

# **DRKS Manual**

# - Public Search Portal -

# A: Content

A:	Content	1
B:	New DRKS application - Known errors	1
C:	General information	2
D:	Search studies	2
1)	With search term	2
2)	With further search criteria	5
E:	Search Results	6
F:	History	8
G:	Export of study data	9
1)	Download of single study records	9
2)	Download of multiple study records	9

# B: New DRKS application - Known errors

In November 2022, the old German Clinical Trials Register application, in German called "Deutsches Register Klinischer Studien" and from here on abbreviated as DRKS, has been replaced by a new software and now presents itself in a modern look. In the course of this, the DRKS was once again fundamentally revised and adapted to the current requirements.

In the first published version, however, not all bugs have been fixed yet. The most important known errors are described below and will be corrected in the future. Further inaccuracies are known, but cannot be listed here completely.

- Phrase search (search terms in quotation marks) does not work yet
- Not all parameters can be searched. For detail see item D 1.



If you are missing a function in the new software, please feel free to contact us via the contact form.

# C: General information

The DRKS offers you the possibility to search for information on ongoing and completed clinical trials (mainly) in Germany or to make your own studies accessible to others via registration.

In order to meet the specific requirements of the different interest groups, the DRKS website is divided into a public and a closed area.

- The public area covers the search of clinical studies in the registry and general information about the registry. It is accessible to all users via the internet. The contents of this help document refer only to the public area.
- The closed area is reserved for authenticated users and is used to collect data for the registration of studies.
   You can access the online help for the closed area via the corresponding web pages of the portal.

Questions and suggestions can be sent to us via the contact form in the menu item "Contact".

## **D: Search studies**

At the moment of initial registration, the new study is written into the public DRKS database. It can be accessed publicly immediately via the direct link (www.drks.de/search/en/trial/DRKS12345678). However, the study can be found in the search only the next day (e.g. when searching for the DRKS-ID), because the search index is renewed only daily around 5:45 in the morning.

## 1) With search term

Study Search	
Search term Study search	
Other Study Search Terms	
	Reset Search Search

The study search gives you access to all clinical studies registered in the DRKS. You can simply use one or more search terms to perform a "full text" search in all registered clinical studies in the DRKS.

Please not, that the "full text" search is not yet completely working. Currently, only the content of following fields is being searched:

- Title of the study
- Study description in lay language
- Study description in scientific language
- DRKS ID



### **Boolean Operators**

Searching with Boolean operators (AND, OR or UND, ODER) is possible.

Q Search Studies Pattern covid-19 or pandemic		
Results per page   10   \$     7122 Search results   «   1	Order by Score 3 4 5 6 7 > » page 1 / 713	e 🗢 descending 🗢
Title of the study		
Accompanying monitoring of primary care in GP practices during the COVID - 19 pandemic	Date of Registration: 2020-04-02 Last update: 2020-05-04 ()	DRKS-ID : DRKS00021231 Status: Recruiting ongoing
COVID -NA: Changes in emergency department utilitzation during the COVID -19 pandemic	Date of Registration: 2020-09-21 Last update: 2020-09-21 ()	DRKS-ID : DRKS00023117 Status: Recruiting ongoing
Palliative care expertise as an integral part of pandemic management (COVID-19)	Date of Registration: 2020-08-27 Last update: 2020-08-27 ()	DRKS-ID : DRKS00022473 Status: Recruiting ongoing
Longitudinal Prediction of Individual Resilience and Difficulties in Coping with the COVID -19 - Pandemic and its Consequences	Date of Registration: 2021-02-22 Last update: 2021-02-22 ()	DRKS-ID : DRKS00024616 Status: Recruiting ongoing
Retrospective analysis of the effects of the COVID - 19 pandemic on the pediatric emergency department at the University Hospital Duesseldorf	Date of Registration: 2021-07-09 Last update: 2021-07-09 ()	DRKS-ID : DRKS00025736 Status: Recruiting planned
Impact of the COVID - 19 Pandemic on Symptoms of Obessive Compulsive Disorder	Date of Registration: 2020-05-19 Last update: 2020-05-19 ()	DRKS-ID : DRKS00021757 Status: Enrolling by invitation
COVID - 19: National Strategy for Palliative Care during Pandemic Crisis" (Pandemic) - sub project specialist inpatient palliative care	Date of Registration: 2021-04-08 Last update: 2021-04-08 ()	DRKS-ID : DRKS00024979 Status: Recruiting complete, study complete

### **Truncation with asterisk**

A search with right-hand or left-hand truncation is also supported. With the wildcard asterisk (\*) at the end of the search term (right) or its beginning (left), linguistic variants can be taken into account.

