

<b>To all participants</b> .....	1
Help file .....	1
How to fill in Case Record Forms (CRFs) .....	2
EURAP organisation .....	3
Passwords .....	4
Who needs the "coordinator" password? .....	4
Who needs the "local" password? .....	4
How to install the EURAP software .....	4
How to set Default Values for your centre .....	6
Status field .....	8
Options for Reporting Physicians .....	8
Status provided automatically by the software .....	9
9Additional options for National Coordinators .....	9
<b>To Local centres</b> .....	10
How to add a new pregnancy .....	10
How to send CRFs .....	11
When you should send CRFs .....	13
How to import CRFs .....	14
How to correct CRFs according to the requirements of the National Coordinator .....	15
<b>To National Coordinators</b> .....	17
How to import CRFs sent by Local Centres .....	17
How to correct CRFs of Local Centres .....	18
How to send CRFs to Local Centres <b>(after your corrections)</b> .....	19




How to check CRFs received from Local Centres <b>(after their corrections)</b> .....	23
How to forward CRFs to the Central Registry .....	24
How to send CRFs received from the Central Registry to Local Centres .....	26
Forms to recall.....	27
<b>Frequently asked questions</b> .....	28
Who needs the password? .....	28
Do I need a CD-ROM to use EURAP software? .....	28
To whom shall I send my own CRFs?.....	28
Why does the email software lack the Coordinator's email in the recipient field? .....	29
Which is the easiest way to send CRFs?.....	29
When shall I send CRFs?.....	29
Why have my CRFs disappeared?.....	29
Why have red lights added by National Coordinators disappeared?29	
Why has the importing procedure of CRFs failed?.....	30
Why do I get no answers after sending CRFs to the “upper level”?30	
Why have I a duplicate of the same pregnancy? .....	31
How can I change pregnancy IDs? .....	31
What happens with twin pregnancies?.....	31

## TO ALL PARTICIPANTS

### HELP FILE

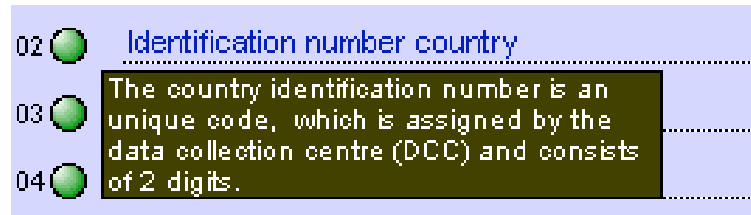
**Please, read the instructions!**


**During the pilot use of the software we found out that failure to read the instructions was the most common cause of failure to complete or transmit CRFs**


1. The software has a “help” function, which is intended to guide you through all the procedures. Please, make sure that you use this function
2. To read the help file click on  (on the top right of any subform) and on  in the next window
3. After clicking on “More help” you can click on  and print the entire file


## HOW TO FILL IN CRFS

Click on the blue caption of each field: a message will appear with the instructions for entering information correctly



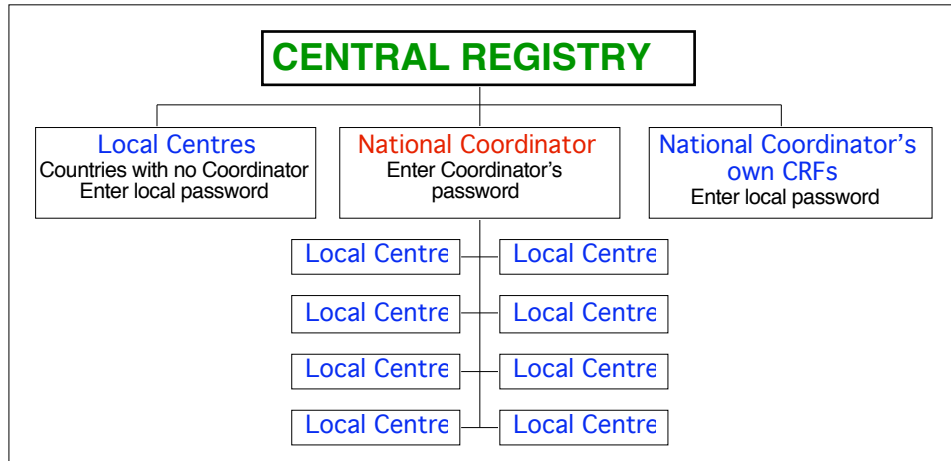
02  Identification number country

03  The country identification number is an unique code, which is assigned by the data collection centre (DCC) and consists of 2 digits.

