



ETHIK-KOMMISSION DER
ÄRZTEKAMMER
HAMBURG
Körperschaft des öffentlichen Rechts



Guidelines for Applicants

Version 6.1

Geschäftsstelle der Ethik-Kommission der Ärztekammer Hamburg
Weidestraße 122 b • 22083 Hamburg
Phone 040/202299-240 • Fax 040/202299-410
ethik@aekhh.de • www.aerztekammer-hamburg.de

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1 Access to Website

ethikPool can be accessed with any current internet browser (e.g. Microsoft Internet Explorer/Edge, Google Chrome, Mozilla Firefox etc) using the following address:

<https://ethikpool.aerztekammer-hamburg.de/app/> .

1.2 Create User Account

If you are using ethikPool for the first time, please register by clicking on **"Benutzerkonto erstellen"** on the right.

The screenshot shows the login interface for ethikPool. It includes a header with the logo and 'Login' text. The main area contains input fields for 'Benutzername' and 'Passwort', followed by a dark blue 'Einloggen' button and a link to 'Impressum'. On the right, there are three links: 'Benutzername vergessen?', 'Passwort vergessen?', and 'Benutzerkonto erstellen'. The 'Benutzerkonto erstellen' link is highlighted with a yellow border. The text for 'Benutzerkonto erstellen' reads: 'Benutzerkonto erstellen. Wenn Sie noch kein Benutzerkonto haben klicken Sie hier um eines anzulegen.'

A registration window will open. The fields marked with * are mandatory. After entering the required data, click on „**Benutzerkonto erstellen**“ at the bottom right of the page to create your user account.

After completion, you will receive an automatically generated e-mail.

Das Benutzerkonto wurde angelegt. Sie erhalten in Kürze eine Email um Ihr Konto zu bestätigen. Anschließend können Sie sich einloggen. x



Sehr geehrte/r ethikPool BenutzerIn,

Sie haben sich als Benutzer auf dem ethikPool Portal angemeldet.

Um Ihr Benutzerkonto und Ihre Anmeldung abzuschließen, bitten wir Sie den folgenden Link zu klicken oder in Ihren Browser zu kopieren.

Link um Benutzerkonto zu bestätigen

Sobald Ihr Benutzerkonto von der Geschäftsstelle freigegeben wurde, können Sie es vollumfänglich nutzen.

Mit freundlichen Grüßen

Geschäftsstelle der Ethik-Kommission
Telefon 040 / 20 22 99-240
Fax 040 / 20 22 99-410

ethik@aekhh.de
www.aerztekammer-hamburg.de

Ärztchammer Hamburg
Weidestr. 122 b
22083 Hamburg

Ihr Weg zu uns: www.aerztekammer-hamburg.org/kontakt.html

[Impressum](#)

Now you will have to wait for the activation of your account by our office. Once completed, you will be informed of the activation of your account by e-mail.

In addition to the confirmation of your activation, you will receive another e-mail with the data required to set up the Authenticator App for your smartphone or the web-based Authenticator for your PC. For further information, please refer to **section 1.3 Login** and **section 4 Authenticator**.

1.3 Login

As soon as the activation is completed, you can log in with your user name and password.



 Login	Passwort vergessen? Wenn Sie Ihr Passwort vergessen haben klicken Sie hier.
Benutzername <input type="text"/>	Benutzerkonto erstellen Wenn Sie noch kein Benutzerkonto haben klicken Sie hier um eines anzulegen.
Passwort <input type="password"/>	
<input type="button" value="Einloggen"/>	
Impressum	

Data security has top priority in the ethikPool portal. Therefore, we protect your access to the system with a multi-factor authentication.

In addition to your user name and password, you also need to enter a security token to access your account. Data needed for the set-up of Google Authenticator or a similar app is sent to you in an e-mail. You can download these apps free of charge from any App Store.

To set it up the app you either enter the code in the e-mail you received from us or you scan the QR code in the aforementioned e-mail with the app. After completion, the app is ready and will generate the necessary security tokens (6 digits).

