

User Manual for ToetsingOnline

**Internet portal for the submission, review, registration and
publication of medical research**



Version May 2010

Central Committee on Research Involving Human Subjects

Summary

The internet portal ToetsingOnline allows submitters of medical research proposals to create a digital research file containing the ABR form and the EudraCT Application Form.

You can 'submit' your research file to the corresponding ethics committee and, in the case of research with medicinal products, to the competent authority. It is presently still required that you also submit your file in hard copy to the Medical Review Ethics Committee (MREC). As of the 1st of January 2008 digital submission of your file to the competent authority is compulsory.

The ethics committee and, when applicable, the competent authority, can then begin a digital review of your file. It is possible for you to follow the review process and the timelines attached via the portal.

As a submitter you manage your own various research files on your personal page within the portal. You only have to register once to manage several files.

As a submitter you can also authorise other users to be able to view your file. Access rights can also be given to allow authorised users to report adverse reactions which occur during the course of the study.

The internet portal ToetsingOnline can be found at: <https://toetsingonline.ccmo.nl>

The portal is developed in modules and there are plans for further future development. For more information on the development of ToetsingOnline go to the CCMO website at www.ccmo.nl.

Questions and suggestions which could lead to improvement of the portal ToetsingOnline or this manual are welcome. Contact the CCMO at: tel. 070 340 6700 or e-mail us at admin@ccmo.nl

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1. Registration

1.1 Single registration for use of the portal

To gain access to the portal ToetsingOnline you must first register. After successful registration you can create, edit, and manage a file within the portal. Go to <https://toetsingonline.ccmo.nl>, click on the button 'English' in the black toolbar at the top of the page, and select 'Register as a new user'. The registration window opens and shows you how to register.



Registration is needed to access the ToetsingOnline portal.

Select an action:

[Register as new user](#)
[Log in to ToetsingOnline](#)

Important: ToetsingOnline uses popup screens. Refer to the [documentation](#), paragraph 3.3, for more information on popups.

Note: If you have problems logging in you may have entered a wrong username/password combination. Delete all fields on the next attempt. Contact CCMO for help logging in:
tel: (+31) 70 - 340 67 00
e-mail: admin@ccmo.nl
Forgot your password? Click [here](#) to receive a new password
Forgot your user name? Click [here](#) to receive your user name.

Certain information must be supplied in the registration window, such as name and address. When registering choose a user name. After you have completed registration you will receive an e-mail with a temporary password. Clicking on the link in the e-mail will take you to an internet page where you can change the temporary password in a chosen password. Your chosen user name and password will be the information you use to log into ToetsingOnline after registration is completed. The link in the e-mail is purely for altering your password. Once you have altered your password you can log in directly to <https://toetsingonline.ccmo.nl>.

If you do not receive the e-mail with the link for altering your password contact the CCMO.

It is possible to create more than one file, and therefore more ABR forms, under the same user name. There is no need to register repeatedly every time you wish to create a new file. The information you supply for your registration is automatically entered in each ABR form that you create. It is however possible to alter this information on the ABR form.

1.2 Altering present information

If you wish to alter your information after registration, then you can do so on the registration page.

The registration page can be accessed by logging into ToetsingOnline, and selecting '*Edit account settings*' at the top of the page. You can edit all information, except your user name.

Welcome, A Mast

User name	mast
E-mail	a.mast@ccmo.nl
Phone	
Fax	

[Edit account settings](#)

Concept ABR New submissions All reviews Current research All files

All fields marked with an asterisk (*) are mandatory. [?](#)

Username	mast
User code	89df5d
* Last name	Mast
* Title and initials	A
Family name prepositions	
Company type	Medical Devices industry <input type="button" value="v"/>
Company	Other
* Company name	CCMO
Department	ToetsingOnline
Internal address	
* Address	Parnassusplein 10
* Postcode and city	2511 VX
* Country	Nederland
* Phone	070
* Fax	
* E-mail (max. 1)	a.mast@ccmo.nl
* Voorkeertaal / Preferred language	<input type="radio"/> Nederlands <input checked="" type="radio"/> English
* New password	
* Repeat new password	

Your password will be changed only when you fill in a new password. Leave the password fields blank to

If you would rather have a different user name, then you have to register again. Any files and/or concept ABR forms can be transported into your new account by the CCMO. See [9.1 Changing submitter](#).

Note: are you planning on managing another file? It is possible to set access to your file for other users. However, editing your account settings is not the right way to go about this. See how you can set access rights for another user under [chapter 8](#).

1.3 **Changing the language settings**

ToetsingOnline is bilingual. You can choose between Dutch or English language settings. ToetsingOnline is automatically opened in Dutch. You can change the language settings by logging in and clicking on '*Edit account settings*'.

Welcome, A Mast

User name	mast
E-mail	a.mast
Phone	070
Fax	

[Edit account settings](#)

The page that opens is where you can change your language of choice, by either clicking on the 'Nederlands' or 'English' button, followed by 'Save changes'.

* Fax	<input type="text"/>
* E-mail (max. 1)	<input type="text" value="a.mast@ccmo.nl"/>
* Voorkeertaal / Preferred language	<input type="radio"/> Nederlands <input checked="" type="radio"/> English
* New password	<input type="text"/>
* Repeat new password	<input type="text"/>

Your password will be changed only when you fill in a new password. Leave the password fi

Once you have altered the language settings ToetsingOnline will open in the chosen language. You can always change the language again if you wish.

The printed version of the questions on the ABR form for the accredited MREC is in Dutch. Whether you can answer all of the ABR questions in English, depends on the MREC responsible for reviewing your file.

1.4 Have you forgotten your user name or password?

Have you forgotten your user name or password? On the web page <https://toetsingonline.ccmo.nl> is a link which you can use to request your user name and a new password.

Would you like to alter your information? Contact the CCMO at:

tel: +31 - 70 - 340 67 00

e-mail: admin@ccmo.nl

2. Portal

2.1 Personal portal window

After logging in to ToetsingOnline you will enter your personal page. Your contact details as supplied during registration can be found there.

Welcome, A Mast

User name	mast	Company	CCMO
E-mail	a.mast@ccmo.nl	Address	Parnassusplein 10
Phone	070	Postcode and city	2511 VX
Fax		Country	Nederland

[Edit account settings](#)

Concept ABR	New submissions	All reviews	Current research	All files	Active files	Shared files	Archive
-------------	-----------------	-------------	------------------	-----------	--------------	--------------	---------

The page consists of a number of tabs (views)

- **Concept ABR**
 - Here you can find your concept ABR form, as long as it has not yet been submitted. All information on concept ABR forms can be found under 3.2 New ABR form
- **New submissions**
 - Here you can find your file as submitted to the ethics committee and/or competent authority, though which have not yet entered the reviewing process.
- **All reviews**
 - Here you can find your files which are currently being reviewed by the ethics committee and/or competent authority. The files are sorted by file number.
- **Current research**
 - Here you can find your file which has been registered by the ethics committee as having a definite starting date.
- **All files**
 - Here you can find all files which are categorised in the other views. It is also possible in this view to search by EudraCT number and local MREC registration numbers.
- **Active files**
 - Here you can find all files which have been categorised in the other views, except the files which have been placed in the archive.
- **Shared files**
 - Here you can find the files which other users have been given access rights to.
- **Archive**
 - Here you can find all files concerning research studies which have ended definitively and research proposals which have been given a negative review by the ethics committee and/or competent authority or which have had their review retracted.

Important: the files are only shown in the correct view if the ethics committee works with ToetsingOnline. In all other cases your file will remain in the view 'New submissions'.

2.2 Navigation bar

At the top of your personal page you can find a navigation bar. This is a black toolbar containing various options. This bar can be found at the top of every form and views of the portal.

Important: use the options in the navigation bar and not in your internet browser!



3. New concept ABR form

3.1 Introduction

In the ToetsingOnline portal you can create and manage research files. The ABR form and the EudraCT Application Form together form the research file. (see also [3.7 Compulsory addition of the EudraCT Application Form in research with medicinal products](#)).

The ethics committee, and for research with medicinal products also the competent authority, can create a review in your research file (see also [5.1 Review by ethics committee and/or competent authority](#)). The ethics committee also manages the general file information (see also [4.8 Research file](#)).

3.2 New ABR form

You can create a new ABR form by clicking on the link '*New file*'. By doing so you create a file and in that file the ABR form. You can attach any future documents and forms to this file. Each new ABR form is given a unique ABR number.

Research file	
ABR number	23807
Version	concept

You can hold your ABR form in concept for as long as is necessary. After closing the concept ABR form you can find it in the tab view '*Concept ABR*'.

[Edit account settings](#)

Concept ABR New submissions All reviews Current research All files Active files Shared files Archive

(see also [3.12 Opening/editing an existing ABR form](#))

Only after the ABR form has been submitted is a file number created (see also [4.1 Submitting an ABR form](#)).

3.3 Sections

The ABR form consists of a number of sections (A to L). You can select all sections simultaneously, or you can choose a single or a number of chosen sections. After selecting the desired sections click on '*Show selected sections*', after which the selected sections will be displayed. In this way you can open and close the different sections of the ABR form whilst filling in the necessary information.

Select the section you wish to edit:

- [B. Administrative](#)
- [C. Research](#)
- [D. Human subjects](#)
- [E. Benefits and disadvantages of participation](#)
- [F. Information and privacy](#)
- [G. Financial matters](#)
- [I. Submission and review](#)
- [J. Additional remarks](#)
- [K. Summary](#)
- [L. Signature](#)
- [History](#)

The sections which are displayed at the top of the ABR form can also be used as hyperlinks. Clicking on the underlined text allows you to navigate to that particular section.

It is also possible to pull down the sections in the ABR form by clicking on the blue triangle displayed before each section. This option only works in Internet Explorer.

▼ [B. Section - Administrative](#)

A link 'go to top' is displayed at the end of section. Clicking on this link takes you back to the selection list.

[Go to top](#) [Save](#)

3.4 ABR form toolbar

A toolbar is displayed at the top of the ABR form which contains a number of options. The options displayed depends on the status of the ABR form.

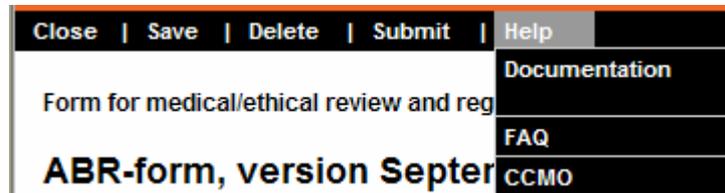
Opening a concept ABR form which has previously been saved opens the form in read only mode. You can alter the ABR form by selecting the 'Edit' option.

Close | Edit | Delete | Submit | Set access for others | Help

Selecting the 'Edit' option also alters the options in the tool bar.



The 'Save' and 'Help' options serve as pull-down menus.



3.5 Help

A list of frequently asked questions (FAQ) is displayed in the black toolbar which serves as further assistance to this user manual.