04 

The image shows a light blue rectangular box containing three numbered items. Each item starts with a number (02, 03, 04) followed by a green circle icon. Item 02 is a blue hyperlink 'Identification number country'. Item 03 is a text box with a black background and white text explaining the country identification number. Item 04 is a green circle icon without text.

# EURAP ORGANISATION



## **PASSWORDS**

### **Who needs the “Coordinator” password?**

Only National Coordinators for processing CRFs that they electronically receive from local centres.

The reason is that this password allows National Coordinators to:

1. ask local Reporting Physicians for corrections
2. send CRFs in two directions: to Local Centres and to the Central Registry

If you are a National Coordinator ask the Central Registry for this password

### **Who needs the “Local” password?**

1. Local Centres
2. National Coordinators when working with their own CRFs; in this case they need to follow the procedure described in the section “To Local Centres” (page 10)

The Local password is **EURAP**

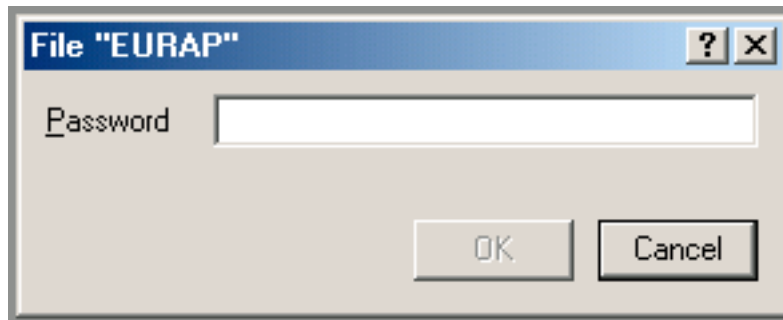
## **HOW TO INSTALL THE EURAP SOFTWARE**

1. Insert the CD-ROM, open the “EURAP win” and copy the “EURAP2” folder to your Hard disk (preferably to your disk C)

2. Eject the CD-ROM

Please, do not modify in any way the name of the files contained in the folder "EURAP2"

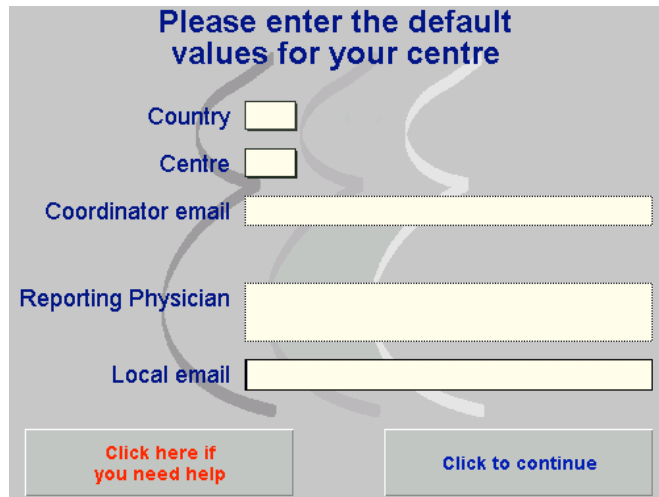
3. Open the "EURAP2" folder and start the program by clicking twice on "EURAPexe". At this point a window will open asking for the password



**Please, type the right password!** You need the "Coordinator" password only if you are a National Coordinator and plan to work on the Local Centres' CRFs, otherwise **use the Local password.** Everybody needs a password for privacy reasons

## HOW TO SET DEFAULT VALUES FOR YOUR CENTRE

After installing the software, the following window will open:



Please enter the default values for your centre

Country

Centre

Coordinator email

Reporting Physician

Local email

[Click here if you need help](#) [Click to continue](#)

