

DRKS Online-Help - Public Area

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Overview

The German Clinical Trials Register (DRKS) offers the possibility to find information about planned, ongoing and completed clinical trials in Germany. Furthermore, by registering your own study you can make it accessible to the public.

The internet portal of the DRKS is divided into a public and an authenticated area to meet the needs of specific interest groups.

- The public area contains a search engine to browse the clinical trials registered with DRKS and some general information about the project. It is accessible to all users via internet. The public area is designed in an easy way so that it can be used by people of all abilities and disabilities. (Therefore JavaScript is not used in this part of the website.). This guide will only describe the features of the public area.
- The authenticated area can only be used by authenticated users. It is used to collect and record data for the registration of trials. There is a guide for the authenticated area as well which can be found (after login) on the top right corner of the page. The chapter "Trial Registration" will provide information on how to access the authenticated area.

The Glossary can be used to get further, clarifying information about the terminology used in this guide and on the website of the DRKS. You will find the tool in the navigation of the portal under "Service".

If you have any questions or suggestions, feel free to get in touch with us by using the contact information on the contact page. You will also find a contact form there which can be used to send us an e-mail.

The contents of the portal of the DRKS are completely available in German and in English. You can switch languages with the corresponding icons at the top of the page.

User registration

You can create a user account at DRKS under "Register user" in the navigation. A user account gives you access to the authenticated area of the DRKS where you can insert and edit trial data. At the beginning of your registration you will have to choose a user name and password. The registration process contains two steps. First, you have to enter the necessary details to create an account. After submitting your information by pressing the "OK" Button the data will be saved in the system and you will get a confirmation e-mail. You can now activate your account with the included link. This is necessary in order to prevent misuse. In addition, your e-mail address can be verified. Please consider that automatic communication with DRKS is generally via e-mail. It is important that you enter a personal, institutional e-mail address which you are allowed to access and which you will check regularly.

User account data

The information in the upper section of the dialogue as well as the affiliation and telephone are required to create a user account which then allows you to enter the authenticated area.

User account data

This is your personal account and your personal password. If you would like to allow another person to edit your trial, please use the function "Responsible persons" within the software (s. online help of the authenticated area).

Title * :	<input type="text" value="Please select..."/>	Academic title:	<input type="text"/>
Firstname * :	<input type="text"/>	Lastname * :	<input type="text"/>
E-mail address * :	<input type="text"/>	User name * :	<input type="text"/>

Please enter your institutional e-mail address only.

Password rules: The password must be at least 8 characters long. It may not contain any space character and it has to contain at least 2 special characters (digits, capitalized letters, all other non-letters).

Password * :	<input type="text"/>	Password confirmation * :	<input type="text"/>
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Please repeat the text to be seen in the image right * : | If you cannot read the characters, please click on the image to refresh it. | |

To avoid possible loss of data the system can save your data automatically in the background while editing trial data. To use this functionality please check the checkbox. You will find further information in the online help.

Allow automatic interim saving:

Address

Address:	<input type="text"/>		
Postal code:	<input type="text"/>	City:	<input type="text"/>
Country:	<input type="text" value="Please select..."/>		
Telephone * :	<input type="text"/>	Fax:	<input type="text"/>
Affiliation * :	<input type="text"/>		
URL:	<input type="text"/>		

Password

Please enter a password you want to use to log in to the system. You can choose a password freely but it has to match the following criteria

- it is at least 8 characters in length
- it contains at least 2 special characters;

Special characters are:

- numeric characters
- capital letters
- other characters besides alphabetic or numeric characters

Password confirmation

Please re-enter your password to prevent typing errors.

Security check

Please enter the character string which you can see in the image to prevent misuse of the website.

If you have any difficulties to read the code, click on the image to generate a new one.

Allow automatic interim saving

While inserting trial data, you will have to fill in a lot of slots. The DRKS provides the possibility to save the currently inserted data automatically and periodically (every 2 minutes) on the server of the DRKS to prevent loss of entered yet still unsaved data in case of a system crash or a session timeout.

This is just a backup copy of your input which can be used to recreate the last state of your work when reopening the study. However, no other user will be able to see this data. The data will be finally saved as a new, changed version after you pressed "Apply changes".

To enable automatic interim saving (and thus data transmission to the server while editing) please check this option.

Address data

Entering address data except for the affiliation and telephone number is voluntary, but it will make it easier for the DRKS to retain an overview of the registered users and to get in touch with them. The function "Change user profile" allows you to make changes at any time after registration when logged in.



The screenshot shows a form titled "Address" with the following fields:

- Address:
- Postal code: City:
- Country:
- Telephone *: Fax:
- Affiliation *:
- URL:

We implement the double-opt-in procedure for registration, whereby your registration is only complete once you have confirmed your registration by clicking the links in the confirmation email sent to you for this purpose.

