

## **Clinical Trials Platform**

Charité Mental Health  
Infrastructure Platform

### **Platform Leadership:**

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### **Participating Institutions:**

- 1) *Charité - Universitätsmedizin Berlin, Departments of Psychiatry and Psychotherapy, Psychosomatics, Child and Adolescent Psychiatry, and Neurology*
- 2) *Berlin Institute of Health (BIH), Berlin, Germany*
- 3) *Freie Universität Berlin, Dept. of Clinical Psychology*
- 4) *Humboldt Universität zu Berlin, Dept. of Psychology*
- 5) *St. Hedwig-Krankenhaus Berlin, Department of Psychiatry and Psychotherapy*
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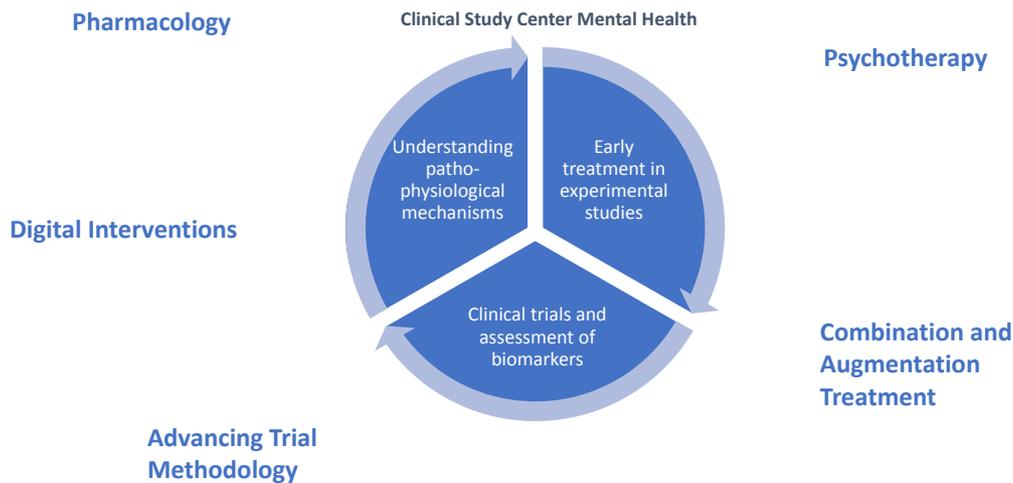
### **Unmet medical need:**

Although much progress has been made in understanding the brain and the pathophysiology of mental disorders, this was not immediately paralleled in major therapeutic breakthroughs. Ultimately, improving the mental and physical health of patients with mental disorders requires large-scale clinical trials, the gold standard for evidence-based medicine. However, in this regard, Germany has not exploited its full potential yet (Wissenschaftsrat, 2018). The Charité Mental Health has organized its resources for clinical trials to bridge that gap. A participation of Charité Mental Health in the new German Center of Mental Health offers the unique opportunity to establish a national network of clinical sites that will collaborate in large-scale clinical trials using new innovative research approaches and outcome measurements for people with mental disorders.

### **Research Focus:**

A primary aim of Charité Mental Health is to improve mental and physical health of people with mental disorders. To this end, we are currently conducting a plethora of clinical trials to strengthen the evidence base for immediate patient benefit. A full list of our ongoing clinical trials can be found here [\(link\)](#).

The basic principle of our approach is a reiterative process, in which mechanistic insight informs novel treatment approaches or guide tailoring of available treatments (translation). At the same time, biomarker assessment in clinical trials informs our basic understanding of the pathophysiology of mental disorders (back-translation) that can be used again to modify treatment approaches. Importantly, Charité Mental Health covers a large range of treatment modalities including psychotherapeutic, digital, pharmacological, and brain stimulatory interventions that can also be combined, for example as augmented psychotherapy.



Furthermore, to accelerate and further improve clinical research, we are active in advancing the methodology of clinical trials. As a case in point, within the EU consortium EU-PEARL (<http://EU-PEARL.eu>) we are developing a study protocol for an adaptive platform trial in treatment-resistant depression.

#### **Infrastructure:**

Charité Mental Health is ideally suited as nucleus of a national network of clinical sites collaborating in large-scale clinical trials. First, on a national level, we already host the newly founded Network of Academic medical research, in which members of the faculty of Charité Mental Health and others have established within the Covid19-pandemic the first German research data infrastructure connecting all medical schools. Within the Berlin Institute of Health (BIH), the Clinical Study Center (CSC) is the interdisciplinary and cross-campus Charité platform for clinical studies with Clinical Research Units (CRU) on every Campus. This includes a cross-campus Neuroscience CRU in collaboration with the excellence cluster NeuroCure that hosts several members of Charité Mental Health. Furthermore, our psychopharmacological trials program has recently partnered with BIH to establish a unit for drug repurposing and repositioning. This endeavour is not limited to psychiatry but will be open for any medical speciality. Our consortium also hosts an expert center for Innovation in Psychotherapy (INNO-PSY). Finally, within the BIH academy, we are training the next generation of clinician scientists in our Clinician Scientist Program ([link](#)), a modern career pathway within academic medicine that allows physicians to pursue a structured residency with time set aside for clinical and basic research. This includes four tracks: 1) Junior Clinician Scientist, 2) Junior Digital Clinician Scientist, 3) Clinician Scientist, and 4) Digital Clinician Scientist.

In summary, we are confident that our **Clinical Trials Platform** can not only promote research in the Charité Mental Health network, but will also serve as core element of a newly built national network of clinical trial sites, thereby improving targeted intervention for the mental and physical health of patients with mental disorders.