Help texts can be found at a number of questions in the ABR form. You can open these help texts by clicking on the question mark symbol () displayed at the end of the question.

3.6 Publication of information

As of the 1st of November 2009 certain information from each ABR form is made public. The questions concerned are marked with a globe symbol (). The core information from the ABR form are automatically entered in the CCMO public register after the CCMO has received and processed the review by the ethics committee.

For more information on the publication of information see <http://www.ccmo.nl>.

3.7 Compulsory addition of the EudraCT AF in research with medicinal products

In the case of research with medicinal products (including gene therapy, somatic cell therapy and GMOs, see further information at question B1), the EudraCT Application Form must also be submitted to the ethics committee and the competent authority, as well as the ABR form. You can find the form at <http://eudract.emea.europa.eu>. More information on this subject can be found at <http://www.ccmo.nl>.

We advise filling in the EudraCT AF first before you fill in the ABR form as it is only possible to submit the ABR form after the EudraCT AF has been attached.

B1. Does the research concern a trial with medicinal products (including gene therapy, somatic cell therapy, vaccine research, GMOs, see explanation) as described in the Medical Research Involving Human Subjects Act (Dutch abbreviation WMO)? 

yes

no

[Add EudraCT](#)

B1a. Do you wish to import information from your EudraCT XML file? 

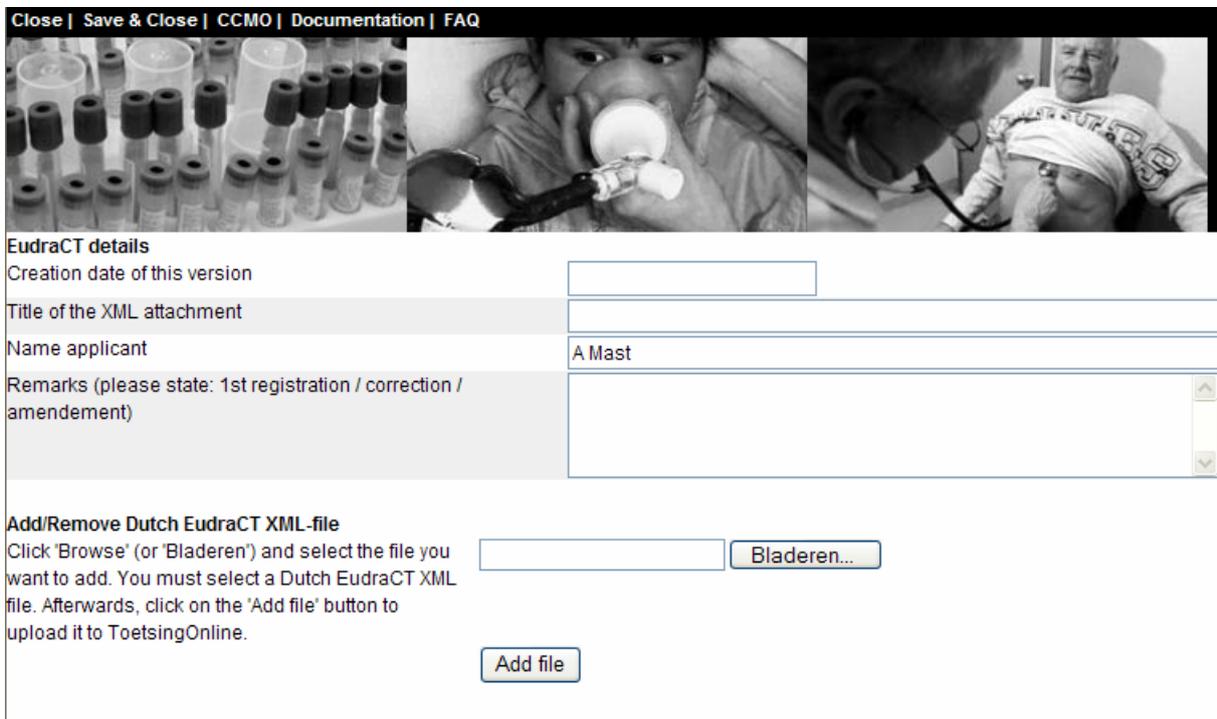
yes

no

Digital submission of the completed EudraCT AF to the ethics committee and/or competent authority is compulsory in the case of research with medicinal products on one of the research fields listed in the figure shown above (at question B1). Your digital EudraCT form is sent directly to the Medicine Evaluation Board (College Beoordeling van Geneesmiddelen (CBG)) as soon as your ABR form has been submitted. The CBG then ensures that your EudraCT AF is registered in the EudraCT databank.

Note: importing answers is not the same as attaching the EudraCT Application Form (see [3.8 Importing answers from your EudraCT Application Form in research with medicinal products](#)). Importing is not compulsory. However, attaching the EudraCT Application Form in research with medicinal products at question B1 is compulsory.

Clicking on the button 'Add EudraCT' opens a window which allows you to upload your EudraCT.



Close | Save & Close | CCMO | Documentation | FAQ

EudraCT details

Creation date of this version

Title of the XML attachment

Name applicant

Remarks (please state: 1st registration / correction / amendment)

Add/Remove Dutch EudraCT XML-file

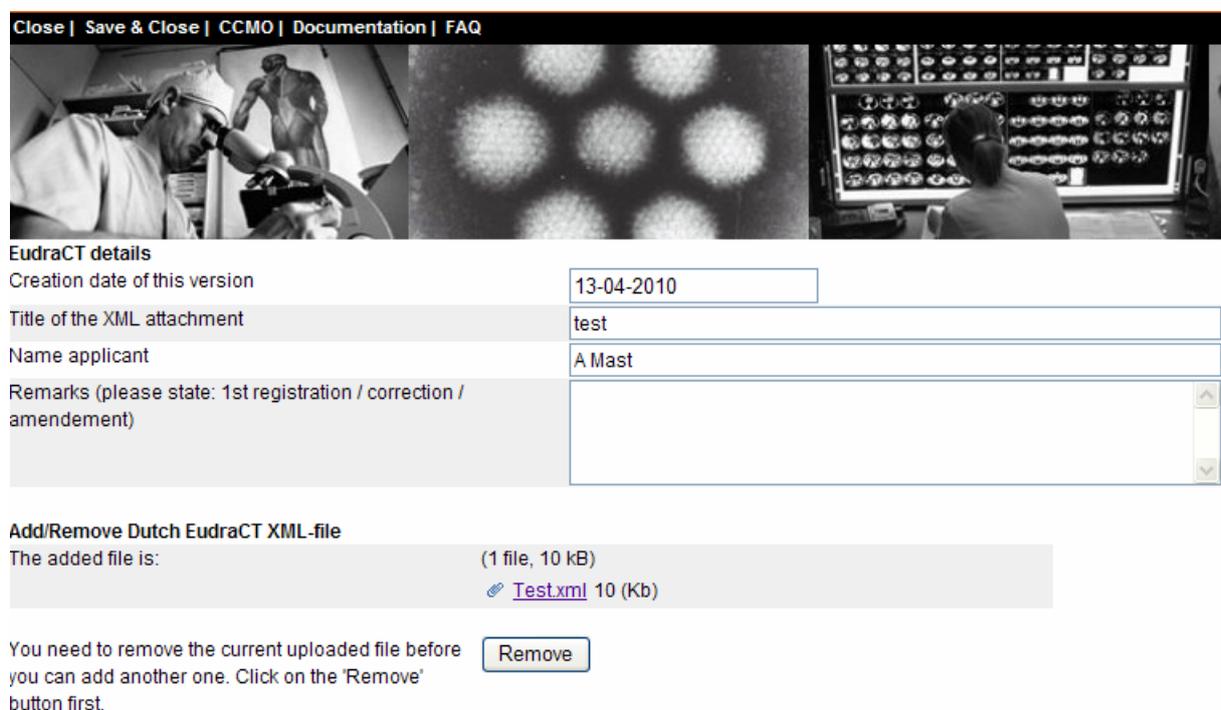
Click 'Browse' (or 'Bladeren') and select the file you want to add. You must select a Dutch EudraCT XML file. Afterwards, click on the 'Add file' button to upload it to ToetsingOnline.

Clicking on the button 'Browse' ('Bladeren') allows you to select the location where your EudraCT AF is saved. After selecting your EudraCT AF it is added to your file, and after submission of your ABR form it is automatically forwarded to the CBG for registration in the European EudraCT databank.

It is only possible to attach XML files. The title and name of the document is used only for your own registration.

In order for the CBG to process your file efficiently it is necessary that you indicate whether your XML file concerns a primary submission, correction or amendment.

After selecting 'Add file' your file is displayed. You can delete this file at a later date and replace it with another XML file.



Close | Save & Close | CCMO | Documentation | FAQ

EudraCT details

Creation date of this version	13-04-2010
Title of the XML attachment	test
Name applicant	A Mast
Remarks (please state: 1st registration / correction / amendment)	

Add/Remove Dutch EudraCT XML-file

The added file is: (1 file, 10 kB)

[Test.xml](#) 10 (Kb)

You need to remove the current uploaded file before you can add another one. Click on the 'Remove' button first. [Remove](#)

B1. Does the research concern a trial with medicinal products (including gene therapy, somatic Medical Research Involving Human Subjects Act (Dutch abbreviation WMO)? 

- yes
 no

[Add EudraCT](#)

The EudraCT XML file was added successfully

It is also possible to add newer versions of your EudraCT AF to your research file via the link 'Add EudraCT'. Doing so allows you to add an extra EudraCT file to your research file.

Close | Edit | CCMO | Documentation | FAQ

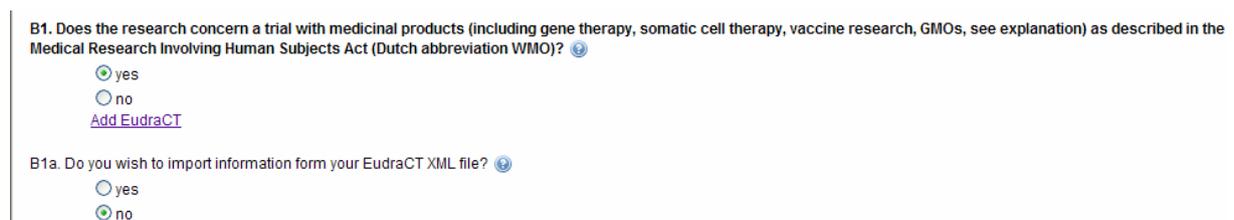
You can also replace your present form. To do so click on the link to the EudraCT file in your research file under 'Documents'. You can also add an edited EudraCT file to a new version of your ABR form.

3.8 Importing answers from your EudraCT AF in research with medicinal products

If you have filled in the EudraCT Application Form it is possible to import certain answers into your ABR form. At Section B, at the beginning of the ABR form, you can indicate whether you wish to import answers from your EudraCT AF. The questions concerned are marked with an EU symbol (). The answers can still be edited once imported.

After importing, the answer to question B1a is once again set to 'no'. However, this does not affect the review of the form.