Your personal data serves to enable us to correspond with you. This data will not be disclosed to third parties nor will it be visible to third parties.

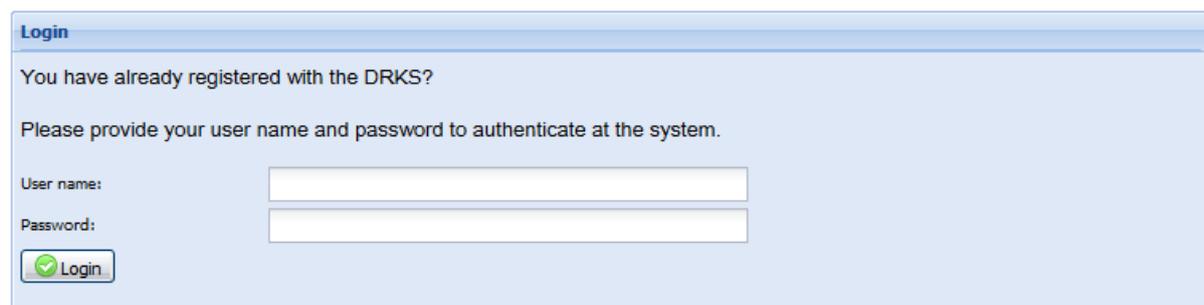
User authentication

You have to log in to the authenticated area to enter or change trial data. Therefore you need your username and your password.

If you do not have an account yet, you can create a new account [registering as a user](#).

If you have forgotten your password you can use the online system to [reset your password](#).

User login



The screenshot shows a form titled "Login" with the following content:

You have already registered with the DRKS?

Please provide your user name and password to authenticate at the system.

User name:

Password:

You need your username and your password to log in to the system. If the entered username and password matches the registered user account data, you will get access to the features of the authenticated area. You will be logged in afterwards for the time of your interaction with the system. If you are inactive for more than 20 minutes (session timeout) your session will be cancelled, to prevent misuse by others.

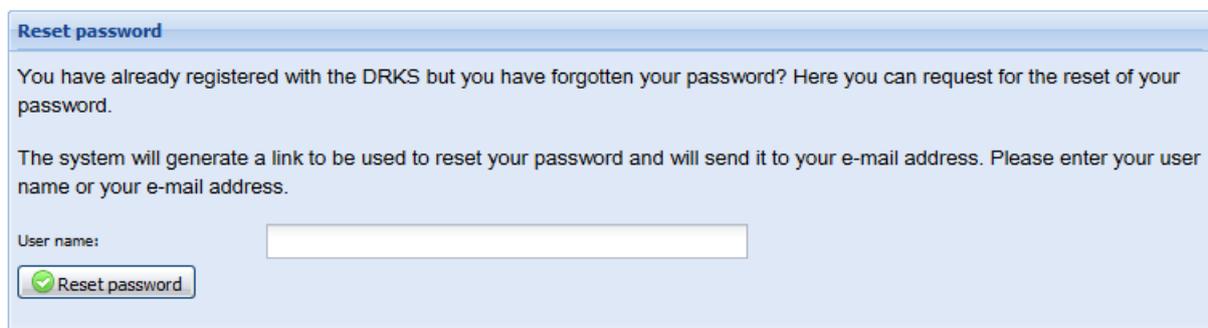
User name

Please enter your username. The username is unique and is used to identify a person in a system. It was chosen by the user during [registration](#). The registration confirmation e-mail confirms the user name as well.

Password

Please enter your password. You either choose your password during [registration](#) or it was changed when changing user data.

Reset password



Reset password

You have already registered with the DRKS but you have forgotten your password? Here you can request for the reset of your password.

The system will generate a link to be used to reset your password and will send it to your e-mail address. Please enter your user name or your e-mail address.

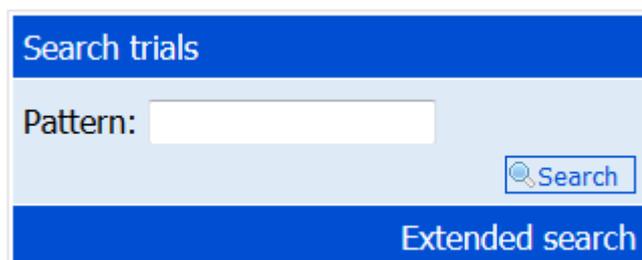
User name:

If you have forgotten your password, you can reset it online. To prevent misuse the password is not reset right away. The system will generate an e-mail containing a link which triggers the actual reset of your password. It will be sent to the e-mail address you entered when registering with DRKS, so that only you can trigger the reset.

Please enter your user name or the e-mail address which you entered during [registration](#) so that the system can identify your user account.

When you received the confirmation e-mail, please use the included link to trigger the reset of the password. The system will now generate a new password for your user account and send another e-mail with this new password to your e-mail account. The new password is valid right away. You can immediately use it to log in.