You do not have a smart phone at your disposal? For a PC alternative to Google Authenticator or a similar smart phone app, see section **4.2 Authenticator for PCs**.

2 Explanation regarding the Header

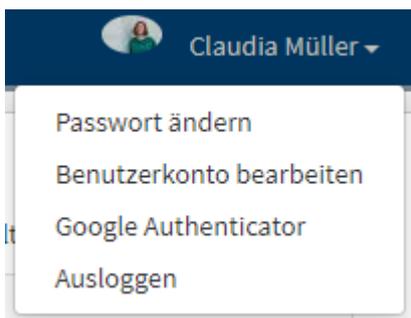
2.1 User Display

In the upper right corner you will find the user display, which shows the user who is currently logged in (your name).



2.2 User Menu

By clicking on your name you can open a user menu:

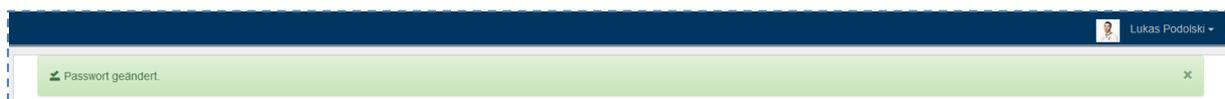


Here you can change the initial password, revise your user account details, or log out.

2.2.1 Change Password

If you click on " **Passwort ändern** ", a new dialogue box will open. In this dialogue box, you have to enter your new password twice. To exit the dialogue box you clicking on „**Schließen**“ in the bottom left corner or on „**X**“ in the top right corner. Please click on „**Speichern**“ to save your new password.

On successful completion, the dialogue box will close and the following message appears:



2.2.2 Edit User Account

Clicking on „**Benutzerkonto bearbeiten**“ will open a new dialogue box where you can change various details of your user account.

Fields marked with * are mandatory fields and must be filled in.

If you like you can upload an image of yourself. To do so, click on „**Durchsuchen**“, select a picture (JPEG) and upload it.

To exit the dialogue box click on „**Schließen**“ in the bottom left corner or on „**X**“ in the top right corner. Clicking on „**Speichern**“ will save the your changes.

2.2.3 Logout

By clicking on "**Logout**" you will be logged out of ethikPool and return to the login page.

3 Overview

On the left-hand side of your screen you will find a menu which starts with „**Übersicht**“. When you log in to ethikPool for the first time the „**Übersicht**“ will be empty. Older submission will not be visible. Please contact our office and tell us which studies you need access to. In order to process your request, we need the respective processing numbers (Bearbeitungsnr.).

3.1 News & Dateien

Under this heading you will find a weblog, which will provide you with information about current developments, new templates or other important news and files.

Dateien & News

Hier sehen Sie aktuelle Nachrichten und Dateien aus der Kommission.

Neue Regeln des Dekanats bzgl. Unbefangenheit
sdolf gunjoppdshtfg uoisdhtfgio ls djfrvbo udijlkhv sobduifjkhmv .bsdofuujlvmh, bdsthjkvmhsd nfpuvik,
[brief-formB-5008-2011.pdf](#)

Neue Studienordnung bei RV
Seit dem 01.01.2016 gibt es eine neue Studienordnung bei RV. Dies besagt, dass die folgenden Bereiche für Studien bei RV abgedeckt sein müssen.

3.2 Applications

3.2.1 New Applications

To submit an application, please click on the menu item „**Anträge**“. A new window will open where you can click on „**Neuer Antrag**“.

Anträge

Unten aufgelistet finden Sie Ihre eingestellten Projekte.

Nummer	Name	Letztes Update	Status
Keine Anträge			

 Neuer Antrag

After clicking on „**Neuer Antrag**“ you will be guided through the application process step by step. Please select the category in which you wish to submit your application.

Neuer Antrag

Auf den folgenden Seiten werden Sie Schritt für Schritt durch den Prozess der Antragstellung geleitet. Dieser Ablauf dient dazu, die möglichen Fehler im Prozess der Antragstellung zu minimieren und dadurch die Bearbeitungszeit zu reduzieren.