Note: importing answers is not the same as attaching the EudraCT Application Form (see 3.7 Compulsory addition of the EudraCT Application Form in research with medicinal products). Importing is not compulsory. However, adding the EudraCT Application Form in research with medicinal products at question B1 is compulsory.



B1. Does the research concern a trial with medicinal products (including gene therapy, somatic cell therapy, vaccine research, GMOs, see explanation) as described in the Medical Research Involving Human Subjects Act (Dutch abbreviation WMO)? 

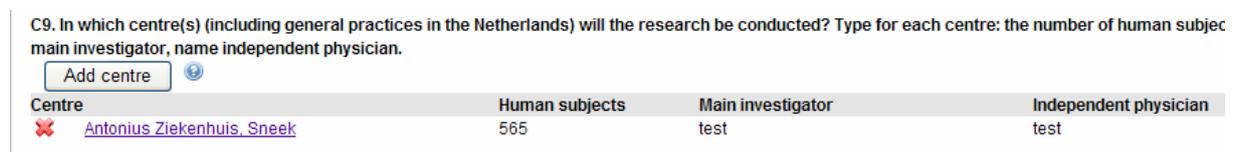
yes
 no
[Add EudraCT](#)

B1a. Do you wish to import information from your EudraCT XML file? 

yes
 no

3.9 Supplying details of participating centres

In the ABR form you can supply information on which centres are participating in the research. You must fill in a separate form per centre. Selecting the option 'Add centre' opens the form 'Centre information'.



C9. In which centre(s) (including general practices in the Netherlands) will the research be conducted? Type for each centre: the number of human subjects, main investigator, name independent physician.



Centre	Human subjects	Main investigator	Independent physician
 Antonius Ziekenhuis_Sneek	565	test	test

The centre concerned is displayed at C9 in the ABR form once the form has been saved.

You can alter the information by clicking on the hyperlink of the participating centre, which opens the form. You can delete the centre by clicking on the red cross.

Centre information

* Centre type	Universal Medical Centre
* Centre name	Select
* Number of human subjects	<input type="text"/>
* Name of main investigator	<input type="text"/>
* Name of independant physician	<input type="text"/>

3.10 Saving periodically

It is advised you save your ABR form periodically. This prevents the loss of information if your internet connection were to suddenly disconnect or if an unexpected error were to occur.

Note: It is also required you save the ABR form before selecting an ethics committee.

The 'Save' option can be found in the toolbar at the top of the ABR form, and at the end of each section. There is an additional 'Save' button at 'Add centre' and 'Select ethics committee'.

[Go to top](#) [Save](#)

3.11 Closing an ABR form

You can close the ABR form by clicking on the option 'Close' in the toolbar at the top of the ABR form or, if you have not yet saved your ABR form, by clicking on 'Save & Close' found under the 'Save' button.



3.12 Opening/editing an existing concept ABR form

All previously created ABR forms can be found in your personal page under the view 'Concept ABR'. Selecting an existing ABR form opens it in the read only mode. Selecting the

'*Edit*' option allows you to edit and/or add information. The '*Edit*' option can be found in the toolbar at the top of the ABR form.

Close | Edit | Delete | Submit | Help

3.13 Printing a concept ABR form

Printing a concept ABR form is simple and can be done by using the printing functionality of your internet browser. This creates the so-called 'print screen'. This is only possible if the ABR form is opened in the read only mode as this is the only way to display all the answers on the screen. If you select the '*Edit*' option and in doing so change the form into the edit mode, it is possible that some longer answers no longer fit in the input fields and will flow over the space supplied.

If the text is not displayed on the full page you can alter the page settings to landscape. This can be done in the page settings of your internet browser.

After submitting the ABR form you can print the official version (see [4.2 Printing](#))

Note: A print of the screen in which you are filling in your ABR form is not suitable as a print version and can therefore not be used for submission to the ethics committee.

3.14 Deleting the ABR form

A concept ABR form can be deleted by selecting the '*Delete*' option in the toolbar at the top of the ABR form. The ABR form is then deleted forever.

An ABR form which has the status 'submitted' cannot be deleted.

3.15 Selecting an ethics committee

It is required that you supply information on which ethics committee you plan to submit to your research proposal to. Selecting the option '*Select ethics committee*' opens a pull-down menu where you can select the ethics committee concerned.

Note: it is required you save your ABR form before selecting an ethics committee.

11. Save this form before selecting the review committee which will reach the decree based on the Medical Research Involving Human Subjects Act 

Save

Committee



Select ethics committee

CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Before the pull-down menu opens, the programme goes through the answers you have supplied. Which ethics committees which will be displayed in the pull-down menu depends on the answers given to the questions. You can then choose an ethics committee.

There are three lists of ethics committees from which you can choose: ethics committees which are competent to review non medicinal product research, those which are competent to review all research which falls under the Medical Research Involving Human Subjects Act (WMO) (including those with medicinal products), and the CCMO.

If you edit the ABR form after selecting an ethics committee, then it is possible that you will be requested to select an ethics committee again after submitting the form. This is due to the programme once again going through all your supplied answers after submitting the form.

You can edit your choice of ethics committee at a later date, as long as you have not yet submitted your ABR form. After submission it is no longer possible to change the ethics committee (see also [4.5 Blocking of questions in the ABR form](#)).

4. Submitting an ABR form and digital file

4.1 Submitting an ABR form

You can submit the ABR form once you have completed all questions and you are ready to submit your research proposal together with the ABR form to the ethics committee. To do so click on the option 'Submit' in the toolbar at the top of the ABR form.

Close | Save | Delete | Submit | Help

Once you have selected this option a validation process takes place. That is to say, the system controls whether all the necessary questions have been answered.



The ABR form is only given the 'submitted' status if no errors are found during the validation process. If a compulsory question has not been filled in, then the section concerned is opened and the question is marked with red text stating that the question has not been answered (correctly).

E3. Will human subjects require hospitalisation in the context of the research? 

- yes, the hospitalisation/stay in the institute will be extended because of the research
- yes, the hospitalisation/stay in the institute is required for the research
- no

You must select an option.

Note: The red marked text remains after you have correctly filled in the question concerned. This only disappears after the validation process has been successful or the ABR form has been saved.

After submission the following information is added to the ABR number: the reference number of the selected ethics committee and the year in which submission took place. These numbers are preceded by the letters NL. This number is the complete file number. The ABR form is also given a version number.

Research file		Status	Definitief
ABR number	31425	Status per	25-01-2010
Version	01		
Year	10		
Filenumber	NL31425.000.10		

In the example given above the number 207 refers to the ethics committee and 07 is the year 2007.

After submitting the ABR form it is not possible to edit or delete it. You can however make a new version (see also [4.4 Editing a submitted ABR form \(new version\)](#)).

After submission is complete the research file is created (see also [4.8 Research file](#)).

After you have submitted your ABR form you will receive a message informing you of the legislation which applies to your research proposal, and which ethics committee you have selected in the ABR form (and therefore where your research proposal must be submitted). The mail also informs you of the competent authority where you may have to submit your research proposal and what the review timeline is for the ethics committee and the competent authority in the case of submission being required.

4.2 Printing

After submitting your ABR form you are required to send a signed printed version of the form, together with your research file, to the ethics committee selected in the ABR form. You can print the ABR form after submission is complete.

Clicking on the '*Submit*' button in the ABR form automatically opens the print version of the ABR form in a new screen. You can then print the ABR form by selecting the print functionality of your internet browser.

Note: If the printed form is not displayed it is possible that it is being blocked by a pop-up blocker (see [4.3 Problems with pop-up windows](#)).

You can also print the ABR form at a later date by opening the ABR form and selecting the '*Print*' option in the toolbar at the top of the ABR form.



Doing so opens a print version of the ABR form in a new window. You can then print the ABR form by using the print functionality of your internet browser.

You can print your concept ABR form by using the print functionality of your internet browser. Doing so makes a print of your screen (see also [3.13 Printing a concept ABR form](#)). Only the ABR form which is displayed in the 'read only mode' is suitable for this as this displays all of the answers on your screen. Selecting the '*Edit*' option sets the ABR form to 'edit mode' which can result in some of the long answers not fitting in the input fields and flowing over onto the page.

Note: A print of the screen in which you are filling in the ABR form is not suitable as a print version and therefore cannot be used for submission to the ethics committee.

4.3 Problems with pop-up windows

The ABR print form is opened in a separate browser window. This window is viewed as a pop-up window.

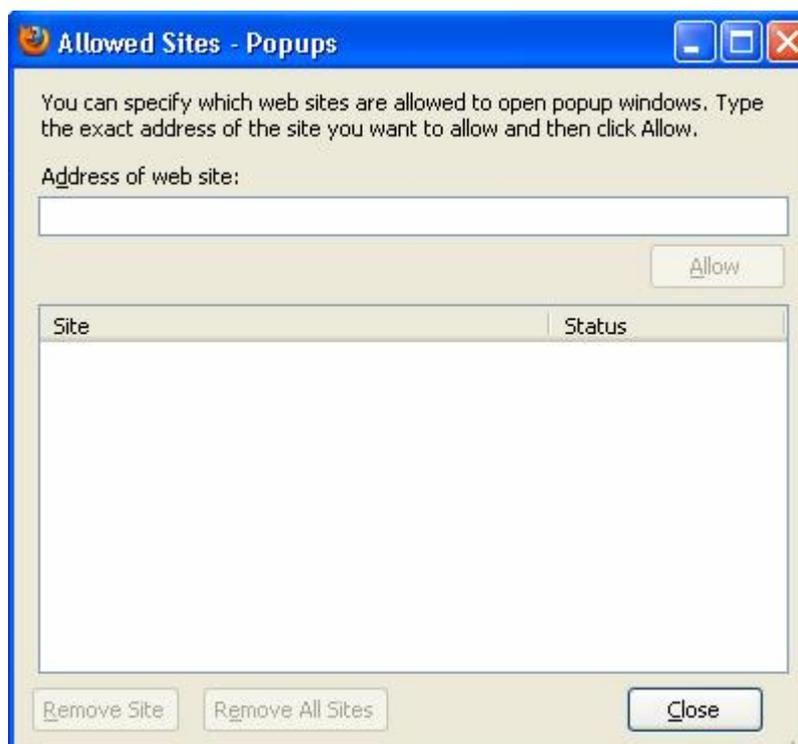
Some internet browsers and toolbars, such as Google and Yahoo, automatically prevent pop-up windows being displayed (if these browsers have been installed with the standard settings). If one of these programmes prevents the ToetsingOnline pop-up windows then you will experience problems printing the ABR form. If you have problems with pop-up windows the programme settings have to be altered.

