

ME/CFS Research Update – part 1-3

We report on ongoing research based on data from the ME/CFS Research Register. This ME/CFS Research Update will be added to step by step to give patients, relatives and interested parties an insight into the current ME/CFS research landscape.

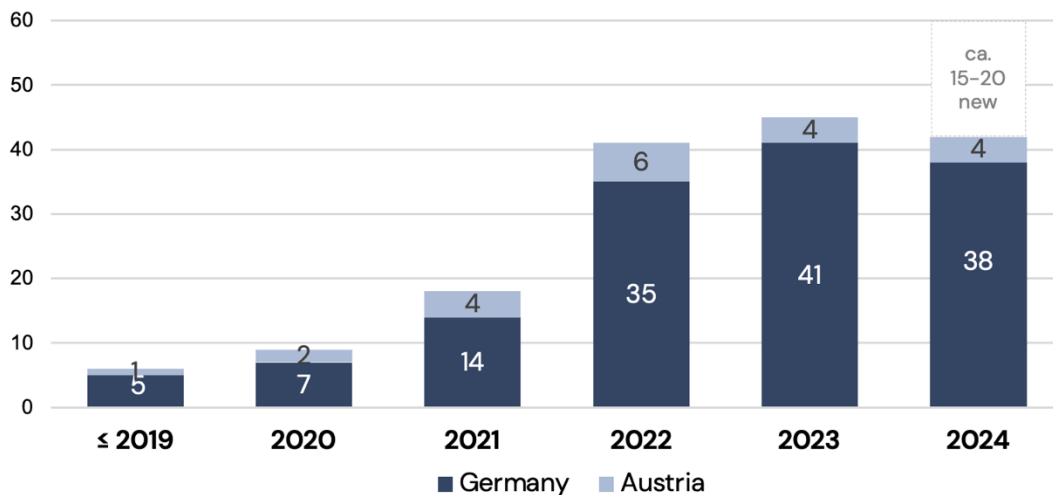
We start with data on ME/CFS research in Germany and Austria. All research projects in these countries are listed in the current "beta version" of the recently introduced [ME/CFS Research Register](#).

Part 1: ME/CFS research is slowly picking up speed

(published 01.03.2024)

The data from the ME/CFS Research Register show the significant increase in research intensity since 2022. The public funding for ME/CFS research (at federal and partly at state level) available for the first time since then has made a number of previously unrealisable projects possible.

current ME/CFS research projects per year



Source: ME/CFS Research Register; analysis and estimate of new projects for 2024 by ME/CFS Research Foundation.

Most of the 42 ongoing research projects were started in 2022 and 2023. These include, for example, the 11 projects of the [NKSG – National Clinical Study Group](#) in the field of clinical research and the five projects of the [IMMME – Immune Mechanism of ME](#) basic research (funded by the BMBF, Federal Ministry of Education and Research in Germany). Four further projects were made possible by other public organisations. Additional research is funded by private foundations and patient organisations.

Public funding that has already been announced will enable further new research projects and the continuation of ongoing initiatives, e.g. the NKSG, from around mid-2024. This will create a positive, but also long overdue dynamic in ME/CFS research in Germany. ME/CFS is a medical research field that is characterised by a [considerable global backlog](#) compared to other diseases. This backlog is due to the amount of available funding and the number of researchers and working groups actively involved in the ME/CFS field to date. Due to the growing importance of post-

infectious diseases in the wake of the COVID-19 pandemic, ME/CFS research is also receiving increased attention and has been receiving more public funding since the end of 2021.

The ME/CFS Research Foundation will make this development transparent with the publicly accessible [ME/CFS Research Register](#) and will also regularly publish up-to-date data on ME/CFS research. In addition to financial project funding, this is an important contribution to supporting ME/CFS research.

Part 2: How are the ME/CFS projects distributed across different types of research?