AMG-Studie

nach §§ 40-42 (Klinische Prüfung)

Arzneimittelstudien nach §§ 40-42

Sie haben erfolgreich eine Kategorie der Antragstellung ausgewählt.

Information: Einige der unten stehenden Dokumente müssen zwingend in der hier vorliegenden Form im Prozess der Antragstellung ausgefüllt werden. Einige unterliegen einer Auswahl, sind optional zu verwenden oder enthalten spezifische Informationen zur Antragstellung. Sie können die Dokumente bereits jetzt herunterladen und ggf. ausfüllen, um sie dann im weiteren Prozess der Antragstellung fertig vorliegen zu haben.

-  AMG_Antragsunterlagen_gemaess_AMG_15_Novelle.doc
-  AMG_Begleitschreiben_Muster_mono.doc
-  AMG_Einwilligungserklaerung_zum_Datenschutz.doc
-  AMG_Erklaerung_Pruefer_Stellvertreter.doc

 Weiter

Please enter the necessary information tab by tab and click on „**Weiter**“ to save the information entered. You have the option to save your information, withdraw or delete the application at any time during the submission process. Make sure all application documents submitted have been labelled appropriately. In addition, please make sure to enter the required contact details of all parties involved (sponsor/authorised representative/invoice recipient (**see also section 3.2.1.1 Partner**) in the „Partner“ tab under „Neuer Partner“. **We also need full details of the trial sites/investigators in the tab „Prüfzentren/Prüfer:in“ (see also section 3.2.1.2 Trial**

Centres/Investigators). When you have reached the last tab „**Einreichung**“ click on „**Antrag einreichen**“ to complete the submission.

Please note: If your submission does not meet the necessary requirements, the office of the local Ethics Committee reserves the right to reject the submission.

3.2.1.1 Partner

To add a sponsor, CRO, invoice recipient, etc. in your application, please click on „**Neuer Partner**“ under the "**Partner**" tab. Enter the complete information of the selected partner type here. Confirm your entries at the end by clicking the button "**Speichern**".

Neuer Antrag

#TEMP454224-BO-ff - Antragstellung

The screenshot shows the 'Neuer Antrag' form with the 'Partner' tab selected. At the top, there is a navigation bar with tabs: Name, Vernetzung, Flags, Antragsdaten, Partner, Prüfzentren / Prüferin, Dateien Prüferin, and Einreichung. Below the navigation bar, a yellow box contains the instruction: 'Bitte machen Sie Angaben über Partner und eventuelle Sponsoren. Firmen-Anträge können ebenfalls selektiert werden. Die angegebenen Daten dienen der Korrespondenz und werden bei eventuellen Nachforderungen berücksichtigt.' The main form area is divided into sections. The first section is 'Antragsteller:in' with a sub-section 'Dieser Antrag wird eingereicht als ...' containing radio buttons for 'persönlicher Antrag' (selected), 'Firmen-Antrag - Bitte erstellen Sie vorab einen Partner vom Typ Industrie-Antragsteller:in', and 'Ich erstelle den Antrag im Namen eines Dritten. Dessen E-Mail-Adresse (also eine mögliche ethikPool Kennung) lautet:'. A 'Speichern' button is located at the bottom right of this section. The second section is 'Partner' with a list of entries. The first entry is '1. - Neuer Partner', which is highlighted with a blue background and a red arrow pointing to it. Below this entry are several checkboxes: 'Sponsor:in', 'CRO', 'Industrie-Antragsteller:in', 'Rechnungsempfänger:in', 'Repräsentant:in', 'Postadresse, wenn abweichend vom Rechnungsempfänger', and 'Sponsor EU-Repräsentant'. Below the checkboxes are three text input fields: 'Name Partner *', 'Abteilung', and 'Vorname Kontaktperson *'. At the bottom of the form, there are three buttons: 'Zurück', 'Zwischenspeichern', and 'Weiter'.