- If you do not find the code of your country or centre, please ask the Central Registry or your National Coordinator respectively for it
- Enter your National Coordinator's email address in the "Coordinator email" field. If you are a National Coordinator enter the email address of the Central Registry: [eurap@istituto-besta.it](mailto:eurap@istituto-besta.it)

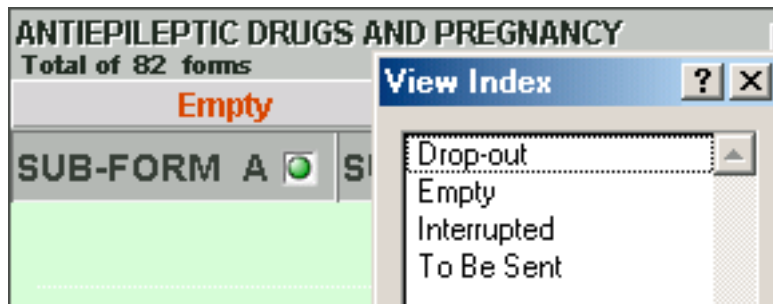
- Complete the “Reporting Physician” field with your full name (this field can be modified on each CRF in case National Coordinators work with more than one Reporting Physician)
- Enter your email address in the “Local email” field

**Please note that you can change Default Values at any moment by clicking on “Set Default Values” in the Menu “Utilities”**

Utilities	Window	Help
<u>1</u> Save to File		Ctrl+1
<u>2</u> Forms to Send		Ctrl+2
<u>3</u> Forms to Check		Ctrl+3
<u>4</u> Forms to Recall		Ctrl+4
<u>5</u> List View		Ctrl+5
<u>6</u> Set Default Values		Ctrl+6
<u>7</u> EURAP Help		Ctrl+7
<u>8</u> About EURAP		Ctrl+8
<u>9</u> Statistics		Ctrl+9
<u>0</u> Export Stats		Ctrl+0

## STATUS FIELD

### Options for Reporting Physicians



By clicking on the Status field, you will open a window showing the following options:

**Empty**            initial Status of each new subform  
**To Be Sent**     Status needed for sending subforms

**Drop-out\***        for patients lost to follow up  
**Interrupted\***    for early terminated pregnancies  
**Not Eligible\***    for pregnancies not meeting inclusion criteria

*\*to be used exclusively by the Central Registry*

}

## **Status provided automatically by the software**

<b>Sent</b>	given <u>by the software</u> once forms are sent
<b>To Be Checked</b>	given <u>by the software</u> to imported subforms
<b>Definitive</b>	given <u>by the software</u> when the single subform (not the entire form) is correct. A “Definitive” subform cannot be modified
<b>Complete</b>	when all 5 subforms are “Definitive”, the software will mark each one of them as “Complete”

## **Additional options for National Coordinators**

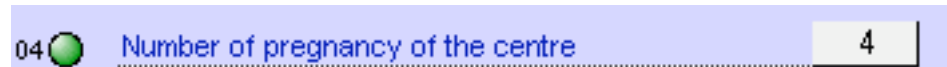
<b>OK</b>	CRFs included in the Central Registry as “Definitive” will be received by National Coordinators with the Status “OK”, so that they can be resent to reporting physicians. Once sent to local centres, their Status will automatically change into “Definitive”
<b>To Be Resent</b>	used <u>by National Coordinators</u> to send CRFs to reporting physicians if corrections are needed
<b>To Be Forwarded</b>	used <u>by National Coordinators</u> to send CRFs to the Central Registry


## TO LOCAL CENTRES

### HOW TO ADD A NEW PREGNANCY

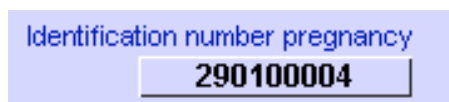
Click on 

If you have set the “Default Values” correctly (see How to set Default Values for your centre, page 6), a progressive number will appear in field 4 of subform A



04  Number of pregnancy of the centre ..... 4

If you have set the Default values correctly the software will automatically produce a code (**Identification number – ID**) made of: the code for your country (2 digits), the code for your centre (2 digits) and the code for the pregnancy (5 digits)