Internet browser

Until now problems with the blocking of pop-ups have only been experienced with the internet browser Mozilla Firefox

To change the settings in Mozilla Firefox so that pop-ups windows are accepted do the following:

Go to '*Extra*' and select '*Options*'. In the options window select '*Content and then Exceptions*' next to '*Block popup windows*'. There you can add the website '<https://toetsingonline.ccmo.nl>' :



Google toolbar

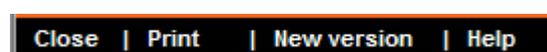
To allow pop-ups, just click Toolbar's Pop-up blocker button. The button's icon should change from 'Pop-ups blocked' to 'Pop-ups allowed'. Once you allow pop-ups on a specific website, Pop-up blocker adds the website to an 'Allowed sites' whitelist.

If you experience problems with pop-up windows with other programmes contact the CCMO.

4.4 Editing a submitted ABR form (New version)

You can edit your submitted ABR form during the review process (on your own initiative or at the request of the ethics committee) by creating a new version.

To do so select the option 'New version' in your toolbar at the top of the ABR form. Your original answers will be transported into the new version.



A new version of the ABR is created which contains all your original answers. The form retains the same file number though the version number increases by one.

Not all questions can be edited in a new version of an ABR form. Some questions are blocked. For more information see [4.5 Blocking of answers on the ABR form](#).

You can once again submit the edited version and print it for sending to the ethics committee (see for more information [4.1 Submitting an ABR form](#) and [4.2 Printing](#)). The original ABR form is saved. Only ABR forms with 'submitted' status can be used to make a new version.

ABR-form, version September 2009

Research file

ABR number	31425	Status	concept
Version	03	Status per	13-04-2010
Year	10		
Filenumber	NL31425.000.10		
Reason for Version	new site		

4.5 Blocking of questions in the ABR form

Once you have selected an ethics committee and submitted your ABR form the answers on the form are checked. After this check has taken place it is established to which ethics committee(s) you should submit your research proposal, and whether it should be submitted to the competent authority. The legal timeline is also established. This validation only happens once.

It is for this reason not possible to edit the following questions as of version 2 of the ABR form:

- Question B1: Does it concern research with medicinal products (including gene therapy, somatic cell therapy, GMOs, see further explanation) as mentioned in the Medical Research Involving Human Subjects Act (WMO)?
- Question C10: Does it concern research with (options: humans, reproductive cells, (remaining)embryos, foetuses in utero)?

Certain subquestions of question C16 cannot be selected as of version 2. This concerns the following subquestions:

- C16b: Vaccine
- C16d: Product as described in the Dutch Opium Act in pharmaceutical preparation for the treatment of addicted subjects
- C16e: Somatic cell therapy
- C16f: GMOs
- C16g: Gene therapy
- C16h: Xeno cell therapy research
- C16i: Interference RNA
- C16j: Anti-sense oligonucleotide research

If these subquestions are already selected in version 1, then they can be edited.

The questions C14 (intervention/observational), D6 (category human subject) and E1 (is/is not therapeutic) may be edited. However, if editing these questions results in another ethics committee having to be selected (from MREC to CCMO or vice versa), then the form cannot be submitted.

The form contains information on the blocking of questions. If you wish to change one or more of the above-mentioned questions, contact the CCMO.

4.6 Amendment

It is not possible to make an amendment to an ABR form which has not yet been reviewed. An ABR form must have the status 'reviewed – positive' or 'took notice of' before you can make an amendment (see also [6.1 Making an amendment to an ABR form](#)).

If you wish to edit the submitted ABR form during the review process you must make a new version (see also [4.4 Editing a submitted ABR form \(New version\)](#)).

4.7 Status ABR form

An ABR form can have the following different kinds of status:

- Concept:

A new ABR form is automatically given the status 'Concept'. A concept ABR form can be

added to, edited or deleted. You can find your concept ABR form in the 'Concept ABR' window.

More information on concept ABR forms can be found in [chapter 3. New concept ABR form](#)

- Submitted:

You can submit a concept ABR form when you are ready to submit your research proposal to the ethics committee. A submitted ABR form can no longer be edited or deleted. You can however make a new version.

More information on submitting ABR forms can be found at [chapter 4. Submitting an ABR form and digital file](#).

- Deactivated:

If you have submitted a new version of an amendment of an ABR form to the ethics committee, then it is possible that they 'activate' the new version or amendment. Only the active version of the ABR form is displayed in the 'Documents' window. New versions and amendments can be found in the window 'New/edited documents'. Deactivated ABR forms can be found in the 'Archive' window. A positively reviewed ABR form is automatically 'active' and any other versions of the form are deactivated.

- Reviewed:

After the ethics committee has reached a decision regarding the review of your form, it is given the status 'reviewed' with the date of the decision.

Positively reviewed ABR forms are automatically activated. Negatively reviewed ABR forms are deactivated and placed in the archive of the file (see also [4.8 Research file](#)).

Files given a negative review are also transferred to the archive.

For more information on digital registration of reviews go to [chapter 5. Digital registration of reviews](#).

- Took notice of:

After the ethics committee has notified receipt of an amendment, which can be submitted after completion of the primary submission, the ABR form is given the status 'Took notice of'

4.8 Research file

Once an ABR form has been submitted a research file is automatically created.

The file number is displayed in the ABR form. The file number consists of the ABR number, the chronological number of the selected ethics committee and the year in which the ABR form is submitted. The number is preceded by the letters NL.

Research file			
ABR number	31425	Status	Definitief
Version	01	Status per	25-01-2010
Year	10		
Filenumber	NL31425.000.10		

The file number is then displayed in the various tabs of your personal portal window.

[Edit account settings](#)

Concept ABR	New submissions	All reviews	Current research	All files	Active files	Shared files	Archive
File number NL31425.000.10	EudraCT number 579568543535576889	Local regno.	Title C2b titel	Ethics c CCMO: Onderz			

You can open the file by clicking on the file number. If the ethics committee, and in the case of research with medicinal products also the competent authority, have begun the review process then this can be viewed by selecting either the review in the overview screen or the review in the file itself (see also [5.1 Review by the ethics committee and/or competent authority](#)).

Concept ABR	New submissions	All reviews	Current research	All files	Active files	Shared files	Archive
File number	Title	Type of review	EC/CA	Ethics Committee	Remaining period		
NL31425.000.10	C2b titel	Eerste beoordeling	EC	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)	3 days		

Your research file consists of the following components:

- File
 - The ABR forms are displayed here and, in when applicable, the EudraCT AF
- Review ethics committee
 - Here you can find the review(s) of the ethics committee.
- Decisions ethics committee
 - Here you can find the decisions of the ethics committee, uploaded as pdf files.
- Review competent authority
 - Here you can find the review(s) by the competent authority (CA)
- Adverse reactions/events
 - Here you can report adverse reaction/events which occur during your research.
[See chapter 7](#)
- Progress/end report
 - This option is not yet in use. It will be possible in the near future to upload your progress reports and end reports here.
- Archive
 - Here you can find your deactivated ABR forms

Certain file details are displayed at the top of the screen. Some of these details are transferred from the ABR form. The other details can be filled in by the ethics committee

[File details](#)

File number	NL23	Coordinator EC	
Local registration number			
Applicant	A Mast	Date review	
Title in English		Result review	
Ethics committee	TC Amsterdam	Expected start date	01-11-2008
Competent authority	Centrale Commissie Mensgebonden Onderzoek (CCMO)	Expected end date	01-10-2010

Status:

File

- Reviews
 - [Review EC](#)
 - [Decreets EC](#)
 - [Review CA](#)
- Adverse reactions/event
 - [SUSAR](#)
 - [SAE](#)
- Archive
- User access
 - [Overview](#)
 - [Manage](#)

File

B. Forms

B1: ABR-Form

01 - smoking and heart disease (active)	Submitted	10 Sep 2008
02 - smoking and heart disease	Submitted	10 Sep 2008

B5: EudraCT files

test (EudraCt)	08 Oct 2008
--------------------------------	-------------

(Local registration number and the coordinator of the ethics committee). If you select the option 'File details', the full overview of the file information is displayed.

At the bottom of this "file details" screen you can see which notifications/alerts have been sent by mail.

4.9 **Status file**

If the ethics committee actively uses ToetsingOnline, the file is given a status after completion of the digital review. A digital research file can have one of the following different types of status:

- Not started
 - A file is given this status if the review is positive and the ethics committee has not yet received a definite start and end date.
- Current
 - A file is given this status if the review is positive and the ethics committee has received a definite start date.
- Ended
 - A file is given this status if the review is positive and the ethics committee has received an end date. A file with this status is transferred to the archive.
- Suspended
 - A file is given this status if the ethics committee has indicated that the research is suspended in the file details.
- Ended early

- A file is given this status if the ethics committee has registered in the file details that the research has ended early. A file with this status is transferred to the archive.

File details

Status:

Suspended

Ended early

File Number: NL31425.000.10

Coordinator Ethics Committee:

Applicant: A Mast

Date review:

Result review:

Title in Dutch: C2b titel

Ethics Committee: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Competent Authority: Minister van Volksgezondheid, Welzijn en Sport

Expected start date: 02-02-2010

Final start date:

Expected end date: 02-03-2010

Final end date:

Company: MucoVax

Department: ToetsingOnline

Address of applicant: Parnassusplein 10
2511 VX

Local registration no.:

Type of research:

Name executor:

Remarks:

5. Digitale registration of reviews

5.1 Review by ethics committee and/or competent authority

After the ABR form is submitted (see also [4.1 Submitting an ABR form](#)), you must also submit the complete research file in hard copy to the ethics committee selected in the ABR form. If the research is with medicinal products then all documents must be submitted digitally in PDF format to the competent authority. For more information on digital submission see our website www.ccmo.nl. Once the complete set of documents have been received in hard copy the ethics committee, and when applicable, the competent authority, can start the review process in the portal. The ethics committee you have selected in the ABR form and, in the case of research with medicinal products, the competent authority, have access (read only access) to your digital research file and can document the review. These reviews are added to your digital file (see also [4.8 Research file](#)).

It is possible for you to view the reviews. You can open a review directly by selecting it in the 'Current reviews' window in your personal portal window. You can also select the review from your research file under the link 'Review EC'



The screenshot displays a web portal interface. On the left is a vertical navigation menu with the following items: 'File', 'Reviews' (expanded), 'Review EC', 'Decrees EC', 'Review CA', 'Adverse reactions/event' (expanded), 'SUSAR', 'SAE', 'Archive', 'User access' (expanded), 'Overview', and 'Manage'. On the right, a panel titled 'Review Ethics Committee' shows the following details: 'Type of review: Primary review', 'Coordinator:', 'Status: Request for more information or change', 'Time lines:', 'number of days: 56', 'start: 15-04-2009', and 'decree date:'.

Afterwards the review window opens.

Review by Ethics Committee

File number	NL31425.000.10
Short title	
Local registration no.	
Type of review	Eerste beoordeling
Coordinator EC	coor
Remarks	opme
Status review	verzoek wijzigingen/aanvullen onderzoeksdossier
Finalizing timeline	Timeline is stopped
Start date timeline (dd-mm-yyyy)	01-01-2010
Sent on (dd-mm-yyyy)	26-02-2010
Desired reaction by (dd-mm-yyyy)	01-03-2010
Received on (dd-mm-yyyy)	
Length of timeline	60 days
Status timeline	Suspended
Date end timeline	17-04-2010
Remaining period in days	3 days
Duration of the review	Ethics Committee: 57 days (total no. of days: 103 days)

▼ Log met wijzigingen

25-02-2010 - De vorige status was:
dossier volledig ontvangen - 01-01-2010

25-02-2010 - tc000 heeft deze beoordeling aangemaakt.

