinical trial is one of those for which information has to be submitted in accordance with article 45 of Regulation (EC) No. 1901/2006 as amended :
    - Article 45(1): "By 26 January 2008, any paediatric studies already completed, by the date of entry into force, in respect of products authorised in the Community shall be submitted by the marketing authorisation holder for assessment to the competent authority."
  - The clinical trial is one of those for which information has to be submitted in accordance with article 46 of Regulation (EC) No. 1901/2006 as amended:
    - Article 46(1): "Any other marketing authorisation holder-sponsored studies which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within six months of completion of the studies concerned."

The EudraCT Number must be included on all Clinical Trial applications within the Community and as needed on other documents relating to the trials (e.g. SUSAR reports, PIP).

Steps 1 and 2 below access the forms that must be submitted in order to obtain a EudraCT Number.

EudraCT Number Step 1
The first stage in the process is to obtain an authenticated security code. This security code will be sent to the e-mail address specified by you, the requestor, on the form, and is needed in order to complete the EudraCT Number request. The security code is valid for one EudraCT Number only and expires after 24 hours.
Apply for Security Code

EudraCT Number Step 2
This is the main EudraCT Number request that allows the requestor to obtain a EudraCT Number that will provide the unique reference for the Clinical Trial. The EudraCT number will be sent to the e-mail address specified by you, the requestor, on the form.
Apply for EudraCT Number

Create New Clinical Trial Application
Once you have the EudraCT Number and wish to enter Clinical Trial Application details please use this link.
Click here to create a new Clinical Trial Application

Load Saved Clinical Trial Application
If you have saved the Clinical Trial Application to disk and wish to load the details please use this link.
Click here to load a saved Clinical Trial Application

Download CT Amendment Form
If you would like an Amendment Form for your Application please use this link.
Download CT Amendment Form

Download CT End of Trial Form
If you would like an End of Trial Form for your Application please use this link.
Download CT End of Trial Form

Return to EudraCT Home Page

Fig. 2 – EudraCT Welcome Page

The EudraCT Welcome page contains the following links into the EudraCT system.

Apply for Security Code
If you require a security code in order to apply for a new EudraCT number, click this link.

Apply for EudraCT number
Once you have the security code and wish to obtain a EudraCT number, click this link.

Click here to Create New Clinical Trial Application
Click to open the main CT Application Menu.

Click here to Load Saved Clinical Trial Application
Click to re-load a saved XML file or resume work on a CT Application in the PC memory.

Download CT Amendment Form
Click here to download a Microsoft Word form template to request a substantial amendment to a CT.

Download CT End of Trial Form
Click here to download a Microsoft Word form template for a declaration of the end of a CT.

Return to EudraCT Home Page
Click here to return to EudraCT home page.

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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 is valid for 24 hours from the time it is sent and can be used for only one request for a EudraCT number.
- It is recommended that you request security codes on the day of the EudraCT number request that they are required for.

5.2   Navigating the EudraCT Number System

There are certain navigation principles applied to the system for obtaining a EudraCT number. In particular:

- The navigation buttons in the browser tool bar itself (forward and back) should **NOT** be used
- Only the navigation buttons within the EudraCT screens should be used

The following Navigation keys are used in this part of the system:

Cancel
This link clears 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 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 return you to the EudraCT Welcome page

5.3   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: 'Apply for Security Code'.

   The following screen appears:

Fig. 3 – Get Security Code Screen

2. Complete the fields, both of which are mandatory.
   The e-mail address should be accurate so that the e-mail containing 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.).

Fig. 4 – 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 5.4.2 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 is sent to the e-mail address used in the request form.

6. Open the e-mail account used on the request from 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.
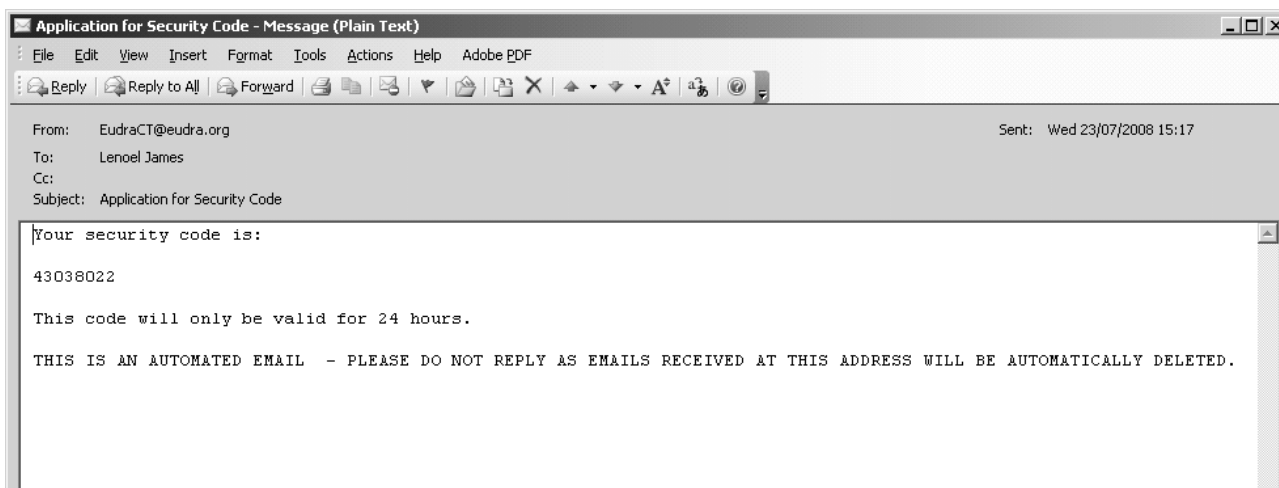
Fig. 5 – Security Code e-mail

8. Keep the e-mail containing the security code for use in your request for a EudraCT number. The security code may be copied and pasted from the e-mail into the EudraCT number request form.

5.4 Problems that may be encountered

5.4.1 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 appears 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, use 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 use 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. 6 – 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.

5.4.2   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.
Note: The system does not check that an e-mail address is live. Simply that the syntax is correct (e.g. somebody@generic.org.uk).

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

Fig. 7 – 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 by e-mail.
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.

5.4.3   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 arrived 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, it will not arrive in your inbox and the e-mail from the EudraCT system will be returned to EudraCT as 'undeliverable'. You should 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 inbox. 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.
   Note: If you have not received the security code within 15 minutes, it is recommended that you request another, ensuring that the e-mail address you supply is correct.

5.4.4 Using incorrect navigation keys

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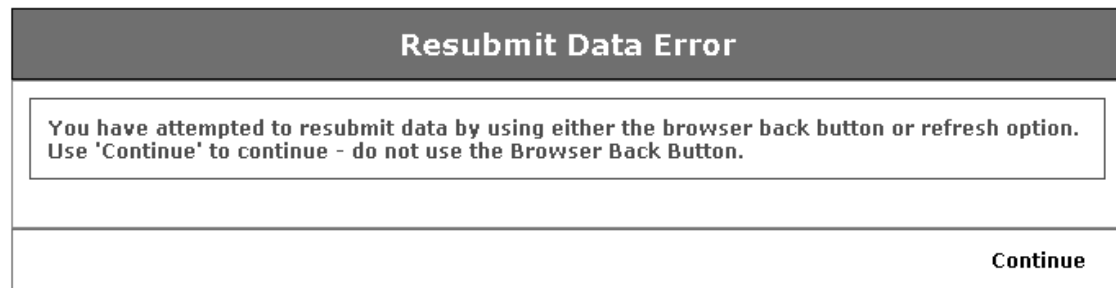
Resubmit Data Error

> You have attempted to resubmit data by using either the browser back button or refresh option. Use 'Continue' to continue - do not use the Browser Back Button.

Continue

Fig. 8 – Resubmit Data Error Screen

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

5.4.5 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 appears. Press the 'OK' link to return to the EudraCT Welcome screen. To prevent further errors you should close the Internet browser, restart it and re-enter the EudraCT system from the main link on the EMEA 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.
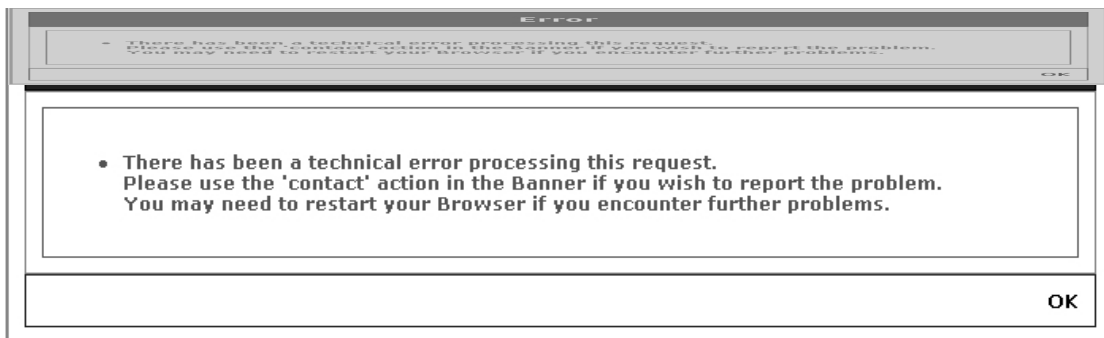
Error

OK

> • There has been a technical error processing this request.
>   Please use the 'contact' action in the Banner if you wish to report the problem.
>   You may need to restart your Browser if you encounter further problems.

OK

Fig. 9 – 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 application. A EudraCT number is needed in order to make a successful Clinical Trial Application within 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.

> **Note:** If you have not yet requested a security number, you should do this before you attempt to request a EudraCT number.

6.2   The Process for Obtaining a EudraCT Number

To obtain a EudraCT number:
1. From the EudraCT Welcome Screen take the link:
   'Apply for EudraCT number'
   The following screen appears

Fig. 10 – Get EudraCT Number screen

2. The requestor now completes all the mandatory fields which are marked with (*).
   - "**Requestor's organisation name**". Include the name of the organisation that the requestor works for in this field.
     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. However, 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 and is not generated by the system. If you are unsure what this value is, you should contact the Sponsor. It should be entered in the normal format used by the requestor's organisation. This is a mandatory field.
   Note: The sponsor's Protocol Code Number field cannot contain blank spaces.
   - "**Requestor name(*)**". Enter your name. This is a mandatory field.
   - "**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. This is a mandatory field.
   - "**Enter the security code sent earlier (*)**". Enter the EudraCT security code obtained by using the 'Get Security Code' link. It may be found in the "Application for Security Code" e-mail you should have received. This security code must not have been used on another application and it should be used within 24 hours, or a new security code must be requested. This is a mandatory field.
   - "**Is it anticipated that this EudraCT Number will be used for a Clinical Trial contained in a Paediatric Investigation Plan (PIP)? (*)**" This is a mandatory field.
   - "**Is it anticipated that this EudraCT number will be used for a Clinical Trial conducted in a third country (outside of the EU/EEA). (*)**" This is a mandatory field.
   Note: A third country is any country outside the European Economic Area (EEA). The EEA contains member states of the EU, plus Iceland, Liechtenstein and Norway.
   - "Please select the Member States where it is anticipated that the trial will be run". This is not mandatory information (unless it relates to the above question), but completion will provide some advanced indication of likely Clinical Trial applications in each Member State. The Member States selected should be the best available information at the time the EudraCT number is requested. This might change, but if it does 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 appears. The e-mail will arrive shortly afterwards (depending on the speed of your local e-mail servers).

Fig. 11 - 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 5.4.2 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

with the subject:

Application for EudraCT Number

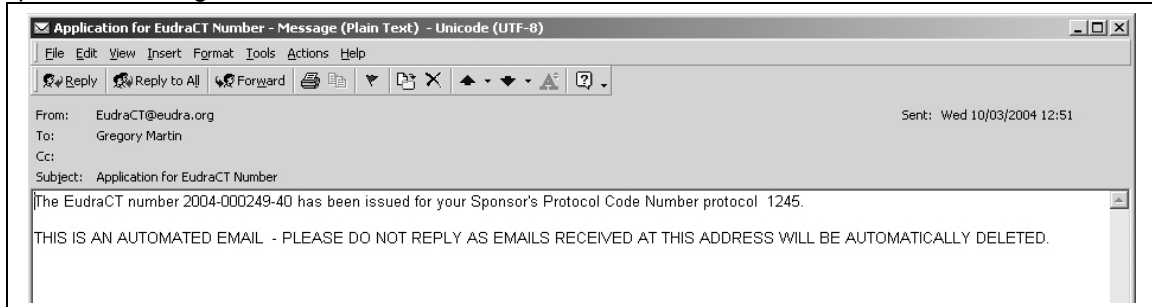7. Open the message to obtain the EudraCT Number.

Fig. 12 – EudraCT Number e-mail

This e-mail also includes the Sponsor Protocol Code Number, you supplied previously for this request.

8. Save this e-mail. It is the 'Receipt of confirmation of EudraCT Number' document and is one of the supporting documents that must be included in the request for the Clinical Trial.
Note: This list of supporting documents is described in Section J of the CT Application Form "Check List of the Information Appended to the Application Form'' (Refer to section 8.4.2 of Section J. Check List of the Information Appended to the Application Form, which can be found under the Forms heading on the EudraCT Supporting documentation page).

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 appears 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.

Fig. 13 – 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 EudraCT Number' link to obtain a EudraCT number.
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

If an e-mail address with an incorrect format is entered, the following error message appears on the screen when the 'Get Security Code' link is pressed.

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

Fig. 14 – 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 EudraCT Number' link to obtain a EudraCT number.
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.

6.3.3   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) arrived 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 EudraCT number or request a new EudraCT number 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 submitted Sponsor's Protocol Code Number already exists, in which case the following warning message appears when the 'Get EudraCT Number' link is taken.

> • **A EudraCT number has already been issued for Protocol Code Number Prot-123-2005. 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. 15. – Duplicate Sponsors Protocol Code Message

If different sponsors *do* use the same Protocol Code Numbers for their trials, then 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.

N.B It is recommended that Requestors should exit the system and check for a previously issued EudraCT number before continuing.

To deal with this warning either:
1. Press the 'cancel' button which will return to the 'Welcome to EudraCT' screen and check within the organisation or amongst collaborating colleagues whether the EudraCT number for the Clinical Trial has already been requested **(This is the recommended action)**.
2. If an error has been made in the Sponsor's protocol Code Number entered then 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.
3. 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.
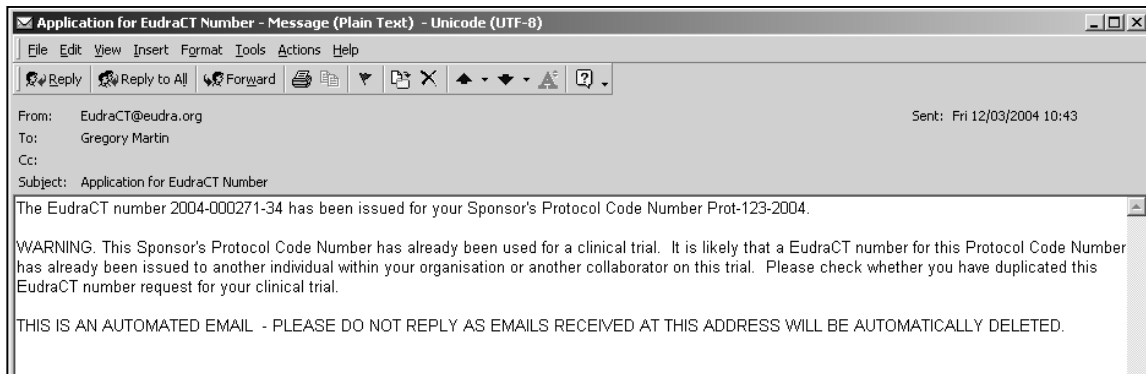
Fig. 16 – Duplicate Sponsors Protocol Code

6.3.5 Using an invalid security code

If the security code is of the wrong format (typically the wrong length) or is a code that has not been issued by the system then either of 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. 17 – 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

Security codes are only valid for 24 hours after they have been issued. 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. 18 – 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.
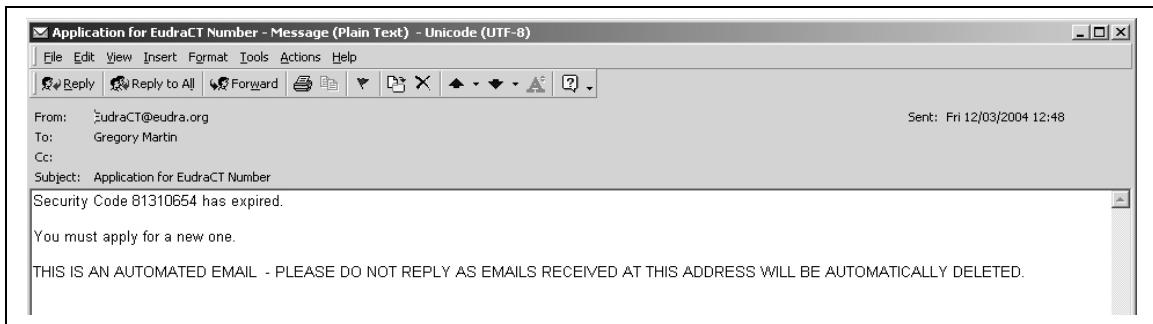
Fig. 19 – Expired security code e-mail

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.