(published 28.03.2024)

A total of 61 research projects have been or are still being conducted in Germany and Austria since 2019. These are distributed fairly evenly across the three [research types](#):

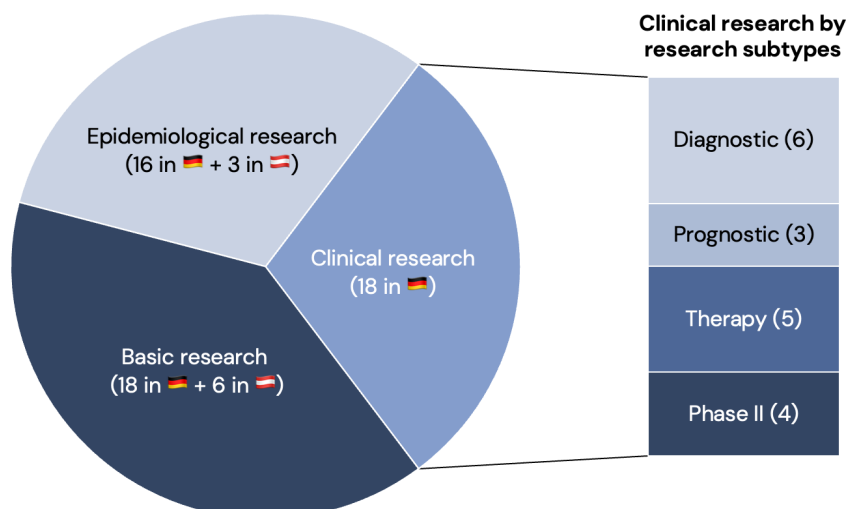
- Basic research (24 projects)
- Epidemiological research (19 projects)
- Clinical research (18 projects)

It should be noted that clinical research projects generally require much higher financial budgets than basic or epidemiological research. Looking at the research types in terms of the costs incurred, projects in the field of clinical research account for the majority of financial expenditure.

Of the 18 clinical research projects, nine projects are in the **Bereichen Diagnostik und Prognostik**. Three of these projects have already been completed. A further nine projects are concerned with research into possible therapies for ME/CFS in the form of **therapy or phase II studies**. These include studies on [Methylprednisolone](#), [BC007](#), [hyperbaric oxygen therapy \(HBOT\)](#), [Vericiguat](#) and several studies on [Immunoadsorption](#). All clinical studies on therapy development are currently still being conducted.

Number of research projects by research type

data for Germany and Austria, includes research projects since 2019



Source: ME/CFS Research Foundation (as of Feb. 24)

In the [ME/CFS Research Register](#) , all 61 projects are described in detail and linked to the involved working groups, researchers and additional information. All projects are assigned to [research types](#) , which are also explained in the register. For example, the following subtypes of clinical studies:

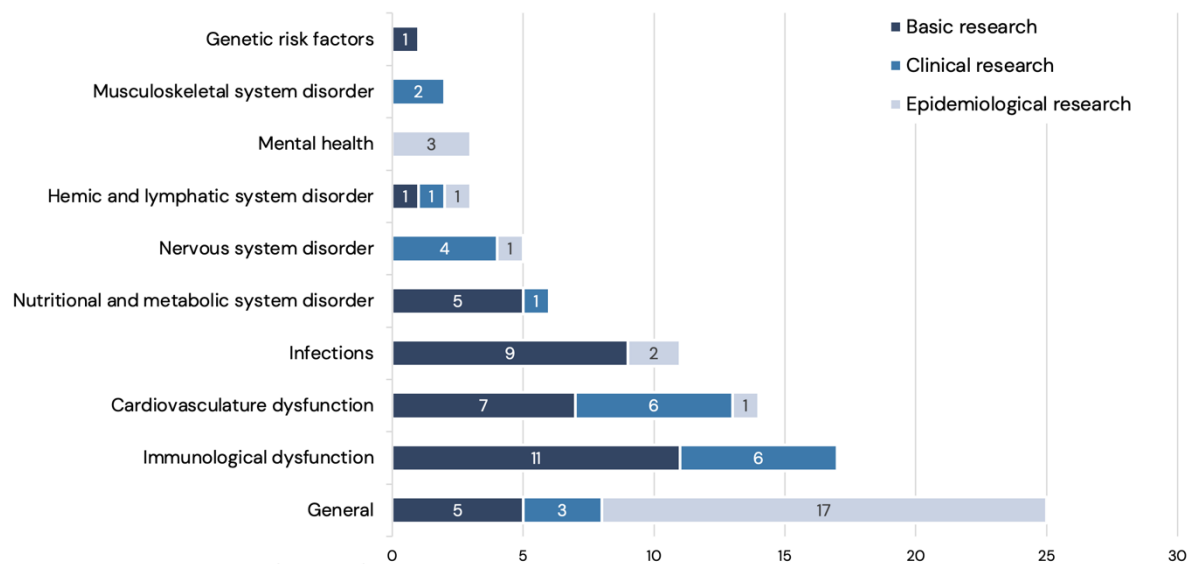
- [Diagnostics studies](#) aim to evaluate the accuracy of a diagnostic test or method in identifying a disease. In this way, new biomarkers can be analysed for their diagnostic suitability.
- [Prognostics studies](#) , on the other hand, examine diagnostic methods in terms of their ability to predict improvement or worsening of a disease over time or following therapy. These studies can be used to determine which biomarkers and diagnostic methods may be able to predict whether a therapy is likely to be successful.
- Observational [therapy studies](#) are used to generate initial findings on the effect of treatment interventions. Therapy studies are adapted to the individual needs of the patients and do not follow a strict study protocol.
- Interventional clinical studies, e.g. so-called [phase II studies](#), follow a strict protocol and also include patients who are treated with a placebo. Phase II studies also include a larger number of patients and evaluate the effectiveness of the treatment as well as possible side effects according to a protocol that is uniform for all patients.