You can view the following information in the review window:

- File number
- Short title
- Local registration number
- Type of review
 - The following types of reviews can be made:
 - First review
 - Review amendment
 - Review of adverse reaction
 - Review of progress report
 - Review of end report
 - Other types of reviews
- Coordinator ethics committee
 - Contact person or room within the ethics committee or competent authority
- Remarks
- Status review
 - A review can have the following types of status:

- complete file received
- placed on the meeting agenda (with the date of the meeting)
- request to change/add to the research file (stating the date sent, desired reaction date and date reaction is received)
- being processed by the executive board
- review research file retracted (stating date)
- review positive (stating date)
- review negative (stating date)
- not WMO research or research on embryos (stating date)

A review by the competent authority is not given the status '*positive review*' and '*negative review*' but rather the status '*no objection*' and '*objection*', both with the date stated.

Any previous status, and therefore the progress of the review, can be found in the review log.

▼ Log met wijzigingen
 25-02-2010 - De vorige status was:
 dossier volledig ontvangen - 01-01-2010

25-02-2010 - tc000 heeft deze beoordeling aangemaakt.

- Date start timeline
 - The date on which the review is started and the review timeline begins
- Length of the timeline
 - The total number of days that the legal timeline consists of. If the timeline is extended then this is visible.
- Status timeline
 - the timeline can have one of the following types of status: current, suspended, completed
 - the timeline can be suspended if the ethics committee has additional questions regarding your file or has requested you change certain information.
- Date end timeline
 - The date on which the valid timeline ends
- Days left till end of timeline
 - The number of days left for the review
- Duration of the review
 - The total duration from submission till review (total duration) is displayed here, including the number of days it took the ethics committee or competent authority to complete the review. When the ethics committee requests additional information the timeline is suspended. When the timeline is suspended a difference occurs between both these numbers.

5.2 Stating the decision of the ABR form

After completion of the review the status of the reviewed ABR form is altered. The ABR form can have one of the following types of status:

- Reviewed – Positive
- Reviewed – Negative
- Took notice of
- Retracted
- Not WMO research or research on embryos

An ABR form with the status '*Reviewed – Negative*', '*Retracted*' or '*Not WMO research or research on embryos*' is automatically deactivated, together with any versions, and transferred to the file archive.

The ABR form which has been given the status '*Reviewed positive*' or '*Took notice of*', is automatically active and transferred to '*Documents*'. Any other versions are deactivated and transferred to the file archive (see also [4.7 Status ABR form](#) and [4.8 Research file](#)).

6. Amendments

6.1 Making an amendment to an ABR form

After the first review has been completed you can submit amendments to the ethics committee and, in the case of research with medicinal products, to the competent authority.

If an amendment has consequences for a previously reviewed ABR form, then you can create an amendment in your ABR form. Only ABR forms with the status '*Reviewed – Positive*' or '*Took notice of*', and which are therefore active, can be amended (see also [4.7 Status ABR form](#))

To make an amendment open the present active ABR form and select the option '*Make amendment*' in the toolbar at the top of the ABR form.



You will then be asked to give a reason for making the amendment. A new version of the ABR form is made and all your original answers are retained. This amended ABR form is given a higher version number and can be saved periodically as a concept (see also [3.11 Closing an ABR form](#)). A concept ABR form can be printed (see also [3.13 Printing a concept ABR form](#)) and submitted (see [4.1 Submitting an ABR form](#)).

It is possible to delete a concept ABR form (see also [3.14 Deleting the ABR form](#)), however a submitted form cannot be deleted.

Not all questions can be edited in an amendment. Some are blocked. See [4.5 Blocking of questions on the ABR form](#).

6.2 Editing a submitted amendment to the ABR form

You can only make one amendment at a time. For any changes to this amendment during the review process you can make a version of the submitted (amendment) ABR form (see also [4.4 Editing a submitted ABR form \(New version\)](#)).

After the ethics committee has positively reviewed the amendment or higher version, the amendment ABR form is displayed in the '*Documents*' window and the originally reviewed ABR form is transferred to the archive within your file (see also [4.7 Status ABR form](#)).

A negatively reviewed amendment ABR form is deactivated and transferred to the archive. In such a case, your original ABR form with a positive review remains active and unedited.

After the amendment has been reviewed you can then make a new amendment to the ABR form.

6.3 Amendments to research proposals submitted before the 1st of March 2006

Research proposals submitted before the 1st of March 2006 still make use of the 'old' ABR form. You can still request your 'old' form at the CCMO. The ABR form in ToetsingOnline is only for research proposals submitted after the 1st of March 2006. It is not possible to register amendments to research proposals which were submitted before this date in ToetsingOnline.

7. Reporting adverse reactions/events

7.1 Introduction

It is possible to report suspicions of serious adverse reactions (SUSARs) in ToetsingOnline by filling in a SUSAR report form. Serious adverse events (SAEs) can be reported by filling in the SAE form in ToetsingOnline.

If the adverse reaction is already mentioned in the existing product information, then you can state this in the annual safety report, unless the gravity of the reaction makes immediate reporting necessary. To report the adverse event use the SAE form in ToetsingOnline (see [chapter 7.13](#)).

The SUSAR report form makes a distinction between reports already accepted in the Eudravigilance databank (<http://eudravigilance.emea.europa.eu>) and reports not reported in this databank.

SUSARs already reported to the EMEA Eudravigilance databank do not have to be reported again to the competent authority and the CBG as they have direct access to the Eudravigilance databank. In this case only the questions A1 to A7, B1, B5 and B6 of the SUSAR report form should be filled in and can be attached as a pdf to the report.

All other SUSARs must be reported by completely filling in the SUSAR report form.

After the form has been submitted an xml file is generated which is sent to LAREB. The LAREB ensures that your report is entered in the Eudravigilance databank. The LAREB employees may contact you for additional information. If this leads to changes to the SUSAR report form you will be requested to make a new version of the SUSAR report form in ToetsingOnline.

Note: Reporting to the CBG and competent authority is no longer necessary if you have reported the SUSAR in ToetsingOnline!

Every medical research carries the risk of serious advent events (SAEs). These can also be reported in ToetsingOnline (see [chapter 7.13](#)).

7.2 New SUSAR report

To report a new SUSAR log in to ToetsingOnline and open the concerned file number. The page '*Research file*' will open. Next, select the option '*Adverse reactions/event*' in the left navigation window. Then select the option '*Make*' in the black toolbar and select '*Create SUSAR*'

[File details](#)

File number	NL25	Coordinator EC	
Local registration number			
Applicant	A Mast	Date review	06-03-2009
Title in English		Result review	Besluit Positief
Ethics committee	TC Breda	Final start date	01-02-2010
Competent authority		Expected end date	31-12-2011
Status:	Lopend		

- File
- Reviews
 - Review EC
 - Decreets EC
 - Review CA
- Adverse reactions/event
 - SUSAR
 - SAE
- Archive
- User access
 - Overview
 - Manage

SUSARs

SU001.09.25525					
02	!	- uitbreiding uitslag	Open bijlage	Took Notice Of	01-06-2010
01	!	uitslag	Open bijlage	Took Notice Of	01-06-2010

In the SUSAR window select the option 'Create SUSAR' in the black toolbar.

Close | Create SUSAR | Help

Each new report is given a unique report number which is preceded by the letters SU. The number consists of the report number, followed by the year in which the form is created, and the first five digits of the file number.

Close | Edit | Delete | Submit | Help ...

SUSAR form based on ICH-E2B

Report number	SU002.10.31425	Status	Concept
Version	concept	Status per	
File number	NL31425.000.10	Date review	
Reporter	A Mast	Modification date	30-03-2010

A. Section - Administrative

A1. What is the ToetsingOnline NL-filenumber of the study?
NL31425.000.10

7.3 Attaching PDF file of report in Eudravigilance database

If the report of the adverse reaction is already entered in the Eudravigilance database, then you can attach this file (CIOMS form) in pdf form. Clicking on the option 'Browse' ('Bladeren') opens the window where you can select your documents. Clicking on the option 'Add file' displays the selected file. If you have selected the wrong document, clicking on the 'Delete'

option will delete it. After the document has been uploaded all you have to do is fill in the displayed sections of the form.

7.4 Saving periodically

It is advised that you save your SUSAR report form periodically. This prevents information being lost if your internet connection were to suddenly disconnect or unexpected errors were to occur. You can find the 'Save' option in the toolbar at the top of the SUSAR report form and at the end of every section.

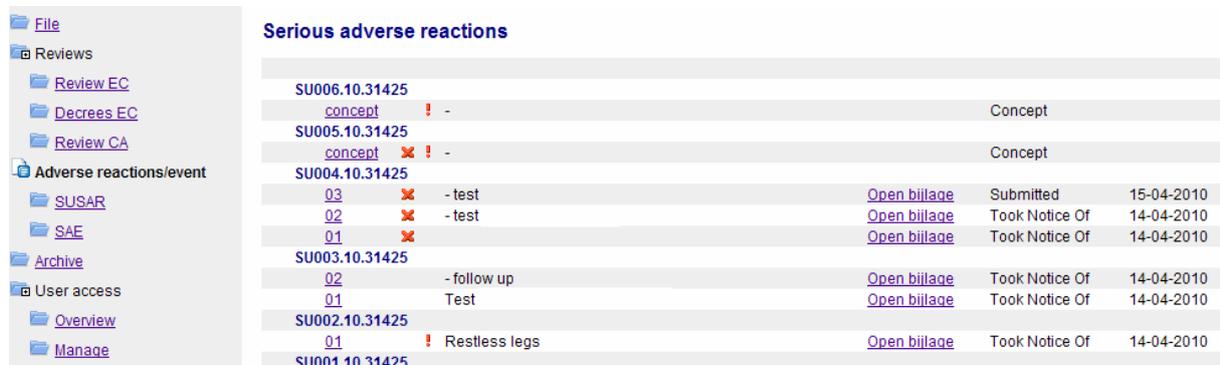
7.5 Closing the SUSAR form

You can close the SUSAR report form by clicking on the 'Close' option in the toolbar at the top of the form. If you have not yet saved the report form you can select 'Save & close' under the button 'Save'.

7.6 Opening/editing a concept SUSAR form

All previously created report forms can be found in your research file under the menu 'SUSAR'.