Identification number pregnancy  
290100004

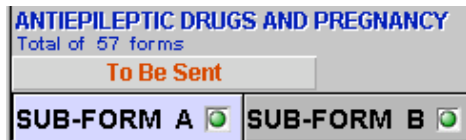
The [identification number \(ID\)](#) cannot be changed directly. To have it automatically modified, you need to add the right data in the corresponding fields



## HOW TO SEND CRFS

**Local Centres need to send CRFs to their own National Coordinator following the procedure here below:**

1. Open your email program
2. Open the file “EURAPexe”
3. Fill in the subforms. When they are ready to be sent, change their status from “EMPTY” or “TO BE CHECKED” into “**TO BE SENT**”.

To do this: click on the Status box and then, in the window that will open, choose “TO BE SENT”




4. Click on  (on the top right)
5. In the next window, click on  and then on OK

If your email program opens automatically, an email message with the National Coordinator's email address and the attached file "EURmail" will appear. The message – automatically saved in the drafts folder – will contain the list of the subforms to be sent. Please, make sure never to delete the list

If your email program does not open automatically, you will have to open it before activating the sending procedure and then:

- click on "New message"
- enter your National Coordinator's email address
- attach the "EURmail" created in your "EURAP2" folder and send it

6. If you are a National Coordinator - or a Reporting Physician of a country with no Coordinators – and plan to send your own CRFs, please enter the email of the Central Registry: [eurap@istituto-besta.it](mailto:eurap@istituto-besta.it)
7. If you now look at the status of your subforms you will notice that it has changed from "TO BE SENT" into  **Sent**
8. Moreover, each subform is now marked with **DO NOT MODIFY** and cannot be changed or updated until you re-import them, corrected by your National Coordinator

After the sending procedure, only the CRFs “SENT” will appear on screen.  
To see all your CRFs, click twice on the “FIND” button



## WHEN YOU SHOULD SEND CRFs

Each subform has to be sent immediately after being filled out.

**Please, do not wait until the end of the pregnancy before sending CRFs!**


**Note** that every time you send a form, you automatically send all 5 subforms (ABCDE) together, even though not all of them need to be checked, and some of them may still be empty

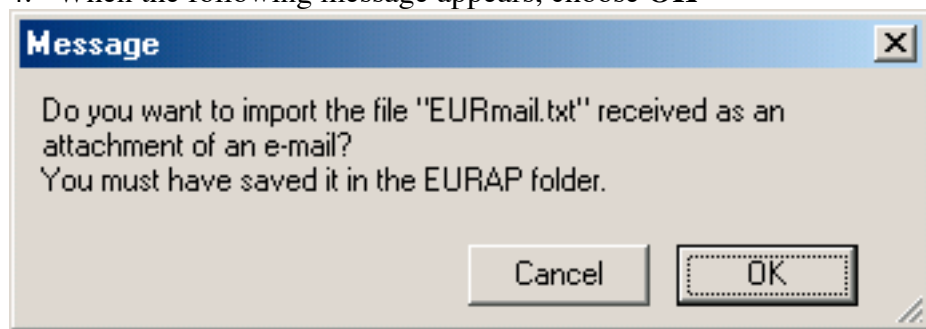
**Please avoid multiple sending.** Different forms can be included in the same EURmail. To do this, you should just change the Status of all the forms ready to be sent, and start the sending procedure only once

## HOW TO IMPORT CRFs

1. You will receive an email message from your National Coordinator with an attached file called "EURmail"
2. **Save the attached file into your "EURAP2" folder**  
**Attention!** An alert message may appear saying that there is an older "EURmail", and asking you if you want to substitute it. **Click on Yes**