Part 3: Which medical research areas are covered by ME/CFS projects?

(published 09.04.2024)

In addition to the distribution of projects across [research types](#), i.e. basic, epidemiological and clinical research (see part 2 above), all projects in the ME/CFS Research Register are also differentiated according to medical [research areas](#). Research areas include organs, body systems and health factors studied in connection with the occurrence of ME/CFS. This enables the targeted search for research projects according to thematic focus (e.g. [autoimmunity](#) or [nervous system disorder](#)) in the ME/CFS Research Register. Please note that most projects are assigned to more than one research area. Hence the total number of research projects in the illustration below exceeds the 61 research projects in Germany and Austria listed in the register so far.

Medical research areas by number of research projects (and share of research types)
data for Germany and Austria since 2019



Source: ME/CFS Research Foundation (as of Feb.24)

The "[general](#)" research area is the most frequently represented with 25 projects. The term "general" is used when research project is not limited to specific body or organ systems. This includes projects that deal with [patient care](#), [biobanking](#), general [risk factors](#) or studies dealing with [proteomics](#) or [transcriptomics](#). Projects from epidemiological research in particular are assigned to "[general](#)" (17 projects), alongside projects dealing with clinical research (3) and basic research (5). As described above, individual projects can also be assigned to other research areas at the same time.

In addition to "general", the research areas of [immunological dysfunction](#) (17 projects, 11 of which are in the field of basic and 6 in the field of clinical research) and [cardiovascular dysfunction](#) (14 projects) are among the most frequently investigated areas of ME/CFS research in Germany and Austria to date.

Research projects to date have also focused on the role of [infections](#), the influence of a disturbed [nutritional and metabolic system](#) as well as the role of [nervous system disorders](#). Fewer projects to date have focussed on disorders of the [blood and lymphatic system](#), [mental health](#), a [disturbed musculoskeletal system](#) or [genetic risk factors](#) in ME/CFS.

In total, the ME/CFS Research Register lists 82 medical research areas. The terminology used to describe research areas is largely based on the [MeSH \(Medical Subject Headings\) terminology of the National Institutes of Health \(NIH\)](#) as well as on selected literature. The register contains a short description for each of the used terms, incl. a reference to their respective source online. We will publish a comprehensive and systematic overview of the research areas used in the ME/CFS Research Register and their interconnections at a later date.

Part 4: When can results from the therapy and phase II studies be expected?

(published 16.04.2024)

Research on possible treatment approaches targeting the underlying disease mechanisms of ME/CFS is crucial for improving long-term patient care. To date, limited data is available in the form of research on clinical trials for the treatment of ME/CFS. However, in the wake of Long COVID and post-COVID syndrome, more public funding has been made available since 2022 in order to expand the knowledge about possible treatment approaches for ME/CFS.