Fig. 20 – 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.
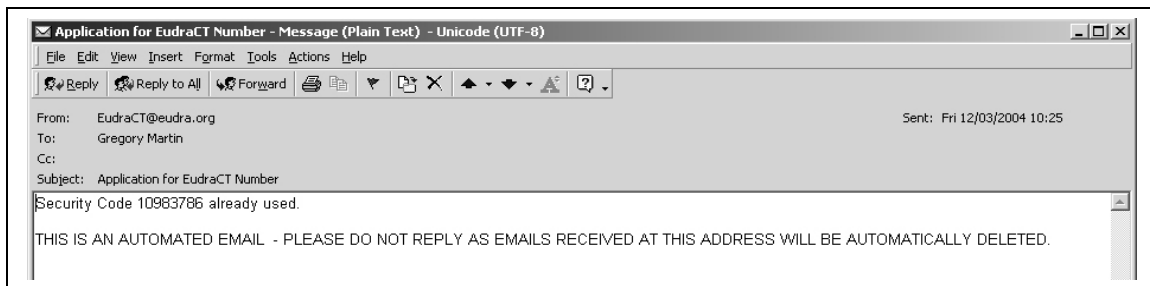
Fig. 21 – Duplicate security code e-mail

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   Third Country involvement in a Clinical Trial

Fig. 20 –CT third country involvement security code error message

The above error message attempts to explain that the field required is the following field in the previous screen:

Is it anticipated that this EudraCT Number will be used for a Clinical Trial conducted in a third country (outside of the EU/EEA)? (*)   ○ Yes ○ No

To correct this error:
- Ensure that the correct radio button option (either 'Yes' or 'No') is selected before you click 'Get EudraCT number'.

6.3.9 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:

Resubmit Data Error

You have attempted to resubmit data by using either the browser back button or refresh option. Use 'Continue' to continue - do not use the Browser Back Button.
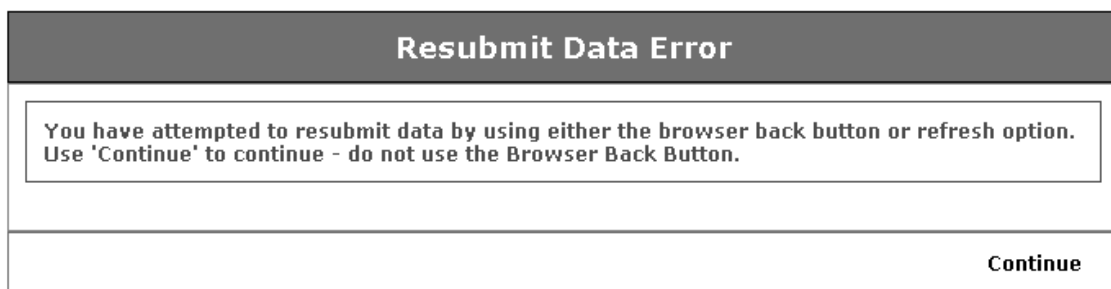
Continue

Fig. 22 – 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 number, 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'

6.3.10 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 appears. Press the 'OK' link to return to the EudraCT Welcome screen. To prevent further errors exit your Internet browser, restart it and re-enter the EudraCT system from the main link on the EMEA 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
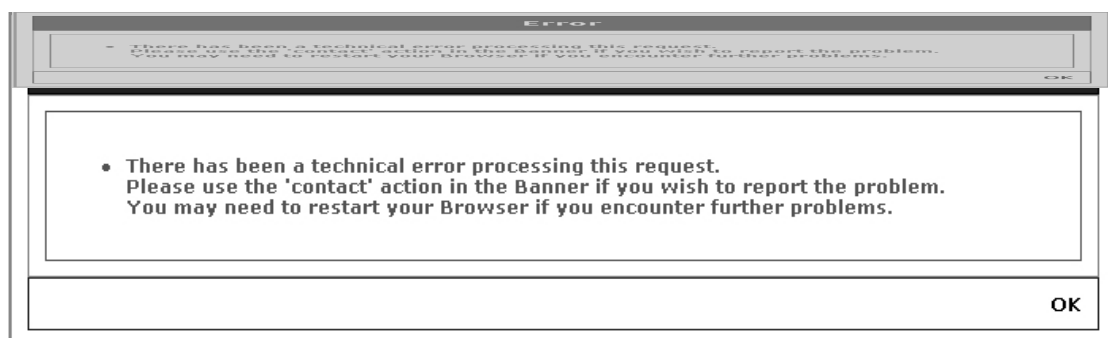
Error

- There has been a technical error processing this request.
  Please use the 'contact' action in the Banner if you wish to report the problem.
  You may need to restart your Browser if you encounter further problems.

OK

Fig. 23 – EudraCT Technical Error Processing screen

7 COMPLETING THE CT APPLICATION FORM

7.1 Introduction

This section of the document describes the system for completing an electronic version of the Clinical Trial Application form (CT Application Form) that is used in all Member States of the Community. The CT Application Form system is designed to use Internet web pages to collect the CT information. The system is designed with maximum flexibility and although this section will assume that each section is completed in order, this is not necessary. An application can be completed in several sessions, adding, changing or deleting information as required until the final application form has all the required information.

The final application form can then be printed in a version for the National Competent Authority and in a version for submission to the Ethics Committee.

The electronic version of the CT Application form can be saved and submitted with the paper application. This electronic version will be in XML format and can be saved with all the CT information or a subset referred to as the 'Core Data Set'. The electronic version should be submitted to the National Competent Authority with the paper version so that the NCA can include the CT information into the Central EudraCT database without any necessity to re-key the information.

7.2 Data Conventions when Completing the CT Application Form

The on-line web pages used to collect the CT Application form data use a variety of screen elements. These are:

Element	Entry Method	Verification
Single line free text fields	Type into these fields up to the maximum allowed characters. Can copy / paste from other applications or electronic documents.	Entry restricted to the maximum length on input.
Multi-line free text fields	Type in these fields up to the maximum allowed characters. Can copy / paste from other applications or documents.	Entry is not restricted at input but a warning is sent when the form is saved and the data length must be reduced.
Dates	Enter the date in the sequence year, month, day in the format YYYY-MM-DD	Valid date format checked when the form is saved
Radio buttons	The 'Yes' 'No' radio buttons operate in pairs. Except in section C.1.5 of the application form, no radio button is selected when a page is first entered, but make a selection either 'Yes' or 'No' by clicking each radio button. Once a selection has been made it is not possible to unselect both buttons.	No validation
Check boxes	Select a required check box by clicking on it and deselect a box by clicking it again. No check box is selected when a page is first entered.	No validation
Drop-down lists	Select the appropriate item from the drop-down lists. Lists will show a blank entry when the page is first entered.	No validation
Combination lists	Used only for routes of administration. Select items required and move from the list headed 'Select to add' to the 'Routes of Administration for this IMP' list. Changes can be made by moving items on the 'Routes of Administration for this IMP' list back again.	No validation

7.3 Saving the CT Application

It is most important that all users of this application understand the meaning of the 'Continue' button on the web pages. Pressing this button only saves data temporarily in the webpage. This is NOT a permanent record and will be lost if the Internet browser is closed, times out or the Internet connection is broken.
It is important to realise that the information entered into the web pages is held in the computer memory and MUST be saved locally to preserve the work. It is therefore good practice to create an XML file on the local PC or network and save the CT application frequently to ensure that work is not lost (See section 7.5.4 Save as XML).

The system has a 'time-out' facility, which will end any session if there is no activity for 30 minutes. Any work not saved when the system times out will be lost.

7.4 Navigating the CT Application System

7.4.1 Navigating the CT Application Form

Navigation through the CT Application Form must be done by following the navigation buttons on the screens. The sections of the CT Application Form are accessed via the Clinical Trial Application Menu, which provides the main navigation through the system. These sections may be selected in any sequence in order to complete the CT Application form and at any time a section can be saved (within the browser) and then returned to at a later date to add additional information as it becomes available or to edit existing data.

Fig. 24 – Clinical Trial Application Menu

The CT Application Menu includes the following links:

Sections 'A' to 'H'

Links to the web pages designed to collect the CT information for each section of the CT Application form.

Save as XML

This allows the contents of the current CT Application to be saved on a local drive or network as an XML file. **This is the only way of saving a permanent electronic version of the CT Application**.

Get Printable Copy

This allows for the contents of the current CT Application to be printed for submission to either the NCA or Ethics Committee.

Validate XML

This runs a data consistency check on the current application data and reports inconsistencies.

Compare XML

This feature runs a detailed comparison of CTA XML files, enabling differences between files to be identified at the lowest level of granularity within the system.

Prepare Submission Package

This feature automatically creates submission packages for NCAs or IECs, containing 3 files: the Clinical Trial Application XML file, a PDF rendition of the data that is included in the XML file and a PDF of the Validation Report for the XML file.

Section J

Section 'J' is the "Check List of The Information Appended to the Application Form" and can be downloaded as a MS Word form template.

Update XML File Identifier

This feature enables you to update the XML File Identifier, which issues the CTA, as it stands, a unique ID.
Note: When the Validate XML tool and the Prepare Submission Package options are used, the XML File Identifiers are automatically updated within the files themselves. However, to align the onscreen display with the XML and PDF renditions, users may wish to use the 'Update XML File Identifier' option.

Welcome Page

This returns to the EudraCT Home Page (See Fig. 1).

7.4.2 Navigating the Individual Web Pages

The navigation through the individual pages should be by using the on screen navigation buttons. **Do not use the standard Internet browser buttons.** This will cause errors and lost data. The navigation buttons within the pages of the CT Application form system are shown below.

Continue

This saves the contents of the current webpage, but **does NOT make a permanent electronic version**. Using the 'Save as XML' option to produce a permanent electronic version.

Cancel

This button clears the current web page and returns to the CT Application Menu Page.

Next

Multi-page forms have this button to navigate to the next page.

Application Menu Page

This is a direct link back to the 'Clinical Trial Application Menu' page (See Fig. 24).

7.5 The Process for Creating a New CT Application

7.5.1 Accessing the CT Application Menu

1. From the EudraCT homepage (Fig. 1) take the link "Access to EudraCT Application". This opens the EudraCT Welcome page:

Welcome to EudraCT

For further assistance on use of the system and completion of the form, refer to 'Help' and 'FAQ' in the Banner above.

EudraCT Number:
You need a EudraCT number in order to provide a unique reference for clinical trials in one, or more, of the following circumstances. It is emphasized that one individual clinical trial should be identified by one unique EudraCT number:
- There is at least one investigator site in the Community.
- The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) (it may involve sites in the Community, in third country(ies) or both).
- The clinical trial is one of those for which information has to be submitted in accordance with article 45 of Regulation (EC) No. 1901/2006 as amended :
    Article 45(1): "By 26 January 2008, any paediatric studies already completed, by the date of entry into force, in respect of products authorised in the Community shall be submitted by the marketing authorisation holder for assessment to the competent authority."
- The clinical trial is one of those for which information has to be submitted in accordance with article 46 of Regulation (EC) No. 1901/2006 as amended:
    Article 46(1): "Any other marketing authorisation holder-sponsored studies which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within six months of completion of the studies concerned."

The EudraCT Number must be included on all Clinical Trial applications within the Community and as needed on other documents relating to the trials (e.g. SUSAR reports, PIP).

Steps 1 and 2 below access the forms that must be submitted in order to obtain a EudraCT Number.

EudraCT Number Step 1
The first stage in the process is to obtain an authenticated security code. This security code will be sent to the e-mail address specified by you, the requestor, on the form, and is needed in order to complete the EudraCT Number request. The security code is valid for one EudraCT Number only and expires after 24 hours.
Apply for Security Code *a*

EudraCT Number Step 2
This is the main EudraCT Number request that allows the requestor to obtain a EudraCT Number that will provide the unique reference for the Clinical Trial. The EudraCT number will be sent to the e-mail address specified by you, the requestor, on the form.
Apply for EudraCT Number *b*

Create New Clinical Trial Application
Once you have the EudraCT Number and wish to enter Clinical Trial Application details please use this link.
Click here to create a new Clinical Trial Application

Load Saved Clinical Trial Application
If you have saved the Clinical Trial Application to disk and wish to load the details please use this link.
Click here to load a saved Clinical Trial Application

Download CT Amendment Form
If you would like an Amendment Form for your Application please use this link.
Download CT Amendment Form

Download CT End of Trial Form
If you would like an End of Trial Form for your Application please use this link.
Download CT End of Trial Form

Return to EudraCT Home Page

2. Click 'Apply for Security Code' (*a*) and then enter your Name and work email address.
3. An email containing the Security Code is sent to you. Retrieve the Security Code from your email client and then click 'Apply for EudraCT Number' (*b*).
4. Once the details have been completed as outlined in the Get EudraCT Number screen, an email containing your EudraCT number will be sent to your designated email client's inbox.
5. From the EudraCT Welcome Page (Fig. 2) take the link 'Click here to create New Clinical Trial Application' and the 'Initial Required Information' screen appears:

Initial Required Information

This allows you to specify the initial required information for your Clinical Trial Application.
Enter the EudraCT Number obtained for this protocol and the National Competent Authority, and use 'Continue', which will then take you to the main Clinical Trial Application menu.
If you want to create a general set of data for a multi-state trial, you can leave the 'Authority' field blank at this stage.

National Competent Authority   UK - MHRA

EudraCT Number   TEST-000529-24

Continue   Cancel

Fig. 25 – CT Initial Required Information

Note: If a CT Application has already been started then the link "Create New Clinical Trial Application" provides the option to "Create New Application" or to "Use Current Application". **If a new application is started then the current application (which is only in the computer memory) will be lost unless it has been saved as a local XML file** (See section 8.2 Saving the CT Application). If the link "Use Current Application" is taken then the 'Clinical Trial Application Menu' appears displaying the current CT Application you are working on.

6. Enter the EudraCT number in this screen obtained from the system, via e-mail (subject: Application for EudraCT Number), and select the National Competent Authority to whom the application is to be made from the drop-down list. The entry of a National Competent Authority is not mandatory at this point and this feature allows for a template CT Application Form to be generated if required (See section 12 Using the CT Application Form as a Template.).

7. Click on the '**Continue**' link and the 'Clinical Trial Application Menu' appears (See Fig. 24).

7.5.2   Starting the CT Application

From the CT Application Menu the information required for making the CT Application is entered section by section. The application has a 'Timeout' feature after a five minute period of inactivity within the browser window. This could cause loss of data entry. For this reason it is recommended users click the 'Save as XML' link if they plan to leave their CT application for any period of time.

7.5.3   Section A. – Trial Identification.

1. The heading on this page shows the EudraCT number of this application and the NCA entered in the 'Initial Required Information' screen. The Sponsor's Protocol Code Number will be updated based on the entries in the 'Trial Identification' screen if the screen is refreshed following input.
)
2. Complete the information on the form. The EudraCT number cannot be changed, but all other data fields are available for input. It is even possible to change the NCA at this stage so that a copy of this application could be sent to the group of NCAs in whose MS the trial will run (See section 12 Using the CT Application Form as a Template.).

3. Click the '**Continue**' button to return to the CT Application Menu, saving the information you have entered in Section A. Note that if you are not going to complete the CT application in one go, you are advised to save your progress using the 'Save as XML' option at the bottom of the Clinical Trial Application Menu.

Fig. 26 – A. Trial Identification

7.5.4 Save as XML

At this point it is advisable to create an XML file so that an electronic version of the information to be entered can be permanently preserved.

1. Click the link 'Save as XML' on the CT Application Menu. The following dialogue box opens:

Save as XML

EudraCT Number : TEST-000529-24
Sponsor's Protocol Code Number : 23232323j
National Competent Authority : UK - MHRA

You can choose to save all the data as XML, or just the Core Dataset. It is suggested that the 'Full XML' option is chosen as this incorporates the Core Dataset.
NOTE: These options download the XML into a new Browser window. You then need to use File/ Save As in the new Browser window to store the XML on disk. It is suggested the file is named with a '.xml' extension.

NOTE: Please ensure that you have validated the application form prior to the final saving of the XML file.

Save Full XML
Save Core Dataset XML

Continue

Fig. 27 – Save as XML

2. Click on the link 'Save Full XML'.
    The 'File Download' dialogue box appears. Ensure that you click 'Save' (or choose the 'Save to Disc' option) to save the file to disk.

File Download

Some files can harm your computer. If the file information below looks suspicious, or you do not fully trust the source, do not open or save this file.

File name: FullData.xml

File type: XML Document

From: eudract1.emea.eu.int

Would you like to open the file or save it to your computer?

Open   Save   Cancel   More Info

☑ Always ask before opening this type of file
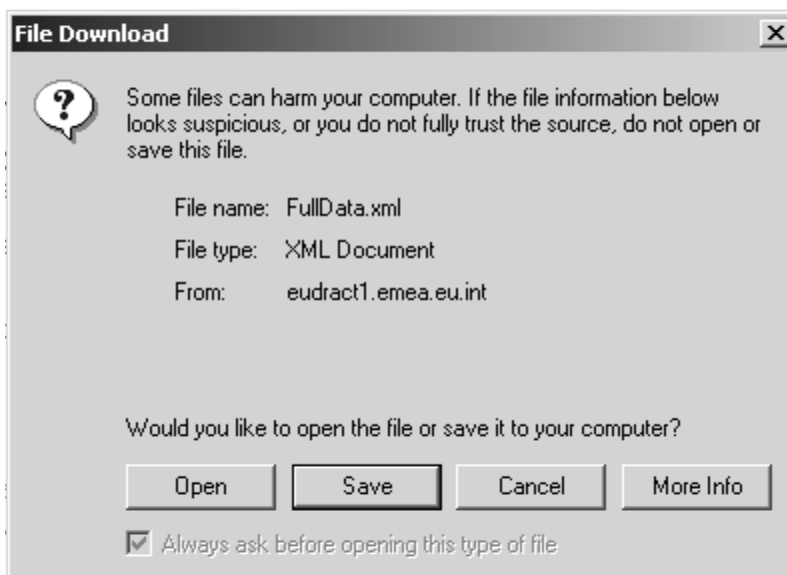
Fig. 28 – Saving the XML file –Internet Explorer 'File Download' Dialogue.