3. Open the "EURAPexe" and click on 
4. When the following message appears, choose **OK**

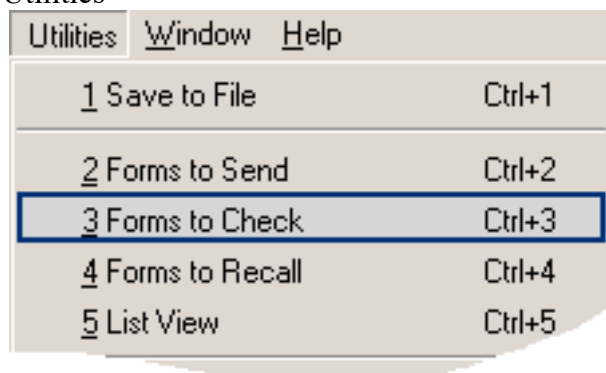


5. The imported subforms will automatically get the Status

**To Be Checked**

## HOW TO CORRECT CRFs ACCORDING TO THE REQUIREMENTS OF THE NATIONAL COORDINATOR

1. To find the subforms which need corrections, select “Forms to Check” in the Menu “Utilities”

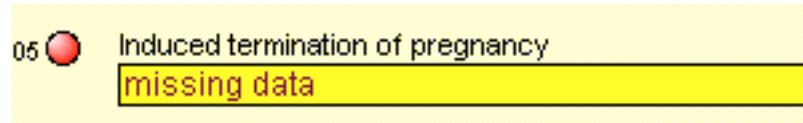



2. You will find a red dot on top of each subform which needs to be corrected



3. Click on the subform with the red dot 

4. Click on the dot  and the Coordinator's comments will appear in a yellow field



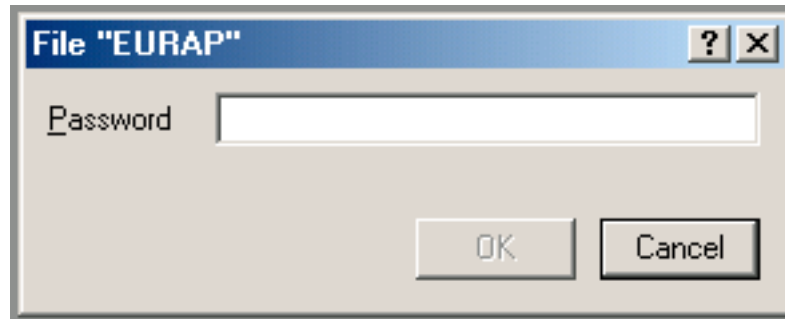
5. Read the comments, but **NEVER REMOVE IT!**
6. Make the requested corrections into the appropriate field near the dot 
7. If you have any comments, enter (or add) them in the comment field at the bottom of the subform, but please do not change the content of the yellow field
8. Change the Status of the corrected subforms into **“TO BE SENT”**
9. Finally, send the corrected CRFs again, following the procedure described in the section **“How to send CRFs”** (page 11)

## TO NATIONAL COORDINATORS

**(It is only for when you work with the CRFs of your Local Centres!  
When working with your own CRFs you need to apply the same  
procedure followed by Local Centres)**

## HOW TO IMPORT CRFs SENT BY LOCAL CENTRES

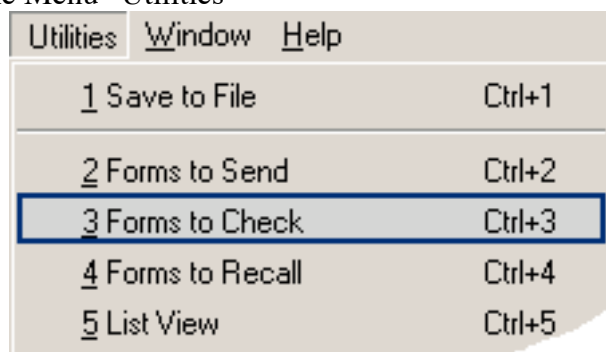
1. See section “How to import CRFs” (page 14)
2. Remember to open the “EURAP” file with the National Coordinator’s password




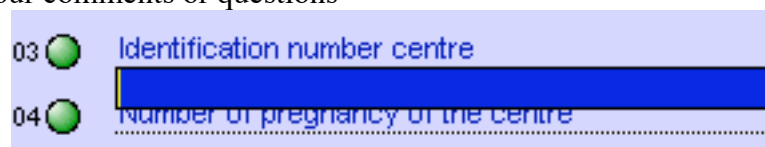
3. The imported subforms will automatically get the Status “TO BE CHECKED”