#### Examples:

Therap\* finds studies including the words "therapy", "therapies" and the German words "Therapie" or "Therapien". Since a MeSH is included in the search tool, the word "treatment" will also be found.

Therapeuti\* covers "therapeutisch" or "therapeutic".



Q Search Studies Pattern therap*		
Results per page 10 8457 Search results « < 1 2	Order by         Score           3         4         5         6         7         >         »         page 1 / 846	<ul><li>♦ descending</li><li>♦</li></ul>
Title of the study		
EWOG - MDS 98 Myelodysplastic Syndromes in Childhood Prospective Study of the Diagnosis and Treatment of Myelodysplastic Syndromes (MDS) in Childhood - EWOG-MDS 98	Date of Registration: 2008-08-07 Last update: 2018-01-31 ()	DRKS-ID : DRKS0000001 Status: Recruiting complete, study complete
HERAKLES:- Multi-Center, open-label, prospective, randomized, parallelgroup. long-term study investigating a standard regimen in de novo kidney transplant patients versus a CNI-free regimen and a CNI-low dose regimen.	Date of Registration: 2008-09-05 Last update: 2017-10-30 ()	DRKS-ID : DRKS00000014 Status: Recruiting complete, study complete
The effectiveness of occupational therapy at home in persons with dementia and their primary caregiver - a multicentre randomised controlled trial evaluating the Dutch occupational therapy programme within the German context.	Date of Registration: 2008-11-14 Last update: 2013-09-02 ()	DRKS-ID : DRKS00000053 Status: Recruiting complete, study complete
Analysis of renal function during angiostatic therapy with the COX- II inhibitor rofecoxib, in combination with pioglitazone, and trofosfamide or capecitabine in patients with metastatic / advanced cancer.	Date of Registration: 2009-06-22 Last update: 2010-07-14 ()	DRKS-ID : DRKS00000119 Status: Recruiting complete, study complete
Internet-based therapy for parents after loss of a child during	Date of Registration: 2009-05-07	DRKS-ID : DRKS00000127

For the studies found, a weighting of the hit relevance is performed depending on the occurrence of the search term.



### **Excluding words**

Search terms can also be excluded by placing a minus sign in front of the word. Then results are shown, which do not include the excluded word.

### Example "pandemic" - "covid" - "covid19"

Q Search Studies Search term pandemic -covid -covid19				
Results per page 10 v	Order by Score	<ul> <li>✓ descending</li> </ul>		
51 Search results « <	1 2 3 4 5 6 > »	page 1 / 6		
Title of the study				
Breastfeeding in NRW: what can be learned from experiences in the Corona pandemic for breastfeeding promotion around clinical obstetrics?	Date of Registration: 2022-02-24 Last update: 2023-02-02	DRKS-ID : DRKS00027975 Status: Recruiting complete, study complete		
Open-label placebos and stress during the Corona pandemic. A randomized controlled trial.	Date of Registration: 2021-12-27 Last update: 2021-12-27 (!	DRKS-ID : DRKS00027476 Status: Recruiting ongoing		
Diagnostic delay of malignant melanoma due to the corona- pandemic	Date of Registration: 2023-01-10 Last update: 2023-01-10	DRKS-ID : DRKS00030310 Status: Recruiting ongoing		
NAPKON - National Pandemic Cohort Network – Monkeypox Platform Analysis of pathophysiology and pathology of Monkeypox Virus (MPV), including chronic morbidity.	Date of Registration: 2022-08-17 Last update: 2023-01-31	DRKS-ID : DRKS00029147 Status: Recruiting planned		
Feasibility, acceptance, and user satisfaction of virtual reality as a supportive offer during the Corona pandemic in the Psychiatric Outpatient Department	Date of Registration: 2022-01-25 Last update: 2022-08-31	DRKS-ID : DRKS00027911 Status: Recruiting complete, study complete		

#### Phrase search

**ATTENTION:** The phrase search (search terms in quotation marks) does not work yet.

## 2) With further search criteria

By making entries in the "Additional search criteria" area, you can use further filter criteria or specifically limit the number of hits. You can combine the individual search parameters as you wish. They are logically linked in the search query by means of "AND". If you leave a parameter blank, it will not be taken into account when the studies are queried.