3. The 'Save as' dialogue box appears.
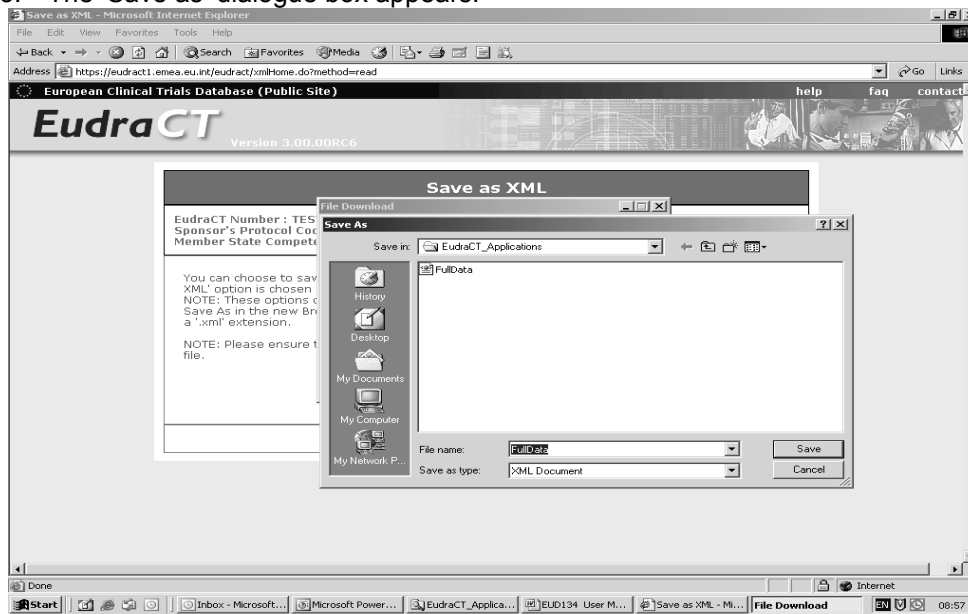
Fig. 29 – Saving the XML file – 'Save As' Dialogue (Internet Explorer)

Note: If you are using a browser other than Internet Explorer, check your browser preferences for the location where downloads are saved to.

4. Select an appropriate filename and folder and save the file. Resave the XML file to this same filename and folder as you continue completing the CT application form to ensure that there is a permanent record of the CT application form. In that case when the warning that the file already exists appears select 'Yes' to replace the existing file with the new updated version.
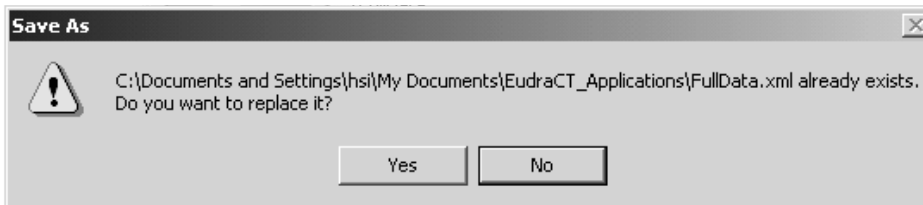
Fig. 30 – Saving the XML file – 'Save As' Warning

5. Click '**Continue**' to return to the Clinical Trial Application Menu page.

7.5.5 Section B. – Sponsor Identification

1. When the link 'B. Sponsor Identification' is clicked the Sponsor Identification Index screen is displayed. For a new CT Application this will show that there are no sponsors.

Fig. 31 – B. Sponsor Identification Index – No entries.

2. Click the link to 'add sponsor' and the Sponsor Identification details screen appears.

B.1 and B.3 Sponsor Identification Details

EudraCT Number : TEST-000429-25
Sponsor's Protocol Code Number : CODE A-B/C TEST
National Competent Authority : UK - MHRA
Reference ID : SP3

These are the details for section B.1 and B.3 Sponsor Identification Details. Enter details, and use 'Continue'.

B.1.1 Name of organisation ▲ — EMEA - EUROPEAN MEDICINE A

B.1.2 Contact person - Given name — John
Also known as first name or forename.

Middle name — George
The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth".

Family name — Smith
Also known as Surname.
Use this field to record a functional role.

B.1.3 Street address — 7 WESTFERRY CRESCENT ROAD

Town/ city ▲ — CANARY WHARF

Post code — E15 E8H

Country ▲ — UNITED KINGDOM

B.1.4 Telephone number — 0207 418 8424

B.1.5 Fax number — 0207 418 8669

B.1.6 E-mail address — KEMI.OYEFESO@EXT.EMEA.EUR

For section B.2, first complete B.3 below then select 'Continue' and then add a legal representative if required by Article 19 of Directive 2001/20/EC.

B.3.1 and B.3.2   Status of the sponsor ▲ — Non-Commercial

A commercial sponsor is a person or organisation that takes responsibility for a trial which is part of the development programme for a marketing authorisation of a medicinal product at the time of the application

Continue   Cancel

Fig. 32 – B.1 and B.3 Sponsor Identification details

3. Complete the information required on the form to describe the sponsor. Select the sponsor's country from the list of countries and identify the status of the sponsor from the drop-down list as either "commercial" or "non-commercial".

4. Click '**Continue**' when the Sponsor ID form is completed. The sponsor's name will now be displayed on the main Sponsor Identification Index page (See Fig. 33).

5. If it is necessary for this sponsor to have a legal representative in accordance with Article 19 of Directive 2001/20/EU then click the 'add legal rep' link alongside the appropriate sponsor.

Fig. 33 – B. Sponsor Identification Details – Sponsor added

6. From this screen the following options can be taken.

- If another sponsor is involved with the trial, then repeat the option 'add sponsor'.
- If any sponsor data needs to be changed then click the 'edit' link. The 'B.1 and B.3 Sponsor Identification Details' page (see Fig. 32) appears with all the entered data for the selected sponsor. This can then be changed by repeating steps 2 to 5, above.
- If the information for a sponsor is not required, it can be deleted by clicking the 'delete' link for the selected sponsor.
Note: This delete is immediate and final and there is no warning or verification screen.
- If it is necessary for a sponsor to have a legal representative in accordance with Article 19 of Directive 2001/20/EU then click the 'add legal rep' link alongside the appropriate sponsor. The screen 'B.2 Legal Representative Identification Details' appears.

Fig. 34 – B.2. Legal Representative Identification Details

7. Complete the information on the screen for the legal representative.

8. Click the '**Continue**' button to return to the Sponsor Identification Index. The index screen now shows the details of the legal representative under those of the sponsor they represent.

Fig. 35 – B. Sponsor Identification Index – Sponsor and Legal Representative added

9. From this screen the following options can be taken:

    *   If another sponsor is involved with the trial, then repeat the option 'add sponsor'.

    *   If sponsor data should need to be changed then take the 'edit' link and the page 'B.1 and B.3 Sponsor Identification Details' appears with all the entered data for the selected sponsor, which can then be changed by repeating steps 2 to 5 above.

    *   If the information for a sponsor is not required, it can be deleted by clicking the 'delete' link for the selected sponsor.
    Note: This deletion is immediate and final and there is no warning or verification screen and any associated Legal Representative is also immediately deleted.

    *   To change legal representative data click the 'edit' link and the page 'B.2 Legal Representative Identification Details' appears with previously entered data for the selected legal representative. This can then be amended as described in steps 7 and 8 above.
    Note: When a sponsor has a legal representative, there is no option to add an additional legal representative for that sponsor.

10. When all sponsor and any required legal representatives have been added to the system, click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML).

7.5.6   Section C. Applicant Identification

1.   Click '**C. Applicant Identification**' in the Clinical Trial Application Menu to open the Applicant Identification Menu screen. The following two options are available:

   1.   **C.1. Application to the National Competent Authority**. Click this link to open a form to add or edit the details of the NCA applicant.

   2.   **C.2. Application to the Ethics Committee**. Click this link to open a form to add or edit the details of the Ethics Committee applicant.

Fig. 36 – C. Applicant Identification Menu

2.   Click the link '**C.1 Applicant to the National Competent Authority**' and the '**C.1 Applicant Identification – Request for the Competent Authority**' screen appears (See Fig. 37.).

3.   Complete the information on the screen. Select the appropriate applicant from the drop-down list, which may be 'The sponsor', 'The legal representative of the sponsor' or 'A person or organisation authorised by the sponsor' and the country of the applicant from the list of Member States.

Fig. 37 – C.1 Applicant Identification – Request for the Competent Authority

4. If you wish to receive an XML file copy of this CT Application when it is stored on the EudraCT database then select 'Yes' at C.1.5.1 and enter the e-mail addresses to which this XML file is to be sent at C.1.5.1.1.

• If you select this option when this XML file is later saved to the EudraCT database a copy of the file is automatically attached to a EudraLink message and sent to each of the addresses in C.1.5.1.1.

Note: If you select 'Yes' at C.1.5.1.2 then users require EudraLink accounts and passwords in order to retrieve the EudraLink message. Similar EudraLink messages will subsequently be sent whenever the Application is amended and re-saved to the EudraCT database by the NCA. Note that this facility for sponsors to receive XML file copies of their CT applications as saved in the EudraCT database is new functionality implemented in iteration 4 of EudraCT. Click the '**Continue**' link to return to the 'Applicant Identification Menu'.

5. Click the link 'C.2. Application to the Ethics Committee' and the 'C.2 Application Identification – Request for the Ethics Committee' screen appears.

6. Complete the information on the screen. Select the appropriate applicant from the drop-down list which may be 'The sponsor', 'The legal representative of the sponsor', 'A person or organisation authorised by the sponsor', 'Coordinating investigator (for multicentre trial)' or 'Principal investigator (for single centre trial)' and the country of the applicant from the list of Member States.

Fig. 38 – C.2 Application to the Ethics Committee

7. Click the 'Continue' link to return to the 'Applicant Identification Menu'.

8. At this point if any of the applicant information should require change, then the information can be accessed using the same links 'C.1 Application to the National Competent Authority' and 'C.2 Applicant to the Ethics Committee' and changed accordingly. After changes the 'Continue' button should be pressed.

9. When details of the applicants have been added to the system, click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML).

Note: The name and address details of the applicant must be provided on both the NCA and Ethics Committee Applicant Identification screens even if these details have been provided elsewhere on the form.

7.5.7   Section D. Information on IMPs

1. **Click** 'D. Information on the IMPs' in the Clinical Trial Application Menu to open the IMP Identification Index screen. If it is a new CT Application, clearly there are no IMPs and the option to '**add IMP**' is available as well as a statement that '**No IMPs have been added for this application**'.

Fig. 39 – D. IMP Identification Index – No IMPs added

2. Click '**add IMP**' and the '**D.1 / D.2 IMP Identification and Status Details**' screen appears (see overleaf).

D.1/D.2 IMP Identification and Status Details

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA
Reference ID :

This is a multi-screen form; use the navigation key 'Next' to navigate to each of the screens.
Use 'Next' at the foot of each screen to ensure completion of all questions in Section D.
NOTE: If there is no clear 'Test IMP' or 'Comparator' in your study design, indicate all IMPs as 'Test IMP'.

D.1.2 and D.1.3   Category   [Comparator ▼]

D.2 Status of the IMP to be used in the clinical trial
If the IMP has a Marketing Authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2

D.2.1   Has the IMP to be used in the trial a marketing authorisation? ▲   ○ Yes ○ No

If No then go to D.2.3

D.2.1.1 If 'Yes', specify the product to be used in the trial
Tradename, MA holder and MA number are available from the Summary of Product Characteristics (SmPC)

D.2.1.1.1   Trade name ▲   [Tradename1]

D.2.1.1.2   Name of the MA holder   [____]

D.2.1.1.3   MA number (if MA granted by a Member State)   [____]

D.2.1.1.4   Is the IMP modified in relation to its MA?   ○ Yes ○ No

D.2.1.1.4.1   If 'Yes', please specify   [____]

D.2.1.2   Which country granted the MA? ▲   [____ ▼]

D.2.1.2.1   Is this the Member State concerned with this application? ▲   ○ Yes ○ No

D.2.1.2.2   Is this another Member State? ▲   ○ Yes ○ No

D.2.2 For situations where the IMP to be used in the CT has a MA in the MS concerned but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

D.2.2.1   In the protocol, is treatment defined only by active substance? ▲   ○ Yes ○ No

D.2.2.1.1 If 'Yes', give active substance in D.3.8 or D.3.9

D.2.2.2   In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS? ▲   ○ Yes ○ No

D.2.2.2.1 If 'Yes', give active substance in D.3.8 or D.3.9

D.2.2.3   The products to be administered as IMPs are defined as belonging to an ATC group. ▲   ○ Yes ○ No

D.2.2.3.1 If 'Yes', give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.3

D.2.2.4   Other: ▲   ○ Yes ○ No

D.2.2.4.1 If 'Yes', then please specify ▲   [____]

D.2.3   IMPD submitted:
D.2.3.1   Full IMPD: ○ Yes ○ No
D.2.3.2   Simplified IMPD: ○ Yes ○ No
Provide justification for using simplified dossier in the covering letter
D.2.3.3   Summary of product characteristics (SmPC) only: ○ Yes ○ No

D.2.4   Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?   ○ Yes ○ No
D.2.4.1   If 'Yes', specify which Member States:

AUSTRIA ☐	BELGIUM ☐	BULGARIA ☐
CYPRUS ☐	CZECH REPUBLIC ☐	DENMARK ☐
ESTONIA ☐	FINLAND ☐	FRANCE ☐
GERMANY ☐	GREECE ☐	HUNGARY ☐
ICELAND ☐	IRELAND ☐	ITALY ☐
LATVIA ☐	LIECHTENSTEIN ☐	LITHUANIA ☐
LUXEMBOURG ☐	MALTA ☐	NETHERLANDS ☐
NORWAY ☐	POLAND ☐	PORTUGAL ☐
ROMANIA ☐	SLOVAKIA ☐	SLOVENIA ☐
SPAIN ☐	SWEDEN ☐	UNITED KINGDOM ☐

D.2.5   Has the IMP been designated in this indication as an orphan drug in the Community? ▲   ○ Yes ○ No
D.2.5.1   If 'Yes', give the orphan drug designation number ▲   [____]

According to the Community register on orphan medicinal products (Regulation (EC) n° 141/2000): http://pharmacos.eudra.org/F2/register/orphreg.htm

D.2.6   Has the IMP been the subject of scientific advice related to this clinical trial?   ○ Yes ○ No
D.2.6.1   If 'Yes' to D.2.6., Please indicate the source of advice and provide a copy in the CTA request:
D.2.6.1.1 From the CHMP ?   ○ Yes ○ No
CHMP = Committee for Medicinal Products for Human Use
D.2.6.1.2 From a National Competent Authority?   ○ Yes ○ No

Next   Cancel

Fig. 40 – D.1 / D.2 IMP Identification and Status

3. Complete the information on the screen to describe the IMP.

Note: If any of the questions that allow for the IMP to be described only in terms of its active substance or ATC code is selected it is necessary to create a 'dummy' IMP record to which the active substances may be attached.

*   As far as the EudraCT system is concerned, this record needs very little information and the correct responses to the questions in this case are beyond the scope of this manual. Guidance can be found on the Clinical Trial Application Form that is included with the 'EudraCT Supporting Documentation' on the EudraCT homepage.

4. When the information is complete click the '**Next**' link to progress to the '**D.3 Description of the IMP**' page for this IMP.

Fig. 41 – D.3 Description of the IMP

5. When the information is complete click the '**Next**' link to progress to the routes of administration selection for this IMP.

Fig. 42 – D.3.7 IMP Identification Details (Route(s) of Administration of this IMP)

6. On this screen one or many routes of administration may be selected. Highlight the appropriate route of administration from the list on the left and click on the '>>>' symbol. This adds the route of administration to IMP and updates the list on the right.

- This procedure can be repeated to add additional routes of administration.
- To remove a route of administration from the list on the right, click on the route of administration in the right column so it is highlighted, then click the '<<<' symbol to move the route of administration back to the list on the left.

7. When the route of administration information is complete click the '**Next**' link to progress to the'D.3.11 Type of IMP' section.

D.3.11 Type of IMP

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA
Reference ID : PR1

This is a multi-screen form; use the navigation key 'Next' to navigate to each of the screens. Answer all questions 'Yes' or 'No' as applicable. Further detailed questions in D.4 Biological/Biotechological products, D.5 Somatic Cell Therapy or D.6 Gene Therapy Products only appear if you answer 'Yes' to the relevant questions on this screen. Answer all questions then use 'Next'.

Type of IMP:

Does the IMP contain an active substance:

D.3.11.1	Of chemical origin? ▲	○ Yes ○ No
D.3.11.2	Of biological/ biotechnological origin? ▲	○ Yes ○ No

Is this IMP a:

D.3.11.3	cell therapy medicinal product? ▲	○ Yes ○ No
D.3.11.4	gene therapy medicinal product? ▲	○ Yes ○ No
D.3.11.5	radiopharmaceutical medicinal product? ▲	○ Yes ○ No
D.3.11.6	immunological medicinal product (such as vaccine, allergen, immune serum)? ▲	○ Yes ○ No
D.3.11.7	plasma derived medicinal product? ▲	○ Yes ○ No
D.3.11.8	other extractive medicinal product? ▲	○ Yes ○ No
D.3.11.9	herbal medicinal product? ▲	○ Yes ○ No
D.3.11.10	homeopathic medicinal product? ▲	○ Yes ○ No
D.3.11.11	medicinal product containing genetically modified organisms? ▲	○ Yes ○ No

If 'Yes', has the authorisation for contained use or release been granted? ▲

D.3.11.11.1	granted?	○ Yes ○ No
D.3.11.11.2	or is it pending?	○ Yes ○ No
D.3.11.12	another type of medicinal product? ▲	○ Yes ○ No
D.3.11.12.1	If 'another type of medicinal product' specify the type of medicinal product ▲	

Next   Cancel

Fig. 43 – D.3.11 Type of IMP

8. When the 'D.3.11 Type of IMP' screen is complete click the '**Next**' link. Then the next screens to be displayed will depend on the answers to questions on 'D.3.11 Type of IMP' as follows:

    1. If the question: 'Does this IMP contain an active substance of biological / biotechnological origin?' (Section D.3.11.2) is answered 'Yes' then the 'D.4 Biological / Biotechnical IMPs including vaccines' screen appears (See Fig. 44.).

Fig. 44 – D.4 Biological / biotechnological IMPs including vaccines

2. If the question: 'Is this IMP a cell therapy medicinal product?' (Section D.3.11.3) is answered 'Yes' then the 'D.5 Somatic cell therapy IMPs (no genetic modifications)' screen appears (See Fig. 45.).