This procedure should be repeated for all other contact types listed:

The screenshot shows the 'Partner' tab with a list of entries. The first entry is '1. - Test - Test Test' and the second entry is '2. - Neuer Partner', which is highlighted with a blue background and a red arrow pointing to it. Below the list are the same checkboxes as in the previous screenshot: 'Sponsor:in', 'CRO' (checked), 'Industrie-Antragsteller:in', 'Rechnungsempfänger:in', 'Repräsentant:in', 'Postadresse, wenn abweichend vom Rechnungsempfänger', and 'Sponsor EU-Repräsentant'. Below the checkboxes is a text input field: 'Name Partner *'.

3.2.1.2 Trial Sites/Investigators

This tab describes the trial site(s) in which the study is to be conducted. The office of the ethics committee requires information on **all** trial sites participating in the study, including the investigators. **Please make sure to fill in every field completely.** Please click on the green button „+ Prüfzentrum“ behind the field „Ethik-Kommission der Ärztekammer Hamburg“ to create a trial site that belongs to the designated area of ethics committee Hamburg. After entering a keyword, known trial sites will be suggested to you. However, if you would like to enter a trial site in an area designated to a different ethics committee, click the green button „+ Ethikkommission hinzufügen“. Enter the ethics committee in question and select the green button „+ Prüfzentrum“ thereafter.

Please note that complete information on all investigators is required too!

Neuer Antrag

#TEMP454224-BO-ff - Antragstellung

Auf dieser Seite müssen / können Sie Prüfzentren und Prüferinnen eintragen. Sie können pro Prüfzentrum mehrere Prüfer:innen anlegen. Außerdem können Sie für multizentrische Anträge auch weitere Prüfzentren im Bereich anderer Ethikkommissionen anlegen.