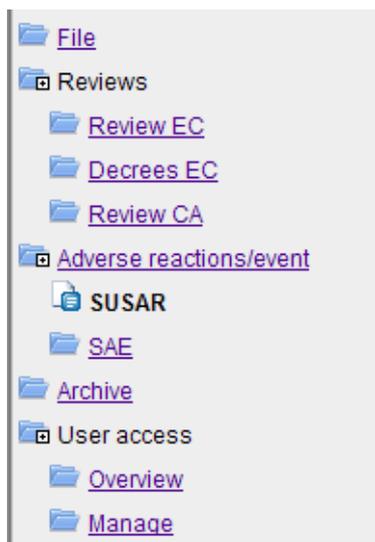
In the window certain file details are displayed, such as the version number, the file number of the file concerned, the status of the form (this can be either concept or submitted) and the date of the review by the ethics committee or the competent authority.



The screenshot shows a software interface with a sidebar menu on the left and a main content area on the right. The sidebar menu includes 'File', 'Reviews' (with sub-items 'Review EC', 'Decreases EC', 'Review CA'), 'Adverse reactions/event' (with sub-items 'SUSAR', 'SAE'), 'Archive', 'User access' (with sub-items 'Overview', 'Manage'). The main content area is titled 'Serious adverse reactions' and displays a table of data.

Serious adverse reactions			
SU006.10.31425			
concept	!	-	Concept
SU005.10.31425			
concept	✘ !	-	Concept
SU004.10.31425			
03	✘	- test	Open biilage Submitted 15-04-2010
02	✘	- test	Open biilage Took Notice Of 14-04-2010
01	✘		Open biilage Took Notice Of 14-04-2010
SU003.10.31425			
02		- follow up	Open biilage Took Notice Of 14-04-2010
01		Test	Open biilage Took Notice Of 14-04-2010
SU002.10.31425			
01	!	Restless legs	Open biilage Took Notice Of 14-04-2010
SU001.10.31425			

Select an existing concept report form opens it in the read only mode. If you wish to edit or add to the form select 'Edit'. You can find the 'Edit' option in the toolbar at the top of the report form.



SUSARs

SU002.10.31425		
concept	!	-
SU001.10.31425		
01	✘!	headache

Close | **Edit** | Delete | Submit | Help ...

SUSAR form based on ICH-E2B

Report number	SU002.10.31425	Status	Concept
Version	concept	Status per	
File number	NL31425.000.10	Date review	
Reporter	A Mast	Modification date	30-03-2010

7.7 Printing a concept report form

You can print a concept report form by using the print functionality of your internet browser. Doing so makes the so-called print screen.

Only the report form in the 'read only mode' is suitable for printing as this displays all of the answers in the screen. Selecting the 'Edit' option places the form in the 'edit mode' and it is then possible that some of the long answers will not fit in the input fields and will flow over onto the page.

If the text is not displayed on the full page then you change the page settings to landscape to print. Use the page settings of your internet browser to change the page view.

After you have submitted the report form you can print the official print version (see also [7.10 Printing a submitted report form](#)).

7.8 Deleting a report form

A report form which has the status 'concept' can be deleted by selecting the 'Delete' option in the toolbar at the top of the report form. The report form is then deleted forever. A report form with the status 'submitted' cannot be deleted.

7.9 Submitting a SUSAR form

You can submit the report form once you have filled in all compulsory questions. To do so select the option 'Submit' in the toolbar at the top of the report form.

The report form is only given the status 'submitted' if no errors are found during the validation process. If a compulsory question has not been filled in the section concerned is opened and the question concerned is marked with red text telling you that the question has not been (completely) answered.

Note: Once you have properly filled in the question the red text remains displayed. The text only disappears after the validation process has been successful or you save the report form. After successful submission of the report form the form can no longer be edited or deleted. However, you can still make a follow-up report (see also [7.12 Editing a submitted SUSAR form \(follow-up\)](#)).

7.10 Printing a submitted report form

Once you have submitted the report form you can print it if you so wish. To do so select the 'Print' option in the black toolbar which will start the print functionality of your internet browser.

7.11 The coding of the submitted SUSAR form

Once you have successfully submitted your report form and have closed it, all reports can be found under the link 'SUSAR'. A red cross or red exclamation mark may be displayed at the left of the report number. This is a reference to question B6 and gives an indication of the gravity of the effects. A red cross refers to an adverse reaction which is life threatening or can be fatal, a red exclamation mark indicates that the adverse reaction can have consequences for the safety of the research subject participating in the research (question A6). Next to the report number is a column containing information on whether the suspected adverse reaction has occurred in the study concerned, the symptoms, the status of the report form (concept, submitted, took notice of) and the status date.



The screenshot shows a web interface for managing SUSARs. On the left is a navigation menu with the following items: File, Reviews (with sub-items: Review EC, Decreases EC, Review CA), Adverse reactions/event (with sub-items: SUSAR, SAE), Archive, User access (with sub-items: Overview, Manage). On the right, under the heading 'SUSARs', there is a table with the following data:

Report Number	Severity/Status	Symptoms	Status
SU002.10.31425	concept	-	Concept
SU001.10.31425	01	headache	Submitted

7.12 Editing a submitted SUSAR form (follow-up)

You can edit or add to a SUSAR report by clicking on the button '*Report follow-up*' after opening the report form.

Close	Print	Report follow-up	Help ...
-------	-------	------------------	----------

SUSAR form based on ICH-E2B			
Report number	SU001.10.31425	Status	Definitief
Version	01	Status per	01-03-2010
File number	NL31425.000.10	Date review	
Reporter	A Mast	Final date	01-03-2010 10:55:13

A pop-up field appears in which you can give the reason for the report follow-up. An example of a reason could be that there is additional information on the progress of the event (for example, the research subject has recovered). Using the '*Report follow-up*' option gives the form a higher version number.

After you have edited or added to the information in the report form you can save and submit the form.

7.13 New SAE report

SAEs must be reported to the reviewing ethics committee (accredited MREC or CCMO).

To report a new SAE log in to ToetsingOnline and open the file by clicking on the file number. Then select the option '*Adverse reactions/events*' in the list of links on the left. Then select then the '*Create*' option in the black toolbar at the top of the page and subsequently the pull-down menu '*Create SAE*'.

If you select the option '*Adverse reactions/event*', it is also possible to select '*SAE*' in the same overview menu. You then select '*Create SAE*' in the toolbar.

Each new report is given a unique report number which is preceded by the letters AE. The number consists of the report number, followed by the year in which the form is filled in, and the first give digits of the file number.

7.14 Periodically saving an SAE form

It is advised to save the SAE report form periodically. This prevents the loss of information is the internet connection were to suddenly disconnect or an unexpected error were to occur. You can find the '*Save*' option in the toolbar at the top of the SAE report form and at the end of every section.

7.15 Closing an SAE report form

You can close the SAE report form by selecting the 'Close' option in the toolbar at the top of the form, or if you have not saved the form, by selecting 'Save & close' under the 'Save' button.

7.16 Opening/editing a concept SAE form

All previously created report forms are stored in the 'SAE' menu of your research file.

Certain information is displayed in the window: the version number, the file number of the research protocol concerned and the status of the form (for example, concept, submitted or took notice of).

Serious adverse events				
AE002.10.31425	concept	-	Concept	
AE001.10.31425	03	! - Double vision	Took Notice Of	14-04-2010
	02	! - Trouble vision	Submitted	24-03-2010
	01	! losse connectie	Submitted	01-03-2010

You can select an existing SAE form, after which the form opens in the read only mode. Selecting the 'Edit' option allows you to edit and/or add to the information. You can find the 'Edit' option in the toolbar at the top of the report form.



SAE form

Report number	AE002.10.31425	Status	Concept
Version	concept	Status per	
File number	NL31425.000.10	Review date	
Reporter	A Mast	Date last modification	13-04-2010

7.17 Printing an SAE report form

You can print a concept report form by using the print functionality of your internet browser. This makes the so-called print screen.

Only the report form in the 'read only mode' is suitable for printing as this displays all of the answers on the screen. Selecting the 'Edit' option places the form in the 'edit mode' which can result in some long answers not fitting in to the input fields and flowing over on to the page.

If the text is not displayed on the full page then you can change the page settings to landscape. To do so use the page settings of your internet browser.

After you have submitted the report form you can print the official version (see also [7.10 Printing the submitted report form](#)).

7.18 Deleting an SAE report form

A report form with the status 'concept' can be deleted by selecting the 'Delete' option in the toolbar at the top of the report form. The report form is then deleted forever. A report form with the status 'submitted' cannot be deleted.

7.19 Submitting an SAE form

You can submit the report form after all questions have been answered. To do so click the option 'Submit' in the toolbar at the top of the report form.

The report form is only given the status 'submitted' if no errors are found during the validation process. If a compulsory question has not been answered then the section concerned opens and the question concerned is marked with red text stating that the question has not been (completely) answered.

Note: after the questions has been answered properly the red text remains displayed. It only disappears after the validation process is successful or you have saved the report form.

After submitting the form you can not edit or delete it. You can however make a follow-up report (see also [7.21 Editing a submitted SAE form \(follow-up\)](#)).

7.20 The coding of a submitted SAE form

After you have submitted the report form and have closed it, you will find all of the reports under the link 'SAEs'. A red cross or red exclamation mark may be displayed at the left of the report number. This is a reference to question B6 and gives an indication of the gravity of the effects. A red cross refers to an adverse reaction which is life threatening or can be fatal, a red exclamation mark indicates that the adverse reaction can have consequences for the safety of the research subject participating in the research (question A6). Next to the report number is a column containing information on whether the suspected adverse reaction has occurred in the study concerned, the symptoms, the status of the report form (concept, submitted, took notice of) and the status date.

7.21 Editing a submitted SAE form (follow-up)

You can edit or add to an SAE report by clicking on the button 'Report follow-up' after opening the report form.

After you have edited or added to the information in the report form you can save and submit the form. A pop-up field appears in which you can give the reason for the report follow-up. An example of a reason could be that there is additional information on the progress of the event (for example, the research subject has recovered). Using the 'Report follow-up' option gives the form a higher version number.

Serious adverse events		
AE001.09.25525		
02	!	- worsening
01	!	dyspnoe leidt tot ah stilstand
		Concept
		Ter Kennisgeving Aangenomen

7.22 Printing a submitted report form

Once you have submitted the report form you can print it if you so wish. To do so select the 'Print' option in the black toolbar which will start the print functionality of your internet browser.

7.23 Review by the MREC

After you have submitted a SUSAR or SAE an e-mail is automatically sent to the MREC. The MREC will review the SUSAR or SAE.

Serious adverse reactions				
SU001.09.25525				
02	!	- uitbreiding uitslag	Open bijlage	Took Notice Of
01	!	uitslag	Open bijlage	Took Notice Of
AE001.09.25525				
02	!	- worsening		Concept
01	!	dyspnoe leidt tot ah stilstand		Took Notice Of
				4-13-2010
				01-06-2010

8. Access rights

8.1 Introduction

As owner of a file you can authorise others to access your file. For example, you can authorise others to view your ABR form, or give access rights to report SUSARs and SAEs. Access rights can only be given to registered users of ToetsingOnline. Every registered user has a user code (see [chapter 8.2](#)).