Fig. 45 – D.5 Somatic Cell Therapy IMPs (No genetic modifications)

3. If the question: 'Is this IMP a gene therapy medicinal product?' (Section D.3.11.4) is answered 'Yes' then the 'D.6 Gene Therapy IMPs' screen appears (See Fig. 46.).

Fig. 46 – D.6 Gene therapy IMPs – Part 1

9. Complete the details on this page and click the link '**Continue**' to return to the 'IMP Identification Index' page that will now show that an IMP has been added.

Fig. 47 – D. IMP Identification Index – One IMP added

10. From this screen the following options can be taken:

1. If another IMP is included in the trial, then repeat the option 'add IMP'.
2. If the information for an IMP is not required, it can be deleted by clicking the 'delete' link for the selected IMP. Note: This delete is immediate and final and there is no warning or verification screen and any active substances will also be deleted. Except if the IMP is linked to a Placebo or responsible sites then an integrity constraint warning message appears that the item you are attempting to delete is referenced elsewhere.
3. If IMP data should need to be changed then take the 'edit' link and the page 'D.1 / D.2 IMP Identification and Status Details' appears showing all data that has been entered for the selected IMP, which can then be changed by repeating steps 3 to 9 above.
4. If another very similar IMP is included in the trial then an existing IMP can be copied and the record edited to include the differences.

11. There are **two ways** to add an active substance to this IMP: Active substance details can either be filled in manually, or can be retrieved via an Active Substances Search. To add an active substance manually, click the 'add active substance' link and the 'IMP Identification Details (Active Substances)' screen will appear.

Fig. 48 – D.3.8 to D.3.10 IMP Identification Details (Active Substances)

12. Complete the details on this page and click the '**Continue**' link which will return to the 'IMP Identification Index' page which will show that an active ingredient has been added to the IMP. Note that the concentration units and concentration types are selected from drop-down boxes. The allowed concentration types are 'equal', 'not less than', 'up to' and 'range'. The concentration number should be entered in the left box and the right box **is only used** to enter the upper limit when 'range' is selected. In all other instances it should remain empty.

13. Alternatively, use the 'search MPD to add active' link to search the Medical Product Dictionary for an active substance. The screen 'D. MPD active Substance Search Criteria' should appear (see Fig. 49.).

14. Enter active substance search parameters and operators as required, and click 'Search' to view 'MPD Search Results'. If you do not wish to carry out the search, click 'Return to IMP Identification Index' to clear the search parameters and return to the 'IMP Identification Index' screen. Note that preferred terms in English that will appear in the search results (e.g. a search for Acetaminophen will return Paracetamol).

*Fig. 49 – D. MPD Active Substance Search Criteria*

15. Select from the search results the substance that you wish to add as an active substance to this IMP by pressing 'add' next to that substance in the results list. The substance details (EV code, CAS code, molecular formula and substance aliases and translations) can be checked using the 'view' link before being added to the IMP as an active substance.
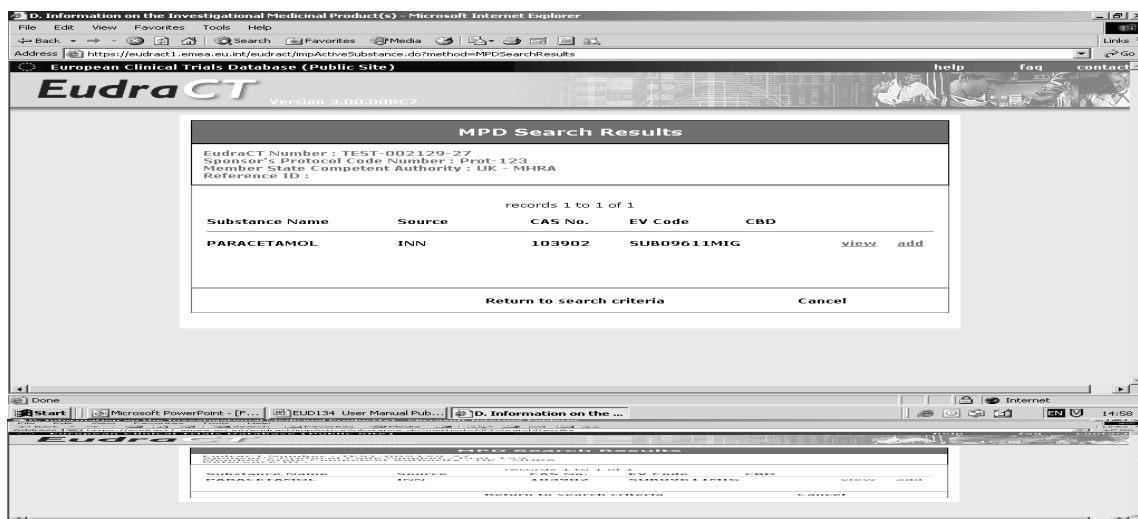
MPD Search Results

EudraCT Number : TEST-000397-23
Sponsor's Protocol Code Number :
National Competent Authority : Greece - EOF
Reference ID :

records 1 to 1 of 1

Substance Name	Source	CAS No.	EV Code	CBD		
PARACETAMOL	INN	103902	SUB09611MIG		view	add

Return to search criteria   Cancel

Fig. 50 – MPD Search Results

16. Clicking 'add' for the relevant substance will cause the INN and CAS number fields to be automatically filled in on the 'D.3.8 to D.3.10 IMP Identification Details (Active Substances)' screen (see Fig. 48). The rest of this screen can now be completed as normal as in step 12 above.

Note: If the source of the substance name is not INN then the substance name will populate the 'Other descriptive name' field.

17. Click '**Continue**' to return to the 'IMP Identification Index' screen with the active substance now added (see Fig. 51).

D. IMP Identification Index

EudraCT Number : TEST-000397-23
Sponsor's Protocol Code Number :
National Competent Authority : Greece - EOF

Click 'add IMP' to start the first IMP or create another one. Once an IMP is added, links for 'edit', 'delete', 'copy', 'search MPD to add active' and 'add active substance' are displayed for that IMP. Use 'search MPD to add active' to find and create an active substance from the list of available active substances in the Medical Product Dictionary (MPD). Use 'add active substance' for all active substances in that IMP.
Complete all questions in Section D for each IMP, but if most of the answers are the same for any additional IMP(s) (e.g. 3 tablets of different strength), then enter one IMP, use the 'copy IMP' function on this screen, then edit the relevant fields in the copy.

add IMP

ID	Details			
PR1	Trade Name	edit delete copy IMP	search MPD to add active	
			add active substance	
AS1	PARACETAMOL	edit delete		
	PARACETAMOL/103902/ based on MPD record: SUB09611MIG on 2007-11-30			

Application Menu Page

Fig. 51 – D. IMP Identification Index – One IMP added with one active substance

18. From this screen the following options can be taken:

• If another IMP is included in the trial, then repeat the option 'add IMP'.

- If IMP data should need to be changed then take the 'edit' link and the page 'D.1 / D.2 IMP Identification Status Details' appears with all the entered data for the selected IMP, which can then be changed by repeating steps 3 to 9 above.
- If the information for an IMP is not required, it can be deleted by clicking the 'delete' link for the selected IMP. Note: This will delete any associated actives substances and the delete is immediate and final and there is no warning or verification screen.
- If another very similar IMP is included in the trial then an existing IMP can be copied and the record edited to include the differences by repeating steps 3 to 10 above.
- The details of the active substance can be by deleted by clicking with the 'delete' link by the active substance. Note: this delete is immediate and there is no warning or verification screen.
- If the existing active substance information should need to be changed then take the 'edit' link for the active substance and the page 'IMP Identification Details (Active Substances)' screen will appear. Repeat step 12 above to change active substance data and click the link '**Continue**' which will return to the 'IMP Identification Index' page which will show that the active ingredient has been added to the IMP.
- If another active substance is to be added to an existing IMP then follow steps 1 to 6 below in MPD Lookup.
- Note that if an active substance has been added from the MPD then the IMP Identification Index display will show the data retrieved, the EV code of the substance record and the date on which this occurred (as in figure 51 above). If retrieved data is subsequently amended then it will cease to appear in this text line. If all retrieved data is amended then the text line will cease to appear.

7.5.7.1 MPD Lookup

1. When details of the IMPs and active substances have been added to the system, click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML)
2. When an IMP is added, if the question '' D.2.1 Has the IMP to be used in the trial a marketing authorisation?" is answered as ' Yes' , this in turn affects the following screen.
3. To create additional active substances for this IMP, click "add active Substance" and the lookup prompt screen appears, stating that the IMP entered has a marketing Authorisation:

D. MPD Lookup Prompt

EudraCT Number : TEST-003489-38
Sponsor's Protocol Code Number : NV19865
National Competent Authority : UK - MHRA

The IMP that you have entered has a Marketing Authorisation. You should try and find the Active Substances in the MPD (Medicinal Product Dictionary) rather than create a new Active Substance.

This list does not yet contain all active substances. If you do not find the one you are looking for, please proceed to "Add Active Substances" and enter the information manually.

Click the Lookup in MPD link to go to the D. MPD Active Substance Search Criteria page, otherwise click Continue to enter an Active Substance.

Lookup in MPD   Continue

Fig. 51a – D.MPD Lookup Prompt Screen

4. Click 'Continue' if you want to enter an active substance manually in which case the ''Add Active Substances'' screen appears:

Fig. 51b – D. Add Active Substances Screen

5. Now you may manually enter the active substance.
6. Alternatively, click the 'Lookup in MPD link' in the 'D - MPD Lookup Prompt' screen and 'D. MPD Active Substance Search Criteria page' appears:

Fig. 51c– D. MPD Active Substance Search Criteria Screen

7. You may now carry out a search from the database.

7.5.8	Section D.7 Information on the Placebos

1. When the link 'D.7 Information on the Placebos' is clicked the Placebo Information Index screen appears. For a new CT Application this will show that there are no placebos.

2. Click the link to 'add placebo' and the screen 'D.7 Information on the Placebo' appears. This screen will list all the IMPs entered for the trial so far. There is a check box by each IMP so that the IMPs that will be replaced by this placebo can be selected.

D.7 Information on the Placebo

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA
Reference ID : PL1

The following applies for one Placebo. Repeat 'add placebo' for each different Placebo. The PRnn is the IMP identity number shown in the 'D IMP Identification Index'. Tick the box at D.7.5 for IMPs for which this is a placebo. Entries at D.7.5.1, D.7.5.2 and D.7.5.2.1 are only preserved for IMPs for which this is a placebo (i.e. D.7.5 is ticked).

| D.7.3 | Pharmaceutical form | Blood Fraction Modifier ▼ |
| D.7.4 | Route of administration | ▼ |

D.7.5 Which IMP(s) is it a placebo for? Specify IMP number(s) from D.1.1

PR1 :   ☐
Tradename1/Product Name

D.7.5.1 Composition, apart from the active substance(s):
D.7.5.2   Is it otherwise identical to the IMP? ○ Yes ○ No
D.7.5.2.1   If composition is not otherwise identical, specify the major ingredients

                                                              Continue   **Cancel**

Fig. 52 – D.7 Placebo Information Details

3. Enter the pharmaceutical form and route of administration for the placebo and then select the IMP or IMPs that this placebo is for by ticking the appropriate check boxes. Note: Only one route of administration is allowed here. Choose the most representative route of administration in the case where more than one is used. Remember the CT Application form is not intended to capture all the detail of the trial that is included in the protocol.

4. Click the '**Continue**' link which will return to the 'D.7 Placebo Information Index' page which will show that a placebo has been added to the trial. Click 'Yes' at D.7.1 to confirm that a placebo is included in the trial.

Fig. 53 – D.7 Placebo Information Index – one placebo added

5. From this screen the following options can be taken.

    1. If another placebo is included in the trial, then repeat the option '**add placebo**'.

    2. If placebo data should need to be changed then take the '**edit**' link and the page 'D.7 Placebo Information Details' appears with all the entered data for the selected placebo, which can then be changed by repeating steps 3 and 4 above.

    3. If the information for a placebo is not required, it can be deleted by clicking the '**delete**' link for the selected placebo.
    Note: This delete is final and there is no warning or verification screen.

6. Once a placebo has been associated with a particular IMP, attempting to delete that IMP in the 'D IMP Identification Index' section results in the following warning:

Fig. 54 – Integrity Constraint (Trying to delete an IMP with an associated placebo)

7. When details of the placebos have been added to the system, answer 'Yes' to the question 'Is there a placebo?' and click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

7.5.9 Adding Placebos without an IMP

1. If an attempt is made to add a placebo before any IMP has been added then the following screen appears.

D.7 Information on the Placebo

EudraCT Number : TEST-000397-23
Sponsor's Protocol Code Number :
National Competent Authority : Greece - EOF
Reference ID :

The following applies for one Placebo. Repeat 'add placebo' for each different Placebo. The PRnn is the IMP identity number shown in the 'D IMP Identification Index'. Tick the box at D.7.5 for IMPs for which this is a placebo. Entries at D.7.5.1, D.7.5.2 and D.7.5.2.1 are only preserved for IMPs for which this is a placebo (i.e. D.7.5 is ticked).

D.7.3 **Pharmaceutical form**

D.7.4 **Route of administration**

No IMPs have been added for this application

Continue Cancel

Fig. 55 – D.7 Placebo Information Details – No IMPs Added

2. In this case it is best to add the IMPs at this stage in using sections D.1 – D.6 first, and then return to create the Placebo information.

7.5.10 Section D.8 Sites where the qualified person certifies batch release

1. When the link 'D.8 Site(s) where the qualified person certifies batch release' is clicked the 'D.8 Index of Sites where the qualified person certifies batch release' screen appears. For a new CT Application this indicates that no responsible sites have been added.

Fig. 56 – D.8 Index of Sites where the qualified person certifies batch release – no sites added

2.   Press 'List the IMPs and placebos for which no responsible site needs to be identified' and you will be asked to complete the following page:

Fig. 57 – D.8.1 IMPs and placebos for which no responsible site needs to be identified

3.   Check the relevant boxes to indicate those IMPs and placebos which have already been defined and for which no responsible sites need to be identified. Press '**Continue**' to return to the 'D.8 Index of Sites…' page.

4. Click the link 'add responsible site' and the first page of the 'D.8 Sites where the qualified person certifies batch release' section appears.

Fig. 58 – D.8 Sites where the qualified person certifies batch release

5. Enter the information to describe the responsible site. When the information is complete click the 'Next' link to progress to the 'Responsible Sites Identification Details (IMPs / Placebos)' screen that lists the IMPs and placebos from which to select those that this site is responsible for releasing.

Fig. 59 – D.8 Site where the qualified person certifies batch release (IMPs / Placebos)

6. Select the IMPs and / or placebos that this site is responsible for releasing, by ticking the appropriate check box(es).

7. When the IMPs and placebos that this site is responsible for have been selected, click the '**Continue**' link to return to the 'D.8 Index of Sites…' page.

Fig. 60 – D.8 Index of Sites… – Two sites added

8. From this screen the following options can be taken:

    1. If another site is included in the trial, then repeat the option 'add responsible site'

    2. If responsible site data should need to be changed then take the 'edit' link for the appropriate site and the page 'D.8 Sites where the qualified person certifies batch release' appears with all

the entered data for the selected site, which can then be changed by repeating steps 2 to 5 above. If the information for a site is not required, it can be deleted by clicking the 'delete' link for the selected site. Note: This delete is immediate and final and there is no warning or verification screen.

3. If details need to be edited for IMPs and placebos that need no responsible site then select 'D.8.1 list IMPs and placebos for which no responsible site needs to be identified' and make any necessary changes.

9. When details of the sites have been added to the system, click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

7.5.11 Adding Responsible Sites before IMPs

1. Add the site information as described in section 7.5.10 Section D.8 Sites

2. When the 'next' button is pressed the following screen appears, showing that there are no IMPs or placebos.

Fig. 61 – D.8 Site where the qualified person certifies batch release (IMPs / Placebos) – No IMPs or Placebos

3. In this case it is best to add the IMPs at this stage in sections D.1 – D.6 and the Placebo information in section D.7 and then return to link IMPs and placebos to the sites that release them.

7.5.12 Section E. General Information on the Trial

1. When the link 'E. General Information on the Trial' is taken the 'General Information on the Trial' screen appears.

E. General Information on the Trial

EudraCT Number : TEST-000529-24
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA

This is a multi-screen form; use the navigation key 'Next' to navigate to each of the screens.
Scope, Type and Design of the Trial are on the next screen.
Free text can be copy/pasted from a word-processed copy of the Protocol, but be brief as long copies of protocol text are not required.

E.1 Medical condition or disease under investigation.
  E.1.1 Specify the medical condition(s) to be investigated (free text) ▲

  In the case of healthy volunteer trials, the intended indication for the product under development should be provided.
  E.1.2 MedDRA version, level, term and classification code is detailed on the next screen. ▲

  E.1.3 Is any of the conditions being studied a rare disease? ▲ ○ Yes ○ No
  Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation: COM/436/01 (http://www.emea.europa.eu/pdfs/human/comp/043601.pdf)

                                                              Next   Cancel

Fig. 62 – E. General Information on the Trial

2. Complete the information required on the form to describe the trial. If you insert a large quantity of text in the large text field a scroll bar appears on the right side of the text field. Click the arrows or click, hold and drag the lozenge to review the information that has been added. When the information has been added click the 'Next' link.
- It is possible to copy and paste information into these boxes from other electronic documents. Remember that graphic characters (typically the 'symbol' character set) and subscript or superscript characters use in chemical notation will not be recognised.

3. The 'E.1.2 MedDRA Information' screen will now appear (Fig. 63) for the search and selection of MedDRA codes and terms.

Fig. 63 – E.1.2.MedDRA information

4. Once the relevant information has been added in the Term and Level fields, click the '**Look up MedDRA code and term**' link.