Quick access to the search engine



Search trials

Pattern:

Extended search

You can use the search engine to have quick and easy access to the clinical trials registered with DRKS. To start a full text search, you have to enter a search term into the search box which will then be searched for in all categories of the trial document e.g. title, description or health conditions.

All trials found will be weighted and sorted by relevance according to the given search term. Further information can be found in chapter [Search results](#).

If you want to search more detailed for clinical trials you can use the "Extended Search" which can be found in the menu. Further information on how to use the search engine can be found in chapter Search trials.

Search trials

This function makes it possible to access all clinical trials registered with the DRKS. There are two possible ways:

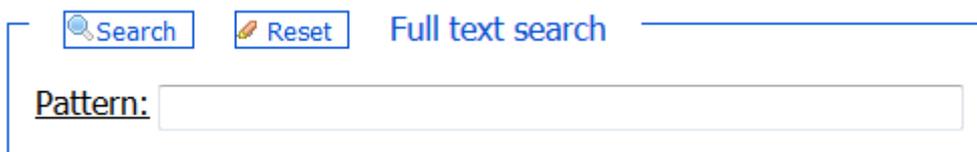
- Simple search

Performs a full text search for the terms entered.

- Extended search

You can limit your search results by entering further criteria.

Simple search



The image shows a search interface with a blue border. At the top left, there is a magnifying glass icon followed by the word "Search" in a blue box. To its right is a trash can icon followed by the word "Reset" in a blue box. Further right, the text "Full text search" is displayed in blue. Below these elements is a large, empty text input field. To the left of this field, the word "Pattern:" is written in blue and underlined.

Enter a word or words that you want to use to find trials registered with DRKS. A full text search will then be performed which means that it will be searched for the words in all parts of the trial document, e.g. title, description or health condition.

Search with boolean operators (AND, OR) is possible. A truncation at the beginning or at the end of a word is also possible. An asterisk (*) can be used as wildcard.

You can start the simple search as follows:

- You can either use the [Search box](#) on the start page
- You can use the link "Search trials" in the navigation which leads you to the Extended search form with which you can perform a simple search as well.

The trials found will be sorted by relevance that means that the trials which contain all of the search terms will come up first. Further information can be found in the chapter Search results.

Extended search

Characteristics

Trial-ID:

Investigator

Sponsored/Initiated - any -

Trial (IST/IIT):

Outcome:

Health Condition or

Problem studied:

Address: - any -

The extended search form makes it possible to narrow your search results by searching for specific attributes of the trial.

It is not necessary to fill in all of the additional fields, you can mix and match according to your needs. The parameters are then linked by "AND". If you leave one of the slots empty it will not be considered in your search.

Search results

The studies which fit your search best will then be presented in table. "Fit best" means that the studies are weighted according to the number of matches with the terms you entered. Words that match the search terms will be highlighted in colour.

You now have further opportunities, e.g. to refine your search or to change the way the results are presented.

Pattern: pancrea* , Countries of recruitment: Germany , Study Type: Interventional
Hits 1 - 10 of 162 | Hit list navigation: << < 1 2 3 4 5 6 7 8 9 10 11 ... > >> | Hits
per page 10 | Order by Score | Display options: Short Version

You can:

- Change the terms searched
- Let the results be displayed
- Navigate through the results
- Change the number of hits per page
- Open trial as HTML
- Open trial as pdf
- Download search results

Definitions of the recruiting status:

Recruitment Status	Definition
Recruiting planned	Recruiting planned
Recruiting ongoing	Recruiting ongoing
Enrolling by invitation	Enrolling by invitation
Recruiting completed	Recruiting complete, follow-up continuing
Recruiting stopped	Recruiting suspended on temporary hold, stopped after recruiting started or withdrawn before recruiting started
Study completed	Recruiting complete, follow-up complete

Register trials

Clinical trials can only be registered with DRKS in the authenticated area of the website. There is a further help file available which describes the functions which can only be used in this area. For further information log in and restart the online help by pressing the help button in the top right corner.

If you want to enter trial data and edit trials you will have to log in. In order to do so you have to create a user account. At "Register trials" you will find a link which leads you to a page where you can then enter your user details (username and password) to get access to the authenticated area where you then can enter new trial data and edit trials.

It is possible to look around and try out this authenticated area without actually registering a trial as there is a demonstration environment. This is a separate application with all the functions of the actual register. You can enter, save and edit trial data in this environment. However, the study you entered will by no means be registered.

Trial history

The history (audit trail) of a trial can be seen after opening the HTML by clicking on "Change History". You can have a look at previous versions or you can compare two versions with each other. Choose "Compare version" and "to version" in the columns of the versions that you would like to compare. Deleted text will be shown highlighted in red and crossed out, newly inserted text will be highlighted in green and changed text will be shown in a combination of crossed out, highlighted in red and highlighted in green text.