FAQ; ToetsingOnline



**What is ToetsingOnline?**
Investigators can use the ToetsingOnline portal to submit their research to be reviewed to a Medical Research Ethics Committee (MREC) and competent authority (CA).
These committees and authorities then use the Toetsingonline portal to register the reviewing process and monitor the review time periods.
The submitter can follow the process over the internet.

https://toetsingonline.ccmo.nl
ToetsingOnline User Manual

**Current status**
The ToetsingOnline module 'Reporting unwanted adverse reactions/events' came online in 2008, following close cooperation with the Dutch Adverse Reactions Centre (LAREB), responsible for entering part of the data to the EudraVigilance data bank.
Users/investigators can use this module to report SUSARs and SAEs to both the MREC and the competent authority (CA). This digital reporting through ToetsingOnline concerns a pilot study and is currently only accessible to investigators who have received a relevant report from their MREC.

The test version of the public CCMO trial register was launched in December 2008. This means that everyone with access to the internet can search the public data bank for information on research involving human subjects. The register will be optimised in the coming year and the WHO will be asked to give recognition to the CCMO trial register.

**Longer term**

The portal will be further expanded in the coming future. Current efforts include the translation of ToetsingOnline into English and continuous system maintenance.
The long-term objective is to make it possible to submit the entire research file digitally.

**Questions and comments**
For more information on the portal, please contact the CCMO Secretary on +31 (0)70-340 6700 or at admin@ccmo.nl. Your feedback is greatly appreciated.

**Background**
The OnlineAssessment portal is the result of an initiative of the Central Committee on Research Involving Human Subjects (CCMO), in cooperation with the accredited Medical Research Ethics Committees (aMRECs). The portal was made possible partly as a result of a grant from the Ministry of Health, Welfare and Sport (VWS).

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**Where can I practise completion of the new ABR form?**
You have three options: instruction film, text version and the manual.

- Instruction film for completing the ABR form (.exe, 1,6Mb, only in Dutch)
  The film lasts about six minutes and shows the main steps in completing the form.
- Text version of the ABR form (with explanation to questions)
  The text version is only for information and does not include an option for completing the form. It nonetheless contains all the questions. This is in contrast to the online form, which only shows questions relevant to the submitter.
- User Manual ToetsingOnline

Important! The new ABR form can only be completed online. To do so, visit the ToetsingOnlineportal (prior registration required).

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**Why can't I log in with my temporary password?**
We recommend that you copy and paste the temporary password into the login form to prevent typing errors.

When using the temporary password to log in for the first time, you must immediately change it into your own chosen password. If you log out after this, it can take a while for the server to process the new data, so you might not be able to log in again immediately with your new password. Try again an hour or so later if this is the case.
Only use the link in your e-mail when you log in for the first time and still have to change the password. Do not use the link after this to log in again.

If it is indeed impossible to log in with the temporary password, it may also be because you have accidentally copied and pasted a space too many at the end. Try it once again without any extra spaces.

If it still doesn't work, please contact the CCMO at admin@ccmo.nl.

See also the User Manual ToetsingOnline.

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**I would like to print my draft ABR form.**
You can easily print out a draft ABR form by using the print function of your web browser. You then make a so-called screen print by right-clicking on the form and selecting the 'print' option. Only the ABR form in the 'reading mode' is suitable for this, as it shows all your answers on the screen. Some long answers may run outside the entry field after you have selected 'changes' and set the form to 'writing mode'.

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**I have created the definitive ABR form, but now want to make some changes.**
You can only make changes in your ABR form by creating a new version. To do so, open the ABR form and click on 'create version' under 'actions'.
All your previously provided answers can be found in this new version. Just as with the first version, you can store this version as a draft and later make it definitive.

There is no limit to the number of versions you may create.

See also the User Manual ToetsingOnline.

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**I have already made my form definitive, but I want to change questions B1, C10 and/or C16.**
You can no longer change these questions, even if you were to create a new version. The ABR form is reviewed on the basis of the answers provided a Medical Research Ethics Committee has been selected and the version is definitive. After this review, a decision is made on which Medical Research Ethics Committee(s) the study can be submitted to, whether the study should be submitted to the competent authority instead, and which legal time periods will apply. This is done only once.

This is why it is not possible to change any answers to questions B1, C10 and/or C16 as of version 2 of the ABR form.
You can ask the CCMO to reset the form to its draft status, after which you can indeed change your answers to the relevant questions.

See also the User Manual ToetsingOnline.