5. All records corresponding to the MedDRA search are displayed in the 'MedDRA code and term search results' screen.

MedDRA code and term search results

EudraCT Number : TEST-000529-24
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA

If the MedDRA code and term you wish to use is displayed below then select each term required and click add once all required terms have been selected. Note that any inactive MedDRA codes that satisfy your search criteria will be displayed but should not be selected unless this can be justified to the NCA.

records 1 to 5 of 5

Level	Classification code	Term	
LLT	10005411	Blood catecholamines	☐
LLT	10005412	Blood catecholamines abnormal	☐
LLT	10005413	Blood catecholamines decreased	☐
LLT	10005414	Blood catecholamines increased	☐
LLT	10005415	Blood catecholamines normal	☐

add once all required terms selected from all pages

If the MedDRA code and term you wish to use has not been found but you are sure you know the version, level and classification code then enter this data manually below and enter the term in section E.1.1 'Specify the medical condition to be investigated' of the form.

Version [_____] Level [LLT ▼] Classification code [_____] add

Return to MedDRA information screen Cancel

Fig. 64 –MedDRA code and term search results

6. If the MedDRA data you require is displayed in the 'records' section on the 'MedDRA code and term search results' screen, click the check box next to those terms. When you have checked all the terms necessary from the list of results, click 'add'. Note that you can move between pages in the results to view more terms displayed and click the check box next to the terms you want before clicking the 'add' link.
7. Your selected MedDRA data should now be displayed in 'E.1.2 MedDRA information' (Fig. 65, below), with a 'delete' option beside each Term. Codes not required or added incorrectly can be deleted.
Note: This deletion is immediate and final and there is no warning or verification screen
8. If the data you require does **not** appear, and you know the version, level and classification code, this information can be manually entered at this stage. Complete the relevant section at the bottom of the screen and click 'add'.

Fig. 65 – MedDRA Information – MedDRA data added

9. At this stage you may choose to add further MedDRA data by looking up additional MedDRA codes and terms (steps 4 and 5), for example, at other levels (High Level Group Term, High Level Term, Low Level Term, Preferred Term, System Organ Class). Note that the capability to add more than one MedDRA code to a CT Application is new functionality available from iteration 4 of EudraCT.

10. Once all MedDRA information has been added successfully, click the 'Next' link to progress to the 'E.2 Objective of trial' screen (See Fig. 66.).

Fig. 66 – E.2 Objective of the Trial

11. After adding the necessary trial objective information, click 'Next' to display the 'E.3, E.4 and E.5 Principal inclusion criteria, Principal exclusion and Primary end point(s)' page.

Fig. 67 – E.3, E.4 and E.5 Principal inclusion criteria, Principal exclusion and Primary end point(s)

12. When the necessary information has been added, click the 'Next' link and the 'E.6 and E.7 Scope of the Trial, Trial type and Phase' screen appears.

E.6 and E.7 Scope of the Trial, Trial Type and Phase

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA

This is a multi-screen form; use the navigation key 'Next' to navigate to each of the screens. Complete all questions then use 'Continue'.

E.6 Scope of the trial

E.6.1 Diagnosis ▲ ○ Yes ○ No
E.6.2 Prophylaxis ▲ ○ Yes ○ No
E.6.3 Therapy ▲ ○ Yes ○ No
E.6.4 Safety ▲ ○ Yes ○ No
E.6.5 Efficacy ▲ ○ Yes ○ No
E.6.6 Pharmacokinetic ▲ ○ Yes ○ No
E.6.7 Pharmacodynamic ▲ ○ Yes ○ No
E.6.8 Bioequivalence ▲ ○ Yes ○ No
E.6.9 Dose response ▲ ○ Yes ○ No
E.6.10 Pharmacogenetic ▲ ○ Yes ○ No
E.6.11 Pharmacogenomic ▲ ○ Yes ○ No
E.6.12 Pharmacoeconomic ▲ ○ Yes ○ No
E.6.13 Others ▲ ○ Yes ○ No
E.6.13.1 If 'others', specify scope of the trial [   ]

E.7 Trial type and phase

E.7.1 Human pharmacology (Phase I) ▲ ○ Yes ○ No
E.7.1.1 First administration to humans ▲ ○ Yes ○ No
E.7.1.2 Bioequivalence study ▲ ○ Yes ○ No
E.7.1.3 Other ▲ ○ Yes ○ No
E.7.1.3.1 If 'other', specify trial type ▲ [   ]
E.7.2 Therapeutic exploratory (Phase II) ▲ ○ Yes ○ No
E.7.3 Therapeutic confirmatory (Phase III) ▲ ○ Yes ○ No
E.7.4 Therapeutic use (Phase IV) ▲ ○ Yes ○ No

Next   Cancel

Fig. 68 – E.6 and E.7 Scope of the Trial, Trial type and Phase

13. Click 'Next' when the required information has been given, and screen 'E.8 Design of the Trial' will appear.

E.8 Design of the Trial

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA

This is a multi-screen form; use the navigation key 'Next' to navigate to each of the screens. Complete all questions then use 'Continue'.

E.8.1 Controlled ▲   ○ Yes ○ No

If 'controlled', specify

▲ E.8.1.1 Randomised ○ Yes ○ No
E.8.1.2 Open ○ Yes ○ No
E.8.1.3 Single blind ○ Yes ○ No
E.8.1.4 Double blind ○ Yes ○ No
E.8.1.5 Parallel group ○ Yes ○ No
E.8.1.6 Cross over ○ Yes ○ No
E.8.1.7 Other ○ Yes ○ No
E.8.1.7.1 If 'other', specify the design of the trial [   ]

E.8.2 If controlled, specify the comparator
E.8.2.1 Other medicinal product(s)   ○ Yes ○ No
E.8.2.2 Placebo   ○ Yes ○ No
E.8.2.3 Other   ○ Yes ○ No
E.8.2.3.1 If 'other', specify the comparator   [   ]

E.8.3 Single site in the Member State concerned (see also Section G)   ○ Yes ○ No
E.8.4 Multiple sites in the Member State concerned (see also Section G)   ○ Yes ○ No
E.8.4.1 Number of sites anticipated in Member State concerned   [   ]
E.8.5 Multiple Member States   ○ Yes ○ No
E.8.5.1 Number of sites anticipated in the Community   [   ]
E.8.6 Does this trial involve countries outside the EU?   ○ Yes ○ No

E.8.7 Does this trial have a data monitoring committee?   ○ Yes ○ No
E.8.8 Definition of the end of the trial and justification in the case where it is not the last visit of the last subject undergoing the trial, if not provided in the protocol

[   ]

E.8.9 Initial estimate of the duration of the trial (years, months, days)
E.8.9.1 In the MS concerned   years [   ] months [   ] days [   ]
E.8.9.2 In all countries concerned by the trial   years [   ] months [   ] days [   ]
from the 1st inclusion until the last visit of the last subject

Continue   Cancel

Fig. 69 – E.8. Design of the Trial

14. Complete the information required on the form to describe the details of the trial.

15. When details of the sites have been added to the system, click the link '**Continue**' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

7.5.13 Section F. Population of Trial Subjects.

1. When the link 'F. Population of Trial Subjects' is clicked the 'Population of Trial Subjects' screen appears.

F. Population of Trial Subjects

EudraCT Number : TEST-000529-24
Sponsor's Protocol Code Number :
National Competent Authority : UK - MHRA

If there are no subjects under 18 it is sufficient to answer 'No' and then answer the questions on adults and elderly. Complete each question then use 'Continue'.

F.1 Age span

F.1.1 Less than 18 years ▲ ○ Yes ○ No

If 'Yes', please select from the following:

F.1.1.1 In utero ▲ ○ Yes ○ No

F.1.1.2 Preterm newborn infants (up to gestational age < 37 weeks) ▲ ○ Yes ○ No

F.1.1.3 Newborn (0-27 days) ▲ ○ Yes ○ No

F.1.1.4 Infant and toddler (28 days-23 months) ▲ ○ Yes ○ No

F.1.1.5 Children (2-11years) ▲ ○ Yes ○ No

F.1.1.6 Adolescent (12-17 years) ▲ ○ Yes ○ No

F.1.2 Adult (18-65 years) ▲ ○ Yes ○ No

F.1.3 Elderly (>65 years) ▲ ○ Yes ○ No

F.2 Gender

F.2.1 Female ▲ ● Yes ○ No

F.2.2 Male ▲ ○ Yes ○ No

F.3 Group of trial subjects

F.3.1 Healthy volunteers ▲ ○ Yes ○ No

F.3.2 Patients ▲ ○ Yes ○ No

F.3.3 Specific vulnerable populations ▲ ○ Yes ○ No

F.3.3.1 women of childbearing potential ▲ ○ Yes ○ No

F.3.3.2 women of childbearing potential using contraception ▲ ○ Yes ○ No

F.3.3.3 pregnant women ▲ ○ Yes ○ No

F.3.3.4 nursing women ▲ ○ Yes ○ No

F.3.3.5 emergency situation ▲ ○ Yes ○ No

F.3.3.6 subjects incapable of giving consent personally? ▲ ○ Yes ○ No

F.3.3.6.1 If 'Yes', specify ▲

F.3.3.7 others ▲ ○ Yes ○ No

F.3.3.7.1 If 'others', specify the specific vulnerable populations ▲

F.4 Planned number of subjects to be included

F.4.1 In the member state

F.4.2 For a multinational trial

F.4.2.1 In the European Community ▲

F.4.2.2 In the whole clinical trial

F.5 Plans for treatment or care after the subject has ended his/her participation in the trial. If it is different from the expected normal treatment of that condition, please specify (free text):
if not already provided in the protocol

Continue   Cancel

Fig. 70 – F. Population of Trial Subjects

2. Complete the information required on the form to describe the population of subjects included in the trial. It is possible to copy and paste information into these boxes from other electronic documents. The text boxes will scroll to show the information that has been added.

3. When details of the population of trial subjects have been added to the system, click the link '**Continue**' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

<table>
<tr><td colspan="2">**7.5.14 Section G. Clinical Trial Sites / Investigators in the Member State**</td></tr>
</table>

1. When the link 'G. Clinical Trial Sites / Investigators in the Member State' is clicked the 'G. Index of Clinical Trial Sites / Investigators in the Member State' appears. For a new CT Application this will show that no sites have been identified.

Fig. 71 – G. Index of Clinical Trial Sites / Investigators in the Member State – no sites entered

2. Click the 'add investigator' link and the 'G.1 and G.2 Investigator Details' page appears (See Fig. 72.).

3. Complete the information on the screen to describe the investigator. Be sure to specify the role of the investigator by selecting either 'National coordinating investigator for a multicentre trial', 'Principle investigator for a single centre trial' or 'Other principle investigator for a multicentre trial' from the drop-down menu at the top of the page.
   Note: The name given must be that of the investigator and not a third party contact.

G.1 and G.2 Investigator Details

EudraCT Number : TEST-000429-25
Sponsor's Protocol Code Number : CODE A-B/C TEST
National Competent Authority : UK - MHRA
Reference ID : IN2

Complete the Investigator Sites in this Member State only.

What is the role of this investigator?	G.1 Principal investigator for a single centre trial ▾
G.1.1 or G.2.1 Given Name Also known as first name or forename.	KEMI
G.1.2 or G.2.2 Middle Name, if applicable The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth".	
G.1.3 or G.2.3 Family name Also known as Surname. Use this field to record a functional role.	OYEFESO
G.1.4 or G.2.4 Qualification (MD...)	
G.1.5 or G.2.5 Institution name	Thames valley university
Institution department name	
Street address	
Town/ city	
Post code	
Country	▾

Continue   Cancel

Fig. 72 – G.1 and G.2. Investigator Details

4. When the information is complete click the 'Continue' link to return to 'Proposed Sites Index' screen.

Fig. 73 – G. Index of Clinical Trial Sites / Investigators in the Member State – one investigator added

5. From this screen the following options can be taken.

    1. If another investigator site is included in the trial, then repeat the option 'add investigator'.

    2. If investigator site data should need to be changed then click the '**edit**' link for the appropriate investigator site and the page 'G.1 and G.2 Investigator Details' appears with all the entered data for the selected investigator. This can then be edited, or added to.

    3. If the information for an investigator site is not required, it can be deleted by clicking the '**delete**' link for the selected investigator site.
    Note: This deletion is immediate and final and there is no warning or verification screen.

G3. Central Technical Facility Details

EudraCT Number : TEST-000429-25
Sponsor's Protocol Code Number : CODE A-B/C TEST
National Competent Authority : UK - MHRA
Reference ID : CTF2

Only central facilities should be completed who supply services for at least this Member State. The facility may be in this Member State, another Member State or a 3rd Country.

G.3.1 Organisation

Central technical facility organisation name | Central Test Laboratory

Central technical facility organisation department | Test Laboratory

G.3.2 Contact person - Given name
Also known as first name or forename. | Martin

Middle name
The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth".

Family name
Also known as Surname.
Use this field to record a functional role. | Roberson

G.3.3 Street address

Town/ city

Post code

Country | BARBADOS

G.3.4 Telephone number

G3.5 Enter the details of any duties subcontracted to this central technical facility in this trial

Routine clinical pathology testing	Yes ⦿ No ○
Clinical chemistry	Yes ⦿ No ○
Clinical haematology	Yes ⦿ No ○
Clinical microbiology	Yes ○ No ○
Histopathology	Yes ○ No ○
Serology/ endocrinology	Yes ○ No ○
Analytical chemistry	Yes ○ No ○
ECG analysis/ review	Yes ○ No ○
Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	Yes ○ No ○
Primary/ surrogate endpoint test	Yes ○ No ○
Other Duties subcontracted?	Yes ○ No ○
If 'Yes', specify the other duties	

Continue   Cancel

Fig. 74 – G.3 Central Technical Facility Details

6. Click the '**add central technical facility**' link and the 'G.3 Central Technical Facility Details' page appears (See Fig. 74.).

7. Complete the information on the screen to describe the Central Technical Facility (CTF).

8. When the information is complete click the '**Continue**' link to return to the 'G. Index of Clinical Trial Sites… ' screen.

Fig. 75 – G. Index of Clinical Trial Sites… – one investigator and one CTF

9. From this screen the following options can be taken.

    1. The options for investigators detailed in step 5.

    2. If another CTF is included in the trial, then repeat the option '**add central technical facility**'.

    3. If CTF data should need to be changed then take the 'edit' link for the appropriate CTF and the page 'G.3. Central technical Facility Details' appears with all the entered data for the selected CTF, which can then be changed by repeating steps 7 and 8 above.

    4. If the information for a CTF is not required, it can be deleted by clicking the 'delete' link for the selected CTF. Note: This delete is immediate and final and there is no warning or verification screen.

10. Click the '**add sponsor's subcontractor facility**' link and the 'G.4 Organisations to whom the sponsor has transferred trial related duties and functions' page appears.

G.4 Organisations to whom the sponsor has transferred trial related duties and functions

EudraCT Number : TEST-003489-38
Sponsor's Protocol Code Number : NV19865
National Competent Authority : UK - MHRA
Reference ID :

Only central CRO facilities supplying services for at least this Member State should be entered (not e.g. individual field-based CRAs). The facility may be in this Member State, another Member State or a 3rd Country

Note that the answer to question 'G.4.1 Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party will be filled in automatically by the system once the details of the first subcontractor have been entered.

G.4.1.1 Organisation name

Organisation department

G.4.1.2 Contact person - Given name
Also known as first name or forename.

Middle name
The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth".

Family name
Also known as Surname.
Use this field to record a functional role.

G.4.1.3 Street address

Town/ city

Post code

Country

G.4.1.4 Telephone number

Enter the details of any duties/ functions subcontracted to this sponsor's subcontractor facility in this trial

G.4.1.5 All tasks of the sponsor   Yes ○ No ○

G.4.1.6 Monitoring   Yes ○ No ○

G.4.1.7 Regulatory (e.g. preparation of applications to CA and Ethics Committee)   Yes ○ No ○

G.4.1.8 Investigator recruitment   Yes ○ No ○

G.4.1.9 IVRS - treatment randomisation   Yes ○ No ○

G.4.1.10 Data management   Yes ○ No ○

G.4.1.11 E-data capture   Yes ○ No ○

G.4.1.12 SUSAR reporting   Yes ○ No ○

G.4.1.13 Quality assurance auditing   Yes ○ No ○

G.4.1.14 Statistical analysis   Yes ○ No ○

G.4.1.15 Medical writing   Yes ○ No ○

G.4.1.16 Other Duties subcontracted?   Yes ○ No ○

G.4.1.16.1 If 'Yes', specify the other duties

Continue   Cancel

Fig. 76 – G.4 Organisations to whom the sponsor has transferred trial related duties and functions

11. Complete the information on the screen to describe the sponsor's subcontractor facility

12. When the information is complete click the 'Continue' link to return to the 'Index of Clinical Trial Sites…' screen.

Fig. 77 – G. Index of Clinical Trial Sites… – one investigator, one CTF and one Subcontractor added

13. From this screen the following options can be taken.

    1. The options for adding, editing and deleting investigators described in step 5.

    2. The options for adding, editing and deleting Central Technical Facilities described in step 9.

    3. If another subcontractor is included in the trial, then repeat the option 'add sponsor's subcontractor facilities'.

    4. If subcontractor data should need to be changed then take the 'edit' link for the appropriate sponsor's subcontract facility and the page 'G.4 Organisations to whom the sponsor has transferred trial related duties and functions' appears with all the entered data for the selected sponsor's subcontract facility, which can then be changed by repeating steps 11 and 12 above.

    5. If the information for a sponsor's subcontract facility is not required, it can be deleted by clicking the 'delete' link for the selected sponsor's subcontract facility. Note: This delete is immediate and final and there is no warning or verification screen.

14. When details of the proposed trial sites have been added to the system, click the link 'Application Main Menu' to return to the CT Application Menu. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

7.5.15 Section H. Ethics Committee / National Competent Authority

1. When the link 'H. Ethics Committee / National Competent Authority' is clicked the 'Ethics Committee / National Competent Authority Information' screen appears. The two options collect Ethics Committee information for inclusion on the printed request to the National Competent Authority and National Competent Authority Information for inclusion in the printed request to the Ethics Committee.