Ethikkommissionen

Name	Aktionen
Ethik-Kommission der Ärztekammer Hamburg	+ Prüfzentrum E-Mail X

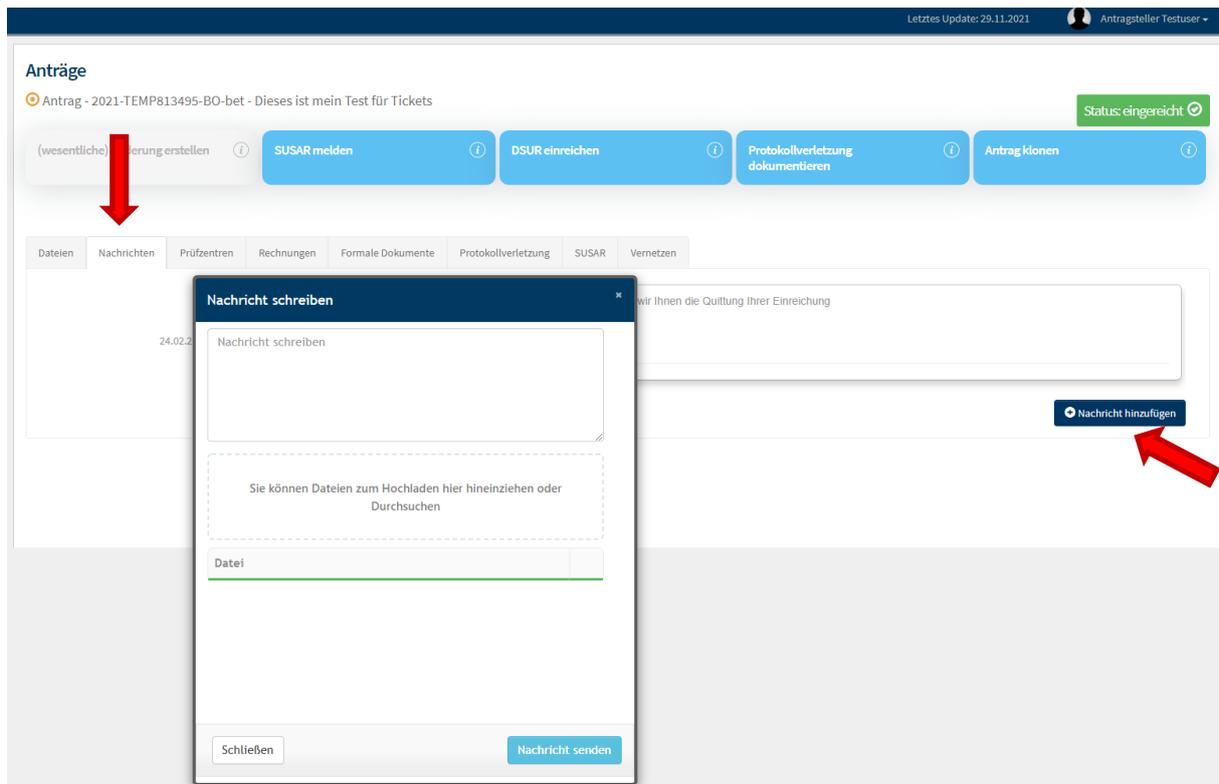
+ Ethikkommission hinzufügen

Antrag zurückziehen | Lösche Antrag

To finish, click „weiter“ in the bottom right corner.

3.2.2 Subsequent Submission of Documents

If you want to submit additional files after your initial submission, before study approval, please use the „**Nachrichten**“ tab within in the respective study. Here you can send a message to our office directly and attach pdf files using drag&drop. Please note that once a vote has been cast, files cannot be submitted using the „**Nachrichten**“ tab. In this case, please proceed as described under section 3.2.3.

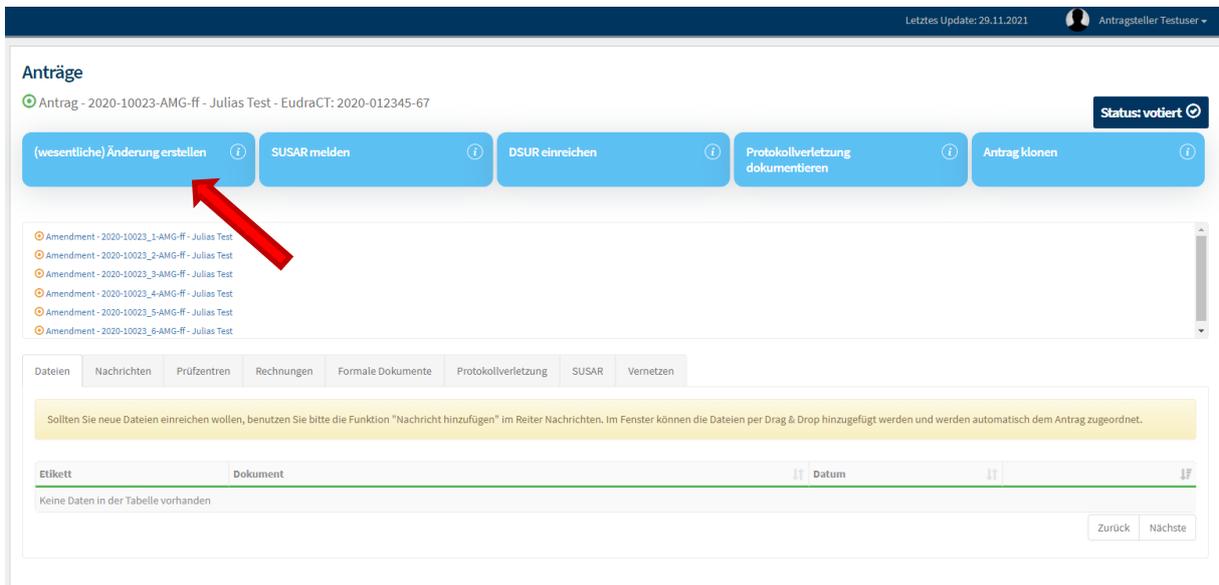


3.2.3 Communication with our office

If you have any questions about your application, you can send your inquiries directly to the office via the "Messages" tab. This way, a message thread between you and the office is created within your application.