#### Health condition or problem studied

In this field you can enter an ICD10-GM code or a description of the condition, e.g. "Covid".

#### **Address**

Please note, that this search cannot yet find single sites of multicenter studies but only the principal investigator or the study site of the principal investigator.



# E: Search Results

Please note: Newly registered studies will not be found until the next day.

### Summary of search criteria

The selected search terms and filters are displayed in a blue box:

Search term mammary carcinoma, Investigator Sponsored/Initiated Trial (IST/IIT) Yes, Date of registration from 2022-01-01

#### Information displayed in the search results list

The following information is displayed in the results list:

- Study title = The stored link leads to the study entry.
- Registration date = The day on which the study entry was first published in the DRKS.
- Last updated = The day the study entry was last updated in DRKS (The exclamation mark indicates study entries that have not been updated for more than 12 months. For completed studies, this information can be disregarded. For ongoing or planned studies, this information may be important for evaluating the information in the study entry).
- DRKS ID = the unique DRKS ID
- Status = The recruitment status of the study. Provides information on whether participants are currently enrolled in the study. If necessary, note the date of the last update. If the last update was a long time ago, the information may no longer be up to date.
- Exclamation mark = Attention, this study has not been updated for more than 12 months. The data may be out of date. For studies that have been internally marked as complete by DRKS data management, this exclamation mark is no longer displayed.

Date of Re	gistration: 2021-05-21
Last upda	te: 2021-05-2

Q Search Studies	Search term <b>mamm</b>	nary carcino	<b>ma,</b> Inves	tigator Sp	onsored	d/Initia	ated Tria	al (IS	ST/IIT) <b>y</b>	<b>'es,</b> Date	of registration <b>from</b> 2	2022-01-01	
Results per page 10		~						0	order by	Score	~	descending	~
189 Search results			« <	1 2	34	5	67	>	> »				page 1 / 19
Title of the study													
Breast cancer in a teen age with literature review from	<u>girl with BRCA mutat</u> a LMIC	ion: A case r	<u>eport</u>	Date of Last up	Registr date: 20	<b>ation:</b> 022-06	2022-0 -07	06-07	7		DRKS-ID : DRKS000 Status: Recruiting co	029187 omplete, study	complete
Breast cancer risk after mo	<u>dern radiotherapy</u>			Date of Last up	Registr date: 20	<b>ation:</b> )22-04	2022-0 -29	)4-29	9		DRKS-ID : DRKS000 Status: Recruiting p	028896 lanned	
CardiovasculaR and haemat patients at High risk caused Indeterminate Potential - S	tological sUrvivorship I bY Clonal Hematopo tudy	<u>iN breast Ca</u> iesis of	ancer	Date of Last up	date: 20	<b>ation:</b> 023-01	2023-0 06	) <b>1-0</b> €	6		DRKS-ID : DRKS000 Status: Recruiting p	031021 lanned	



### **Relevancy of results**

Sorting is possible by relevance, DRKS ID, registration date, recruitment date or last update.



The studies that "best match" your search query are displayed in tabular form as search results (order by score). "Best matching" means that a weighting is performed based on the search criteria you selected and the hits with the most matches are displayed. Text passages matching the search criteria are highlighted in color. The MeSH is included in the search, therefore synonyms are also found automatically. E.g. a search for "mammary carcinoma" also returns hits with "breast cancer" in the title.