Fig. 78 – H. Ethics Committee / MS Competent Authority Information

2. Click the link '**H.1.1 National Competent Authority**' to enter NCA information and the National Competent Authority screen displays (See Fig. 79.).

3. Complete the information on the screen to describe the National Competent Authority to which the application will be made.

4. When the information is complete click, the '**Continue**' link to return to 'Ethics Committee / National Competent Authority Information' screen.

Fig. 79 – H.1.1 National Competent Authority

5. Click the link 'H.1.2 Ethics Committee' to enter Ethics Committee information and the Ethics Committee screen displays (See Fig. 80.).

6. Complete the information on the screen to describe the Ethics Committee to which the application will be made.

7. When the information is complete click the '**Continue**' link to return to 'Ethics Committee / National Competent Authority Information' screen.

8. When details of the Ethics Committee and NCA have been added to the system, click the link 'Application Main Menu' on the Ethics Committee / National Competent Authority Information screen. Then click the link 'Save as XML' and resave the CT Application form to the local XML file (See section 7.5.4 Save as XML.).

Fig. 80 – H.1.2 Ethics Committee

8 SAVING, RESTORING AND PRINTING THE CT APPLICATION

8.1 Introduction

This section describes the processes included in the CT Application system for saving electronic versions of the CT Application Form and restoring them for review and / or editing. In addition the processes for printing the final application form for submission to the National Competent Authorities and Ethics Committee are described.

8.2 Saving the CT Application

As explained in section 7.5.4 Save as XML the CT Application form should be saved regularly to avoid loss of data. The options for saving the CT Application data are included on the 'Clinical Trial Application Menu'.

1. Navigate to the 'Clinical Trial Application Menu and click the link 'Save as XML'.

Save as XML

EudraCT Number : TEST-000001-88
Sponsor's Protocol Code Number :
National Competent Authority : Austria - BASG

You can choose to save all the data as XML, or just the Core Dataset. It is suggested that the 'Full XML' option is chosen as this incorporates the Core Dataset.
NOTE: These options download the XML into a new Browser window. You then need to use File/ Save As in the new Browser window to store the XML on disk. It is suggested the file is named with a '.xml' extension.

NOTE: Please ensure that you have validated the application form prior to the final saving of the XML file.

Save Full XML
Save Core Dataset XML

Continue

Fig. 81 – Clinical Trial Application Menu

The 'Save as XML' menu appears with the following options:
Save Full XML
> This option saves all the data entered on the application form as an XML file. This is the option to be used throughout the CT Application preparation process to permanently save the entered information.

Save Core Dataset XML
> This option saves only part of the total data entered in the Application form. This partial data is sufficient to meet the minimum requirement for data to be held in the central EudraCT database maintained by the National Competent Authorities within the Community.

Note: The below instructions are intended for users running Internet Explorer in its default configuration.

2. Click either link on the 'Save as XML' menu and the XML file requested will be downloaded and the File Download dialogue appears.
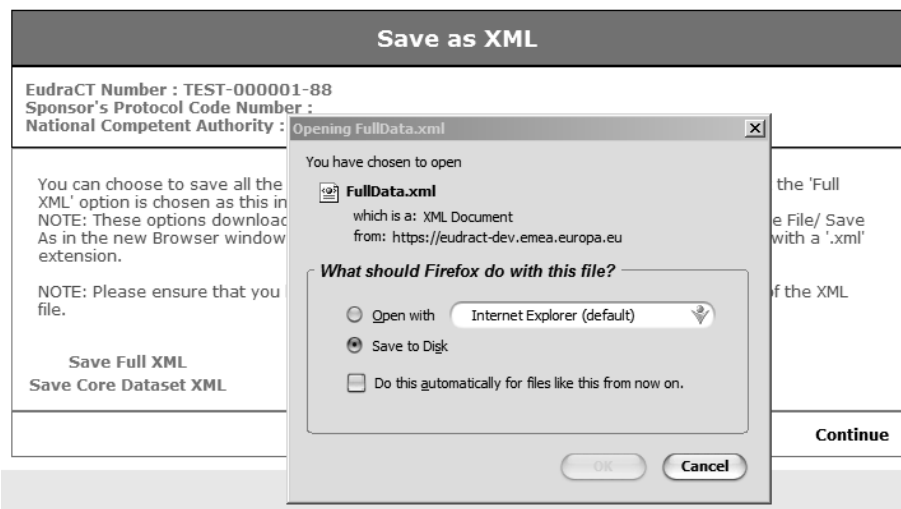
Fig. 82 – Saving the XML file – 'File Download' Dialogue.

3. Ensure that the 'Save this file to disk' is selected and press 'OK'. The 'Save As' dialogue appears.
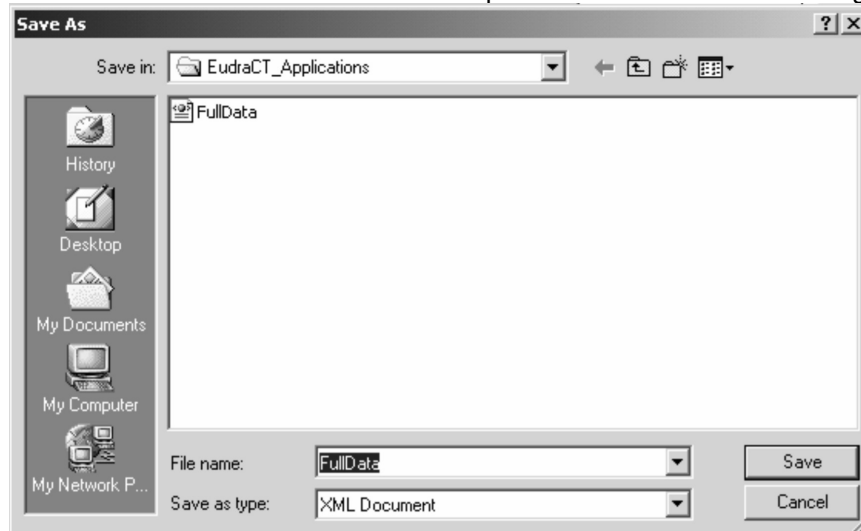
Fig. 83 – Saving the XML file – 'Save As' Dialogue.

6. Select an appropriate filename and folder and save the file. The file saved should have an extension of '.xml'. If the warning that this file already exists is given check the filename and make the save. In general, if the CT Application data is saved regularly during the creation of the CT Application then the filename should already exist.
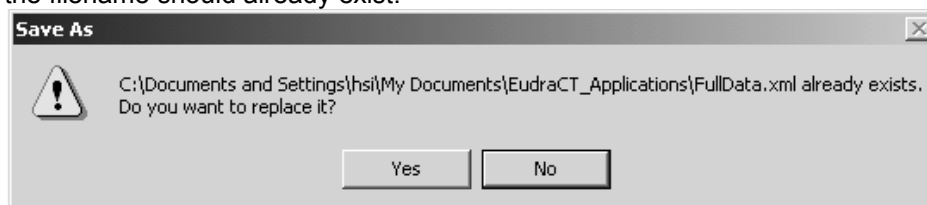
Fig. 84 – Save XML Warning

8.2.1   Saving the Core Dataset as XML

The electronic submission of the CT Application form to the National Competent Authority may be sent containing only the minimum core dataset. The process to prepare this XML file is the same as the steps above. In general this save should be performed following the preparation and save as an XML file of the complete CT Application.

Note: If the Core Dataset is saved to an XML file and then the CT Application system is exited without also saving the full CT Application data, then any data in the CT Application that is not included in the Core Dataset will be lost.

## 8.3 Restoring a Saved CT Application

CT Application information is saved as XML files using the processes described in section 8.2 Saving the CT Application The stored files can be restored to the web browser for review or edit by clicking the option 'Click here to load a saved Clinical Trial Application' on the EudraCT Welcome page (See Fig. 2). The next sequence will depend on whether there is already a CT Application in the PC memory that has been worked on.

8.3.1 Reloading a Saved Application where no CT Application is loaded in the PC

1. From the EudraCT Welcome page click the link '**Click here to load a saved Clinical Trial Application**'.

2. If no CT Application has been worked on since the PC was started then the 'Load Application from File' screen appears with a request for the filename to be loaded.
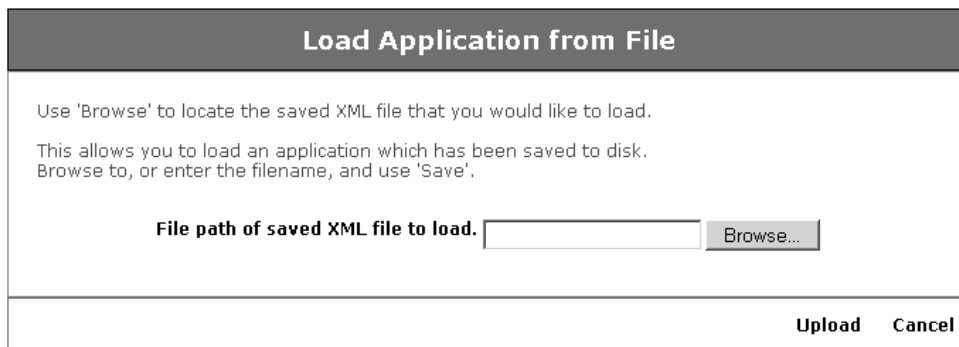

Fig. 85 – Load Application from File – no existing loaded application

3. Enter the filename by typing it in or browse to find it. When the filename has been entered click the 'Upload' link and the 'Load Application from File Success' page appears.

Fig. 86 – Load Application from File Success

4. Click the '**Continue**' link and the 'Clinical Trial Application Menu' appears with the reloaded Application available for review and / or edit.

8.3.2 Reloading a Saved Application where a CT Application is already loaded in the PC

1. From the 'EudraCT Welcome page click the link 'Click here to load a saved Clinical Trial Application'.

2. If a CT Application has been worked on since the PC was started then the 'Load Application from File Confirmation' screen appears to provide the option to use this current application before overwriting it with a new one from disc.

Fig. 87 – Load Application from File – with a CT application already loaded on the computer

3. Click the link 'Load Application from File' and the 'Load Application from File' screen (Fig. 85) appears to request the name of the file to be loaded.
4. Enter the filename path by typing it in or browse to find it. When the filename has been entered click the '**Upload**' link and the '**Load Application from File Success**' page appears:
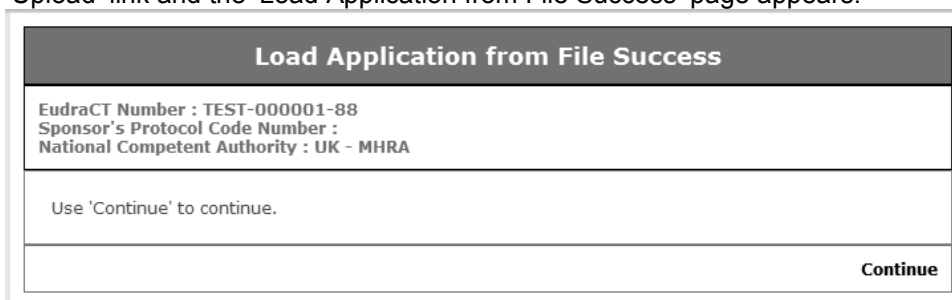

Fig. 86 – Load Application from File Success

5. Click the '**Continue**' link and the 'Clinical Trial Application Menu' appears with the reloaded Application available for review and / or edit.
    Note: In this instance the CT Application that is already loaded will be overwritten by the new file, so it is important to save the current application first if information is not to be lost.

6. If the link 'use Current Application' is clicked, then the 'Clinical Trial Application Menu' appears with the current Application available for review and / or edit.

8.4 Printing the CT Application and Associated Documents

The information collected in the CT Application includes details of the National Competent Authority and the Ethics Committee related to the application. The print options within the system will select the appropriate information and produce a complete paper version of the CT Application for either recipient.
In addition, there are separate document templates for Section K – 'Check List of The Information Appended to the Application Form', the 'Request for Authorisation of a Substantial Amendment' and for the 'Declaration of the End of a Clinical Trial'

8.4.1 Printing the CT Application Forms

1. It is recommended that before the CT Application forms are printed, the data validation checks have been completed (see section Error: Reference source not found Error: Reference source not found) and that the full XML has been saved (see section 8.2 Saving the CT Application).

2. From the 'CT Application Menu' page select the option '**Get Printable Copy**'. This displays the '**Printable Copy Warning**' page, reminding you to validate the application if you have not already done so.

Fig. 89 – Printable Copy Warning

3. If the application has already been validated, click '**Continue to PDF creation**', and the 'Printable Copy' screen appears (see Fig. 90). Otherwise follow the '**Validate application form**' as described below.

Fig. 90 – Printable Copy

4. Select the language (English or Spanish) and the form that is required. The 'Current Form' options will produce the paper CT Applications for the NCA and the Ethics Committee. The 'Blank' forms produce empty CT Application templates that can be used as data entry sheets during the completion of the CT Application using EudraCT, or may be completed by hand as CT Applications in their own right.

5. When one of these options is selected the CT Application system creates a PDF file that appears on the screen and can be saved or printed.

Note: It is essential that the PC being used has Adobe Acrobat Reader installed. If Adobe Acrobat is not installed then the PDF file will not be displayed on the screen. If Adobe Acrobat Reader is installed but the PDF screen is blank except for a small graphic image in the top left hand corner it might be because the setting 'Display PDF in Browser' is not checked in the Adobe 'Preferences / Internet / Web browser options'.
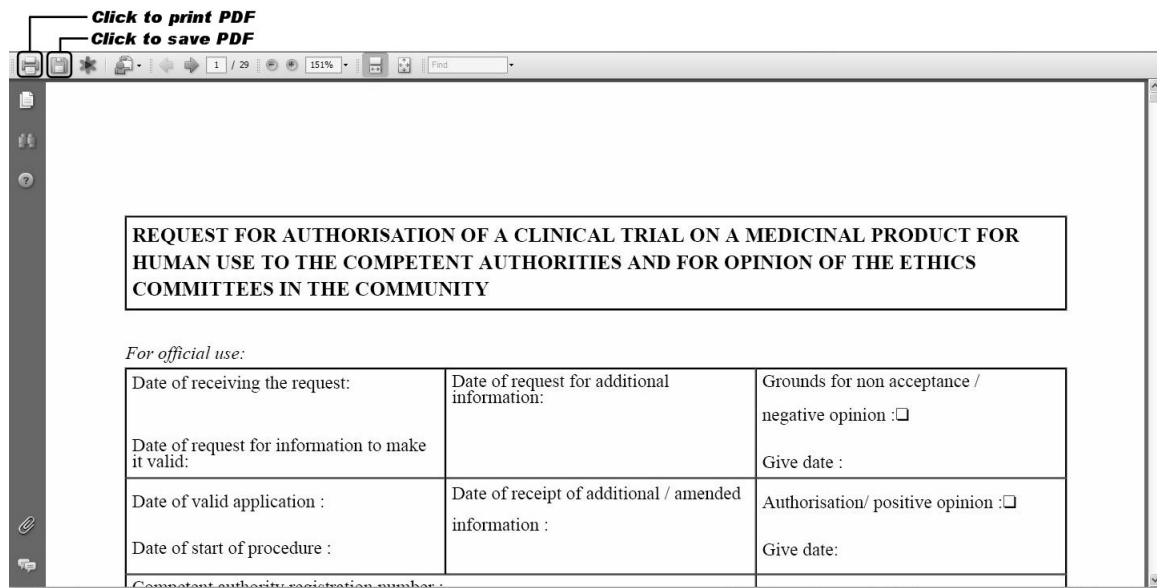

Fig. 91 – Adobe Acrobat Window

6. To save the PDF file it is essential that the 'Save a copy' icon on the Adobe toolbar is used (See Fig. 91). This is the only way that the file can be saved in PDF format.
Note: If the Adobe toolbar you are using does not display this icon, then click 'File' in the tool bar and select 'Save As…' from the menu that drops down.

7. The 'Save a Copy' dialogue box opens. Enter the appropriate path and filename and press 'Save'.
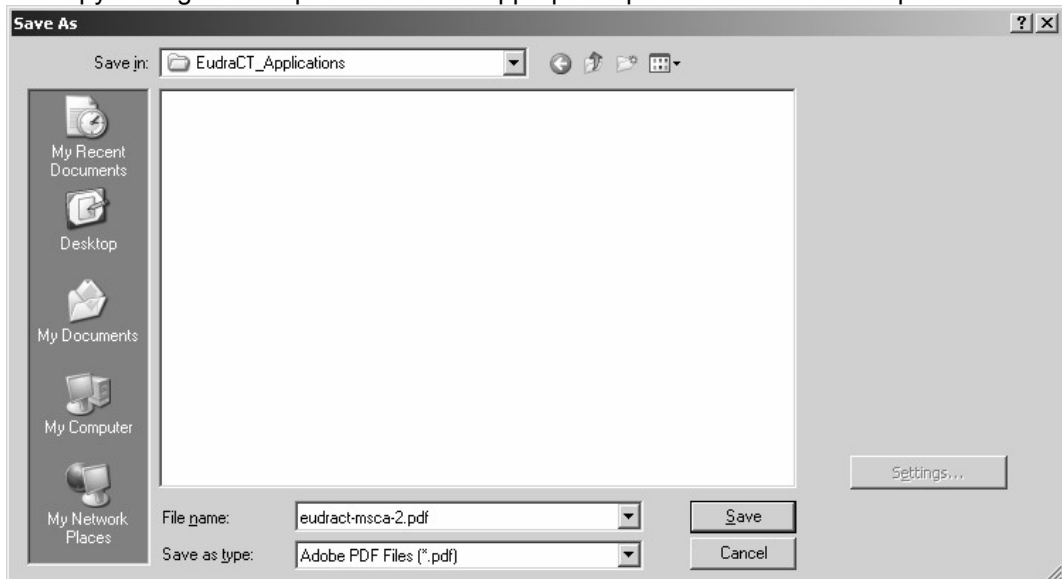
Fig. 92 – Save a Copy Dialogue

8. To print the PDF file, either use the Windows 'File/Print' menu or select the print icon (see Fig. 91) from the Adobe toolbar. In either case the normal printer options window opens and the file can be printed.