3.2.4 Amendments

To submit an amendment to a study that has already been approved for you, press the blue button „(wesentliche) Änderung erstellen“ in the top left corner. A new window will open where you can add the following changes:



Please note that each amendment must be submitted separately! Due to different deadlines, it is not possible to submit, for example, a protocol amendment AND a trial site amendment/registration etc. in one submission. Please create one submission per amendment.

Neues Amendment

2020-10000_780409-AMG-ff - Test - Dies ist ein Testantrag

Prüfzentren hinzufügen

bestehende Prüfzentren ändern (inkl. neuer Prüfer:in / Prüfer:in abmelden)

geänderte Dateien einreichen

Weiter

Lösche Amendment

You can submit a new trial site by using the „**Prüfzentrum hinzufügen**“ button.

Neues Amendment

2020-10000_980026-AMG-ff - Test - Dies ist ein Testantrag

Beschreibung Prüfzentren ändern **Prüfzentren hinzufügen** Dateien Speichern

Neue Prüfer:innen / Prüfzentren hinzufügen Alle ausklappen Alle einklappen

Name	Art	Aktionen
Ethik-Kommission der Ärztekammer Hamburg		<input style="background-color: #4CAF50; color: white; border: none; padding: 2px 10px; border-radius: 4px;" type="button" value="+"/>

To submit a trial site in Hamburg, please click on the green button with the "+".

To submit a trial site in the area of a different ethics committee, either add the ethics committee in question via the green button „**+ Ethik-Kommission hinzufügen**“. A list of the ethics committees known to us will be displayed via dropdown. Please select an ethics committee and click on the green button „**+ Prüfzentrum**“ behind the respective ethics commission to add more trial sites.

After entering a keyword, e.g. under „Name Prüfzentrum“, „Abteilung“, or "Straße" a list of suitable sites known to us will be displayed.