As explained in Part 2 above, nine clinical trials are currently being implemented in Germany, probing biomedical treatment approaches for ME/CFS. Five of them are so-called [therapy studies](#). Another four studies are so-called [phase II studies](#), three of which are being carried out as part of the [National Clinical Studies Group \(NKSG\)](#) and one as part of the [COVID-19 Research Network Lower Saxony \(COFONI\)](#) research network. Results of these studies are expected by the end of 2024 and predominantly during 2025 (see figure).

Planned study completion dates of clinical trials (therapy and phase II) in Germany



- 1 Investigate improvement in physical function (SF-36) with **Vericiguat** compared with placebo in participants with Post-COVID-19 Syndrome (VERI-LONG) ^{NKSG}
- 2 Repeat **Immunoabsorption** Post Covid ME/CFS (RIA) ^{NKSG}
- 3 Application of **Direct Current Transcranial Stimulation**, remotely supervised in Chronic Fatigue (ACTIVATE)
- 4 **Immunoabsorption** in patients with ME/CFS including patients with Post-COVID-19 CFS (IA-PACS-CFS) ^{NKSG}
- 5 **Methylprednisolone** in patients with cognitive deficits in Post-COVID-19 Syndrome (PCS) (PoCoVIT) ^{NKSG}
- 6 **Immunoabsorption** vs Sham Treatment in Post-COVID-19 with Chronic Fatigue Syndrome (EXTINCT post COVID) ^{COFONI}
- 7 **Hyperbaric High Pressure Oxygen Therapy** (HBOT) in Post-COVID Syndrome and ME/CFS ^{NKSG}
- 8 **Immunoabsorption** in patients <18 years of age with ME/CFS with evidence of Autoantibodies (BIAKI)
- 9 unCOVER Erlangen - ME/CFS (extension of the research project on BCO07 as a therapy option for Long-COVID). Information on the project timeline is currently not available.

Source: ME/CFS Research Foundation (as of Feb.24) color coding: # therapy study # phase-II study

Towards the end of 2024, results are expected from the phase II study on **vericiguat** (1: [VERI-LONG](#)). At the beginning of 2025, results will come through of the therapy studies on **repeat immunoabsorption** (2: [RIA](#)) and on **direct current transcranial stimulation** (3: [ACTIVATE](#)), as well as of the phase II studies on **immunoabsorption** (4: [IA-PACS-CFS](#)) and on **methylprednisolone** (5: [PoCoVIT](#)). The results of another phase II study on **immunoabsorption** (6: [EXTINCT post COVID](#)) are due in mid-2025. The results of the therapy studies on **hyperbaric oxygen therapy** (7: [HBOT](#)) and on **immunoabsorption in young patients** (8: [BIAKI](#)) will follow at the end of 2025. No information is available yet on the planned completion date for the **therapy study on BCO07** (9: [unCOVER](#)). Note: planned completion dates serve as an overall orientation. Actual completion dates may differ from these dates for various reasons.

In summary, by the end of 2025, first data on the effectiveness of five potential therapies for ME/CFS will likely be available, including results from three phase II studies (randomized, placebo-controlled). In order to assess how the interventions and drugs tested may potentially benefit ME/CFS patients in the long-term, further controlled clinical trials with larger numbers of test subjects will be required (phase II and III studies). Additional findings can also be expected stemming from the clinical trials carried out under the [NKSG](#), as a result of the data obtained from