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**I can't get my definite ABR form to print.**
After you have made the form definite, your ABR form automatically opens in a new window. Click on 'file' at the top and then on 'print'. This printout is suitable for the Medical Research Ethics Committee.
If the window doesn't open (even after clicking on the 'print' button in the black toolbar), then it is possible that pop-ups are blocked on your system. A very brief message about pop-up blocking may appear in the upper part of your screen. You can click on this message and change the settings to allow pop-ups for OnlineAssessment portal. You can now click on the 'print' button in the black toolbar again. After the form has been opened in a new window, you can print it by clicking on 'file' and 'print'.

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**I am unable to answer question E1 by clicking on 'yes, therapeutic research'.**
This question is linked to question C15. The program automatically selects 'no, non-therapeutic' under E1 if you clicked on phase 1 under question C15.
A phase 1 study is never therapeutic.

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**I want to make an amendment but receive a message that only 1 amendment is possible for the ABR form.**
You can only create a new ABR amendment once the Medical Research Ethics Committee has approved your amendment. This assessment must therefore first be processed in OnlineAssessment. After the Medical Research Ethics Committee has approved your amendment, you can create a new amendment on the assessed ABR form and resubmit it to the Medical Research Ethics Committee.
You can find the most recently assessed ABR form in the 'documents' screen in your digital research file.

See also the User Manual ToetsingOnline.

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**I want to create a new amendment, but the previous one has not yet been assessed.**
You will find your pending amended ABR form in the 'new documents' screen in your digital research file. You can open it and subsequently create a new version. You can also do this if the assessment is already in process.

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**I want to work on ToetsingOnline in English.**
ToetsingOnline is bilingual. You can choose between working in Dutch or English. Its default language is Dutch, but you can change this setting by logging in and then clicking on ‘change registration data’.
You can choose at the bottom in which language you want to work in ToetsingOnline.

Or you can click on the following link: ToetsingOnline in English

Important! The print version of the ABR form is always in Dutch.

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**I want to change my registration data.**
If you want to change your details once you have registered on the ToetsingOnline portal, you can do so yourself on the registration page. You can access the registration page by logging in to ToetsingOnline and clicking on ‘change registration data’ at the top of the page. Your can change all your data, except your user name.

Please note: Is someone else going to manage your file? Then you must transfer your file to the other user. This cannot be done by simply changing your data.

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**I want to transfer my file to another user.**
The new user must first register with ToetsingOnline.
The current file owner should then send an e-mail to admin@ccmo with the request to transfer the file.
Your e-mail must include the current user name, the new user name and the NL number of the file.
You must also send a copy of the e-mail to the new user.

After the transfer, the CCMO will send a confirmation of the change to the old and the new user.

See also the User Manual ToetsingOnline.

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**Does my Medical Research Ethics Committee work with ToetsingOnline?**
The following Medical Research Ethics Committees work with ToetsingOnline (1 April 2010):

METC Noord-Holland, Alkmaar
STEG, Almere
Independent Review Board, Amsterdam
Nederlands Kanker Instituut, Amsterdam
Vrije Universiteit Medisch Centrum, Amsterdam
Stichting Beoordeling Ethiek Bio-Medisch Onderzoek, Assen
METC Zuidwest Holland, Delft
Catharina Ziekenhuis, Eindhoven
Medisch Spectrum Twente, Enschede
Universitair Medisch Centrum, Groningen
Atrium medisch centrum & Maaslandziekenhuis, Heerlen
Regionale Toetsingscie Patiëntgebonden Onderzoek, Leeuwarden
Academisch Ziekenhuis, Maastricht
VCMO Verenigde Commissies voor Mensgebonden Onderzoek, Nieuwegein
Commissie Mensgebonden Onderzoek, Nijmegen
IRB Nijmegen (Institutional Review Board), Nijmegen
Erasmus Medisch Centrum, Rotterdam
TWOR, Rotterdam
St Elisabeth Ziekenhuis, Tilburg
METOPP, Tilburg
Universitair Medisch Centrum, Utrecht
METIGG, kamer Noord, Utrecht
Máxima Medisch Centrum, Veldhoven
Wageningen Universiteit
Isala Klinieken, Zwolle

As of 1 January 2010, all accredited Medical Research Ethics Committee (aMRECs) are required to use ToetsingOnline for processing adverse reactions.

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**What is a user code, en where can I find this code?**
Every registered user of ToetsingOnline has an user code. This code is necessary
to be able to get access to parts of a research file. The code looks like, for instance,: h12345.

Your user code is displayed on the right-hand side of the toolbar, at the top of your welcome page. The user code is also displayed in your registration information.

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.

See also the User Manual ToetsingOnline.