Name Prüfzentrum *

Abteilung

Straße

PLZ

Stadt

Telefon

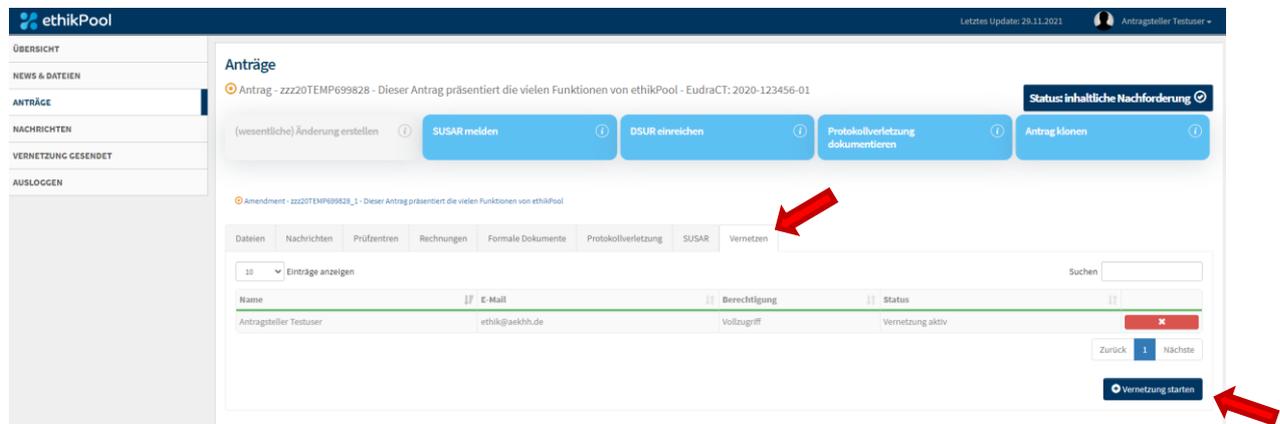
Fax

E-Mail

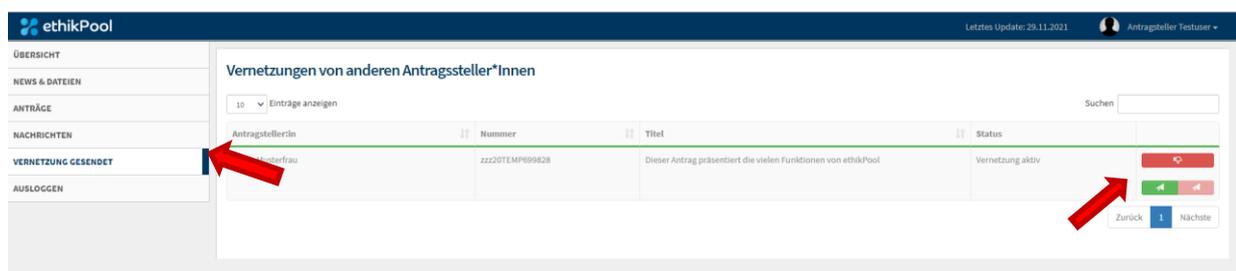
By selecting „**bestehendes Prüfzentrum ändern**“, you can make changes to a trial site that has already been registered with us (e.g. change of investigator, etc.).

3.2.5 Network

In order to grant other authorised persons full access or viewing rights, please use the tab „**Vernetzen**“ in the respective study. Here you can set up as many links as you like by clicking the button „**Vernetzung starten**“ and entering the e-mail address that you would like to connect with. Please note that a link will only work if the e-mail address belongs to a user account that has already been authorised by us.



In order to include another user in the entire communication with our office, please use the tab „**Vernetzungen gesendet**“. Please select the user linked to the respective study and activate the green button behind their name. Both you and the other user will receive all e-mails sent by our office via ethikPool concerning the study in question. If you wish to disconnect the other user, you can also remove the link as shown in the picture below:



3.2.5.1 Connecting with pharmacovigilance

If DSUR / SUSAR reports have to be submitted for your trial (according to AMG), it is also possible to involve pharmacovigilance staff via the "**Network**" function. You can connect with staff from both external companies and colleagues in your own institution.

To connect, please proceed as described under section „3.2.5 Network“. Please make sure that the user's rights are set to „**Vollzugriff**“, because otherwise files cannot be submitted. As soon as the connected user opens a trial for the first time, they will be

asked which "rights" they have (which data they are allowed to see). Here, **the 3rd option „Ich bin für die Pharmakovigilanz zuständig..“** must be selected:

Test - Dies ist ein Testantrag

Um eine GCP-konforme Benutzung unseres Antragsportals gewährleisten zu können, treffen Sie bitte für sich in Bezug auf diesen Antrag folgende Auswahl:

- Ich bin Antragsteller:in einer unverblindeten klinischen Prüfung und möchte Vollzugriff auf die Akte einschließlich SUSARs und DSURs (Meldungen und Einsicht).
- Ich bin für den Antragsteller:in einer verblindeten klinischen Prüfung in der Projektleitung tätig und darf daher SUSARs und DSURs nicht sehen.
- Ich bin für die Pharmakovigilanz zuständig und darf daher SUSARs und DSURs einreichen und einsehen. Ansonsten sehe ich bei dieser klinischen Prüfung nur die Stammdaten, nicht aber die einzelnen Vorgänge.

[Speichern](#)

After clicking on „speichern“ the following window will open:

Sie haben aufgrund Ihrer Rolle als ‚Pharmakovigilanz Benutzer:in‘ nur teilweisen Zugang zum Projekt. Sie haben die Befugnis SUSARs und Nachrichten diesbezüglich zu sehen.

Anträge

- Antrag - 2020-10000-AMG-ff - Test - Dies ist ein Testantrag - EudraCT: 2012-123456-12

[SUSAR melden](#) ⓘ [DSUR einreichen](#) ⓘ

- Amendment - 2020-10000_1-AMG-ff - test

SUSAR [Vernetzen](#)

Datum	erstellt von
Kein Inhalt verfügbar	

The connection has been successfully completed.