8.4.2   Section J. Check List of the Information Appended to the Application Form

The CT Application is required to contain a checklist of the documents that will be submitted with the CT Application. This checklist is provided as a Microsoft Word template that can be downloaded from the EudraCT system.

---

1. From the EudraCT Clinical Trial Application Menu, select the option '**Section J**'. The Section J Check List menu appears.

Fig. 93 – J. Check List Menu

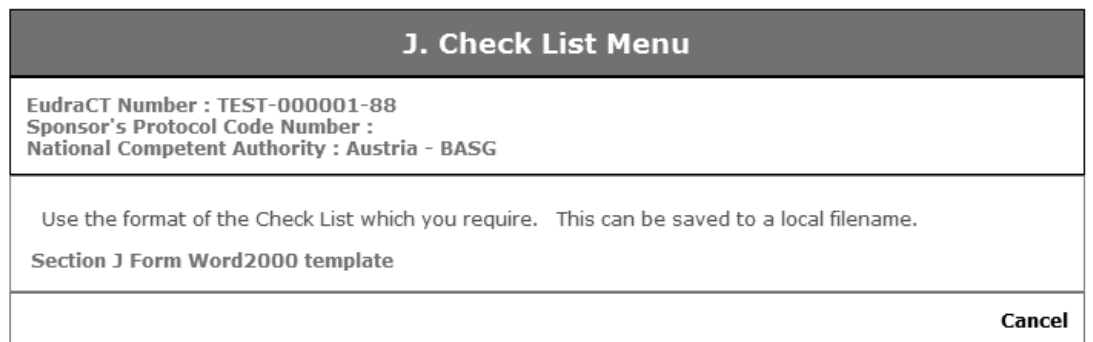2. Click the link and the checklist appears as an active template with check boxes that can be checked to indicate the documents that are included in the application to the NCA and Ethics Committee.
3. When the list has been completed, it may be saved to your PC or network in the same way as any other Microsoft Word document.

8.4.3 Completing a Request for Authorisation of a Substantial Amendment

The EudraCT CT Application system includes the forms that are required to make a request to the NCA or Ethics Committee to 'Request for Authorisation of a Substantial Amendment'.

1. Navigate to the EudraCT 'Welcome' screen and select the option '**Download CT Amendment Form**'.
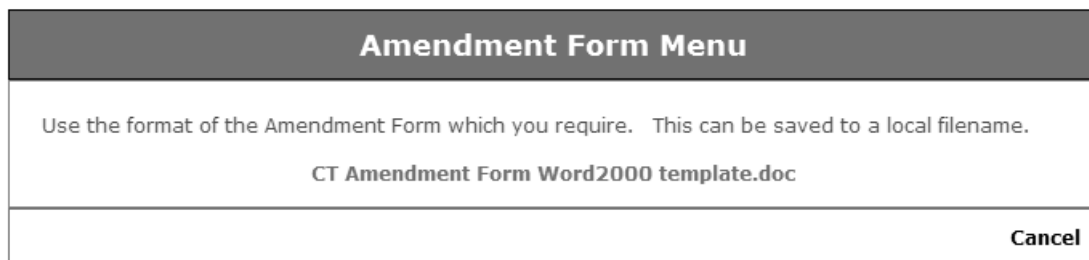

Fig. 94 – Amendment Form Menu

2. Select the appropriate link to download the form template. The 'File Download' dialogue opens, or the form template opens (dependent upon your PC's settings).

Fig. 95 – File Download Dialogue

3. The Word template can be opened and then saved using the standard Windows menu 'File/Save As' or saved directly to the PC or network (See Fig. 96.).

4. This form is a Microsoft Word template. Complete the form by filling in the form fields, saving the document with an appropriate filename.

Fig. 96 – Amendment Form Template

8.4.4 Completing a Request for Authorisation of a Substantial Amendment

The EudraCT CT Application system includes the forms that are required to make a request to the NCA or Ethics Committee to make a 'declaration of the End of a Clinical Trial'.

1. Navigate to the EudraCT 'Welcome' screen and select the option '**Download CT End of Trial Form**'.

Fig. 97 – End of Trial Form Menu

2. Select the appropriate link to download the form template. The 'File Download' dialogue opens, or the form template opens (dependent upon your PC's settings).
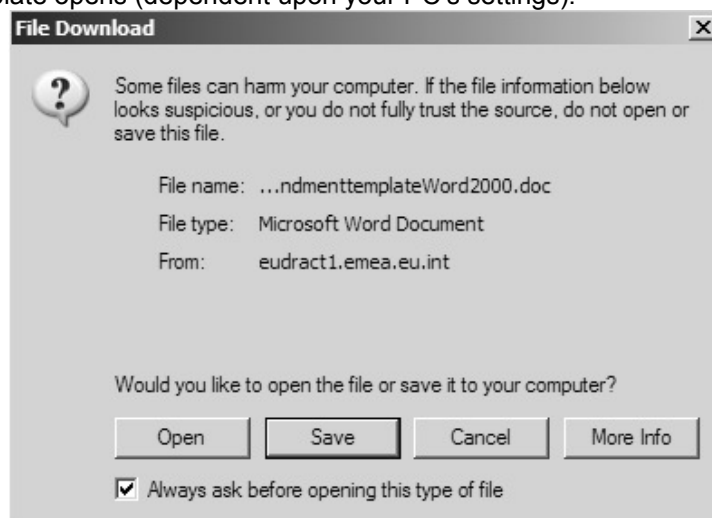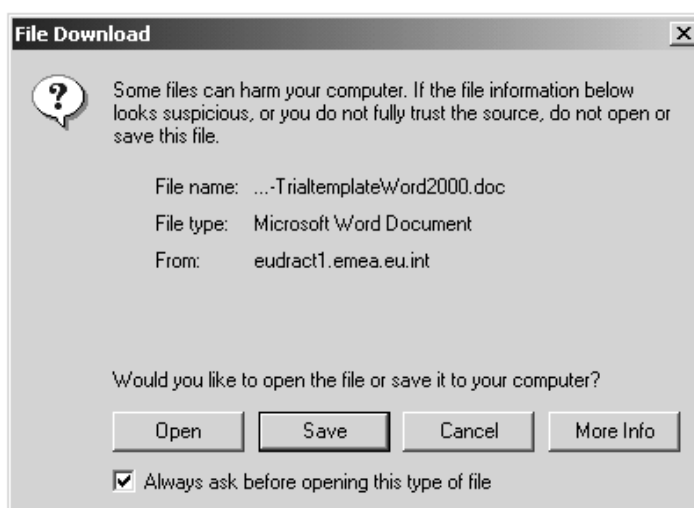
Fig. 98 – File Download Dialogue

3. The Word template can be opened and then saved using the standard Windows menu 'File/Save As' or saved directly to the PC or network.
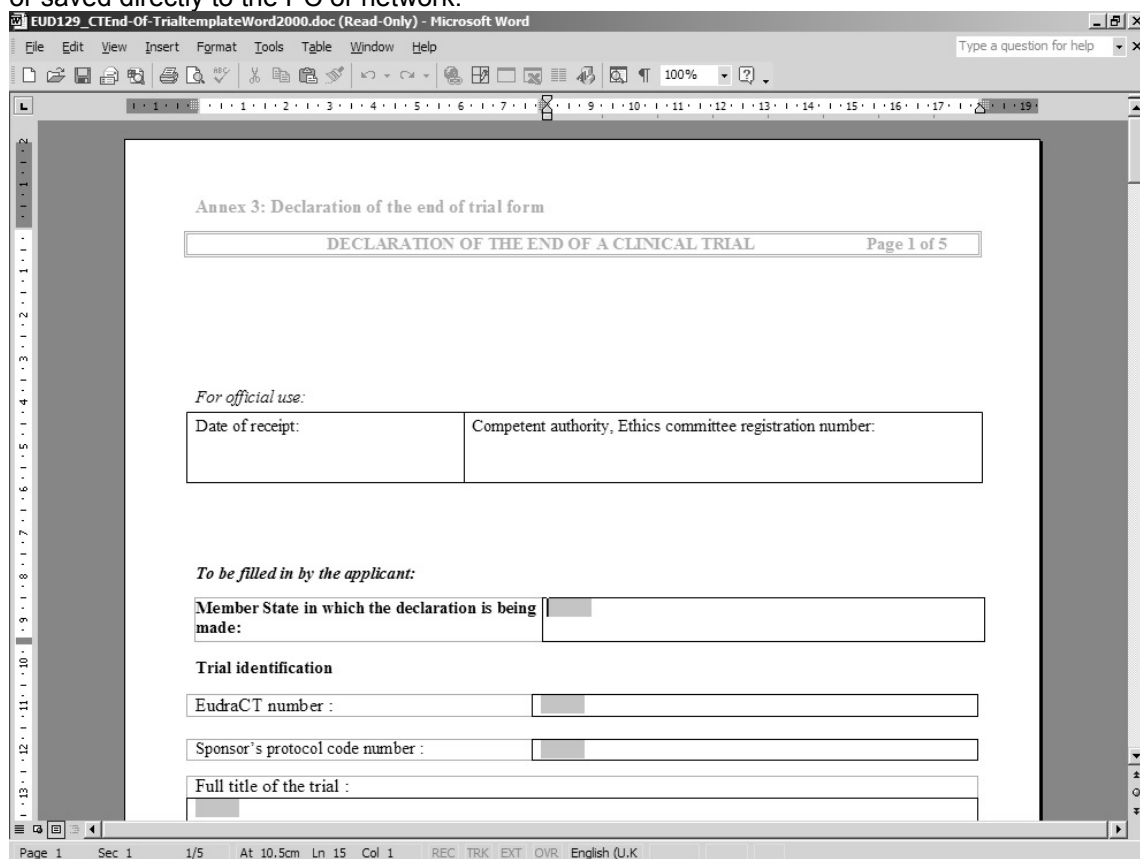
Fig. 99 – End of Trial Form Template

4. This form is a Microsoft Word template. Complete the form by filling in the form fields, saving the document with an appropriate filename.

8.5 Problems that May be Encountered

8.5.1 Loading the XML Schema

There are validation checks on the XML schema when a CT Application XML file is loaded into the system. If the schema of the XML does not conform to the EudraCT schema then the following error message appears:

> • **The XML file that you have tried to load does not conform to the EudraCT XML schema Unexpected element {http://eudract.ClinicalTrialApplication.xsd}: "eeeeeeeeeeeeeeee"**

Where "eeeeeeeeeeeeeeee" is the element name that caused the problem.

The XML loaded is possibly created with a superseded version of the XML schema, but the error can also be caused by directly editing the XML outside the EudraCT system.

There are also checks for a valid EudraCT number and NCA. If these are incorrect then the following messages appears.

> • **The EudraCT number in the file that you have loaded does not exist in the system**

> • **The MS Competent Authority in the file that you have loaded does not exist in the system**

These kinds of errors are almost certainly created by editing the XML file outside EudraCT. This editing is possible but has inherent dangers if not completed accurately.

In either case the XML file needs to be changed to contain a valid EudraCT number and / or NCA in order to load.

8.5.2   EudraCT number validation

Two validations are performed on EudraCT numbers: a format check and a check that the number exists. The following error messages may be encountered.

> • **The EudraCT number that you have loaded does not exist in the system**

> • **EudraCT number entered does not match the format xxxx-xxxxxx-xx**

In either case a valid EudraCT number that exists in the database must be entered.

8.5.3   Date Validation

Dates entered in the system are all in the format yyyy-mm-dd. The format of dates is checked and also the correctness of the date.
The following messages will be seen:

> • **Date entered for xxxxxxxxxxxxx date is not in a valid date format**

> • **Date entered for xxxxxxxxxxxxx date is not a valid date**

Where "xxxxxxxxxxx" is the name of the date that is being entered. The first error occurs if the format yyyy-mm-dd is not adhered to and the second error will occur is an invalid date is entered (i.e. more than 12 months or too may days for the month etc.). In either case a valid date in the correct format must be entered.

8.5.4 Text Box Allowable Length Validation

The scrolling text boxes in the system are all set with a maximum allowable number of characters. If the length is exceeded the following message appears.

- **You have exceeded the max length of nnn characters for xxxxxxxxxxxxx**

Where "xxxxxxxxxxxxxx" is the name of the text field being entered and "nnn" is the number of characters allowed in the text box. If this error is encountered, then the amount of text must be reduced to fit the text box.

8.5.5 Numeric Field Validation

There are a few numeric fields within the application. There is a validation check that numeric data is added. If alpha characters are include then the following message appears.

- **The field xxxxxxxxxxxxxxxxxxxxx must be a number**

There is also a check for positive numeric values in the population of trial subjects. If a negative number is entered then the following message appears.

- **The field xxxxxxxxxxxxxxxxxxxxx must be a positive number**

Where "xxxxxxxxxxxxxxxxx" is the name of the numeric field that is being completed. In either case enter correct numeric data that is a positive value if that is appropriate.

8.5.6 Search Field Validation

There are two search facilities in this application. There are a number of checks that the search criteria are valid. If there is no information in the search fields, or the criteria do not make sense, the following message appears:

- **You have entered invalid search criteria**

Where the search prompts for an operator (for example 'contains' or 'equals') before a give field, the operator **must** be specified if its subsequent field is filled out. If is not the case, the following appears:

- **You must select a logical operator from the Term dropdown list**

A specific validation is carried out on the classification code for the MedDRA database search. If a non-integer code is placed in this field and then a search is initiated, then the result will be the following message:

- **You must enter an integer value into the Classification code**

9 VALIDATING THE CT APPLICATION

9.1 Introduction

The system includes very few data consistency checks whilst the CT Application form is being created. The application now allows users to validate the Clinical Trial Application based on predefined business rules. These business rules may now be reviewed online in the EudraCT page.

- Click on the 'EudraCT Validation Rules' link in the User Guides section of the page.

9.2 Validate Application

1. Navigate to the 'Clinical Trial Application Menu' and click the link '**Validate Application**' The validation routine runs through the current application and produce a screen report of inconsistencies:

Validate Application Results

EudraCT Number : 2008-006022-34
Sponsor's Protocol Code Number : BAY43-9006/13337
National Competent Authority : UK - MHRA
XML File Identifier : RXSvR3JopIqFTlMgNnfCESbebCk=
Validation Date and Time : 2009-05-12 17:07:11 BST

This is the list of inconsistencies found in your application. Please go back and correct the inconsistencies before submission.

a
Expand All **Collapse All** *d*
b **Sections**
▶ D IMP Identification Index - ID: PR1 *c*
▶ D.8 Responsible Sites - ID: RS1
▶ D.8 Responsible Sites - ID: NR1
▶ D.8 Responsible Sites - ID: RS3
▶ H. Ethics Committee/ National Competent Authority
Total *e* **5 Failed**

Fig. 100 – Validate Application Results - Précis

Note: It is recommended that Internet Explorer is used to ensure the formatting of the report displays correct. There are known issues surrounding the display of the reports within Firefox.

9.3 Review Validate Application Results

2. The précis within the grey area details the section where inputs to the CTA failed the business rules (e.g. *c*) as well as providing a total number of inconsistencies within the entire CTA (*e*). In the above example, five business rules were not met.

3. To expand an individual section, click the arrow alongside a particular section (*b*). The issue expands (click the arrow again to close the section). To drill down further click subsequent arrows. Alternatively, click 'Expand All' (*a*). To examine the detail of an inconsistency, click the text and you

jump to the detail view:

Fig. 101 – Validate Application Results – Detail View

- ***a***: 'D.8 Responsible Sites' denotes the section of the CTA form in which the rule has been broken.

- ***b***: Field denotes the field of the particular section in which the rule has been broken.

- ***c***: 'Rule ID' denotes the rule that has been broken.

- ***d***: 'Description' provides instructions for how to properly meet the rule in question.

- To view the latest business rules for the Clinical Trial Application, please go to the Supporting Documentation page of the EudraCT website: https://eudract.emea.europa.eu/document.html

4. Use the information to more rectify all identified data inconsistencies.

Note: Whilst it is hoped that the validation process will enable applicants to submit CTAs that adhere to all of the business rules, it is appreciated that this may not always be possible. For this reason, applicants may still create a submission package with a CTA that does not meet the validation rules. It is expected that such issues are kept to an absolute minimum, and should be accompanied by an explanation in the covering letter for the submission. This will help NCAs and IEC ensure a more efficient processing of the Clinical Trial Application.