## HOW TO CORRECT CRFs OF LOCAL CENTRES

1. To find the subforms received from Local Centres click on “Forms to check” in the Menu “Utilities”



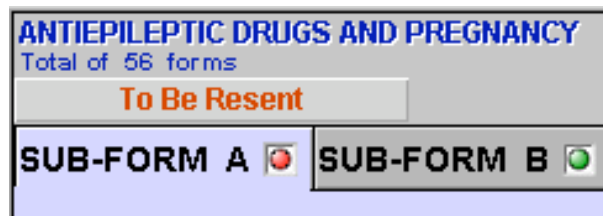
2. Check all the CRFs carefully and click on the dots  near the fields that need explanations or corrections. A blue field will open: enter here your comments or questions



3. The dot  will become red, highlighting the correction requested



4. When finished, change the Status of the subforms **with red dots** from “TO BE CHECKED” to “**TO BE RESENT**”



5. In case the subforms from your Local Centres do not need any correction, please forward them to the Central Registry following the procedure described in “How to forward CRFs to the Central Registry” (page 24)

## **HOW TO SEND CRFs TO LOCAL CENTRES** **(after your corrections)**

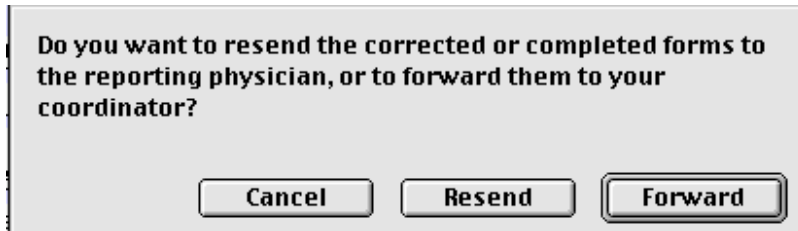
1. Open your email program

2. If you have closed the “EURAPexe” after correcting the CRFs, re-open it using the National Coordinators’ password



3. Click on **Send** (on the top right)

4. If your “EURAPexe” also contains CRFs ready to be forwarded to the Central Registry you will get the following message:

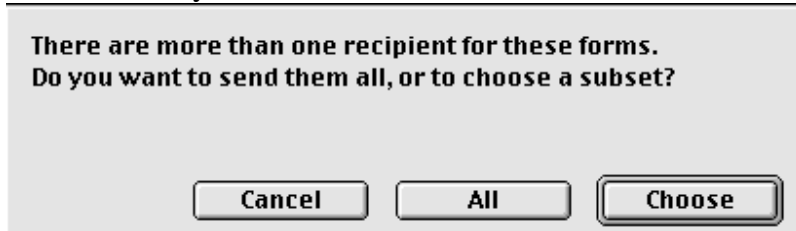


Click on **Resend**



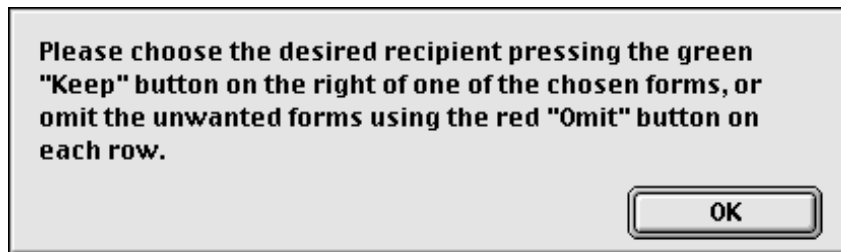
5. In the next window, click on **Email** and then on OK

6. If your “EURAPexe” contains CRFs ready to be sent to different Local Centres you will be asked:



Click on **Choose**

At this point the following message will appear:



7. Click on the “green button” of one of the CRFs of the recipient you want to send forms to:

FORMS TO RESEND							Print	Preview	Find	Email	Export	Close	Help	
2 forms out of 433														
ID pregnancy nr	1st Notification	Last Menstr.	Family Name	First Name	Reporting Physician	Omit								
A 140700040 A to be resent			BAT	DIN	Dina Battino	<input type="checkbox"/>								
A 140700041 A to be resent			MAM	DAN	Daniela Mamoli	<input type="checkbox"/>								