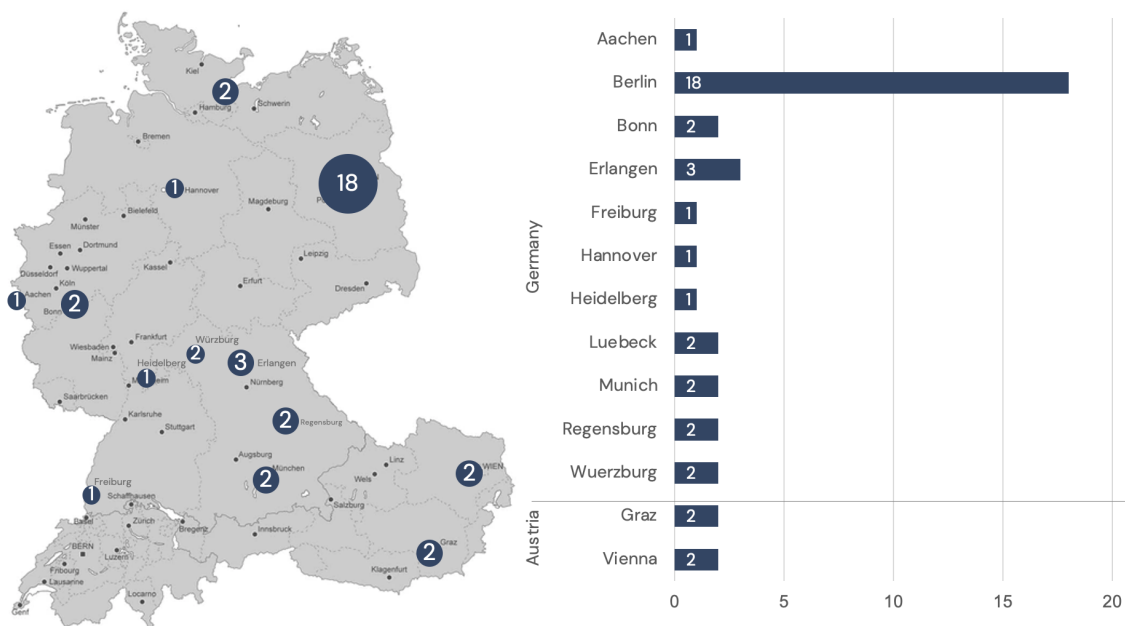
the research network’s comprehensive diagnostics and biomarker studies in connection with these trials.

Part 5: How many working groups are conducting research on ME/CFS?

(published: 25.04.2024)

A total of 39 working groups are involved in the ME/CFS research projects ([working groups](#)), 35 of them in Germany and 4 in Austria. These working groups are spread across a total of 20 different organizations, including universities, university hospitals and research centers. Working groups in medical and scientific research (also referred to as laboratories or “labs”) are groups of people conducting research on specific topics under the direction of experts in their field and that are hosted by at least one organization (e.g. university hospital).

Working groups in ME/CFS research by city



Source: ME/CFS Research Foundation (as of April '24)

In Germany, 18 of the 35 working groups conducting research on ME/CFS are based at Charité – University Medicine Berlin and affiliated research institutions. These include the Berlin Institute of Health (BIH) and the Max Delbrück Center (MDC). Other working groups are based at the German Center for Neurodegenerative Diseases (DZNE), the Berlin School of Mind and Brain, Helmholtz Munich and the Max Planck Institute in Erlangen. Remaining groups are based at the university hospitals in Aachen, Erlangen, Freiburg, Lübeck and Munich as well as at the universities in Heidelberg, Munich, Regensburg and Würzburg.

Of a total of four working groups involved in ME/CFS research are found in Austria, out of which two are based at the Medical University of Vienna and one each at the Medical University and the FH Joanneum in Graz.

All [working groups](#) conducting research on ME/CFS are listed with descriptions and links to their individual research projects in the [ME/CFS Research Register](#).

What happens next?

Subsequent parts of the ME/CFS Research Update will address the following questions:

- How are the ME/CFS research working groups networked with each other?
- How much has been and is being published on ME/CFS in Germany and Austria?

We will address these questions based on the data from the [ME/CFS Research Register](#) and publish them in the coming weeks.

Like the ME/CFS Research Register, this compilation of research data is a free service of the ME/CFS Research Foundation for ME/CFS patients, relatives and the interested public.

How can you support the work of the ME/CFS Research Foundation?

There is still a long way to go before diagnosis, care and treatment of ME/CFS sufferers will one day become the medical and social standard. We are focusing on biomedical research, which we see as the key element in solving these problems (more on this in [our funding strategy](#)). To do this, we need extensive support from private donors – those affected, relatives, families, friends, associations, schools, networks, companies, initiatives, event organizers and all supporters. And those who cannot support us directly can share our stories and content to motivate others to help. Because only together is such a feat possible.

[Please support our work!](#)

We fully translate donations and other support into scientifically excellent research, networking and ultimately visible successes, i.e. better ME/CFS diagnostics and therapies. We are happy to work together with other organisations and initiatives – please contact us!

And please extend our reach **and follow us** on social media on [Instagram](#), [Facebook](#), [X/Twitter](#) and [LinkedIn](#). THANK YOU!



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