5. To close the expanded list of inconsistencies, click 'Collapse All'.

6. You may now click 'Save As PDF' (***a***) at the bottom of the screen to save the entire report as a PDF document or click 'Return to Application Menu' (***b***) to go back to the Clinical Trial Application Menu:

10 COMPARING CT APPLICATIONS

10.1 Introduction

A further enhancement, this feature enables users to compare Clinical Trial Application forms on the system (and stored locally) in a way that actually indicates differences between the two CTAs, much like a track changes function in MicroSoft Word:

10.2 To Compare two CTA Forms

1. One Clinical Trial Application (or CTA in progress) must be loaded in the system. Choose either 'Click here to create a new Clinical Trial Application' or 'Click here to load a saved Clinical Trial Application' in the EudraCT Welcome page.
2. Once a CTA is loaded, the Clinical Trial Application Menu appears:

Fig. 102 – Clinical Trial Menu – Compare XML option highlight

3. Click on the 'Compare XML' link (*a*) to compare the currently loaded CTA with another CTA. The 'Find XML to Compare to' page appears:

Fig. 103 – Find XML to Compare – Browse function highlight

4. Click 'Browse…' (highlighted, above) to find the XML file you wish to compare with the currently loaded CTA and the 'Choose file' dialogue appears:
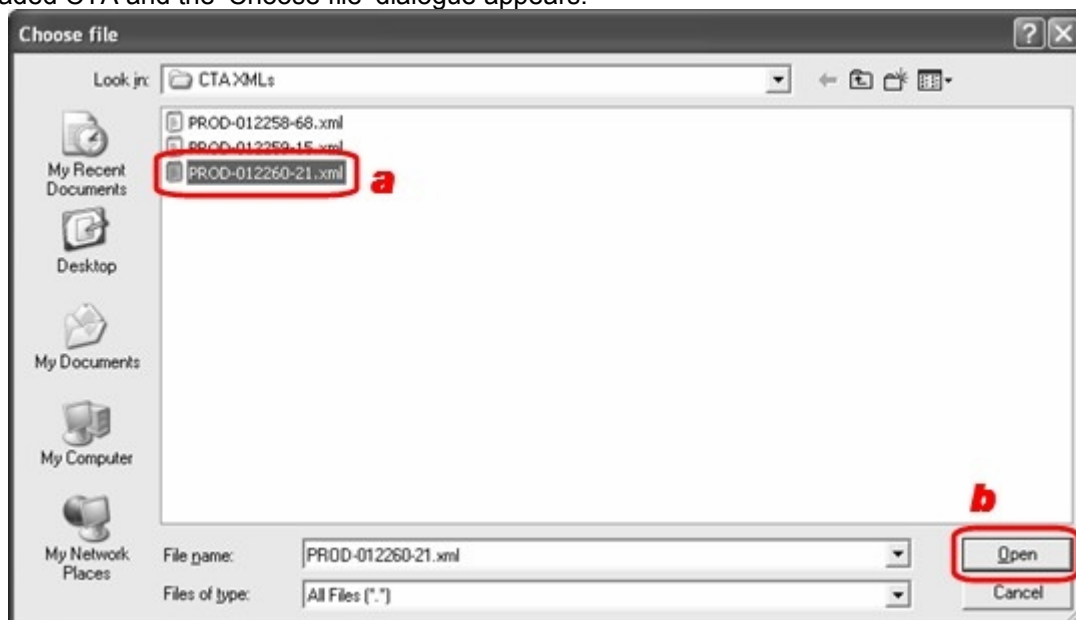

Fig. 104 – Find XML to Compare – Choose File dialogue – Open highlight

5. Now, find the CTA, which will end with the '.xml' file extension. Once you have found it, click to select it (*a*). Then click 'Open'(*b*).

6. The 'Find XML to Compare to' page appears, with the XML File's path in the field (*a*, below):

Fig. 105 – Find XML to Compare – Compare function highlight

7. Click 'Compare' (***b***, above) and the two CTA files undergo a comparison. When the comparison is complete, the 'Comparison Results' page appears.

10.3 Clinical Trial Application Comparison Results

Fig. 106 – Find XML to Compare – Compare function highlight

Note: It is recommended that Internet Explorer is used to ensure the formatting of the report displays correct. There are known issues surrounding the display of the reports within Firefox.

8. The Comparison Results Page appears with a précis of the differences between the two xml files. It includes:

- Details of all insertions, updates and deletions (***d***, above)

- Ability to expand and collapse the entire report to the lowest level of granularity (***b*** & ***c*** above).

- **Click** a section to expand and display child elements (e.g. ***a***, above).

- **Click** 'Cancel' to return to the Clinical Trial Application Menu (***e***, above).

9. To view detail of the changes between the two compared files, click on the Section you wish to view in more detail (in this example 'A. Trial Identification'). The Details drop down beneath the section heading:

Sections	Inserted	Updated	Deleted
Expand All Collapse All			Cancel
▼ A. Trial Identification	0	5	0
A.2 Eudract Number		✔	
A.3 Full title of the trial		✔	
A.4 Sponsor's protocol code number		✔	
A.4 Sponsor's protocol version		✔	
A.4 Sponsor's protocol date yyyy-mm-dd		✔	
▶ B. Sponsor Identification	0	10	0
▶ C. Applicant Identification	12	9	0
▶ D. Description of the IMP	4	13	32
▶ D.7. Information on the Placebos	0	2	0
▶ D.8. Site(s) where the qualified person certifies batch release	2	12	2
▶ E. General Information on the Trial	0	28	0
▶ F. Population of Trial Subjects	0	4	3
▶ G. Investigators/Facilities	61	36	32
▶ H. Ethics Committee/ National Competent Authority Information	5	1	0
Total	84	120	69

Fig. 107 –Compare Results – Section A. – Changes detail

10. To view the details as tracked changes, scroll down the page. The struck through text (~~replaced~~) is that which is in the 'compare' file, whilst the underlined text (inserted) is that which is in the loaded file (the CTA currently loaded/being worked on):

A. Trial Identification

These are the details for section A. Trial Identification. Enter details, and use 'Continue'.
You can Copy/ Paste items of free text (e.g. Protocol Title) from a word processing file of the Protocol.
The Sponsor's Protocol Code Number must be that used to obtain the EudraCT Number.

A.1 National Competent Authority ▲   UK - MHRA
A.2 EudraCT Number ▲   2008-00~~6022~~345121-11
A.3 Full title of the trial ▲

~~Randomized phase II study of sorafenib plus bicaluamide vs. placebo plus bicalutamide in castration-resistant asymptomatic or mildly symptomatic metastatic prostate cancer patients who had orchiectomy or are receiving a LHRH analogue~~An Exploratory Phase I, Single Centre, Double-blind, Randomised, Placebo-controlled, Parallel-group Study to Assess the Pharmacokinetics of Increasing Oral Doses of AZD5985 in Healthy Male Volunteers

A.4 Sponsor's protocol code number ▲   ~~BAY43-9006/13337~~D23OOC00001
  Sponsor's protocol version   ~~3.3~~1
  Sponsor's protocol date yyyy-mm-dd   2008-~~10-06~~09-29
A.5 Name or abbreviated title of the trial where available
A.6 ISRCTN number, if available
  International Standard Randomised Controlled Trial Number
A.7 Is this a resubmission? ▲   No
  Indicate the resubmission letter or else select 'First submission' ▲   First submission
For a first submission select 'First submission'. For a resubmission select A for the first resubmission, B for the second resubmission, etc.

Fig. 108 –Compare Results – Section A.3 Tracked Changes

11. To return to the Clinical Trial Application Menu, click 'Cancel' at the top of the page.
Note: It is recommended that Internet Explorer is used to ensure the formatting of the report displays correct. There are known issues surrounding the display of the reports within Firefox.

11 PREPARING SUBMISSION PACKAGES

11.1 Introduction

In order to more efficiently and quickly prepare a Controlled Term Application package, EudraCT now gives users the option to prepare a submission package for National Competent Authority or for the Independent Ethics Committee.

Fig. 109 –Clinical Trial Application Menu – Prepare Submission Packages option highlighted

Note: Before a submission package is prepared, a Clinical Trial Application must first be completed, then validated.

11.2 To Prepare a Submission Package for NCA:

1. One completed and validated Clinical Trial Application must be loaded in the system. If the CTA has not been validated, please select the 'Validate XML' option at the bottom of the Clinical Trial Application Menu (see (See section 9 Validating the CT Application for details on this feature). This ensures that your Clinical Trial Application is error and issue free before submission.
2. If you have a complete and validated CTA loaded, **click** 'Prepare Submission Package' in the CTA Application Menu (see screenshot above). The Prepare Clinical Trial Application Package screen appears:

Fig. 110 – Prepare Clinical Trial Application Package – Create Submission Package For NCA option highlighted

3. Select your favoured language from English or Spanish using the Select Language drop-down, then **click** 'Create Submission Package for National Competent Authority'.
4. The Package is created automatically, with the following name convention "[EudraCT number] [Country of CT] [YYYYMMDD] CTA Package.zip":

Fig. 111 – Opening Clinical Trial Application Package dialogue

5. You can either open the file to examine its contents, which include the full data xml file, a PDF of the completed form and a PDF of the Validation Report:

Fig. 112 –Clinical Trial Application Package – Zip file open

6. Alternatively, simply click the 'Save to Di<u>s</u>c' radio button and click 'OK'. The file is saved to the folder you have designated for web browser downloads.
7. Then you are free to send the package to the relevant NCA contact according to your own business processes.

11.3 To Prepare a Submission Package for Independent Ethics Committee:

1. One completed and validated Clinical Trial Application must be loaded in the system. If the CTA has not been validated, please select the 'Validate XML' option at the bottom of the Clinical Trial Application Menu (see (See section 9 Validating the CT Application for details on this feature). This ensures that your Clinical Trial Application is error and issue free before submission.
2. If you have a complete and validated CTA loaded, **click** 'Prepare Submission Package' in the CTA Application Menu (see screenshot above). The Prepare Clinical Trial Application Package screen appears:

Fig. 113 – Prepare Clinical Trial Application Package – Create Submission Package For IEC option highlighted

3. Select your favoured language from English or Spanish using the Select Language drop-down, then **click** 'Create Submission Package for Independent Ethics Committee'.
4. The Package is created automatically, with the following name convention "[EudraCT number] [Country of CT] [YYYYMMDD] CTA Package.zip":
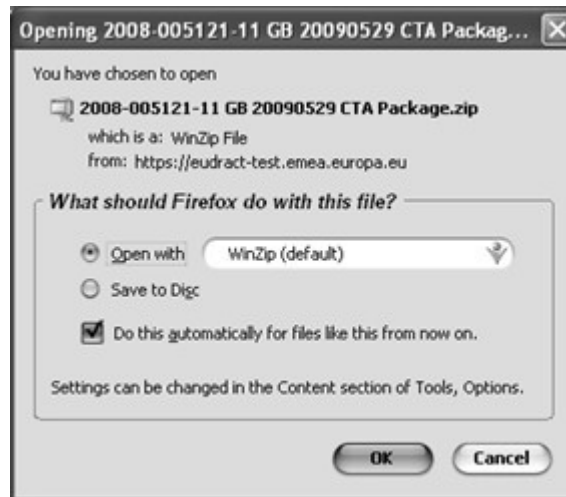
Fig. 114 – Opening Clinical Trial Application Package dialogue

5. You can either open the file to examine its contents, which include the full data xml file, a PDF of the completed form and a PDF of the Validation Report:
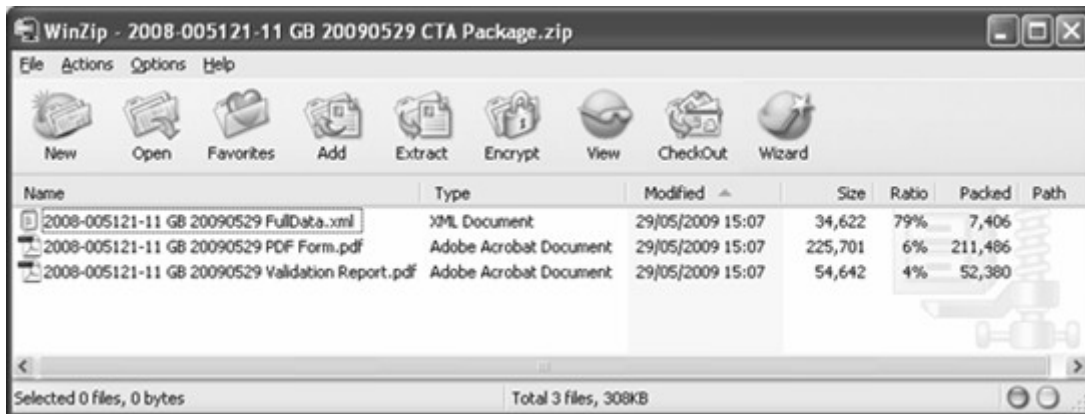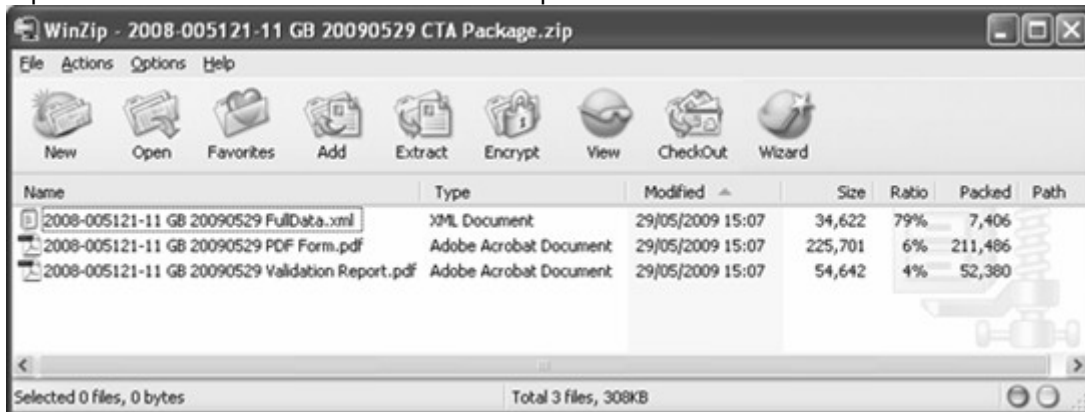

Fig. 115 – Clinical Trial Application Package – Zip file open

6. Alternatively, simply **click** the 'Save to Di<u>s</u>c' radio button and **click** 'OK'. The file is saved to the folder you have designated for web browser downloads.
7. Then you are free to send the package to the relevant NCA contact according to your own business processes.

12 USING THE CT APPLICATION FORM AS A TEMPLATE

12.1 Introduction

The system has been designed so that the CT Application may be created as a template for a multi-centre trial that will run in several Member States. The template can be developed to include all the CT information that will be identical irrespective of the Member State in which the CT will run.
This template application may then be completed for each of the Member States in which the trial will be run by including the NCA specific information.

12.2 Creating a new Template

The template is created using the normal application. From the Welcome screen the option 'Click here to create a new Clinical Trial Application' and the 'Initial Required Information' screen appears.

Fig. 116 – Initial required Information

1. Enter the EudraCT number for the CT Application and press '**Continue**'. The 'Clinical Trial Application Menu' appears without an NCA selected (See Fig. 117).

2. The CT Application is then completed as described in the body of the document (saving as an XML at frequent intervals).

3. When the CT information common to the trial has been completed, then the final template can be saved as an XML file.

4. This template can then be used to create the NCA specific versions.

Fig. 117 – CT Application Menu

12.3 Producing Member State Specific CT Applications from a Template

1. Reload the template created using the process described in section 12.2 Creating a new Template to the CT Application using the link from the Welcome page 'Click here to load a saved Clinical Trial Application'.

2. The CT Application template data loads into the application.

3. Access the '**A. Trial Identification**' section from the CT Application Menu and select the appropriate NCA from the drop-down list.

4. Save the CT Application as a new XML file, with a new filename relating to the NCA.

5. Add to the CT Application all the additional information that is specific to the CT Application for the NCA selected saving as an XML at frequent intervals to create the final NCA specific CT Application.

6. Repeat the process of loading the template, selecting a MS and then adding the MS specific information for all Member States to which an application will be made.

12.4 Other Options for Creating Templates

The process described here for completing a template is the most straightforward. However, a CT Application that has a EudraCT number (which is a mandatory field) and also a NCA can be loaded into the application. The NCA can then be changed and any data specific to the new NCA can be updated to produce the completed CT Application for the second NCA.

By paying proper attention to a file naming convention, the XML files for the different MS can be saved separately and submitted correctly.

13 GLOSSARY OF TERMS

CT	Clinical Trial
CTF	Central Technical Facility
EC	Ethics Committee
MedDRA	The Medical Dictionary for Regulatory Activities
MPD	Medical Product Dictionary
NCA	National Competent Authority (replaces Member State Competent Authority, MS Competent Authority and MSCA for v5.0 of EudraCT).
MS	Member State
PDF	A standard document format that is used to produce the printable version of the CT Application Form. Download the Adobe PDF viewer Adobe Acrobat from www.adobe.com if you cannot view this file type.
XML	The data format of the saved CT Application Form information
HLGT	High Level Group Term
HLT	High Level Term
LLT	Low Level Term
PT	Preferred Term
SOC	System Organ Class

14 SUMMARY OF SYSTEM ERROR MESSAGES

Message	Screen	Correction	Ref.
Requestor name is required	Get Security Code	Enter correct information or cancel	5.4.1
Requestor e-mail is required	Get Security Code	Enter correct information or cancel	5.4.1
You have entered an invalid Requestor's e-mail Address	Get Security Code and Get EudraCT number	Enter correct information or cancel	5.4.2 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.	5.4.4 6.3.9
There has been a technical error processing this request.	Get security code and Get EudraCT number	Press 'OK' and restart your Browser.	5.4.5 6.3.10
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

Message	Screen	Correction	Ref.
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
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
The XML file that you have tried to load does not conform to the EudraCT XML schema. Unexpected element {http://eudract. ClinicalTrialApplication.xsd}:"eeeeee"	Load XML	Check that the XML file is correct. If the load operation fails consistently then refer tot eh the EudraCT Help desk.	8.5.1
The EudraCT number that you have entered does not exist in the system	Application section A	Enter correct EudraCT number	8.5.2
EudraCT number entered does not match the format xxxx-xxxxxx-xx	Application section A	Enter correct EudraCT number	8.5.2
Date entered for xxxxxxxxxxxxx date is not in a valid date format	Application sections A, D.8, H	Enter correct data format	8.5.3
Date entered for xxxxxxxxxxxxx date is not a valid date	Application sections A, D.8, H	Enter a valid date	8.5.3
You have exceeded the max length of 'nnn' characters for xxxxxxxxxxxxx	Application sections A, D, D.7, D.8, E, H.	Reduce the amount of information added in the text box.	8.5.4
The field 'xxxxxxxxxxxxx' must be a number	Application section E, F	Enter only valid numeric data in the field.	8.5.5
The field 'xxxxxxxxxxxxx' must be a positive number	Application section E	Enter positive number	8.5.5
You have entered invalid search criteria	Application section D, E	Enter search criteria in at least the minimum number of fields	8.5.6
You must select a logical operator from the Term dropdown list	Application section E	Select 'equals', 'contains' or 'starts with' from the list	8.5.6

Message	Screen	Correction	Ref.
You must enter an integer value into the Classification code	Application section E	Enter a valid classification code in the MedDRA search.	8.5.6