If your email program opens automatically, an email message with the local centre's email address and the attached "EURmail" will appear  
If your email program does not open automatically, you will have to open it before activating the sending procedure and then:

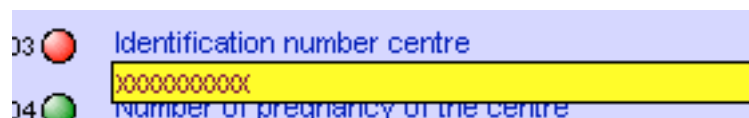
- click on "New message"
- enter the email address of the Local Centre
- attach the "EURmail" created in your "EURAP2" folder and send it

After that, only the sent CRFs will appear in your "EURAPexe". To see all your CRFs, click twice on the **FIND** button



## HOW TO CHECK CRFs RECEIVED FROM LOCAL CENTRES (after their corrections)

1. Follow the procedure described in “How to import CRFs sent by Local Centres” and “How to correct CRFs of Local Centres”
2. For each field modified according to your suggestions, click on the  dot and remove the content of the yellow field



3. The red dot will change into a green dot showing a corrected field
4. If all the fields are corrected, send the CRFs to the Central Registry (see page 24)
5. If some corrections are still needed, send the CRFs again to the Local Centres (see “How to send CRFs to Local Centres, after your corrections”, page 19)


## HOW TO FORWARD CRFs TO THE CENTRAL REGISTRY

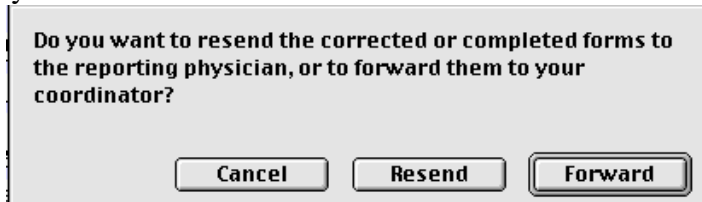
1. When CRFs from Local Centres are ready to be sent to the Central Registry (after checking them and only when they are corrected), change their Status from “TO BE CHECKED” into “**TO BE FORWARDED**”



ANTIEPILEPTIC DRUGS AND PREGNANCY  
Total of 56 forms  
To Be Forwarded  
SUB-FORM A  SUB-FORM B




2. Click on  (on the top right)
3. If your “EURAPexe” also contains CRFs ready to be sent to Local Centres you will be asked



Do you want to resend the corrected or completed forms to the reporting physician, or to forward them to your coordinator?

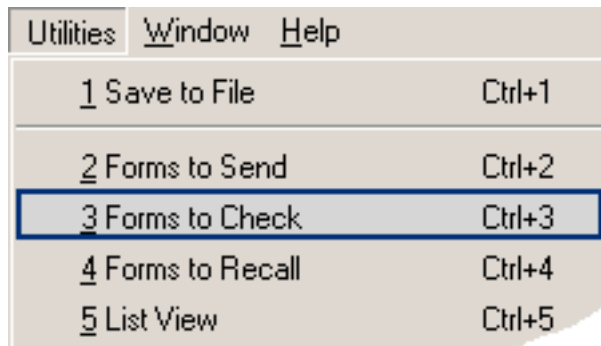
Cancel Resend Forward

Click on **Forward**

4. In the next window click on  and then on OK
5. If your email program opens automatically, an email message, with the Central Registry email address and the attached file “EURmail” will appear  
If your email program does not open automatically, you will have to open it before activating the sending procedure and then:
- click on “New message”
  - enter the email address of the Central Registry ([eurap@istituto-besta.it](mailto:eurap@istituto-besta.it))
  - attach the “EURmail” created in your “EURAP2” folder and send it