8.2 User code

Every registered user of ToetsingOnline has a user code. Your user code is displayed on the right-hand side of the toolbar, at the top of your welcome page



Your user code is also displayed in your registration information. The registration information is displayed by selecting '*Edit account settings*' on the welcome page.

Welcome, A Mast

User name	mast
E-mail	
Phone	070
Fax	

[Edit account settings](#)

Username	mast
User code	89df5d
Last name	Mast
Title and initials	A
Family name prepositions	
Company type	Medical Devices industry

The user code of a user who is to be given access rights to your file is necessary to be able to delegate these rights. This user should inform you of his/her user code.

8.3 Overview of types of access rights

The following types of access rights can be given:

- Read concept ABR form
- Read (sections) of file
- Report SUSARs and SAEs
- View SUSARs and SAEs
- View blinded overview of SUSARs and SAEs

8.4 Giving others access rights to read your ABR form

You can create a new ABR form by clicking on the link 'Make new file' (see [chapter 3.2](#)). After saving and closing the concept ABR form it is possible to set access for others to read this concept. To do so open the ABR form again and select 'Set access for others' in the black toolbar.



Note: you can only set access for others for your concept ABR form if the form is in the so-called read only mode. That is to say, you have not yet clicked on the 'Edit' function. If you have selected the 'Edit' option the 'Set access for others' button is no longer visible.

A window opens where you fill in the user code of the user who is to be given access rights.



Save Cancel Documentation FAQ	
 	
Set access for others on this concept ABR form 	
ABR number	32323
Title	test
User code	<input type="text"/>
	<input type="button" value="Search"/>

After filling in the user code you then click on 'Search' after which the name of the user to be given access will appear on the screen.

Set access for others on this concept ABR form

ABR number	32323
Title	test
User code	<input type="text" value="g27554"/>
	<input type="button" value="Search"/>
Name	Dr. L. Duinen
Access	<input type="checkbox"/> Read access on this ABR form

Click on 'Save' to enforce the selected access for this user on this concept ABR form.
Access to this form will be propagated to the complete file after submittal of the concept.

Select 'Read access to this ABR form' and 'Save' in the black toolbar to set access for this user.

Afterwards both you and the authorised user will receive an e-mail with the access rights given:

You are authorised to access ABR-form ABR-form 32323 on ToetsingOnline. The form is located on the tab 'Concept ABR' on the main screen of ToetsingOnline.

For further detailed information please consult the manual which can be found on the website.

This is a generated e-mail please do not reply.

Save this e-mail for your own administration.

The authorised user sees your ABR form after logging in with his/her own information in the tab 'Concept ABR' on the welcome page.

An icon is displayed at the end of the ABR form and '(view)' so that it is clear for the authorised user that this is not his/her own ABR form but a form which he/she has been given read access for. The authorised user can open the ABR form, as well as view, print and close the form. However the authorised user cannot edit the file.

[Edit account settings](#)

Concept ABR New submissions All reviews Current research All files Active files Shared files Archive

ABR no	Title	Created	Changed
32339		14 Apr 2010	14 Apr 2010
32337		14 Apr 2010	14 Apr 2010
32323 (read only)	test	13 Apr 2010	14 Apr 2010

You can submit an ABR form as owner of the form if all of the questions have been answered (see [chapter 4.1](#)).

After submitting the ABR form the user given access rights to the concept ABR form is automatically given access to the file. The authorised user is given read access to section B.

Submitting the ABR form creates a file in ToetsingOnline. You can check what access rights you have in the file. To do so click on 'Overview' in the left menu 'User access'.

File

- Reviews
 - [Review EC](#)
 - [Decreets EC](#)
 - [Review CA](#)
- Adverse reactions/event
 - [SUSAR](#)
 - [SAE](#)
- Archive
- User access
 - [Overview](#) ←
 - [Manage](#)

File

B. Forms

B1: ABR-Form

01 - C2A titel (active)	Submitted	25 Jan 2010
02 - C2A titel	Concept	12 May 2010

B5: EudraCT files

test (EudraCT)	01 Jan 2010
--------------------------------	-------------

P. Decisions

P1a - Primaire besluiten

test	01 Apr 2010
test	06 Apr 2010

Here you can see the name of the user, the user code and the access rights delegated.

Gebruiker	Gebuikerscode	Leesrechten	Overige rechten
Dr. L. Duinen	g27554	Sectie B	

In the example above, you have given user Dr. L. Duinen read access to section B of the file, Section B contains the ABR form and any EudraCT forms in the case of research with medicinal products.

The authorised user can find your file under the tab 'Shared files'.

8.5 Retracting reading access to a concept ABR form

You can retract access rights which a user has to your concept ABR form. To do so, open the ABR form concerned, click on 'Set access rights' and type in the user code of the authorised user. The name of the authorised user is displayed for you to check. You can then deselect the option 'Read access to this ABR form' and then 'Save'. The read access rights of the authorised user are now deleted.

8.6 Setting read access for (sections) of the file

You can set read access for your file from within the file concerned. To do so, open the file and click on 'Manage' in the menu on the left.

File

- Reviews
 - Review EC
 - Decreets EC
 - Review CA
- Adverse reactions/event
 - SUSAR
 - SAE
- Archive
- User access
 - Overview
 - Manage**

File

B. Forms

B1: ABR-Form		
01 - C2A titel (active)	Submitted	25 Jan 2010
02 - C2A titel	Concept	12 May 2010

B5: EudraCT files

test (EudraCt)	01 Jan 2010
--------------------------------	-------------

P. Decisions

P1a - Primaire besluiten

test	01 Apr 2010
test	06 Apr 2010

A window opens where you fill in the user code of the user to be authorised.

Authorise other users for this file

File number	NL31425.000.10
Title	C2b titel
Local registration number	
User code	<input type="text"/>
	<input type="button" value="Search"/>
Name	

After entering the user code select 'Search' and the name of the user to be authorised will appear on your screen.

On the left-hand side of the menu you can set read access for sections of your file.

Read access

- B. Forms
 L. Safety information (i.e., SUSAR/SAE)
 P. Decrees

Other access

- Report SUSAR and SAE
 View SUSAR and SAE reports (unblinded: see details on blinded reports)
 View SUSAR and SAE reports (blinded: see overview of blinded reports only)

Click on 'Save' to enforce the selected access for this user on this file.

If you choose 'Section B, forms' and 'Section P, decrees', then the user selected by you who is to be given read access, can view ABR forms, EudraCT forms (section B) and the decrees of the ethics committee and the thereby uploaded decrees (section P).

The overview will look as following:

Overzicht gemachtigde gebruikers

Gebruiker	Gebruikerscode	Leesrechten	Overige rechten
Dr. U. Duinen	g49480	Sectie B, P	

After you have set access rights the authorised user will receive an e-mail which contains information on the access rights given for the file.

The authorised user can find your file in the tab 'Shared files' as well as an indication of which sections of the files he/she has been given read access to.

Welcome, Dr. L. Duinen

User name	duinen	Company	Flevoziekenh
		Department	B1
		Internal address	B1
E-mail	a.mast@ccmo.nl	Address	jansstraat
Phone	034334	Postcode and city	2134
Fax	056565	Country	Nederland

[Edit account settings](#)

File	Title	Access rights for section	Other
NL31425.000.10	C2b titel	B, P	

Overview per section:

<u>Section</u>	<u>gives read access to</u>
B. Forms	ABR, EudraCT
L. Safety information (SUSAR en SAE)	SUSAR, SAE
P. Decrees	Reviews, uploaded decrees

The other sections are not yet in use.

8.7 Retracting reading access to a file

You can retract the access rights of an authorised user to (sections of) your file. To do so open the file concerned, click on '*Manage*' in the left-hand menu and type in the user code of the authorised user. The name of the authorised user appears for you to check. You then deselect the box at, for example, '*B, forms*' and '*P, decrees*' and click on '*Save*'. The access rights of the authorised user for that file are now deleted.

8.8 Authorising others to be able to report adverse reactions

You can authorise users to report adverse reactions which occur during your study. You can set these rights in the file concerned. To do so, open the file and click on '*Manage*' in the left-hand menu (see also [chapter 8.6](#)).

You then fill in the user code of the user to be authorised and click on '*Search*'. The name of the user will appear on the screen.

In the right-hand menu you can set rights for reporting or viewing SUSARs and SAEs. If you wish to give the user access rights to be able to report SUSARs and SAEs for the study concerned, then select the box '*Report SUSAR and SAE*' in the right-hand menu.

Read access	Other access ⓘ
<input type="checkbox"/> B. Forms	<input checked="" type="checkbox"/> Report SUSAR and SAE
<input type="checkbox"/> L. Safety information (i.e., SUSAR/SAE)	<input type="checkbox"/> View SUSAR and SAE reports (unblinded: see details on blinded reports)
<input type="checkbox"/> P. Decrees	<input type="checkbox"/> View SUSAR and SAE reports (blinded: see overview of blinded reports only)
<input type="button" value="Select all"/> <input type="button" value="Deselect all"/>	
	Click on 'Save' to enforce the selected access for this user on this file.

After you have set the rights both you and the authorised user receive an e-mail containing information on the access rights given for sections of the file.

The owner of the file can view all set access rights in the file, under the menu '*Authorise users/overview*'. The authorised user can view the access rights given in the tab '*Shared files*' in the welcome page of ToetsingOnline.

The file overview looks as following:

Overview access rights by others			
Gebruiker	Gebruikerscode	Leesrechten	Overige rechten
Dr. L. Duinen	g27554	Sectie B	Melden SUSAR en SAE, Inzien SUSAR en SAE (ongeblindeerd)
Dr. U. Paars	g04446		Inzien SUSAR en SAE (geblindeerd)

If you have selected the option '*Report SUSAR and SAE*' then the authorised user will only see the SUSARs and SAEs submitted by him/her in the overviews, as well as the attachments of these SUSARs and SAEs.

The file owner can also view these SUSARs and SAEs. The owner cannot make follow-ups to these SUSARs and SAEs, the authorised user however can.

The file owner can however make new SUSARs and SAEs.

8.9 Authorisation for full access to SUSARs en SAEs

You can authorise users to view reports of adverse reactions which occur during your study. You can set these access right in the file itself. To do so, open the file and click on '*Manage*' in the left-hand menu (see also [chapter 8.6](#)).

You then fill in the user code of the user to be authorised and click on '*Search*'. The name of the user will appear on your screen.

In the right-hand menu you can set access rights for unblinded viewing of SUSARs and SAEs.

Both you and the authorised user will then receive an e-mail which contains information on the access rights set for sections of the file.