4 Authenticator

To protect your data and your identity, ethikPool uses a multi-factor authentication with a code generator (Authenticator). Below you will find a list of different types of authenticator apps that you can use. **Please note that without this second authentication factor a login and thus the use of the ethikPool portal is not possible.** If you have any problems or queries, please do not hesitate to contact the ethikPool support team at our office.

The following products have already been tested by us, but there are others that should also work:

- Google Authenticator (see section 4.1.1)
- Microsoft Authenticator (see section 4.1.2)
- Twilio Authy (see section 4.2)

4.1 Authenticator for Smartphones

If you have not used an authenticator app yet, please have a look in your respective App Store (search for Authenticator) and install the app.

After installing the app, please set up your ethikPool account in your authenticator app. To do so you will receive an e-mail with the account information for the authenticator app (after following the link in our confirmation e-mail for your user account). Please follow the instructions in the app to add an account. The account is usually set up by scanning the QR code sent to you in the e-mail mentioned above or by entering the activation code manually (same e-mail). After completing this step, a token (6 digits) will be generated by the app every 30 to 60 seconds. This token is needed to log in to the ethikPool portal.

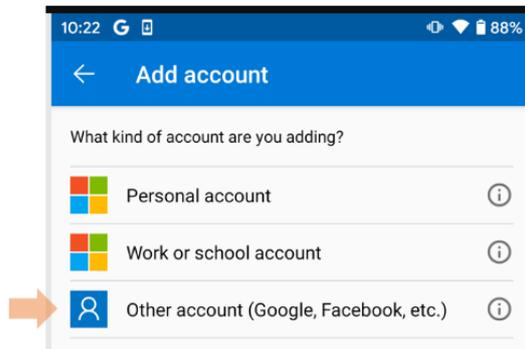
The described steps are mandatory - tokens intended for login to other applications do not work for login to the ethikPool portal!

4.1.1 Google Authenticator and Other Accounts

If you are already familiar with the Google Authenticator or other apps and have already used them for other user accounts, please select the „+“-sign (or similar) within the app to add a new account and follow the app's instructions for scanning the QR code or entering the ethikPool activation code manually.

4.1.2 Microsoft Authenticator

The Microsoft Authenticator distinguishes between different account types. Please note that ethikPool is not a Microsoft account. Therefore, please select the option **"Other account"** during the setup:



4.2 Authenticator for PCs

IMPORTANT: Do not use this type of authentication on publicly accessible computers!

If you do not have a smartphone, you can obtain an Authenticator for your PC (Mac, OS, Windows, Linux) via <https://authy.com/download>, which you can download directly to your **password-protected** device. Please select your operating system and confirm your selection with "Download".

To use Authy, you must register with a phone number¹ that Authy uses to identify you and, if necessary, to obtain your authorisation for security-related actions².

Start the downloaded and follow its instructions.

After completing the download / installation, you can choose to set up Authy by phone call or by text message.

Please protect this application with a password. Please use "Settings" -> "General" -> "Master Password" -> "Enable"! Select a secure password and enter it. Please confirm your password by entering it again. After setting the password, the application will ask you for your password whenever you open it.

After setting up Authy, please scan the QR code from our e-mail or type in the activation code manually using the **"+" sign**. As a next step, you can assign a name and a colour to the token (created by Authy). For example, choose the name "ethikPool" in the field "Account Name" and assign the colour blue. Please keep the token length to 6 digits. After confirming your settings with the **"Save"**-button, a periodically changing token

¹ Make sure that this telephone number can only be used by you personally. Telephones accessible by other people in treatment rooms, at reception desks etc. are unsuitable for this purpose.

² E.g. the initial set-up.

will be generated which is intended for your login to the ethikPool portal. **These steps are mandatory - tokens intended for login to other applications do not work for login to the ethikPool portal!**

If you have any questions about ethikPool, please feel free to ring us during telephone consultation hours of the ethikPool support team at the office of the Hamburg Ethics Committee. You can find further information on our homepage in the section „Kontakt“ or directly under the following link: https://www.aerztekammer-hamburg.org/ethik_kommission.html.