MRI examination of the breast in the context of BI-RADS 3 findings requiring control 6 months after initial pre-operative breast MRI	Date of Registration: 2022-10-13 Last update: 2022-10-13	DRKS-ID : DRKS00030512 Status: Recruiting planned
Research into the effects of tumor therapy and physical activity in the rehabilitation of patients with prostate and breast cancer on physical performance, body composition, fatigue, depression, cognition and quality of life	Date of Registration: 2018-03-26 Last update: 2018-03-26 ()	DRKS-ID : DRKS00014263 Status: Recruiting ongoing
Prospective, single-center, interventional follow-up study to determine the effect of prostate carcinoma and its operative therapy on intraocular pressure and determination of potential mediators.	Date of Registration: 2019-02-11 Last update: 2022-08-11	DRKS-ID : DRKS00015830 Status: Recruiting complete, study complete
Safety and Efficacy of Ho-166-Radioembolisation by SPECT- and MR-Image guidance optimized substrate application - a comparative Study to Y-90-Radioembolisation	Date of Registration: 2018-03-01 Last update: 2022-09-19	DRKS-ID : DRKS00014139 Status: Recruiting stopped (after recruiting started)
Imaging quality and potential clinical relevance of breast computed tomography in-vivo: a single-centre, prospective study.	Date of Registration: 2019-05-02 Last update: 2019-05-02 ①	DRKS-ID : DRKS00015475 Status: Recruiting planned
Oncological safety, esthetics and surgical safety after skin-sparing mastectomy using Latissimus dorsi reconstruction in patients with mamma carcinoma.	Date of Registration: 2012-05-07 Last update: 2012-05-07 ()	DRKS-ID : DRKS00003570 Status: Recruiting ongoing
Mindful walking in patients with breast cancer - a randomized pragmatic pilot study	Date of Registration: 2016-12-21 Last update: 2019-01-16 ()	DRKS-ID : DRKS00011521 Status: Recruiting complete, study continuing



# F: History

To compare different versions of a study entry, first open the entry via the study title and select the tab "Version History".

© Current Version	() Version History	Download	
	,, ,	0	

You can view individual versions or a comparison of two versions of a study.

© back to study details 4 released versions					
Version	Process	Date	Selection	Comparison version	
4	Updated	2022-08-11	۲	0	
3	Updated	2022-01-19	0	۲	
2	Updated	2019-09-03	0	0	
1	Registered	2019-02-11	0	0	
					compare

The "Selection" and "Comparison version" columns are used to select the two study versions to be compared. Deleted text is highlighted in light yellow and crossed out, newly added text is highlighted in light blue and underlined. Changed text is displayed as a combination of light yellow highlighted, strikethrough, and light blue highlighted, underlined text.

Recruitment	Status:	
Recruiting	<del>ongoing</del>	complete, study continuing

Please note: It is not yet possible to view a version without comparison. In the future you would select the same version as selection and comparison version.



# G: Export of study data

The DRKS application offers the ability to download study data in various formats.

## 1) Download of single study records

To download a data record, first open the study entry from the list of results by clicking on the title of the study or enter the direct link to the study in your browser (www.drks.de/search/en/trial/DRKS12345678).

### PDF-Format

The study can be exported as a PDF using the browser function. In Microsoft Edge it can be done via the print function, in which PDF is selected as the printer.

After selecting the tab "Download" you can choose one of the following formats and save the file. Please note that the study data is from the previous day, unless the study was registered for the first time today.

### JSON-Format

The structure of the JSON file follows the DRKS schema, which can be downloaded from <u>https://drks.de/search/download/jsonschema</u>. The schema is based on JSON version 2020-12 (see: <u>https://json-schema.org/specification</u>).

### <u>CSV-Format</u>

If you want to import the CSV into Excel, select New file -> Import data from Text/CSV -> Unicode UTF8 / Separator in Excel: Tab stop

### <u>RIS-Format</u>

With the RIS-format you can easily import your study into a reference management software.

The downloaded file shows following naming convention:

e.g. "DRKS\_trial-DRKS12345678-v2-25.09.2019.csv"

DRKS12345678	= DRKS-ID of the downloaded study
v2	= last public Version (in this example the version 2)
25.09.2019	= dd.mm.yyyy (date of the version)

## 2) Download of multiple study records

Please note that the data current as of the end of the previous day. However, some of the newly registered (not updated) studies may be added to the data set during the course of the day.

The downloaded file is zipped and shows following naming convention:

e.g. "DRKS\_search\_20250129.zip". 20250129 = yyyymmdd (date of the download)



#### **Download of all study records**

- Download via a direct link (JSON only) You can download all study data in JSON format via the following direct link: <u>https://drks.de/search/en/download/all-json</u>
- Download via DRKS search (JSON, CSV and RIS) Carry out an empty search so that all studies are displayed in the results list. You can download these via the download button.

No search filters active



#### **Download of a selection of studies**

Carry out a search so that the desired studies are displayed in the results list. You can download these via the download button.

Search term Prednisolone