## HOW TO SEND CRFs RECEIVED FROM THE CENTRAL REGISTRY TO LOCAL CENTRES

1. Open the “EURAPexe” using the National Coordinators’ password
2. Import the CRFs received from the Central Registry following the standard importing procedure
3. The Status of subforms included as “DEFINITIVE” in the Central Registry will be “OK”, while the Status of subforms which need additional corrections will be “TO BE CHECKED”. In both cases the CRFs are ready to be resent to Local Centres
4. To see the CRFs which need corrections, click on “Forms to check” in the Menu “Utilities”



Utilities	Window	Help
1 Save to File		Ctrl+1
2 Forms to Send		Ctrl+2
3 Forms to Check		Ctrl+3
4 Forms to Recall		Ctrl+4
5 List View		Ctrl+5

5. If you agree with the comments made by the Central Registry, send the CRFs to the Local Centre for additional corrections, using the procedure described in “How to send CRFs to Local Centres” (page 19)
6. If you do not agree, add your comments into the field marked with red dots or, for general comments, use the yellow field on top of each subform (which has been purposely created for communications between National Coordinators and the Central Registry) and re-send the forms to the Central Registry using the procedure described in “How to forward CRFs to the Central Registry” (page 24)

**Registration (to be completed as early as possible)**

## **FORMS TO RECALL**

If you click on “Forms to recall” in the menu “Utilities” you can see a list of all the CRFs ready to be updated. Please check the forms to recall periodically and ask Reporting Physicians to update their CRFs

## **FREQUENTLY ASKED QUESTIONS**

### **Who needs the password?**

Everybody, for privacy reasons. Local centres will always use the password **EURAP**. National Coordinators will use 2 passwords:

- **EURAP** for processing their own CRFs
- the “Coordinator” password for processing CRFs of Local Centres (please ask the Central Registry for this password)

### **Do I need the CD-ROM to use the EURAP software?**

No, once the software is copied to your hard disk the CD-ROM can be ejected and you do not need it any more

### **To whom shall I send my own CRFs?**

To the National Coordinator of your country, if there is one, or to the Central Registry. If you are a National Coordinator you will send your own CRFs to the Central Registry

### **Why does the email software lack the Coordinator's email in the recipient field?**

Because you have failed to set the "Default Values". Click on the Menu "Utilities", choose "Set Default Values" and enter the Coordinator's email in the email field

### **Which is the easiest way to send CRFs?**

The easiest way is to create an "EURmail". See "How to send CRFs"

### **When shall I send CRFs?**

Whenever a subform is completed. Please do not wait until the end of the pregnancy before sending CRFs

### **Why have my CRFs disappeared?**

After each sending procedure, only the CRFs sent will appear on your screen. To see all your CRFs click twice on the FIND button

### **Why have the red lights added by National Coordinators disappeared?**

Because Local Centres have failed to re-import the CRFs re-sent to them after corrections.

### **Why has the importing procedure of CRFs failed?**

If no alert message appears when you save the “EURmail”, asking if you want to substitute the previous file with the same name, something has gone wrong. There may be two possibilities:

1. You have mistakenly saved the “EURmail” in a different folder (not in the “EURAP2” folder)
2. Your email software has automatically named it “EURmail 1, 2 etc”. In this case, change the name of the attached file manually and remove both the number and the dot added

### **Why do I get no answers after sending CRFs to the “upper level”?**

Probably because you have not sent them. Please note that not all email programs will open automatically. If yours does not, a “EURmail” will be created in your “EURAP2” folder, but it will not be sent automatically. In this case you should prepare a message manually, enter your Coordinator’s email and attach the “EURmail” contained in the “EURAP2” folder

### **Why have I a duplicate of the same pregnancy?**

If you change the number of a pregnancy already sent, or the number of its centre, and then send it again to your Coordinator, the software will not recognise the original pregnancy and will make a duplicate of it

### **How can I change pregnancy ID?**

You cannot directly modify the field for the **Identification number (ID)**. The ID will be changed automatically if you change one of the three fields composing it:

1. Field 02, Country Identification number
2. Field 03, Centre Identification number
3. Field 04, Number of pregnancy of the centre

Please be careful when you change those values (see the preceding question)

### **What happens with twin pregnancies?**

You have to fill in 5 subforms for each proband, i.e. each proband needs to have a different ID number