<p>Read access</p> <p><input type="checkbox"/> B. Forms</p> <p><input type="checkbox"/> L. Safety information (i.e., SUSAR/SAE)</p> <p><input type="checkbox"/> P. Decrees</p> <p><input type="button" value="Select all"/> <input type="button" value="Deselect all"/></p>	<p>Other access ⓘ</p> <p><input type="checkbox"/> Report SUSAR and SAE</p> <p><input checked="" type="checkbox"/> View SUSAR and SAE reports (unblinded: see details on blinded reports)</p> <p><input type="checkbox"/> View SUSAR and SAE reports (blinded: see overview of blinded reports only)</p> <p>Click on 'Save' to enforce the selected access for this user on this file.</p>
--	--

If you have chosen the option '*View SUSAR and SAE (unblinded: see details on blinded reports)*', then the authorised user will be able to see all SUSARs and SAEs in overviews, plus the attachments, and the SUSARs and SAEs reported by others. The user can also print these SUSARs and SAEs.

The file owner can make follow-ups to his/her own SUSARs and SAEs, and can create new SUSARs and SAEs.

The authorised user will see the following in the overview:

Concept ABR New submissions All reviews Current research All files Active files Shared files Archive

File	Title	Access rights for section
NL31425.000.10	C2b titel	Other Inzien SUSAR en SAE (ongeblindeerd)

8.10 Giving access to view blinded SUSARs and SAEs in the overview

You can authorise users to view blinded the adverse reactions which occur during your study. These access rights are set in the file itself. To do so, open the file and click on 'Manage' in the left-hand menu (see also [chapter 8.6](#)).

You then fill in the user code of the user to be authorised and click on 'Search'. The name of the user concerned appears on your screen.

You can set access rights for blinded viewing of SUSARs and SAEs in the right-hand menu.

Read access	Other access
<input type="checkbox"/> B. Forms	<input type="checkbox"/> Report SUSAR and SAE
<input type="checkbox"/> L. Safety information (i.e., SUSAR/SAE)	<input type="checkbox"/> View SUSAR and SAE reports (unblinded: see details on blinded reports)
<input type="checkbox"/> P. Decrees	<input checked="" type="checkbox"/> View SUSAR and SAE reports (blinded: see overview of blinded reports only)
<input type="button" value="Select all"/> <input type="button" value="Deselect all"/>	<input type="button" value="Click on 'Save' to enforce the selected access for this user on this file."/>

If you have chosen the option 'View SUSAR and SAE (blinded: see overview of blinded reports only)', the authorised user will only be able to view an overview of the SUSARs and SAEs reported in that study. The SUSARs, SAEs, and the attachments themselves cannot be opened by the user. See the figure below:

File	Reviews	Adverse reactions/event
File	Review EC	SUSAR
Reviews	Decrees EC	SAE
Review EC	Review CA	Archive
Decrees EC	Adverse reactions/event	
Review CA		
Adverse reactions/event		
SUSAR		
SAE		
Archive		

Serious adverse reactions			
SU002.10.33004			
01			Sinusitis
SU001.10.33004			
02			- Uremie
01			Stijging Na, K, Kreat
AE001.10.33004			
02	✘	!	- Co2 slang verkeerd gemonteerd
01	✘	!	O2 slang verkeerd gemonteerd

Note: a combination of blinded and unblinded viewing access to SUSARs and SAEs is not possible.

8.11 Giving access rights to report adverse reactions and to view overviews

You can authorise users to report adverse reactions, and to view these reactions, and those reported by other users, in an overview.

These access rights can be set in the file itself. To do so, open the file and click on 'Manage' in the left-hand menu (see also [chapter 8.6](#)).

You then fill in the user code of the user to be authorised and click on 'Search'. The name of the user will appear in the screen.

You can set access rights for reporting SUSARs and SAEs in the right-hand menu, by clicking on the option 'View SUSAR and SAE (unblinded: see details on blinded reports)'.

Other access

- Report SUSAR and SAE
- View SUSAR and SAE reports (unblinded: see details on blinded reports)
- View SUSAR and SAE reports (blinded: see overview of blinded reports only)

Click on 'Save' to enforce the selected access for this user on this file.

If you have chosen the option 'Report SUSAR and SAE' in combination with the option 'View SUSAR and SAE (unblinded: see details on blinded reports)' then the authorised user will be able to report SUSARs and SAEs, and view the SUSARs and SAEs reported in the study. The SUSARs, SAEs and the attachments can also be opened, viewed, printed and closed.

9. Transferring a digital file

9.1 Changing the submitter

If the submitter or contact person of a research proposal (temporarily) changes during the review or the course of the study, then you can let the CCMO know by mail at admin@ccmo.nl.

To transfer a research file the following information is required in the mail::

- transfer request
- the NL number of the file(s) concerned
- user name of the old user
- user name of the new user. The new submitter/contact person must of course be registered in ToetsingOnline
- permission from the old user for the transfer to take place. This can be arranged by asking the old user to send the transfer request

After the transfer has taken place the information is no longer visible in the overview of the old user.

If the contact person has authorised users to view certain sections of his/her file, then these access rights remain unaltered for the authorised user(s).

10. Trial register

10.1 Introduction

The aim of the CCMO trial register is to contribute to the transparency of research on human subjects in the Netherlands.

As of the 1st of November 2009 every ABR form is (partially) public. The core information from the ABR form is automatically entered in the public CCMO register at the moment that the MREC has reviewed the research file (including the signed ABR form), and has sent the decision to the CCMO. The information which is made public is marked in the online ABR form with a globe symbol.

10.2 Consulting the trial register

The CCMO trial register can be consulted by clicking on '*CCMO register*' in the black toolbar at the top of the page. The trial register can be consulted after logging in to ToetsingOnline, but can also be consulted via the general website of the CCMO.



The search form is opened in a separate browser window such as displayed below.

CCMO Register

Language / Taal

Dutch / Nederlands
 English / Engels

Method

Keyword
 Dossier number ToetsingOnline
 EudraCT number
 Advanced

Keyword

Query

10.3 The limited search method

The search form contains a number of search options. The standard language is Dutch, and the search method is set to search by keyword.

You can however choose between Dutch or English. You can also change the search method to search by keyword, file number ToetsingOnline, or EudraCT number. You can also perform an advanced search. For more information see [chapter 10.4](#).

If you choose to search in Dutch, as you wish to find all studies carried out on for example lyme, then you type in 'lyme' as keyword and then click on 'Search'. All studies which meet this search requirement are displayed, with the NL number and the title of the study. The number of documents that meet the search requirement is displayed at the top of the result list (with a query field containing code. This you can ignore if you are not used to working with queries).

After selecting the study(s) you wish to view click on 'Show selected documents' which will open the ABR form concerned.

The ABR forms displayed appear in a new browser window and are displayed one after the other.

CCMO Register

Language / Taal
 Dutch / Nederlands
 English / Engels

Method
 Keyword
 Dossier number ToetsingOnline
 EudraCT number
 Advanced

Keyword
lyme

Query
lyme

Show selected documents Deselect all

1 document found
 NL161 National Tick bites study
Show selected documents Deselect all

Search

Execute query

After reading the content of the form you can close it by clicking on 'Close' in the black toolbar, or by clicking on the cross on the browser page.

Searching in English will result in the sections of the form which are in English being displayed, as well as the titles of the studies found. You can also search the trial register on file number in the same way as in ToetsingOnline.

If you already know the file number then choose the search method '*File number ToetsingOnline*' and type in the number in the field '*File number ToetsingOnline*', including the letters NL.

CCMO Register

Language / Taal
 Dutch / Nederlands
 English / Engels

Method
 Keyword
 Dossier number ToetsingOnline
 EudraCT number
 Advanced

file number ToetsingOnline
nl161

Query
FIELD DossierNummer CONTAINS nl161

Show selected documents Deselect all

1 document found
 NL161 National Tick bites study
Show selected documents Deselect all

Search

Execute query

The previous search method can also be carried out with the EudraCT number.

10.4 The advanced search method

The 'Advanced' search method gives the opportunity to make use of more than one search options simultaneously. It is for example possible to search for all positively reviewed ABR forms per MREC.

CCMO Register

Language / Taal	<input type="radio"/> Dutch / Nederlands <input checked="" type="radio"/> English / Engels
Method	<input type="radio"/> Keyword <input type="radio"/> Dossier number ToetsingOnline <input type="radio"/> EudraCT number <input checked="" type="radio"/> Advanced
	<input type="button" value="Clear Fields"/> <input type="button" value="New search"/>
File number ToetsingOnline	<input type="text"/>
EudraCT number	<input type="text"/>
Review committee	Select <input type="button" value="v"/>
Decree date	Select <input type="button" value="v"/> <input type="text"/> (DD-MM-YYYY)
Decree	Select <input type="button" value="v"/>
Is the protocol (also) registered in another public trial register?	<input type="radio"/> yes <input type="radio"/> no clear
Name applicant or contact person for the review committee	
Type organisation or company	Select <input type="button" value="v"/>
Name organisation or company	<input type="text"/>
Other	
Surname applicant or contact person	<input type="text"/>
Sponsor of the research	
Type company or institute	Select <input type="button" value="v"/>
Name company or institute	<input type="text"/>
Other	
Full title of the research	<input type="text"/>
Short title of the research or acronym	<input type="text"/>

Note: the search result is displayed at the bottom of the search form. To view the result you must scroll downward. Here you can select which ABR form you wish to view by clicking on 'Display selected documents', or if only one document is displayed by clicking on the (hyperlink in the) title.

The ABR forms displayed appear in a new browser window and are shown one after the other.

You can easily print an ABR form by using the print functionality of your internet browser.

Close | Print | New version | Help

Form for medical/ethical review and registration

ABR-form, version September 2009

Research file			
ABR number	31425	Status	Definitief
Version	01	Status per	25-01-2010
Year	10		
Filenumber	NL31425.000.10		

After reading the content of the form you can close it by clicking on 'Close' in the black toolbar or the cross on the browser page.

You can start a new advanced search by clicking on the button 'Clear fields' or 'New search'

CCMO Register

Language / Taal

Dutch / Nederlands
 English / Engels

Method

Keyword
 Dossier number ToetsingOnline
 EudraCT number
 Advanced

File number ToetsingOnline

EudraCT number

Review committee

Decree date
 (DD-MM-YYYY)

Decree

Once you have selected 'New search' a search form start window appears where you can once again select 'Advanced'.

10.5 Using queries in the search form

The search form contains a field in which queries are displayed. Your search is displayed in this field. For example, in the query field in the figure below you can see that a search was carried out on 'bewegingstherapie'



The screenshot shows a search interface with two main input fields on the left: 'Keyword' and 'Query'. The 'Keyword' field is empty. The 'Query' field contains the text '(Field Bewegingth=beweging)'. To the right of the 'Keyword' field is a 'Search' button. To the right of the 'Query' field is an 'Execute query' button.

If you have experience in working with queries then you can use the query field to perform a search. The query can be given in the query field according to the standard query rules. In this way you can narrow your search. After entering the search click on '*Execute query*' after which the search result will appear at the bottom of the page.

The example given below resulted in all studies being found in which both methotrexaat as psoriasis are contained in the ABR form.



The screenshot shows the same search interface as above. The 'Keyword' field is empty. The 'Query' field now contains the text 'METHOTREXAAT AND PSORIASIS'. The 'Search' and 'Execute query' buttons are still present.